Volume 14 Number 7 November 2011 ISSN 1098-3015

ELSEVIER

Value IN HEALTH

The Journal of **The International Society for Pharmacoeconomics and Outcomes Research**

ISPOR 14th Annual European Congress
5-8 November 2011, Madrid, Spain

ISPOR 3rd Latin America Conference
8-10 September 2011, Mexico City, Mexico

Research Podium Abstracts
Research Poster Abstracts

Health Economic Evaluations
PATIENT-REPORTED OUTCOMES
Health Technology Assessment
Comparative Effectiveness Research
VALUE-BASED DECISION MAKING
Health Policy Analysis
Budget Impact Analyses

INTERNATIONAL SOCIETY FOR PHARMACOECONOMICS AND OUTCOMES RESEARCH • ISPOR

www.ispor.org

VALUE IN HEALTH VOLUME 14 NUMBER 7 NOVEMBER 2011 PAGES A233 - A574 ELSEVIER

Value IN HEALTH

Value IN HEALTH

VOLUME 14 NUMBER 7 NOVEMBER 2011

ISPOR 14TH ANNUAL EUROPEAN CONGRESS RESEARCH ABSTRACTS

Editorial Office. Value in Health, ISPOR, 3100 Princeton Pike, Suite 3E, Lawrenceville, NJ 08648.

ISPOR Office. Marilyn Dix Smith, RPh, PhD, Executive Director, 3100 Princeton Pike, Suite 3E, Lawrenceville, NJ 08648. Tel: (609) 219-0773, Fax: (609) 219-0774, E-mail: info@ispor.org, Web site: http://www.ispor.org/valueinhealth_index.asp.

Value in Health (ISSN 1098-3015) is published 8 times a year on behalf of the International Society for Pharmacoeconomics and Outcomes Research by Elsevier Inc, 360 Park Avenue South, New York, NY 10010-1710.

POSTMASTER: Send address changes to, *Value in Health,* Elsevier Health Sciences Division, Subscription Customer Service, 3251 Riverport Lane, Maryland Heights, MO 63043.

CUSTOMER SERVICE (orders, claims, online, change of address): Elsevier Health Sciences Division, Subscription Customer Service, 3251 Riverport Lane, Maryland Heights, MO 63043. Tel: (800) 654-2452 (U.S. and Canada); (314) 447-8871 (outside U.S. and Canada). Fax: (314) 447-8029. E-mail: JournalsCustomerService-usa@elsevier.com (for print support); JournalsOnlineSupport-usa@elsevier.com (for online support). Address changes must be submitted four weeks in advance.

YEARLY SUBSCRIPTION RATES: United States and possessions: Individual $250.00; Institution $535.00. All other countries (prices include airspeed delivery): Individual $250.00; Institution $535.00. Single Issues $67.00. To receive student/resident rate, orders must be accompanied by name of affiliated institution, date of term and the signature of program/residency coordinator on institution letterhead. Orders will be billed at the individual rate until proof of status is received. Current prices are in effect for back volumes and back issues.

Further information on this journal is available from the Publisher or from this journal's website (http://www.elsevier.com/locate/jval). Information on other Elsevier products is available through Elsevier's website (http://www.elsevier.com).

Author inquiries
For inquiries relating to the submission of articles (including electronic submission where available), visit http:/www.elsevier.com/authors. The site also provides the facility to track accepted articles and set up e-mail alerts to inform you of when an article's status has changed, as well as detailed artwork guidelines, copyright information, frequently asked questions, and more. Please see Information for Authors for individual journal. Contact details for questions arising after acceptance of an article, especially those relating to proofs, are provided after registration of an article for publication.

English language help service: Upon request, Elsevier will direct authors to an agent who can check and improve the English of their paper (*before submission*). Please contact authorsupport@elsevier.com for further information.

Reprints. For queries about author offprints, e-mail authorsupport@elsevier.com. To order 100 or more reprints for educational, commercial, or promotional use, contact the Commercial Reprints Department, Elsevier Inc., 360 Park Avenue South, New York, NY 10010-1710. Fax: (212) 462-1935; e-mail reprints@elsevier.com. Reprints of single articles available online may be obtained by purchasing Pay-Per-View access for $36 per article on the journal website http://www.elsevier.com/locate/jval.

Abstracting and Indexing
Value in Health is indexed in Index Medicus/MEDLINE, Current Contents/Social & Behavioral Sciences, SciSearch/SCI Expanded, Social Sciences Citation Index, International Pharmaceutical Abstracts, Embase/Excerpta Medica, and PsychInfo/Psychological Abstracts, and Journal Citation Reports/Science Edition (Thomson ISI).

Available online at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.elsevier.com/locate/jval

ABSTRACTS

ISPOR 14TH ANNUAL EUROPEAN CONGRESS RESEARCH ABSTRACTS

PODIUM SESSION I: ASSESSING EFFECT OF MEDICATION ADHERENCE AND PERSISTENCE ON COST-EFFECTIVENESS

AD1
COMPLIANCE MEASUREMENT USING ADMINISTRATIVE DATA FROM GERMAN SICKNESS FUNDS

Frey S, Stargardt T
University of Hamburg, Hamburg, Germany

OBJECTIVES: To compare refill compliance and refill persistence measures as to their accuracy in identifying patients with schizophrenia at risk of temporary discontinuance or complete cessation of antipsychotic pharmacotherapy. **METHODS:** Data was obtained from three German sickness funds with approximately 7 million insured (9.9% of SHI members). Information on age, sex, prescription related information and hospitalization were collected. A total of 1484 patients with schizophrenia (ICD-10 F20) who were treated in hospital and subsequently received antipsychotic long-term pharmacotherapy were evaluated. Refill compliance measures based on single-interval availability, multiple-interval availability, as well as refill persistence were calculated for each patient over one year. The resulting 10 derivative measures were compared with respect to their performance in predicting six-month rehospitalization using multivariate logistic regression. C-statistics were calculated to determine each model's predictive performance. **RESULTS:** Likelihood ratio tests showed that the inclusion of a compliance variable significantly improved the predictive performance in six out of ten models over the baseline model with age, sex and severity ($p<0.05$). Refill compliance as a continuous variable of medication persistence including transfer of oversupplies into subsequent periods, performed best in predicting rehospitalization ($C=0.669$). Availability ratios capped at 100% were superior to default availability ratios in predicting rehospitalization. Allowing for cross-period carryover improved the discriminatory performance of our persistence models. **CONCLUSIONS:** Persistence measures appear sufficiently flexible to account for interruptive events, i.e. hospitalization, common in schizophrenia and other psychiatric diseases. It is recommended to use a continuous refill persistence measure to assess compliance in psychiatric conditions when working with administrative data.

AD2
COST-CONSEQUENCE ANALYSIS OF SWITCHING FROM AN ORAL ANTIPSYCHOTIC TO LONG ACTING INJECTABLE RISPERIDONE AMONG PATIENTS WITH SCHIZOPHRENIA

Degli Esposti L, Sangiorgi D, Buda S
CliCon Srl, Ravenna, Italy

OBJECTIVES: Lack in treatment adherence in schizophrenia often leads to an increase of relapses and, consequentially, to an increase for direct health care costs (eg, hospitalizations). The aim of the SMART study (Schizophrenia Medications Adherence: long-acting Risperidone versus other Therapies) is to assess the variation in total health-related costs among schizophrenic patients switching from oral antipsychotics to Long Acting Injectable Risperidone (LAI-R). **METHODS:** A multicenter, retrospective observational cohort study based on Local Health Units administrative databases was conducted. Patients with a diagnosis of Schizophrenia, schizotypal and delusional disorders, with a first prescription of LAI-R between January 1, 2007 and December 31, 2008 and a previous treatment with oral antipsychotics were enrolled. Direct medical costs (drugs, hospitalizations, Department of Mental Health services, outpatient specialist services) were evaluated during the 12 months preceding and following the date of inclusion. **RESULTS:** A total of 116 patients were enrolled, 57 male and 59 female, aged 49±17 years old. Total average disease-related cost per patient was €5.003,49 during the period preceding LAI-R and €4.138,62 during the LAI-R period (-€864,88, -17%, $p=0.021$). The cost increase for antipsychotic drugs (from €291.41 to €2445.94, $p<0.001$) was offset by a cost reduction for semi-residentiality (from €276.69 to €23.78, $p=0.884$), residentiality (from €2,669.90 to €831.52, $p=0.004$), Department of Mental Health services (from €77.25 to €479.88, $p<0.001$) and hospitalizations (from €1723.67 to €772.61, $p=0.005$); we registered a decrease in mean length of stay (LOS) (from 4.1 days to 1.2, $p=0.002$) and in the number of hospitalizations per patient (from 0.27 to 0.08, $p<0.001$); 24% patients were hospitalized during the period preceding LAI-R and 8% during the LAI-R period. Moreover, the cost for services not related to schizophrenia showed a slight reduction (from €1318.78 to €1016.62, $p=0.417$). **CONCLUSIONS:** This therapeutic strategy appears to be cost saving, especially with regard to the reduction in hospitalizations.

AD3
ASSESSING THE COMPLIANCE AND PERSISTENCE OF ALLERGEN IMMUNOTHERAPY IN ALLERGIC RHINITIS USING A RETROSPECTIVE PHARMACY DATABASE FROM THE NETHERLANDS

Kiel MA[1], Gerth van Wijk R[2], Röder E[2], Al MJ[1], Hop WC[2], Rutten-van Mölken MP[1]
[1]*Erasmus University, Rotterdam, The Netherlands,* [2]*Erasmus Medical Center, Rotterdam, The Netherlands*

OBJECTIVES: Long-term compliance and persistence has been poorly assessed in allergen immunotherapy for allergic rhinitis, a frequently applied but costly (€1543/year, 2009 figures), treatment for an increasingly prevalent disease. Allergen immunotherapy with pollen and/or mites requires a three to five year long course of treatment. Immunotherapy may be administered sublingually(SLIT) at home, or subcutaneously(SCIT) at the doctor's office. This study aims to assess the long-term compliance and persistence of allergen immunotherapy and the costs of premature cessation of immunotherapy. **METHODS:** Data from over 8,000 users who started allergen immunotherapy between 1994 and 2009 were extracted from a representative, commercially available database (the PHARMO institute, The Netherlands). Data included drug name, type of allergen, amount of drug prescribed, route of administration, type of prescribing physician, pharmacy visit date, socioeconomic status (SES), sex, age, pharmacy costs and revenues. Compliance was defined as the number of late pharmacy visits, persistence was defined as the total duration of treatment of at least three years. Time to treatment discontinuation was analyzed using Kaplan-Meijer curves and Cox proportional hazard models. **RESULTS:** A total of 48% of SLIT users and 37% of SCIT users discontinued therapy before the first year, and 23% of SLIT users and 37% of SCIT users continue immunotherapy for at least three years. SLIT is predominantly prescribed by GPs, and SCIT by allergologists. 2.6 late pharmacy visits were recorded per patient (SD 2.2). Sex was not a significant predictor of persistence, but higher age, SES, and a rural place of residence were. Nonpersistent behavior is associated with drug costs of over 50M euros over the observation period. **CONCLUSIONS:** A significant difference in persistence exists between users of SLIT and SCIT in favor of the latter. The high costs associated with non-persistence ask for both patient and doctor education and warrants the use of compliance devices.

AD4
HEALTH OUTCOMES AS A FUNCTION OF INTENTIONAL AND UNINTENTIONAL NON-ADHERENCE AMONG ELEVEN COSTLY CONDITIONS IN THE EU

Goren A[1], Gupta S[2], Dibonaventura MD[1]
[1]*1Kantar Health, New York, NY, USA,* [2]*2Kantar Health, Princeton, NJ, USA,*

OBJECTIVES: Patient non-adherence to medications is associated with poorer health status; yet, intentional (e.g., purposefully skipping doses) and unintentional (e.g., forgetting) non-adherence can reflect distinct patient characteristics. This study investigates the burden of intentional (INA) or unintentional (UNA) nonadherence among eleven costly chronic conditions. **METHODS:** EU 2010 National Health and Wellness Survey data were used, including 19,279 (of 57,805) respondents who reported taking prescription medication for any of these conditions: asthma, pain, congestive heart failure (CHF), COPD, diabetes, hypertension, depression, bipolar disorder, peripheral vascular disease (PVD), transient ischemic attack (TIA), and stroke. Morisky Medication Adherence Scale items were summed to create INA ("stop taking medicine when feeling better" and ". . .when feeling worse") and UNA ("forget to take medicine" and "careless about taking medicine") scores ranging from 0_adherence (reference) to 1_moderate and 2_high nonadherence. Generalized linear models predicted health utilities (scored from the SF-12v2) from INA or UNA, controlling for sociodemographic characteristics and comorbidities. **RESULTS:** Among those taking medication for asthma (n_3147), pain (n_6605), CHF (n_248), COPD (n_584), diabetes (n_3062), hypertension (n_8821), depression (n_3714), bipolar disorder (n_240), PVD (n_106), TIA (n_287), or stroke (n_356), 49.7% were male, mean age was 52.9 years (SD_15.0), and 32.3% and 30.8% exhibited some INA and UNA, respectively (rINA/UNA_0.34, p_0.001). Across conditions, adjusting for covariates, high (b_-0.040) and moderate (b_-0.028) INA was associated with lower health utilities, as was high UNA (b_-0.017), all p_0.001. This pattern was significant for high non-adherence in diabetes (INA: b_-0.058; UNA: b_-0.023) and hypertension (INA: b_-0.054; UNA: b_-0.032), p_0.01; it was on average non-significantly negative within other conditions, but significantly positive in pain and PVD. **CONCLUSIONS:** These results suggest INA may have a stronger negative impact on health status than UNA, which can help guide adherence-improving intervention strategies. The results also highlight disease areas in which interventions may yield better outcomes.

PODIUM SESSION I:
ALTERNATIVE VIEWS IN CANCER OUTCOMES RESEARCH TO COLLECT ALL BENEFITS

CN1
MEAN VERSUS MEDIAN OVERALL SURVIVAL (OS) FOR DESCRIBING VALUE OF NEW CANCER THERAPIES: A CASE STUDY

Davies A[1], Briggs A[2], Wagner S[3], Kotapati S[4], Schneider J[5], Ebeid O[5], Levy AR[6]
[1]Oxford Outcomes Ltd, Oxford, UK, [2]Oxford Outcomes, Oxford, UK, [3]Bristol-Myers Squibb Company, Washington Crossing, PA, USA, [4]Bristol-Myers Squibb Pharmaceuticals, Wallingford, CT, USA, [5]Oxford Outcomes Ltd., Morristown, NJ, USA, [6]Oxford Outcomes Ltd., Vancouver, BC, Canada

OBJECTIVES: The impact of new oncology therapies on OS is often assessed by comparing median OS times in randomised controlled trials. Although this data is usually available even when many patients remain alive at the end of the trial, the survival times of those surviving beyond the median point may not be adequately accounted for in this comparison. In this case study, we discuss the median and the mean OS using data from a recently published randomised trial. **METHODS:** Median OS in the ipilimumab-alone (IPI) and gp100 alone-arms of the trial of IPI in pre-treated metastatic melanoma (MM) patients (Hodi et al., 2010, NEJM) was compared with non-parametric estimates of mean survival (area under digitised Kaplan-Meier survivor function) over four years (maximum follow up 55 months). We reviewed the methods literature and approaches adopted in relevant assessments. **RESULTS:** In this case study, for MM population followed over four years median OS was reached in the control arm at 6.4 months, and at 10.1 months in the IPI alone arm, a difference in medians of 3.7 months. Mean OS (area under the curve) over 4 years was 11.5 months in the control arm and 17.6 months in the IPI alone arm, a difference for IPI of 6.1 months. Though larger than the difference in median OS, this represents a lower bound on the mean OS benefit over the remaining lifetime, since the survival benefit was truncated at the end of the trial. **CONCLUSIONS:** Mean and median OS both have a place in characterizing OS. In this case study, it would appear that mean OS may be more informative in describing the potential benefit of the treatment in patients with MM. Health care decision makers should consider all the available data when assessing the potential benefits offered by new therapies in oncology.

CN2
MEASURING PUBLIC PREFERENCES FOR COLORECTAL CANCER SCREENING USING NEW GENOME-BASED NANOTECHNOLOGIES

Fermont JM, Groothuis-Oudshoorn K, IJzerman MJ
University of Twente, Enschede, The Netherlands

OBJECTIVES: Emerging developments in nanomedicine allow the development of genome-based technologies for unobtrusive and individualized screening of colorectal cancer. An example is the nanopill that is currently being developed. The pill collects gastrointestinal fluid and screens DNA for tumour markers. The main objective is to inform further development by determining the public preferences for screening as well as the possible uptake of the nanopill compared to standard CRC screening. **METHODS:** Data was collected through a discrete choice experiment among individuals aged between 50 and 74 years living in the The Netherlands and the UK. A full-profile fractional factorial design with a balanced overlap was implemented. Fourteen random and two fixed choice-tasks with triplets and dual-none response were used. Through an extensive literature search following attributes were included: preparation, technique, sensitivity, specificity, complication rate, and testing frequency. Data were analysed using Hierarchical Bayes analysis and a Multinomial Logit model. **RESULTS:** Thirteen hundred fifty-six respondents completed the questionnaire, from which 884 (65%) passed the consistency test. Most preferred attributes were: technique (pill), preparation (none); sensitivity (100%), specificity (100%), complications (none), and interval (every 5 years). Nanopill was the most preferred screening modality (46%), followed by iFOBT (40%), colonoscopy (2%), and sigmoidoscopy (1%). Eleven percent would choose not to be screened. **CONCLUSIONS:** CRC screening has been implemented in a number of countries using standard screening techniques, like FOBT and virtual colonoscopy. However, current developments in nanomedicine allow the development of new technologies for individualized screening. The expected benefits delivered by the nanopill are an improved screening adherence, earlier diagnosis and an increased test performance. The present study suggests the nanopill to be accepted by the public, which does support further development. However, the study used hypothetical scenarios to describe the nanopill and the results do not guarantee market uptake. Cost-benefit analysis and clinical trials remain mandatory.

CN3
VALIDATION STUDY OF THE BASELINE QUALITY OF LIFE AS A PROGNOSTIC INDICATOR OF SURVIVAL: A POOLED ANALYSIS OF INDIVIDUAL PATIENT DATA FROM NCIC CLINICAL TRIALS

Ediebah DE[1], Quinten C[2], Coens C[3], Zikos E[1], Ringash J[4], Gotay C[5], Flechtner HH[6], Osoba D[7], King M[8], Cleeland C[9], Greimel E[10], Reeve BB[11], Taphoorn M[12], Schmucker-Von Koch J[13], Weis J[14], Bottomley A[3]
[1]European Organisation for Research and Treatment of Cancer Head Quarters, Bruxelles , Belgium, [2]European Center for Disease Prevention and Control, Surveillance and Response Support Epidemiological Methods Unit, Stockholm, Sweden, [3]European Organisation for Research and Treatment of Cancer Head Quarters, Bruxelles, Belgium, [4]The Princess Margaret Hospital, Toronto, QC, Canada, [5]U of British Columbia, Vancouver, BC, Canada, [6]Otto-von-Guericke University Magdeburg, Magdeburg, Germany, [7]Quality of Life Consulting, West Vancouver, BC, Canada, [8]University of Sydney, Sydney, Australia, [9]U.T.M.D. Anderson Cancer Center, Houston, TX, USA, [10]Medical University of Graz, Graz, Austria, [11]University of North Carolina at Chapel Hill, Chapel Hill, NC, USA, [12]VU University Medical Center, department of Neurology, The Hague, The Netherlands, [13]University of Regensburg, Regensburg, Germany, [14]University of Freiburg, Freiburg, Germany

OBJECTIVES: Our aims were to investigate the association between baseline health-related quality of life (HRQOL) scores of the EORTC QLQ-C30 and survival. **METHODS:** We analyzed data from pooled, randomized, controlled trials from National Cancer Institute Canada Clinical Trials Group started between 1991 and 2004, which included survival data from 3635 patients with 8 different cancer sites. Sociodemographic variables were sex (men vs. women) and age (60 vs. > 60), and clinical variables were WHO performance status (0-1 vs. 2-3) and distant metastases (no vs. yes). The prognostic significance of sociodemographic and clinical variables and the 15 QLQ-C30 scales were assessed with Cox proportional hazard models stratified for cancer site. **RESULTS:** In the stratified multivariate model including sociodemographic, clinical, and HRQOL data, the HRQOL parameters of global QOL/health status (hazard ratio [HR] 1.097, 95% CI 1.05- 1.14; p<.0001), physical function (0.94, 0.897-0.98; p=0.0010), dyspnoea (1.04, 1.00-1.07; p=0.0120), and appetite loss (1.06, 1.03-1.09; p<.0001) provided significant prognostic information in addition to the sociodemographic and clinical variables. The gain in predictive accuracy of prognosis of overall survival of the four HRQOL parameters over the sociodemographic and clinical characteristics was 3% (Harrell's C-index for sociodemographic and clinical variables = 0.69, and for sociodemographic, clinical, and HRQOL variables = 0.71). The model developed by Quinten et al. 2009 included pain but this was not found to be statistically significant in our model. **CONCLUSIONS:** Our findings suggest that HRQOL scales of the EORTC QLQ-C30 provide prognostic information in addition to that of sociodemographic and clinical measures. This replicates previous findings (Quinten et al., 2009) showing that HRQOL data can help to predict survival in patients with cancer, although the specific HRQOL domains that are predictive may vary. The impact of these findings for clinical management (e.g., in stratification for clinical trials entry or treatment decision making) need additional study.

CN4
HETEROGENEITY IN PREDICTING THE FUTURE IMPACT OF TECHNOLOGIES TO CONTROL HEPATOCELLULAR CARCINOMA (HCC): A COMPARISON OF STAKEHOLDER VIEWS FROM EUROPE AND ASIA

Bridges JF[1], Gallego G[1], Joy SM[1], Blauvelt BM[2]
[1]Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA, [2]University of Massachusetts, Hadley, MA, USA

OBJECTIVES: Hepatocellular carcinoma (HCC) is both common and deadly; yet predicting the future impact of technologies is difficult. We studied opinions about the potential impact of HCC-control technologies over a 5-10 year horizon and compared results from Europe and Asia. **METHODS:** Clinical, policy and patient advocacy stakeholders were purposively sampled equally from Asia and Europe. Opinions about eleven possible technologies were studied using best-worst scaling. Here a balanced incomplete block design (BIBD) generated 11 choice tasks presenting respondents with subsets of five technologies and asking them to assess which might have the most and least impact on HCC control. Assuming sequential best-worst choice, respondents' choices were analyzed using a stratified conditional logistic regression. Heterogeneity was examined by assessing ordinal and cardinal properties using Spearman's Rho and Wald test respectively. **RESULTS:** A total of 160 stakeholders (response rate: 46%) completed the survey and self-identified as having local/regional (30%), national (46%) or international (24%) influence. Overall, respondents saw molecular targeted therapy (p <0.001) and early detection (p <0.001) as having most potential, while surgical techniques (p <0.001) and biopsy-free diagnosis (p <0.001) were viewed negatively. While the ordinal rankings of technologies were similar (Spearman's Rho=0.81, P=0.003), significant differences were found for some technologies across regions – e.g. interventional radiology was positively valued in Europe (P=0.002), but viewed negatively in Asia (P=0.118), but adjuvant/neo-adjuvant therapy was viewed positively in Asia (P<0.001), but negatively in Europe (P=0.001). **CONCLUSIONS:** While best-worst scaling methods are likely to have an important role in informing horizon scanning and other aspects of health technology assessment, issues of regional heterogeneity are important to explore. Our results indicated that heterogeneity may be more important when considering the cardinal values placed on the elements being examined, as opposed to the ordinal rankings; heterogeneity was not found for either the best or worst technologies.

PODIUM SESSION I:
NEW APPROACHES FOR EFFECTIVE USE OF DATA: BETTER SYNTHESIS AND ENHANCED POWER

DA1
ARTIFICIAL NEURAL NETWORK META-MODELS IN COST-EFFECTIVENESS ANALYSIS OF INTENSIVE BLOOD-GLUCOSE CONTROL: A CASE STUDY APPLIED TO THE UK PROSPECTIVE DIABETES STUDY (UKPDS) INDIVIDUAL PATIENT OUTCOME SIMULATION MODEL

Alam M[1], Briggs A[2]
[1]University of Glamorgan, Pontypridd, UK, [2]Glasgow Universrity, Glasgow, UK

OBJECTIVES: Within cost effectiveness analysis, joint uncertainty in costs and effects is commonly dealt with using probabilistic sensitivity analysis (PSA). Although economic models using patient level data can simulate more complex disease processes than cohort-based models, the computational time required to eliminate 1st-order uncertainty often makes extensive PSA impossible. To overcome this, a non-parametric artificial neural network (ANN) simulation meta-modelling method is presented using a case study that evaluates the cost-effectiveness of intensive blood-glucose monitoring in patients with type 2 diabetes. **METHODS:**

A complex individual patient simulation model (UKPDS Outcome Model version 1.3) was used with quality adjusted life years (QALY) and cost of complications as model outputs. To reduce 1st-order uncertainty, 1000 patients were simulated for each input combination selected. ANN simulation meta-models using a sample of 200 individual runs were developed and cross-validated to approximate the original simulation as these do not require any specific input-output functional relationship and can handle any number of input parameters. Performance was compared with a Gaussian Process (GP) meta-model, and a valid and better predictive meta-model was then used for PSA. **RESULTS:** From ANN meta-models, the mean absolute percentage error (defined as positive difference between the predicted and true output divided by the range in true output) was 3.8 % for costs and 1.4% for QALYs compared with 5.1% and 2.1% in GP meta-models. The distribution of errors was approximately symmetrical around zero meaning that mean costs and QALYs for an intervention are unlikely to be affected by the small inaccuracies associated with ANN approximations. **CONCLUSIONS:** ANN produces better predictive capability than GP meta-models in estimating costs and QALYs from the UKPDS outcome model. A PSA carried out using the ANN meta-model demonstrated the potential for ANN in analysing complex health economic models.

DA2

A CHOICE THAT MATTERS: COMPARING METHODS OF DATA SYNTHESIS IN COST-EFFECTIVENESS MODELLING

Vemer P, Al M, Oppe M, Rutten-Van Mölken M
iMTA, Erasmus University, Rotterdam, The Netherlands

OBJECTIVES: Different methods of meta-analysis on model parameters can lead to different outcomes of cost-effectiveness (CE) modeling. As the "true" CE is unknown, it is unclear which method performs best. We compared different methods of meta-analysis with regards to the underlying "true" CE outcome. **METHODS:** In a simulation study we constructed two patient populations and their treatments ("truth"): a chronic disease with events and a progressive lethal disease. We drew trials from these populations, comparing two treatments, varying the number of trials, trial sizes and between-study heterogeneity in scenarios. From each trial utilities, transition and event probabilities, risk-differences and log-risk-ratios were estimated. These parameters were synthesized using frequentist fixed-effects (FFE) and random-effects (FRE), Bayesian fixed-effects (BFE) and random-effects (BRE) models. A CE model was filled and probabilistic sensitivity analysis was performed. We repeated this trial sampling, leading to 1000 sets of health economic outcomes for each scenario. We compared methods of meta-analysis on bias and coverage, the percentage of draws that the "true" outcome lies in the confidence interval. **RESULTS:** Even in the most heterogeneous scenario, biases were limited to approximately 5%, and similar for all methods, but small biases in individual treatment arms occasionally led to biases up to 30% in the difference between arms. FFE models consistently have lower coverage than BFE. With homogeneous trials, all methods have coverage above 80% for all outcomes. BRE has coverage higher than 99% for all outcomes, regardless of heterogeneity. With heterogeneity, RE methods perform better than FE and FRE has a lower coverage compared to BRE. All methods, even with heterogeneous trials, have 100% coverage around the ICER. **CONCLUSIONS:** BFE or BRE models are preferred in all situations, as they are more conservative. However, insight in the real level of heterogeneity is important, as using BRE without heterogeneity will overestimate uncertainty.

DA3

THE POWER OF ASSUMPTIONS

Van Hout BA, Stevens JW
University of Sheffield, Sheffield, UK

OBJECTIVES: To develop a method which increases the potential to find statistically significant differences in costs and effects when a trial is powered using a dichotomous outcome. **METHODS:** An example is used of a trial assessing an intervention to prevent late pain. Treatment is expected to increase the percentage of pain-free patients from 85% to 92%, giving a power of 80% with 500 patients. Using EQ-5D as outcome decreases the power to 40%. We improve on this by deriving T-tests in which the following assumptions are taken into consideration: 1. quality of life with pain (8% vs 15%) is identical in both arms 2. quality of life without pain (85% vs 92%) is identical in both arms Alternatively, we use a Bayesian approach assuming that the differences between arms follow normal distributions with mean zero and varying precision. Using simulations the frequentist and Bayesian approach are linked and it is analysed to what extent the results depend on the base line probabilities. **RESULTS:** Making both assumptions increases the power to 80% as in the binary assessment. Applying assumption 1 increases the power with only 2%, applying assumption 2 increases it to almost 80%. When assuming that the outcome is 44% versus 56% instead of 85% vs 92% both assumptions contribute to the power approximately equally. The Bayesian model coincides with the assumptions from the frequentist approach when the precision is set to the extremes (zero or infinity). Between these it offers a flexible approach where the road from one extreme to another is defined by cumulative normal distributions on the log of the squared root of the precision. **CONCLUSIONS:** Traditional approaches may disregard common sense. Building this into the analysis and the assessment of the data will decrease suggested uncertainty and may decrease the need for large patients numbers.

DA4

FINDING TREATMENT EFFECTS WITHIN SUBGROUPS WHEN USING THE PROPENSITY SCORE TO CONTROL FOR SELECTION BIAS: A MONTE CARLO SIMULATION STUDY

van Eeren H[1], Spreeuwenberg MD[2], van Manen JG[3], de Rooij M[4], Stijnen T[5], Busschbach J[1]
[1]*Erasmus University Medical Center, Rotterdam, The Netherlands,* [2]*Maastricht University, Maastricht, The Netherlands,* [3]*Viersprong Institute for Studies on Personality Disorders, Halsteren, The Netherlands,* [4]*Methodology and Statistics Unit, FSW, Leiden University, Leiden, The Netherlands,* [5]*Department of Medical Statistics & Bioinformatics, Leiden University Medical Center, Leiden, The Netherlands*

OBJECTIVES: The use of registry databases and indirect comparisons has become important in health economic evaluations. Lack of randomization could lead to selection bias due to pretreatment differences between patients. To control for selection bias, the propensity score method (PS) (Rosenbaum & Rubin, 1983) is often applied. However, average treatment effects can vary within different subgroups. It is yet unclear how to perform subgroups analyses when the propensity score method is applied. **METHODS:** A Monte Carlo simulation is conducted to test the performance of eight different forms of the PS in subgroup analyses. The PSs differ in whether the variables included in the PS were indicators of the subgroup and were related to treatment assignment, to outcome or related to both assignment and outcome. Furthermore the PS is estimated in two ways, primary on treatment assignment only and secondly on a combination of the treatment assignment and subgroup variable. These PSs were used as adjustment in a regression model. Simulations are accomplished for 18 different settings varying sample size, correlation between independent variables and correlation between independent variables and subgroups. **RESULTS:** The PS without inclusion of the variable for subgroups, but with inclusion of variables related to outcome, is the most appropriate. The PS should be included as a covariate in a regression model together with the variable for subgroups as covariate, where the PS is based on treatment assignment only. Larger sample sizes gave less biased results, while a higher correlation between the independent variables resulted in more biased estimates of the treatment and subgroup effect. Correlation between the independent variables and the subgroup variable did not lead to biased results. **CONCLUSIONS:** The results show the feasibility and validity of the PS in subgroups analyses when analyzing registry databases and indirect comparisons in economic evaluations.

PODIUM SESSION I: LATEST INSIGHT IN THE ESTIMATION OF PRODUCTIVITY COST: BETTER DESCRIBING THE SOCIETAL VALUE

PC1

THE USE AND PERFORMANCE OF PRODUCTIVITY SCALES TO EVALUATE PRESENTEEISM IN MOOD DISORDERS

Despiégel N[1], Danchenko N[2], François C[2], Lensberg B[3], Drummond M[4]
[1]*OptumInsight, Nanterre, France,* [2]*Lundbeck SAS, Issy-les-Moulineaux, France,* [3]*OptumInsight, Uxbridge, Middlesex, UK,* [4]*University of York, Heslington, York, UK*

OBJECTIVES: Mood disorders are associated with a high societal cost, mainly due to productivity loss and in particular presenteeism. The latter should therefore be measured with the most appropriate tool. The objective is to review the use of ten instruments in mood disorders and to provide recommendations about the most appropriate instruments according to the situation. **METHODS:** A systematic review was conducted using PubMed focusing on ten instruments: Endicott Work Productivity Scale (EWPS), Health & Labour Questionnaire (HLQ), WHO Health and Work Performance Questionnaire (HPQ), Health and Work Questionnaire (HWQ), Lam Employment Absence and Productivity Scale (LEAPS), Sheehan Disability Scale (SDS), Stanford Presenteeism Scale (SPS), Work and Health Interview (WHI), Work Limitation Questionnaire (WLQ) and Work Productivity and Activity Impairment (WPAI). Study characteristics and major results (by symptom level, by treatment arm, correlation to other scales and use of monetisation) were extracted. **RESULTS:** Twenty-nine studies (21 observational studies) were identified. No studies in mood disorders were retrieved for two scales (HLQ and HWQ). SDS, WLQ and HPQ were the most commonly used instruments. Most scales demonstrated higher presenteeism in patients with symptoms of mood disorders than in patients without. LEAPS, SDS and WLQ showed increased presenteeism with increasing severity of disease. Few studies reported results on presenteeism by treatment and no betweentreatment differences were generally observed. Good correlations between presenteeism instruments and clinical or quality of life scales were reported. Only three studies converted results from presenteeism scales into monetary units. **CONCLUSIONS:** Limited evidence exists to compare the performance of presenteeism scales in mood disorders. Recommendations for inclusion of a presenteeism tool should be driven by theoretical arguments (ease of administration, amenability to monetisation) and the study type. Future research should focus on the responsiveness demonstration and the evaluation of the impact of mood disorders on self-reported assessment.

PC2

ESTIMATION OF PRODUCTIVITY COSTS USING THE FRICTION COST METHOD: NEW EVIDENCE USING NATIONAL DATA

Erdogan-Ciftci E[1], Koopmanschap MA[2]
[1]*Erasmus University, Rotterdam, The Netherlands,* [2]*Erasmus University Rotterdam, Rotterdam, The Netherlands*

OBJECTIVES: Many health economists consider applying the friction cost method to estimate the productivity costs, but lack practical data and tools to apply the method. This study aims to provide estimates for length of the friction period, cost per working hour/day lost and friction costs for several European countries. **METHODS:** Using national aggregate stock and flow time series data on vacancies, we; 1) estimate vacancy durations for several European countries in order to estimate the length of friction period, and 2) examine estimated vacancy durations with unemployment and vacancy rates using regression analysis in order to check the validity of estimated durations. Data for the price component for each country

on hourly labour costs is used for productivity costs per working day/hour. **RESULTS:** Vacancy durations estimated in 2009 for The Netherlands, Belgium, Germany, France, the UK, Norway and Sweden range between 40-80 days. Regression analysis of the vacancy durations shows that, there is a strong negative relationship between vacancy durations and unemployment rates. When unemployment increases, vacancy durations and hence friction period decline. We also find that an increase in the vacancy rate (the ratio of the stock of vacancies to total labor force) has a positive effect on vacancy durations which can be explained by the congestion provoked by the increase in the number of vacancies competing in the labor market. **CONCLUSIONS:** This paper provides estimates on vacancy durations, friction periods and the price component in order to calculate the friction costs. For seven European countries, we present empirical estimates to use the friction cost method in a practical way which can improve more uniform analysis of productivity costs in economic evaluations of diseases. Our regression results confirm the validity of estimated vacancy durations which are necessary to calculate the length of friction period and friction costs.

PC3

BREAST AND PROSTATE CANCER PRODUCTIVITY COSTS: A COMPARISON OF THE HUMAN CAPITAL APPROACH AND FRICTION COST APPROACH

Hanly P, Timmons A, Walsh P, Sharp L
National Cancer Registry Ireland, Cork, Ireland

OBJECTIVES: Productivity costs constitute a substantial proportion of the total societal costs associated with cancer. Cancer patients may leave the workforce permanently post-diagnosis, take time off during treatment and/or return to work with reduced hours or die prematurely; the associated productivity costs have rarely been considered. We applied the dominant human capital approach (HCA) and the emerging friction cost approach (FCA) to estimate breast and prostate cancer productivity costs in Ireland in 2008. **METHODS:** Data from a survey of breast and prostate cancer patients (n=358) was combined with population-level survival estimates (from the population-based National Cancer Registry) and a national wage dataset to calculate costs of temporary disability (cancer-related work absence), permanent disability (workforce departure, reduced working hours) and premature mortality, using the HCA and FCA. Sensitivity analyses were conducted for key parameters: GNP growth and discount rates for HCA and friction period and labour elasticity for FCA. **RESULTS:** According to the HCA, productivity costs per person amounted to €193,425 for breast and €109,154 for prostate cancer. FCA per person costs were €8103 for breast and €8205 for prostate cancer. The HCA generated higher costs for younger patients (breast cancer) due to greater lifetime earning potential. In contrast FCA resulted in higher productivity costs for older male patients (prostate) commensurate with higher earning capacity over a shorter time period. Reduced working hours post-cancer was a key driver of total HCA productivity costs. HCA costs were sensitive to assumptions about discount and growth rates. FCA costs were sensitive to assumptions about the friction period. **CONCLUSIONS:** This study highlights the importance of choosing the correct valuation method for chronic long-term illnesses such as cancer, being explicit about assumptions, and considering a range of cost sub-components, including those due to reduced working hours.

PC4

HEALTH SERVICES UTILIZATION, WORK ABSENTEEISM AND COSTS OF PANDEMIC INFLUENZA A (H1N1)

Garin O[1], Galante M[1], Sicuri E[1], Cots F[2], Garcia-Altés A[3], Ferrer M[4], Nebot M[1], Dominguez À[1], Alonso J[5]
[1]*CIBERESP, Barcelona, Spain,* [2]*Parc de Salut Mar, Barcelona, Spain,* [3]*Catalan Agency for Health Information, Assessment and Quality (CAHIAQ), Barcelona, Spain,* [4]*IMIM-Hospital del Mar, Barcelona, Barcelona, Spain,* [5]*IMIM-Research Institute Hospital del Mar, Barcelona, Spain, Spain*

OBJECTIVES: The aim of this study was to estimate the impact of pandemic Influenza A H1N1/2009 in terms of patient's health care services utilization, work absenteeism and associated costs. **METHODS:** Longitudinal, descriptive, multi-centre study of in- and outpatients with confirmed diagnosis of influenza A H1N1/2009 in Spain. Sociodemographic and clinical characteristics were gathered together with health and social resources use, at the admission or primary visit, and also after recovery. Cost analyses were conducted under a social perspective, incidence focus and with a temporal horizon of 3 months. Unit cost of resources was imputed to calculate the mean cost by inpatient and outpatient. A sensitivity analysis with variations was conducted (Monte Carlo simulation). **RESULTS:** A total of 172 inpatients and 224 outpatients were included, 20% and 30% of whom, respectively, were under 17 years old; 12% of inpatients were at ICU, 7.8 (SD=3.7) days, on average, and stayed in general wards for 9.6 (SD=7.7) additional days. The rest of inpatients had a mean hospitalization length of 5 (SD=4.4) days. The most frequently used ambulatory health resource was the primary care medical assistance; 43.8% of inpatients and 66.1% of outpatients were employed, of whom 100% (inpatients) and 91.7% (outpatients) went on sick leave. Absenteeism length was of 30 (SD=20.7) days for inpatients and 9 (SD=6.3) for outpatients. Caregivers of 21.7% of the inpatients also led work absenteeism, as well as the 8.5% of those of outpatients. The proportion of indirect cost for general-ward-inpatients was 30%. This percentage ascended to 77% in the case of outpatients. The mean costs per inpatient were €6,236 (CI95%=1,384–14,623) and €940 (CI95%=66–3,064) per outpatient. **CONCLUSIONS:** Hospitalizations represents the highest economic cost, together with work absenteeism. Since only a marginal proportion of influenza cases are hospitalized, productivity losses emerge as the most important impact of the disease.

PODIUM SESSION I: IN-DEPTH STUDIES ON DIFFERENCES AND OPPORTUNITIES IN PRICING AND MARKET ACCESS

PR1

KEY MARKET ACCESS DRIVERS FOR A SUCCESSFUL HEALTH TECHNOLOGY APPRAISAL OUTCOME – THE CASE OF RHEUMATOID ARTHRITIS

Ackermann J[1], Urbinati D[2], Strandberg-larsen M[3], Toumi M[4]
[1]*Creativ-Ceutical, Paris, France,* [2]*Creativ-Ceutical, Luxembourg, Luxembourg,* [3]*Novo Nordisk A/S, Søborg, Denmark,* [4]*University Claude Bernard Lyon 1, Lyon, France*

OBJECTIVES: This study evaluated several recent drug launches in Rheumatoid Arthritis (RA) to determine which factors contribute to Health Technology Appraisal (HTA) outcomes. **METHODS:** We reviewed the appraisals of RA drugs launched in the last five years by the following HTA agencies: England (NICE), Scotland (SMC), Sweden (TLV), France (HAS), Spain (CAHTA/CANM) and The Netherlands (CVZ). We analysed the proportion of recommended, restricted and not recommended appraisals and the reasons for these decisions. A subsequent analysis of the evidence and arguments developed in the appraisal by the HTA agency was performed. We classified them as clinical, economic, humanistic or social, in addition we analysed the outcome by country and drug. **RESULTS:** The listed HTA agencies issued a total of 25 appraisals (first appraisal, indication expansion and re-appraisal) for the 4 drugs analysed (certolizumab, golimumab, tocilizumab and abatacept). There were 9 recommendations for use (36%), 13 restricted use decisions (52%) and 3 decisions to not recommend for use (12%). In 96% of the cases, the study design (population, add-on vs. monotherapy, duration of trials, comparators etc.) were systematically quoted as the primary reason for the HTA agency decision. In 44% of these cases, in addition to design issues, the lack of convincing health economic data was mentioned. The reasons for favourable recommendations were 100% clinical and 56% economic, for restricted 100% clinical and 31% economic and in case of non-recommendation 67% clinical and 67% economic. **CONCLUSIONS:** The primary reason for restriction and non-recommendation are clinical design issues. Consequently it is recommended that manufacturers incorporate payer's expectations in their development plan early enough to influence trial design and to collect robust health economic evidence.

PR2

VALUE-BASED PRICING IN THE UK: DEVELOPING AN EVALUATION FRAMEWORK FOR BURDEN OF ILLNESS

Easley C[1], Tang J[2]
[1]*Pope Woodhead & Associates, St Ives, UK,* [2]*Cambridge University, Cambridge, UK*

OBJECTIVES: The recent UK value-based pricing (VBP) consultation proposes that burden of illness, therapeutic improvement/innovation and wider societal benefits are evaluated in addition to cost-effectiveness. This study explored attitudes among industry, academia and UK National Health Service (NHS) stakeholders to the proposed VBP framework, with a focus on how to define the burden of illness component. **METHODS:** Relevant literature was identified via a manual search to assess the use of VBP methodologies in other countries and potential burden of illness (BOI) criteria. In-depth, semi-structured 40-minute telephone interviews were then undertaken with 20 experts identified in UK academic centres, the pharmaceutical industry and the NHS. Discussions explored perspectives on VBP and in particular how to define and evaluate BOI. **RESULTS:** Proposed definitions for BOI varied significantly. Industry representatives wanted the flexibility to use a broad, variable set of criteria, while academic and NHS stakeholders wanted practical, consistent evaluation criteria with the emphasis on ensuring benefits are not 'double-counted'. Stakeholder input was used to develop a framework for assessing BOI comprising disease severity, quality of life impact, treatment availability and performance of existing treatments. Qualitative grading scales for each of the criteria were proposed. While each stakeholder group broadly endorsed VBP objectives, the research highlighted various concerns regarding its implications. In particular, the need for clear government policy and guidance, further development of acceptable evaluation methodologies (including criteria weightings), and enhanced pharmaceutical development processes to ensure evidence of sufficient quality is generated to support evaluation of product value (both at launch and over time). **CONCLUSIONS:** There appears to be sufficient common ground to develop a BOI assessment framework that is acceptable to both industry and NHS stakeholders. We propose a relatively simple model that could form the basis for further research and discussion, with special attention to addressing the implementation challenges.

PR3

INDUSTRY PREPAREDNESS AGAINST GERMAN REFORMS

Devienne E[1], White R[2], Mukku S[2]
[1]*University of Cambridge, Cambridge, UK,* [2]*Double Helix Consulting Group, London, UK*

OBJECTIVES: The Pharmaceutical Market Restructuring Act (AMNOG) came into action in Germany January 2011 with the aim of containing rising health care expenditure, notably by introducing mandatory benefit assessments and price negotiation for all new innovative pharmaceuticals. The impact of the reform for the pharmaceutical industry is predicted to be at its highest with repercussions beyond the country's borders, due to Germany's strategic importance in the European market. This project aimed to identify the challenges and opportunities created for the industry in terms of pricing and market access of innovative pharmaceuticals. **METHODS:** The impact was measured from three angles by developing hypotheses and testing them thanks to a series of exploratory interviews with pharmaceutical companies and Market access stakeholders. **RESULTS:** Results obtained project that the impact of the reform for the industry will be very high, increasing the importance of national stakeholders, altering the cost, time and strategy for mar-

ket access as well as potentially leading to significant price reductions. What do these changes mean for the industry? What are the main challenges and opportunities for companies and how can they best adapt? Many questions remain to be determined. Yet AMNOG sets the scene for a new Market access process in Germany, for which challenges can be foreseen. The industry will need to acquire new skills to interact with national Market access stakeholders, develop internal efficient processes to compile Benefit Dossiers, adapt the European launch sequence as well as investigate new Market access strategies, for example targeting subtarget population groups to demonstrate higher additional benefit or leveraging Phase IV data. **CONCLUSIONS:** Industry needs to prepare itself for developing their launch and commercial strategies in Germany as Germany is a key market from revenue, price referencing and credibility perspective.

PR4

ANALYSIS OF PRICE LEVELS OF PRESCRIPTION DRUGS AND DETERMINANTS OF INTERNATIONAL PRICE DIFFERENCES BETWEEN THE UNITED STATES AND SELECTED EUROPEAN COUNTRIES

Kanavos P, Vandoros S, Ferrario A
London School of Economics and Political Science, London, England, UK

OBJECTIVES: Spending on prescription drugs in key OECD countries has increased by 50% or more in the last ten years, raising questions about overall system sustainability. The study analyses possible reasons for differences in prices and volumes consumed across key OECD countries, taking into account national differences in pharmaceutical policy and regulatory mechanisms. **METHODS:** Panel data modelling is used to investigate the effect of pharmaceutical pricing and reimbursement regulations, drug promotion, drug use, and competition on price levels. Data are from IMS Health and the US Federal Supply Schedule and include top-50 selling on patent and generic prescription drugs used in the study countries. Regulatory variables are included as dummy variables in the model. **RESULTS:** Preliminary results suggest that: a) cross-country price comparisons are only meaningful if the right prices are compared in each case. Here, we demonstrate how significant price differences are when ex-factory prices are compared and how these differences narrow down significantly when *public* prices are compared across countries; b) It seems that price differences of originator brands between the US and Europe have been exaggerated; generic prices are very often significantly lower in the US than in other countries; c) Cross-country public price differences and cross-country *ex-factory* price differences are not the same across the study countries; d) Off-patent originator brands account for a significant proportion of the price variation between US and the other study countries; e) Pricing regulation accounts for a considerable proportion of the variation in prices across the study countries; and f) Distribution and taxation can contribute significantly to the total cost of prescription medicines that health insurers pay. **CONCLUSIONS:** Price differences are significant when *ex-factory* prices are compared but are significantly reduced when *public* prices are compared across countries. Regulation, distribution, and taxes are key contributors to the total cost of medicines paid by insurers.

PODIUM SESSION II:
MIXED TREATMENT COMPARISONS MATURE, IN ABSENCE OF SUFFICIENT HEAD-TO-HEAD COMPARISONS

MT1

IMPACT OF THE CHOICE OF PRIOR DISTRIBUTION ON RELATIVE EFFECT SIZES USING BAYESIAN NETWORK META-ANALYSIS

Goring S[1], Ghement I[2], Kalsekar A[3], L'Italien G[4], Levy A[5]
[1]*Oxford Outcomes, Vancouver, BC, Canada,* [2]*Ghement Statistical Consulting, Richmond, BC, Canada,* [3]*Bristol-Myers Squibb, Princeton, NJ, USA,* [4]*Bristol-Myers Squibb and Yale University School of Medicine, Wallingford, CT, USA,* [5]*Dalhousie University, Halifax, NS, Canada*

OBJECTIVES: Bayesian network meta-analyses incorporate prior distributions ("priors") that are updated with new evidence to generate posterior distributions. The use of uninformative (vague) priors minimizes potential biases and promotes transparency. Guideline developers have recommended values for uninformative priors for binary outcomes. For continuous outcomes, the choice of priors is scale-dependent. In networks with heterogeneity and few studies, a more informed prior for estimation of between-studies standard deviation (σ) is justifiable, yet may impose subjectivity. Using a network meta-analysis of seven studies estimating the efficacy of three renal transplant immunosuppressants (tacrolimus, cyclosporine and belatacept), we estimated the impact of varying priors for σ to the relative effect sizes. **METHODS:** We established a clinically-plausible range for an uninformative prior distribution of σ. We then derived estimates for the indirect comparison of belatacept and tacrolimus expressed as true mean difference (TMD) in renal function, expressed as glomerular filtration rate (GFR; mL/min/1.73m^2); 95% credible intervals (CrI); and model fit (residual deviance and deviance information criterion). We conducted sensitivity analyses using more informed priors: half the uninformative range; a data-driven approach; half the data-driven range; and, as an extreme, a fixed-effect model ($\sigma = 0$). **RESULTS:** Using the uninformative uniform prior, U(0,20), the estimated TMD in GFR was 9.84 higher for belatacept than tacrolimus. This had the best model fit and the widest 95% CrI (−1.97, 20.51). As the upper bound of the prior distribution was restricted, the 95% CrIs narrowed yet the model fit degraded. The point estimate was stable. The narrowest informed prior was U(0,3) (TMD 9.84; 95% CrI 4.89, 15.90). **CONCLUSIONS:** In this analysis, the point estimates for TMD in GFR consistently favored belatacept, yet the CrIs and model fit were affected by the choice of prior for σ. Given the subjectivity in selecting priors for continuous outcomes, transparent reporting is essential.

MT2

THE USE OF CONTINUOUS DATA VERSUS CATEGORICAL DATA IN MTC: THE CASE OF HAQ MULTIPLIER IN RHEUMATOID ARTHRITIS

Schmitz S[1], Adams RC[2], Walsh C[1], Barry M[2]
[1]*Trinity College Dublin, Dublin, Ireland,* [2]*National Centre for Pharmacoeconomics, Dublin, Ireland*

OBJECTIVES: Each of the tumour necrosis factor alpha antagonists (anti-TNF-α) available to treat rheumatoid arthritis have demonstrated considerable efficacy in placebo controlled trials, but few head-to-head comparisons exist to date. This work estimates the relative efficacy among licensed anti-TNFs and highlights the advantages of continuous outcome measures in mixed treatment comparison models. **METHODS:** Relative efficacy was estimated using Bayesian mixed treatment comparison (MTC) models. Three different outcome measures were used; Risk ratios of achieving an ACR20 and ACR50 response (binomial outcomes) and the percentage improvement in HAQ score (continuous outcome). Five anti-TNF-α antagonists were included in the analysis; adalimumab, infliximab, etanercept, golimumab and certolizumab. **RESULTS:** All anti-TNF agents show a significant improvement over placebo across all outcome measures. The HAQ model outcomes provide evidence that all anti-TNF agents show improvement over infliximab. This effect is not found with the ACR outcomes for adalimumab and golimumab. Furthermore, the HAQ model indicates a superiority of etanercept over adalimumab. The evidence of certolizumab pegol providing improvement over golimumab, which can be found in the ACR outcomes, is not apparent in the HAQ outcomes. **CONCLUSIONS:** Continuous outcome measures make better use of the complete data than binomial measures and are therefore more sensitive to change. The results suggest that it may be the case, in mixed treatment comparison models, where the essence lies in detecting differences, a continuous outcome measure is more appropriate. Its enhanced sensitivity to change increases the power of the model to detect differences among treatments. The HAQ multiplier provides one such measure, but others exist.

MT3

A BAYESIAN APPROACH TO MODEL SELECTION PROCEDURES WITHIN MIXED TREATMENT COMPARISON FRAMEWORK

Osiewalski K, Szmurlo D
HTA Consulting, Krakow, Poland

OBJECTIVES: Model fit in Bayesian mixed treatment comparisons (MTC) is often assessed by the deviance information criterion (DIC). In some cases DIC is not conclusive. Our aim was to compare DIC with an alternative approach: formal Bayesian model comparison by estimating the posterior distribution over the model space. **METHODS:** DIC is a criterion which combines posterior mean of the deviance and deviance of posterior means. Models with lower DIC should be preferred, however if the difference in DICs is small the decision should not be based solely on DIC. Marginal data density (MDD) expresses probability of observing given dataset. Decision rule based on Bayesian model comparison is that the model with highest *a posteriori* probability should be chosen. Data from few systematic reviews indexed in Pubmed were extracted in order to find MTC datasets for which DICs for fixed (FEM) and random effects models (REM) are very similar. Two continuous variables datasets were chosen. Posterior distributions and DICs were estimated in WinBugs. The Newton-Raftery estimator of MDD was implemented in Java, together with the Gibbs sampler. In both cases, in which DIC was not conclusive, two *a priori* structures over the model space were assumed: an uniform distribution and one penalizing the models for the excessive number of parameters. **RESULTS:** In the first dataset difference in DICs was 1.3 (in favor REM), in the second dataset this difference was 2,0 (in favor FEM). In both cases REM turned out to have a higher value of MDD. Although a priori odds ratio was around 100:1 for FEM, the posterior distribution was in every case close to have probability of one (~0.9999) for the REM. **CONCLUSIONS:** Decision about model selection should include tools of formal model comparison, as conclusions coming from it are always interpretable and coherent within Bayesian inference.

MT4

MIXED TREATMENT COMPARISONS USING AGGREGATE- AND INDIVIDUAL-PARTICIPANT LEVEL DATA: AN EFFICIENT USE OF EVIDENCE FOR COST-EFFECTIVENESS MODELLING

Saramago P[1], Sutton AJ[2], Cooper NJ[2], Manca A[1]
[1]*University of York, York, North Yorkshire, UK,* [2]*University of Leicester, Leicester, Leicestshire, UK*

OBJECTIVES: Cost-effectiveness analysis must use all relevant sources of evidence to inform reimbursement decisions. Mixed treatment comparisons (MTC) extends the traditional pair-wise meta-analytic framework to facilitate the synthesis of information on more than two interventions. While most MTCs use aggregate data (AD), a proportion of the evidence base might be available at the individual level (IPD). This paper develops novel statistical models aimed to fully exploit the existing data, regardless of the format (i.e. AD or IPD). **METHODS:** We develop a series of novel Bayesian statistical MTC models to allow for the simultaneous synthesis of IPD and AD, while considering study and individual level covariates, and use these to inform a decision model. **RESULTS:** The effectiveness of home safety education and the provision of functioning smoke alarms (binary outcome – Yes/No) for the prevention of childhood injuries in the household was used as a motivating example. Case study included 20 trials (11 AD, 9 IPD), summing up to 11,500 participants. Seven strategies were defined and a network of evidence was constructed. Irrespective of the evidence format used, all models which did not consider information on covariate(s) showed equivalent results, i.e. more intensive interventions (providing education, equipment (with fitting) and home inspection) were more effective (OR vs usual care of 4.5 (95%

credible interval: 1.4 to 14.8). Results of synthesizing IPD using information on a covariate account for possible ecological bias and show a clear improvement in accuracy over estimated treatment-covariate interactions, when compared to results obtained from synthesizing AD. **CONCLUSIONS:** Including evidence at IPD level in the MTC is advisable when exploring participant level covariates; even when IPD are only available for a fraction of the studies forming the evidence base. Our findings suggest that adjusting for covariates impact produces intervention effect estimates of higher accuracy, which is valuable for estimating subgroup effects or adjusting for inconsistency.

PODIUM SESSION II: DISCUSSION ON DECISIONS AND THE IMPACT OF NICE AND OTHER REGULATORY BODIES IN THE UK

NI1

THE UK NICE SINGLE TECHNOLOGY APPRAISAL PROCESS: A QUALITATIVE STUDY BASED ON MANUFACTURERS' SUBMISSIONS

Kaltenthaler E
University of Sheffield, Sheffield, UK

OBJECTIVES: International health technology assessment is increasingly interested in the rapid review of technologies. In the UK NICE Single Technology Appraisal (STA) process, manufacturers present the clinical and cost effectiveness of new technologies in their evidence submissions. These submissions are critically appraised by Evidence Review Groups (ERGs) who produce a report which forms part of the evidence considered by the Appraisal Committees. Early on in the process the ERG requests more information from the manufacturer via a clarification letter. The purpose of this research was to analyse ERG reports and clarification letters in order to develop guidance for manufacturers based on common problems or issues identified in manufacturer submissions (MS). **METHODS:** A thematic analysis of the first 30 completed ERG reports was undertaken using a framework approach. Twenty one of the available associated clarification letters were analysed using a set of open codes to analyse data. Both sources of evidence were used to identify common issues and concerns. **RESULTS:** Inadequate reporting of processes was identified in 90% of reports; criticisms of data used, especially in the model was mentioned for 67% of the reports and issues with the conduct of the systematic review in 57%. The population and comparator represented the key items in the decision problem assessed by the ERGs as being inadequately addressed by manufacturers. The majority of clarification points related to the economic data analysis. Issues identified included clarification of data sources and selection, queries about modelling decisions and requests for additional analyses. Internal inconsistencies between the clinical and economic sections of the MS and inconsistencies within the economic section of the MS were also identified as particular problems. This analysis was used as the basis for the development of 12 recommendations for manufacturers. **CONCLUSIONS:** These recommendations may help to improve the quality of manufacturers' submissions.

NI2

THE IMPACT OF NICE GUIDANCE ON THE DIFFUSION OF MEDICAL DEVICES

Cabo R[1], Sorenson C[2], Lynch P[3], Eggington S[4]
[1]*GE Healthcare, Bucks, England, UK,* [2]*London School of Economics and European Health Technology Institute for Socio-Economic Research, London, UK, UK,* [3]*Medtronic, Tolochenaz, Switzerland,* [4]*Medtronic International, Tolochenaz, Vaud, Switzerland*

OBJECTIVES: Health technology assessments (HTAs) have the potential to influence the diffusion of medical devices into health care systems. This study investigates the impact the National Institute for Health and Clinical Excellence's (NICE) technology appraisals have on the diffusion of implantable devices in the UK (UK). **METHODS:** The analysis focused on the impact of NICE guidance on volume sold of three medical devices: drug eluting stents (DES), implantable cardioverter defibrillators (ICD), and spinal cord stimulators (SCS). UK sales data (2005-2010) for each device were collected from Eucomed and other industry sources. Diffusion patterns before and after publication of NICE guidance were analyzed from an aggregated market-level perspective. A linear regression model was fit to the time series data to illustrate the relationship between the NICE decision and volume. **RESULTS:** The results from the statistical analysis show that NICE guidance has different effects on diffusion across products. NICE guidance had a step increase impact in adoption of DES and SCS ($p=0.026$ and $p=0.00$, respectively).The model suggests that the NICE review did not predict the diffusion of ICDs. Descriptive analysis demonstrated that for SCS and ICDS the NICE decision had a positive effect and no impact on DES diffusion on volume over time. Overall the units sold were positively and significantly correlated with time post-NICE guidance. **CONCLUSIONS:** The study indicates that NICE guidance influences the adoption of medical devices. Positive recommendations were associated with an increase in units sold despite a decrease in units sold experienced before the final recommendation. Additionally, the analysis suggests that there may be a lag between a positive NICE decision and adoption of guidance recommendations in practice. Lastly, there were no consistent trends on NICE's effect on the rate of diffusion. More research is needed to clearly understand the dynamics of HTAs on technology adoption.

NI3

ECONOMIC EVALUATION IN NICHE MARKETS: THE ROLE OF THE UK'S ADVISORY GROUP FOR NATIONAL SPECIALISED SERVICES FOR RARE DISEASES AND DISORDERS

Khan N[1], Kiss N[1], Pang F[2]
[1]*Oxford Outcomes Ltd., Morristown, NJ, USA,* [2]*Shire Human Genetic Therapies, Inc, Basingstoke, UK*

OBJECTIVES: The Advisory Group for National Specialised Services (AGNSS) is a new committee that advises health ministers on which orphan services, including orphan drugs, should be nationally commissioned. The aim of this paper is to provide a description of AGNSS priorities, budget, and synergies with the National Institute for Health and Clinical Excellence (NICE), and an analysis of the decision-making framework used by AGNSS to recommend new drugs and technologies. **METHODS:** A web-based search was conducted for articles and information related to the specialized services of the National Health Service (NHS) and NICE. All documents, including AGNSS meeting minutes were analyzed to provide a comprehensive understanding of the AGNSS program. **RESULTS:** Beginning in 2010 and each year thereafter, AGNSS will recommend approximately 60 highly specialized services and a small number of new drugs and technologies that affect fewer than 500 patients in England. Drugs and stand-alone technologies first must be submitted to NICE. Based on prevalence, disease severity, resource impact, and clinical benefit, a subset of these are referred to AGNSS for consideration. AGNSS can recommend "accept" or "accept with conditions" when the application meets the quality, innovation, productivity, and prevention criteria, or will recommend to "defer" or "reject" otherwise. Currently, AGNSS has identified eight priority areas for 2011-2012. The total program budget in 2010/11, excluding three high-cost drugs categories, is expected to be about £348 millions. Additionally, the planned budget for high-cost drugs such as enzyme replacement therapy, paroxysymal nocturnal hemoglobinuria (PNH), and cryopyrin-associated periodic syndromes (CAPS) is £128,879, £27,592, and £3,080 million, respectively. **CONCLUSIONS:** Under the current NHS framework, access to orphan drugs can be denied if they surpass NICE implicit willingness to pay thresholds. The introduction of AGNSS offers an alternative evaluation mechanism, one that potentially offers the flexibility necessary to comprehensively review orphan drugs and services.

NI4

THE ASSOCIATION BETWEEN FINANCIAL IMPACT AND THE LIKELIHOOD OF RECOMMENDATION OF MEDICINES FOR USE IN ENGLAND AND WALES

Mauskopf JA[1], Chirila C[1], Birt J[2], Boye KS[2], Bowman L[2], Grainger D[3]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*Eli Lilly and Company, Indianapolis, IN, USA,* [3]*Eli Lilly and Company, Indianapolis, IN, USA*

OBJECTIVES: To estimate the relationship between the maximum possible financial impact (MPFI) of a new medicine on the UK (UK) National Health Service (NHS) and the probability of the drug being recommended for use in England and Wales by the National Institute for Health and Clinical Excellence (NICE). **METHODS:** Data were abstracted from the NICE guidance document and costing template for decisions made about drugs between January 2001 and March 2011. MPFI was calculated by multiplying the population eligible for treatment with the new drug based on the UK marketing indication by the upper bound estimate for the annual cost of treatment. Descriptive, logistic, and recursive partitioning decision analyses were used to estimate the relationship between the MPFI of a new medicine and the probability of recommendation for use with or without restrictions. Multivariable analyses controlled for other clinical and economic variables that have been shown to be correlated with the probability of recommendation for use, including the cost per quality-adjusted life-year (QALY) gained. **RESULTS:** In all analyses, MPFI was an important predictor of the recommendation for use, in addition to cost per QALY. In the univariate analysis, the mean MPFI was £140 million for medicines not recommended and £92 million and £31 million for those recommended with and without restrictions, respectively. In the logistic analysis, the coefficient on the MPFI variable was statistically significant. In the recursive partitioning decision analysis, the second split of the data for classifying recommendations, after cost per QALY, was for submissions with an MPFI above or below £130 million. **CONCLUSIONS:** In England and Wales, besides cost-effectiveness ratio, MPFI on the NHS may be an important determinant of whether a new drug is recommended for use with or without restrictions.

PODIUM SESSION II: MERGING PRO AND UTILITY ASSESSMENT: DOES THE GAP INDEED GET SMALLER?

UT1

COMBINING DCE AND TTO INTO A SINGLE VALUE FUNCTION

Van Hout BA[1], Oppe M[2]
[1]*University of Sheffield, Sheffield, UK,* [2]*iMTA, Rotterdam, The Netherlands*

OBJECTIVES: To develop a method that enables estimation of a single value function using data from discrete choice (DC) and time trade off (TTO) questionnaires and to analyse the informative value of an additional TTO question versus that of an additional DC. **METHODS:** Separate DCE and TTO studies are designed with varying numbers of health states (EQ-5D) to be valued. The DC states do not hold a time dimension. An optimal Federov design is chosen for the TTO states, a Bayesian approach is followed for the DC states. The base line is blocked design of 20 blocks with 10 DCE's and 20 blocks of 5 TTO's. Responses are simulated to both study-types using prior expectations about answering behaviour, including 10% of individuals who do not trade time when judging TTO states. Models are estimates separately as well as simultaneously. For the latter all information is combined using a likelihood approach assuming a generalised linear model underlying the answers to the DC comparisons as well as to the TTO questions. The informative value of adding an additional DC or TTO is measured by the average precision surrounding the model parameters. **RESULTS:** While the TTO data offer sufficient data to identify a value function, the DC data need normalizing constants. Combining both approaches by estimating a single likelihood function takes care of this

successfully but only after introducing a multiplicative scale parameter to distinguish between both approaches. With 1600 respondents, adding 1 TTO offers more informative value than adding 1 DC but not as much as adding 2 DC's. **CONCLUSIONS:** The likelihood approach effectively estimates the structure underlying the simulated data. Given that DC is less burdensome than TTO, one may prefer to add more DC's than TTO's. That is – as in this case – when the underlying modelling assumption apply.

UT2

UPDATE OF THE PATIENT-REPORTED OUTCOME AND QUALITY OF LIFE INSTRUMENTS DATABASE (PROQOLID) USING THE FDA GUIDANCE ON PRO MEASURES

Caron M, Perrier LL, Vaissier V, Savre I, Acquadro C, Emory MP
MAPI Research Trust, Lyon, France

OBJECTIVES: In 2002, PROQOLID was launched to provide an overview of existing PRO instruments and facilitate access to the instruments and their developers, through the structured presentation of synthesized, reliable, and updated data. In 2009, the Food and Drug administration (FDA) published its final guidance on the use of PRO measures which describes how the FDA will review PRO instruments used to support claims in approved medical product labeling. The objectives of this study were to review and adapt the template of PROQOLID to harmonize its structure and language with those used in the FDA guidance, acknowledging that PROQOLID and the guidance have different **OBJECTIVES:** provision of information vs. review of information. **METHODS:** Content and structure of PROQOLID and the FDA guidance were compared. Proposed changes in terminology and structure were submitted to a panel of PRO experts (n=2). **RESULTS:** The information on PROQOLID is divided into 12 sections. The FDA guidance categorizes information into 5 parts. Twelve changes in terminology were made across all sections. For instance, Time recall" was changed to "Recall/Observation period", and "Dimensions" to "Domains". Fourteen changes of structure were made, mainly in Sections 6 and 7. Section 6 (Methodology of development) was renamed "Content Validity documentation". In this section, the heading "Information retrieval" was replaced by "Concept elicitation and Item generation". "Conceptual framework" will be moved to Section 5 (Descriptive information). Section 7 (Psychometric properties) was renamed "Measurement Properties". Within the "Reliability" heading, a subheading on "Inter-interviewer reproducibility" was added. A new section was created: "Data analysis and Interpretation". Five sections remained unchanged (1 to 4, and 8). **CONCLUSIONS:** The comparison of PROQOLID and the FDA guidance led to numerous changes in the wording and structure of the database. These changes will improve the functionality of PROQOLID and help users to better fulfill FDA requirements.

UT3

THE VALIDITY OF THE EQ-5D, SF-6D, SF-36 AND SF-12 IN MENTAL HEALTH CONDITIONS: A SYSTEMATIC REVIEW

Papaioannou D, Peasgood T, Brazier J, Parry G
University of Sheffield, Sheffield, UK

OBJECTIVES: To assess the validity and responsiveness of the SF-36, SF-12, SF-6D and EQ-5D in mental health conditions. **METHODS:** Systematic reviews were undertaken in five mental health conditions. Ten databases were searched to August 2009. Studies were appraised and data extracted. A narrative synthesis was performed on construct validity including known groups validity (KGV) (ability to detect differences in HRQL scores between groups), convergent validity (CV) (strength of association between generic HRQL and other related measures (e.g. symptoms or function) and responsiveness (R) (i.e. changes in scores in responders/non-responders to treatment and correlation with changes in related measures). **RESULTS:** Within schizophrenia, the majority of evidence related to the SF-36 (n=25) and EQ-5D (n=9). Both measures demonstrated KGV but this was mostly limited to demonstrating differences between individuals with schizophrenia and the general population. Contradictory results were found in studies measuring CV and R using clinical measures of symptom severity. For bipolar disorder, 23 studies were identified, almost exclusively on the SF-36; which was able to detect known differences in symptom severity and correlated strongly with clinical measures of depression (weakly with mania measures). For personality disorders; the majority of studies (6/9) related to the EQ-5D, which showed good KGV and R. For depression and anxiety, 23 EQ-5D and eight SF-6D studies were identified. Both measures demonstrated good CV and R for depression; however KGV may be driven by the presence of co-morbid depression in patients with anxiety disorders. **CONCLUSIONS:** Overall, the evidence suggests that the generic HRQL measures are appropriate in four mental health conditions, but raises doubts about their use in schizophrenia. Caution is required when interpreting CV evidence using clinical measures, since the lack of relationship may reflect genuine lack of difference in HRQL. More evidence using better indicators for testing validity and responsiveness are required.

UT4

COMPARISON OF THE PERFORMANCE OF EQ-5D AND SF-6D IN PATIENTS WITH CHRONIC PAIN –RESULTS FROM 3 RANDOMIZED CONTROLLED TRIALS

Obradovic M, Lal A, Liedgens H
Grünenthal GmbH, Aachen, Germany

OBJECTIVES: To compare EQ-5D and SF-6D utilities in patients with chronic pain due to osteoarthritis (OA) of the knee or low back pain (LBP) derived from phase III trials with tapentadol. **METHODS:** Three phase III trials with identical design included EQ-5D and SF-36 questionnaires to measure quality of life of patients with pain due to OA or LBP treated with tapentadol prolonged release (PR), oxycodone controlled release (CR) or placebo. EQ-5D and SF-6D indices were obtained using the UK weights. The ability of the two utility measurements to discriminate among different health states was tested. **RESULTS:** Both SF-6D and EQ-5D utility values increased from baseline to endpoint (15 weeks). The increase (mean of all patients with active treatment) was substantially higher when measured with EQ-5D (0.16 vs. 0.06). The EQ-5D better distinguished among health states (different severity of adverse events, pain relief, withdrawal rates). While utilities were very similar in a group of patients who tolerated the treatment (0.695 and 0.694 for EQ-5D and SF-6D, respectively), EQ-5D utilities were considerably lower in patients who withdrew due to adverse events (0.503 and 0.597 for EQ-5D and SF-6D, respectively). A similar pattern was seen in patients with various levels of pain relief. In patients with >30% pain relief mean EQ-5D and SF-6D utility was 0.716 and 0.708, respectively. The EQ-5D utility in patients who withdrew due to lack of efficacy was 0.405, when analyzing the SF-6D utility this resulted in 0.580. **CONCLUSIONS:** Both generic instruments to measure quality of life, EQ-5D and SF-6D, showed that avoidance of severe treatment-related adverse events and sufficient pain relief has a large beneficial impact on patient's wellbeing. In the clinical trials analyzed the discriminative power of the EQ-5D was stronger showing that this instrument is a useful tool also in pain studies to analyze patient's QoL.

PODIUM SESSION II: DISCUSSIONS ON THE ADDED VALUE OF VALUE OF INFORMATION

VI1

DETERMINING THE IMPACT OF MODELING ADDITIONAL SOURCES OF UNCERTAINTY IN VALUE OF INFORMATION ANALYSIS

Corro Ramos I, Rutten-van mölken MP, Al MJ
Erasmus University, Rotterdam, The Netherlands

The conditional reimbursement policy for expensive medicines in the The Netherlands requires real-world data collection on cost-effectiveness within a four years period (T=4) after the initial decision to reimburse a drug (T=0). This introduces *new sources of uncertainty*, which are less important in an RCT than in real life. This may affect the priorities for further (real-world) research as determined in a VOI analysis. **OBJECTIVES:** Identifying and modeling types of uncertainty that are usually not parameterized at T=0 but may become relevant at T=4. Include them in the VOI analysis. **METHODS:** We use a hypothetical model with four states and parameters related to transition and exacerbation probabilities, costs and utilities. Three additional uncertainties were parameterized: persistence, compliance and broadening of indication. Persistence refers to the duration of the treatment and it is determined by the probability of dropping out of the treatment. Compliance is characterized by the fraction of the treatment benefit obtained due to not taking the medication as it was indicated. The impact of indication broadening is modeled as the percentage of the RCT treatment effect realized in the outcome study. These extra parameters were included in the VOI analysis. **RESULTS:** Priorities change when new uncertainties are introduced in the model. Initially, the EVPPI was highest for transition probabilities followed by utilities; and it was very low for exacerbation probabilities and costs. After new uncertainties are included, compliance and broadening of indication (which is applied only to the new treatment) become as relevant as utilities. Persistence however has little impact in the model. **CONCLUSIONS:** VOI analysis at T=0 should anticipate and parameterize new types of uncertainty that may emerge during a four year outcomes study. This would help to focus the real-world outcomes study on those parameters that reduce uncertainty in the decision to continue the reimbursement most.

VI2

A NOVEL APPROACH TO ANALYSING VALUE DRIVER IMPORTANCE ACROSS MULTIPLE TARGET PRODUCT PROFILES

Wild L[1], Mukku SR[2]
[1]*Double Helix Consulting, London, UK,* [2]*Double Helix Consulting Group, London, UK*

OBJECTIVES: To develop a novel semi-quantitative model to assist pharmaceutical companies in making investment decisions, by assessing relative importance of value drivers in a given therapy area and how this translates to perceived value of a product profile. **METHODS:** Perceived value for a number of product profiles is assessed through a semi-quantitative scoring method, followed by an in-depth qualitative interview. In the scoring phase, respondents rate the relative importance of value drivers and provide thresholds for minimal and strong value in each domain. Respondents assess target product profiles, scoring profile performance in each value driver on a pre-defined scale. **RESULTS:** This methodology provides a range of valuable data in understanding the drivers of value in a given therapy area. First, the relative importance of value drivers can be used to understand which product attributes (efficacy, safety and tolerability or administration and others) drive product value. In addition, by providing value thresholds for each driver, we can understand expectations, in effect defining an 'ideal' product scenario. Testing product profiles against a scale calibrated by these expectations allows us to understand perceived product value in a set of likely product attributes. In addition, by testing a number of profiles, trade-offs between different product attributes, and the effect of these on product value, can be assessed. **CONCLUSIONS:** The insights gained from this type of analysis are vital in understanding product development priorities and the likely pricing and reimbursement potential for future products. Multiple applications of this technique have confirmed that this is a valuable approach in supporting pharmaceutical companies to inform their clinical programme, pricing and reimbursement strategy or commercial strategy.

VI3

SEQUENTIAL TREATMENT OF FOLLICULAR NON-HODGKIN LYMPHOMA: COST-EFFECTIVENESS AND VALUE OF INFORMATION

Soini EJ[1], Martikainen JA[1], Vihervaara V[2], Mustonen K[2], Nousiainen T[3]
[1]*ESiOR Ltd, Kuopio, Finland,* [2]*Roche Oy, Espoo, Finland,* [3]*Department of Medicine, University of Eastern Finland and Kuopio University Hospital, Kuopio, Finland*

OBJECTIVES: To assess the lifetime incremental cost-effectiveness ratios (ICER) per quality-adjusted life-year (QALY) gained and multinomial expected value of perfect information (mEVPI) of sequential follicular lymphoma (FL) treatment in Finland. **METHODS:** The novel cancer treatments included rituximab (R) and bendamustine (B). A probabilistic Markov-model was developed to simulate patients' transitions between first-line progression-free (PF1), PF2, progression and death states using a second-order Monte Carlo-simulation, one month cycle, and half cycle correction. All patients received the recommended induction with R-cyclophosphamide-doxorubicin-vincristine-prednisone (RCHOP). For the RCHOP-induction responders, the sequence was continued without the first-line R-maintenance treatment (RCHOP) or with it (RCHOPR). PF1 was based on the best fitting parametric extrapolation (Gompertz; 4-year treatment benefit trunk) of PRIMA (Primary RItuximab and MAintenance) data. After RCHOPR or RCHOP, eligible patients were assigned to second-line RCOPR/B or RCOPR/COP based on the PRIMA results, B indication/labelling and the recent ESMO (European Society for Medical Oncology) guideline for FL. PF2s (5-year treatment benefit trunk) were based on the parametric estimate of EORTC20981 and adjustment based on Rummel's trial. After PF2 (progression), patients received best supportive care (BSC). Age-dependent death was set equal to the larger of EORTC20981 or Finnish background mortality. Payer costs were included in 2010 value, and the most affordable public drug costs (2/2011; wastage included) were used. EQ-5D-based utilities were set 0.78 for PF1/PF2 and 0.62 for progression. 3% annual discounting was used. **RESULTS:** The ICERs for RCHOPR->RCOPR/B->BSC, RCHOPR->RCOPR/COP->BSC and RCHOP->RCOPR/B->BSC were €9575, €9881 and €8812 per QALY gained in comparison to RCHOP->RCOPR/COP->BSC, respectively. According to the cost-effectiveness acceptability frontier, 47% of patients with RCHOP->RCOPR/COP->BSC, 46% and 68% of patients with RCHOPR->RCOPR/B->BSC were cost effective at the ICER-levels of €5,000 (mEVPI €5,047/patient), €15,000 (mEVPI €3,101/patient) and €25,000 (mEVPI €1,564/patient) per QALY gained, respectively. **CONCLUSIONS:** First-line R-maintenance is an efficient and potentially cost-effective start for FL-treatment sequence.

VI4

THE VALUE OF INFORMATION OF A MULTICENTRE RANDOMISED CONTROLLED TRIAL OF INTRAVENOUS IMMUNOGLOBULIN FOR SEPSIS (SEVERE SEPSIS AND SEPTIC SHOCK)

Soares MO
University of York, York, UK

OBJECTIVES: Sepsis is a syndrome characterised by a systemic inflammatory response to infection. Intravenous immunoglobulin (IVIG) has been proposed as an adjuvant therapy for sepsis. The need for a high quality randomised controlled trial (RCT) to evaluate the effectiveness of this treatment has been identified in the literature. The objectives of the current work were to use value of information analyses (VOI) to establish whether the costs of carrying out an RCT are outweighed by the potential benefit of the resulting information. **METHODS:** A decision model was developed to evaluate the cost-effectiveness of IVIG (in terms of cost per quality-adjusted life-year) in adults with severe sepsis. A systematic review coupled with formal modelling selection process was performed to assess evidence on the relative effectiveness of IVIG. Further reviews were conducted to inform other relevant model parameters. Decision uncertainty was presented and the value of information assessed. **RESULTS:** A large degree of between study heterogeneity in the existing evidence base over the relative effectiveness of IVIG could be explained by a measure of study quality and duration of IVIG therapy. When using this model, the incremental cost-effectiveness ratio of IVIG was estimated to be £20,850 per QALY (threshold of £20,000 per QALY), and the probability of IVIG being cost effective was 0.505. No clear clinical rationale for the association between relative effectiveness and duration of therapy emerged from existing studies. Alternative models were evaluated for their impact on cost effectiveness and on the need for further research. The results demonstrate that conclusions are highly sensitive to the choice of model used for clinical effectiveness. **CONCLUSIONS:** Although the analyses suggested potential value from a large multicentre RCT, the uncertainties around the design of such a study mean that further dose-ranging/finding studies should conducted prior to funding any future multicentre RCT.

PODIUM SESSION III:
TAKING HETEROGENEITY INTO ACCOUNT BETWEEN PATIENTS AND BETWEEN STUDIES

HG1

APPLYING FRAILTY MODEL IN LONGITUDINAL SURVIVALS OF CHRONIC DISEASES

Li Y, Holtzer-Goor K, Uyl-de Groot C, Al M
iMTA, Erasmus University Rotterdam, Rotterdam, The Netherlands

OBJECTIVES: Survival analysis plays an important role in assessing the effectiveness of medical product/treatments and the risk factors. Particularly, the accelerated failure time (AFT) model provides the hazard/survival functions to the later health economic decision model to compute the cost-effectiveness. The model estimations of the usual survival models rely on the maximum likelihood estimation (MLE), which works under the assumption of independence of observations. However, this assumption is not always satisfied, especially in the chronic/relapsing disease. A patient with a chronic disease may experience recurrent disease progressions in the life course. When the progression free survivals (PFS) are recorded longitudinally, the PFS of different patients can be considered independent. Nevertheless, owing to sharing some unobserved heterogeneity, PFS of the same patients tend to associate with each other. This within-patient association can affect the estimation accuracy, therefore may misinform the decision makers. Particularly designed for the multivariate survival analysis, the frailty model takes this issue into account. **METHODS:** Fist, in a simulation study, we compared the AFT model and the Frailty model, where 5000 hypothetical patients are assigned to two treatment arms, and each patient experiences 5 treatment lines. Second, we apply both the Weibull AFT model and the Weibull-Gamma frailty model to the real life data, where 254 patients of chronic lymphocytic leukemia(CLL) have been followed, and we conduct a hypothesis test on the significance of frailty term. **RESULTS:** The simulation study shows that the estimates of the AFT model deviate far from the true values when the unobserved heterogeneity is large. The real life study indicates that the AFT model should be replaced by the frailty model due to the significance of the frailty term. **CONCLUSIONS:** In modelling survivals for chronic disease, the frailty models provide more accurate effect estimation than the conventional survival model.

HG2

CHARACTERIZING THE INDIVIDUAL COURSE OF HEALTH-RELATED QUALITY OF LIFE AFTER SUBARACHNOID HEMORRHAGE

Winter Y[1], Klotsche J[2], Ringel F[3], Spottke A[4], Gharevi N[4], Klockgether T[4], Schramm J[4], Urbach H[4], Wittchen HU[2], Rehm J[2], Meyer B[3], Dodel R[1]
[1]*Philipps-University, Marburg, Germany,* [2]*Technical University Dresden, Dresden, Germany,* [3]*Klinikum rechts der Isar, Technical University, Munich, Germany,* [4]*University of Bonn, Bonn, Germany*

OBJECTIVES: Subarachnoid hemorrhage (SAH) is a cerebrovascular disease leading to severe disability. SAH-patients show heterogeneous profiles of health-related quality of life (HrQoL). No methodological approaches to characterize the individual course of HrQoL following SAH have been developed. The objective was to characterize individual trajectories concerning HrQoL following SAH by using latent growth mixture modeling (LGMM). **METHODS:** A total of 113 incident patients with aneurysmal SAH treated in the University of Bonn between January 2004 and December 2005 were recruited in this longitudinal study. Clinical parameters (Hunt and Hess scale, Barthel-Index, Rankin Scale, Beck Depression Inventory) and HrQoL data (EQ-5D) were evaluated at baseline, 6 and 12 months. LGMM was applied to analyse the heterogeneity in individual courses of HrQoL after SAH. **RESULTS:** We identified four subgroups of patients (latent classes) with different patterns of HrQoL-course. Class 1 had the worst HrQoL-course with a low score of the EQ-5D index at baseline (0.33) and a non-significant change in scores over time. Patients in class 3 showed rapid recovery from initially low EQ-5D scores (0.37) during the first 6 months (D=0.47). Patients in classes 2 and 4 had 48-57% better initial HrQoL and similarly high HrQoL scores after 12 months. Patients in class 4 experienced a temporary reduction of HrQoL by 55%. The following clinical parameters were identified to characterize differences between classes: severity of SAH (Hunt and Hess scale), functional outcome, cognitive impairment and post-stroke depression. Treatment of post-stroke depression in classes 1 and 4 can improve HrQoL measures by factor 1.3-2.8. **CONCLUSIONS:** This methodological approach can be applied for more elaborated understanding of individual differences in long-term course of HrQoL after SAH. Identification of different patterns of disease course using LGMM may help to find subgroups of treatment responders and to assist the development of individual therapy regimes.

HG3

COST COMPARISONS AND METHODOLOGICAL HETEROGENEITY IN COST-OF-ILLNESS STUDIES: THE EXAMPLE OF COLORECTAL CANCER

Hanly P[1], O'Ceilleachair A[2], Skally M[3], O'Neill C[4], Sharp L[3]
[1]*National Cancer Registry, Cork, Co. Cork, Ireland,* [2]*National Cancer Registry, Cork, Cork, Ireland,* [3]*National Cancer Registry Ireland, Cork, Cork, Ireland,* [4]*National University of Ireland Galway, Galway, Galway, Ireland*

OBJECTIVES: Colorectal cancer (CRC) is the third most commonly-diagnosed cancer worldwide with over one million new cases globally each year. Advances in treatment and survival have been occurring, which is likely to have increased lifetime costs of managing the disease. We systematically reviewed and critiqued the cost-of-illness (COI) literature on CRC. **METHODS:** We searched Medline, EMBASE, CRD and the Cochrane library for CRC COI studies published in English, January 2000- February 2011. Data was abstracted independently by two reviewers on: setting, patient population, top-down/bottom-up costs, incident/prevalent approach, payer perspective, time horizon, costs included, cost source and per-person costs. We developed a framework to compare study methodologies and assess homogeneity/heterogeneity. **RESULTS:** Twenty-six papers met the inclusion criteria from the US (17), France (3), the UK (2), Canada (2), Switzerland (1) and Taiwan (1). Extensive methodological heterogeneity existed between studies. 17 studies employed top-down costings; 6 studies were prevalent, 8 incident and the remainder mixed. Time horizons ranged from 1-year post-diagnosis to lifetime. 25 studies included healthcare payer direct medical costs; 2 included indirect costs; 1 considered patient costs. The included papers described case-control studies based on claims/reimbursement data(10), examinations of patient charts (5) and analysis of claims data(4). There was broad agreement in how studies accounted for time, but few studies described costs in sufficient detail to allow repeatability. In general costs were not comparable between studies. There were some commonality in findings between studies from the same setting and which estimated costs in the year following diagnosis, but estimates varied greatly for longer time horizons. **CONCLUSIONS:** Methodological heterogeneity and lack of transparency made it almost impossible to compare CRC costs between studies or over time. For COI studies to be more informative, and amenable to external comparison, researchers, decision-makers and funders should adopt more standardised methodologies and promote greater transparency.

HG4

THE VALUE OF HETEROGENEITY FOR COST-EFFECTIVENESS SUBGROUP ANALYSIS: THEORETICAL FRAMEWORK AND APPLICATION

Espinoza M[1], Manca A[2], Claxton K[3], Sculpher MJ[4]
[1]*University of York, York, UK,* [2]*University of York, York, North Yorkshire, UK,* [3]*York University, York, UK,* [4]*The University of York, York, UK*

OBJECTIVES: Decisions about the use of new medical technologies based on estimates of the average cost-effectiveness across a potentially heterogeneous population runs the risk of foregoing net health benefits(NHB) for sub-groups of the population. We propose a general framework within which to assess between-patient heterogeneity and its role in cost-effectiveness subgroup analysis(CESA), complementing this with a practical application. **METHODS:** We first describe how to extend methods for cost-effectiveness analysis (based on current information) to address issues such as estimation of NHB, sources of heterogeneity, definition and selection of subgroups. Next, we define the role of uncertainty in CESA, extending the concept of Value of Information(VoI) to include the notion of a *static* and *dynamic* Value of Heterogeneity(VoH). The application of the proposed theoretical framework is illustrated using a cost-effectiveness model developed for the analysis of a multicentre-trial(RITA-3), which assessed the efficacy of an early arteriography with revascularisation versus standard management in patients with acute coronary-syndrome. Using this model we conducted a re-analysis investigating alternative subgroup specifications, varying between one and five subgroups, with a view to produce an efficiency frontier for subgroup analysis relating to this decision problem. We assessed the static and dynamic VoH under each specification. **RESULTS:** The population expected NHB when considering five subgroups was 105,500 QALYs greater than decision based on estimates for the average population (static-VoH). Although, identifying 5 subgroups reduced in the Expected Value of Perfect Information(EVPI) (920 QALYs, at a threshold of £30,000/QALY), the potential NHB from resolving uncertainty was greater after heterogeneity has been identified (dynamic-VoH). **CONCLUSIONS:** Our initial findings support the argument that explicit consideration of heterogeneity in CEA leads to a positive static and dynamic VoH. In addition, heterogeneity not only may increase the EVPI but can also reduce its magnitude. The VoH framework offers a useful guidance for a more systematic CESA.

PODIUM SESSION III: TOWARDS A BETTER UNDERSTANDING OF REIMBURSEMENT DECISIONS BASED ON HTA ARGUMENTS

HT1

EFFECTIVENESS, EFFICIENCY AND BUDGET IMPACT AFFECT THE BELGIAN DRUG REIMBURSEMENT DECISION (DRD)

Bormans V, Van Wilder P
SMART&BI, Zaventem, Belgium

OBJECTIVES: The European Transparency Directive 89/105 (TD) imposes the use of objective and verifiable criteria in national pharmaceutical reimbursement decisions: for pharmaceuticals claiming added therapeutic value (ATV), the Belgian DRD uses 5 criteria comparing the product to its alternatives: effectiveness, efficiency, price, budget impact and therapeutic need . The study aim was to analyze the effect significance and size on the (yes/no) DRD of a set of parameters including: added therapeutic value ATV (yes/no), trial end-points (clinical or surrogate), level of evidence (RCT yes or no), availability of alternatives (yes/no), ICER and budget impact (in K Euro) in order to estimate the percentage of variability in DRD that could be explained by these explicit factors. **METHODS:** The National Health Insurance administrative database was used for extracting all publicly available DRDs on products claiming ATV submitted between 2002 and 2007. Data retrieval was substantially extended compared to previous work. ICERs expressed per QALY or per LYG were pooled. Logistic regression was performed using SPSS 15.0. The significance level was set at 0.05. **RESULTS:** A total of 110 submissions were retrieved: 40% had complete records. The regression analysis yielded a significant model ($p < 0.01$) with 58% of the variance explained and only 3 significant factors: ATV ($p < 0.001$), budget impact estimate ($p < 0.05$) and the computed ICER ($p < 0.05$). Higher estimates of budget impact and ICER decreased the probability of a positive DRD. No significant interactions were observed ($p > 0.10$). **CONCLUSIONS:** Multivariate analyses identified granting of ATV, pharmaceutical budget impact and the economic ICER to significantly affect the DRD. These 3 factors are among the 5 criteria on which the DRD should be based. Because of missing data some caution is needed on these inferences. Systematic public reporting of key submitted data would increase the feasibility of powerful analyses enhancing transparency.

HT2

VALUE BASED PRICING: ONE THRESHOLD TOO FAR FOR THE UNITED KINGDOM

Roberts G
Double Helix Consulting, London, UK

ISSUE: The budget for the NHS in England is declining in real terms by around 2% per year. Despite productivity having fallen in recent years, the NHS expected to make efficiency savings of between £15 and 20bn over the next 3 years. Will the proposed implementation of value based pricing (VBP) help or hinder the pursuit of a more efficient NHS. **OVERVIEW:** The objectives for implementing VBP and replacing the PPRS in the UK are to encourage innovation where there is unmet need, improve outcomes and ensuring value for money to the NHS with better access to effective medicines. Different willingness to pay thresholds are suggested as a way to incorporate these societal benefits when setting the price of a new pharmaceutical. Using this mechanism to incentivise pharma could be profitable for the industry with the unintended outcome of decreasing efficiency in the heath service at a time when it is not affordable. Let's consider two 'innovative' products (A and B) and assume a WTP of £40,000/QALY is acceptable. It would not be unreasonable to expect the price to be set to this level. Now let's take the price of the new drug out of the equation. Drug A has a cost/QALY of £15K and drug B £25k. The innovation of drug A comes at a higher price than drug B. An alternative would be to fix the innovative component at an additional £20k for example, up to a set maximum threshold. Drug A plus innovation mark-up would be allowed to price to £35k and drug B limited to the £40k maximum threshold. **CONCLUSION:** The efficiency of the UK NHS will be compromised if, as proposed, multiple willingness to pay (WTP) thresholds are implemented in the value based pricing (VBP) scheme for pharmaceuticals.

HT3

UNDERSTANDING THE COMPLEXITY OF HTA NETWORKS

Andreykiv M[1], Van engen A[1], Wiebinga C[1], Zorzi O[1], Mark R[2]
[1]*Quintiles, Hoofddorp, The Netherlands,* [2]*NiAG, Zürich, Switzerland*

OBJECTIVES: In recent years Health Technology Assessments (HTA) are increasingly applied to healthcare decisions, involving a complex constellation of stakeholders. Effective collaboration and communication with the HTA stakeholder community requires a holistic understanding of this ecosystem. To better understand multi-stakeholder influence dynamics across the HTA ecosystem, social network analysis techniques were employed. **METHODS:** Information on 74 HTA agencies was collected from various sources. Four data categories were included: agencies, institutions, people (members) and technologies. For each category a number of attributes were included (location, affiliations, memberships, type of technology, decision on technology, etc.). The connections and types of connections between the datasets were added. The Ni3 software was applied to this data to conduct the analysis and visualize HTA networks. **RESULTS:** The analysis enabled us to establish directions of influence (sources vs. absorbers: e.g., NICE vs. AHTAPol) within a network, correlation between the level of connectivity and the influence on market access, and also to observe HTA impact on the level of a drug or therapeutic area. The tool enabled mapping of relationship links that represent direction and weight of influence, overlaying displayed stakeholders with visual charts summarizing sets of quantitative values (such as number of employees or budget) for visual pattern matching and comparison, and geographic analysis. **CONCLUSIONS:** The application of social network analysis allowed visualization of the complex multi-stakeholder dynamics across HTA ecosystems to answer questions such as who are key influencers when it comes to coverage and reimbursement decisions. Understanding the complexity of healthcare networks is key to answering today's business-relevant questions. Although this research was explorative in nature, it warrants further refinement by combining HTA expert networks with commonly available KOL networks, to further explore the connectivity within the New Health ecosystem.

HT4

WHAT DETERMINES THE RECOMMENDATIONS ISSUED BY POLISH HEALTH TECHNOLOGY AGENCY (AHTAPOL)?

Niewada M, Polkowska MA, Jakubczyk M, Golicki D
HealthQuest, Warsaw, Poland

OBJECTIVES: AHTAPol operates in Poland since 2005. Recommendations issued by Consultative Council of AHTAPol are closely tracked as they support reimbursement decision making. We aimed at evaluating of predictors for positive (supporting covering of costs from public budget) and negative recommendations of AHTAPol. In particular we wanted to see whether a threshold value for ICER (cost per QALY) can be identified to drive AHTAPol decisions. **METHODS:** As only recommendations texts, neither HTA reports nor critical appraisals, are publicly available on the official website, two independent analysts have reviewed all recommendations issued before January 28, 2011. Each recommendation was evaluated using predefined criteria on decision rationales, i.e. whether negative or positive recommendations were supported by arguments on clinical efficacy (with special interest on hard endpoints defined according to Polish HTA guidelines), safety, cost-effectiveness, budget impact and others. PPV, NPV, LR-and LR+ were calculated for each criteria. Although the content of recommendations is structured, not all could be assessed based on each of the predefined criteria. Prediction model was developed for positive and negative recommendations. **RESULTS:** Two hundred eighty-five recommendations were identified including 177 positive and 108 negative ones, which were generally more elaborated. Clinical efficacy motivates recommendations most often, but positive impact on hard endpoints was explicitly reported in 15 negative recommendations and lack of such proven efficacy in 38 positive recommendations. Safety and cost-effectiveness were more often recalled in negative than positive recommendations. Budget impact of novel technology was a weak predictor of recommendation. No threshold value of QALY cost can be specified based on recommendations. **CONCLUSIONS:** Decision making by Consultative Council of AHTAPol is multi-dimensional and can be hardly predicted. Apart from efficacy, negative recommendations are mainly driven by unfavorable safety and cost-effectiveness.

PODIUM SESSION III: FINDING CROSSWALKS BETWEEN QALY INSTRUMENTS AND DISEASE-SPECIFIC PROS

MA1

MAPPING THE EQ-5D INDEX FROM I-QOL IN IDIOPATHIC AND NEUROGENIC OAB PATIENTS: RESULTS FROM A CROSS-SECTIONAL STUDY IN THE UNITED STATES AND FOUR EUROPEAN COUNTRIES

Kay S[1], Tolley K[2], Globe D[3], Piercy J[4], Anderson P[4]

[1]Adelphi Real World, Bollington, Cheshire, UK, [2]Tolley Health Economics, Buxton, UK, [3]Allergan, LLC, Irvine, CA, USA, [4]Adelphi Real World, Macclesfield, Cheshire, UK

BACKGROUND: Disease-specific instruments, commonly incorporated into clinical trials, provide comprehensive insights into the quality-of-life of patients experiencing that disease. However it is not possible to directly elicit preference-based valuations from such instruments for use in cost-utility analysis. **OBJECTIVES:** To provide a mapping algorithm for estimating EQ-5D index scores from the Urinary Incontinence-specific Quality of Life Questionnaire (I-QOL) based on nationally representative samples of patients with idiopathic or neurogenic overactive bladder (OAB) syndrome using EQ-5D preference valuations based on both the UK and US general populations. **METHODS:** Analyses were conducted for 2505 patients from the Adelphi OAB Disease Specific Programme, a cross-sectional study of patients consulting with idiopathic or neurogenic OAB, undertaken in the USA and Europe in 2010. A range of statistical mapping techniques including OLS, CLAD, Tobit, GLMs, reverse GLMs and reverse two-part GLMs were used. Ten-fold cross validation techniques were employed to calculate Mean Absolute Error (MAE) and Root Mean Squared Error (RMSE) goodness of fit statistics. Various predictor lists together with a method combining stepwise selection with multivariable fractional polynomial techniques to allow non-linear relationships to feature were pursued. **RESULTS:** Choice of predictors was consistent for both the UK and USA EQ-5D tariffs. For idiopathic, the best model included IQOL Composite Score and age (both modelled non-linearly). For neurogenic the best model was I-QOL Social Embarrassment Score modelled linearly only. Best fit results were better in the idiopathic (n=2351: MAE = 0.10. RMSE = 0.14) than neurogenic sample (n=254: MAE = 0.17. RMSE = 0.22). **CONCLUSIONS:** This research provides algorithms for mapping EQ-5D index scores from I-QOL allowing calculation of appropriate preference-based health-related quality-of-life scores for use in cost-effectiveness analyses when only I-QOL data are available. The strongest results were for idiopathic patients, but those for neurogenic are consistent with other published mapping studies.

MA2

MAPPING FACT-P TO COUNTRY SPECIFIC PATIENT HEALTH STATUS MEASURED BY EQ-5D IN METASTATIC CASTRATE RESISTANT PROSTATE CANCER PATIENTS

Spencer M[1], Diels J[2]
[1]Janssen-Cilag UK Limited, High Wycombe, UK, [2]Janssen Pharmaceutica, Beerse, Belgium

OBJECTIVES: To construct and validate a prediction model of preference-adjusted health status (EQ-5D) for metastatic castrate resistant prostate cancer (CRPC) patients using FACT-P (Functional Assessment of Cancer Therapy–Prostate), a multidimensional prostate cancer-specific health-related quality of life instrument. **METHODS:** Patient-level data were obtained for CRPC patients from the Adelphi Group Prostate Cancer Disease Specific Program (DSP) data, a multinational cross-sectional study of prostate cancer patients conducted in France, Germany, Italy, Spain and UK during 2009 to 2010. EQ-5D and FACT-P were available for a subset of patients. Country specific utility values were derived from EQ-5D profiles based on value sets available for 8 countries and the EU. Predictive validity of the FACT-P subscales and patient demographics for utility was tested using ordinary least square (OLS), median, Gamma and Tobit multivariate regression models, and predictive algorithms developed to convert FACT-P to EQ-5D utilities for different value sets. **RESULTS:** Values for both FACT-P (mean=85.4) and EQ-5D were available for 291 patients (mean age =70.7). A total of 57% of patients were treated with chemotherapy at the time of assessment, 10% had prior chemotherapy, and 33% were chemotherapy naive. Mean estimated country-specific utilities varied between 0.59 (New Zealand) and 0.76 (Germany). OLS and TOBIT regression were the best-performing models, explaining between 34.6% (Danish) and 46.8% (EU) of the observed EQ-5D variation. The physical and functional well-being subscales had the highest explanatory value. The social well-being and prostate cancer specific subscales, and patient age and BMI did not have statistically significant additional explanatory value. **CONCLUSIONS:** The developed algorithms enable to translate cancer-specific health-related quality of life measures to preference-adjusted health status in metastatic CRPC patients, taking into account local country-specific utility weights. The findings will help to develop health status adjustments in cost-utility analyses used in appraising health care technologies.

MA3

MAPPING THE DIABETES HEALTH PROFILE (DHP-18) ONTO THE EQ-5D AND SF-6D GENERIC PREFERENCE BASED MEASURES OF HEALTH

Meadows K[1], Mulhern B[2], Rowen D[3], Brazier J[2]
[1]DHP Research & Consultancy Ltd, London, UK, [2]University of Sheffield, Sheffield, UK, [3]University of Sheffield, Sheffield, South Yorkshire, UK

OBJECTIVES: To carry out cost utility analysis, utility values can be derived using generic preference based measures such as EQ-5D or SF-6D. In some settings generic measures are not used, and mapping functions are being developed to predict utility scores from condition specific measures. The aim of this study is to map the DHP-18 - a diabetes-specific HRQoL patient reported outcome measure - onto EQ-5D and SF-6D utility scores for type 1 and type 2 diabetes mellitus populations. **METHODS:** The data used was pooled from a longitudinal study of quality of life in diabetes. OLS, GLS and Tobit models regressing DHP dimensions and, separately, DHP items onto EQ-5D and SF-6D index scores for both type 1 (n=236) and type 2 (n=2358) diabetes populations were applied. **RESULTS:** For both the EQ-5D and SF-6D, the GLS model mapping selected DHP-18 item scores, squared item scores, age and gender onto the utility index provided the best fit, and this was the case for both the type 1 and type 2 populations (R2 EQ-5D type 1: 0.516; EQ-5D type 2: 0.290; SF-6D type 1: 0.647; SF-6D type 2: 0.396). The models under predict utility when the state is severe and over predict when the state is mild. The error associated with the models was lower for SF-6D than for EQ-5D due to differences in the range of the measures. **CONCLUSIONS:** The DHP-18 items can predict both the EQ-5D and SF-6D utility scores with acceptable precision with the mapping algorithm for the SF-6D displaying a higher level of precision. The mapping functions developed from the models can be used to predict utility scores in settings where the EQ-5D or SF-6D have not been used alongside the DHP-18. However mapping should be considered second best in comparison to using generic measures in research studies.

MA4

MODELLING EQ-5D HEALTH STATE VALUES: DEVELOPING A LIMITED DEPENDENT VARIABLE, MIXTURE MODELING APPROACH

Wailoo AJ, Hernández M, Ara R
University of Sheffield, Sheffield, UK

OBJECTIVES: We have previously developed an adjusted, limited dependent variable, mixture model (ALDMM) approach for estimating EQ-5D utility values from a range of covariates which reflects the upper bound, skewness and gaps in the distribution of EQ-5D. The three class ALDMM has been demonstrated to perform better than standard approaches on aggregate in a rheumatoid arthritis (RA) dataset but was not superior at very poor health states. Here we refine the method and apply it to a much larger RA dataset. **METHODS:** Using an observational dataset of RA patients (n=16,000) we estimate EQ-5D utility values (UK tariff) as a function of Health Assessment Questionnaire (HAQ), pain, age and sex. This was done using linear, Tobit, three and four class ALDMMs. We further adjusted the ALDMM to account for the lower EQ-5D bound. **RESULTS:** EQ-5D is estimated as a function of HAQ, pain and pain2 as well as age and sex. Previous results were replicated at extremely poor health states in this very large dataset. By including the additional adjustment for very poor health states, the ALDMM outperforms all others tested in terms of model fit and appropriateness of the predictions across the entire range of EQ-5D **CONCLUSIONS:** The ALDMM approach is designed to appropriately reflect the range of challenges that arise from the EQ-5D distribution. Standard models are not as appropriate and fit the data less well. It may be that an additional adjustment to the ALDMM is required to model extremely serious health states, which are often of critical importance in cost effectiveness models, though the relative scarcity and credibility of data at this extreme remain a concern.

PODIUM SESSION III: LOOKING BEYOND EXISTING HORIZONS

MO1

METHODS FOR EXTRAPOLATING SURVIVAL DATA USED IN NICE TECHNOLOGY APPRAISALS: INCONSISTENCIES AND LIMITATIONS

Latimer N
University of Sheffield, Sheffield, South Yorkshire, UK

OBJECTIVES: Treatments that impact upon survival form a high proportion of the interventions appraised by the National Institute for Health and Clinical Excellence (NICE). Survival data are commonly censored and therefore extrapolation is required to estimate the full impact of the new intervention. There are a range of approaches for conducting survival analysis in these circumstances, and these can lead to widely varying survival estimates and incremental cost-effectiveness ratios (ICERs). We reviewed a subset of NICE Technology Appraisals (TAs) to identify and analyse methods that are commonly used in practice. **METHODS:** We identified all completed NICE TAs that appraised new treatments for advanced and/or metastatic cancer and analysed methods for estimating survival and justifications for the chosen approach. **RESULTS:** By December 2009 NICE had completed 45 TAs that focussed on advanced and/or metastatic cancer. Parametric models were used in 71% of these. Weibull and exponential models were most commonly used (in 51% and 44% of the reviewed TAs, respectively), with Gompertz, log-logistic, log normal and gamma models used infrequently. Piecewise parametric models and other more flexible methods were seldom used. Justifications of chosen approaches were not systematic and were usually overly simplistic. **CONCLUSIONS:** Survival analysis methods differ significantly across NICE TAs. This is expected because different methods are appropriate in different circumstances. However, the majority of TAs did not take a systematic approach to survival analysis and did not fully justify chosen methods. Therefore inappropriate methods may have been used. Different models can lead to large variations in ICERs – for example in NICE TA178 log-logistic models led to an ICER of £40,000, compared to £75,000 when Gompertz models were used. Hence it is clearly of great importance to select appropriate models. This review has contributed to a NICE Technical Support Document on extrapolation with patient-level data.

MO2

EXTRAPOLATION IN ONCOLOGY MODELLING: NOVEL METHODS FOR NOVEL COMPOUNDS

Annemans L[1], Asukai Y[2], Barzey V[2], Kotapati S[3], Lees M[4], Van Baardewijk M[5], Wang Q[4], Batty AJ[6], Fisher D[6]
[1]Ghent University, Ghent, Belgium, [2]IMS Health, London, UK, [3]Bristol-Myers Squibb Pharmaceuticals, Wallingford, CT, USA, [4]Bristol-Myers Squibb, Uxbridge, Middlesex, UK, [5]Bristol-Myers Squibb, Braine L'Alleud, Belgium, [6]BresMed Health Solutions, Sheffield, South Yorkshire, UK

OBJECTIVES: Immunotherapies such as ipilimumab and IL-2 show delayed but durable response leading to stabilization of symptoms and extended OS after an initial drop-off in the KM curve. Our objective was to review and challenge currently available economic modelling methods when applied to such emerging therapies with new mechanisms of action (MoA). **METHODS:** As alternatives to stan-

dard OS extrapolation methods which fit 'traditional' parametric survival distributions to patient-level data, two different methods were explored in the modelling of OS beyond the trial duration (55 months) for the novel immunotherapy ipilimumab. In the first approach, the hazard rate from the Kaplan-Meier (KM) curve between 24 and 36 months (before reaching a plateau) was used to extend the curve. In the second approach, different parametric curves were fitted to the period of 18 months onwards. Akaike's Information Criterion (AIC) was used to determine the best fit curve. **RESULTS:** When compared to standard OS extrapolation methods, both methods exhibited a better visual fit to the data. Both approaches allow the hazard of the extrapolated tail to be based on a section of the KM curve that is more appropriate in describing the long-term survival of these patients. The hazard rate approach does not allow for a formal comparison with AIC, but allows extrapolation in line with the clinical interpretation. The 'parametric curves' approach allows for a statistically better fit with the patient level data using conventional AIC criteria. Both methods are in line with long-term observations of immunotherapy. **CONCLUSION:** For novel cancer therapies whose KM curves are not well described by standard survival distributions, other methods of extrapolation should be explored in conjunction with an understanding of the clinical rationale. In this case study, two alternatives are presented that describe the OS of immunotherapy patients in a more suitable way.

MO3

A METHODOLOGICAL FRAMEWORK FOR DEVELOPING MODELS OF WHOLE DISEASE AREAS TO INFORM RESOURCE ALLOCATION DECISIONS

Tappenden P, Brennan A, Chilcott J, Squires H
University of Sheffield, Sheffield, South Yorkshire, UK

OBJECTIVES: Conventional economic evaluation involves piecewise comparisons of competing interventions at a single point in a broader care pathway. **METHODS:** This approach is subject to several problems: a) there remains an ongoing debate surrounding the appropriateness of threshold-based decision rules and whether their repeated use will maximise health; b) restricting the model scope to a single decision point means that other adoption decisions elsewhere in the disease pathway may be treated as independent of the problem under consideration; and c) the absence of model development guidance leads to inconsistencies between analyses addressing similar decision problems. In light of these problems, this study puts forward the notion of "Whole Disease Modelling." This involves simulating whole disease and treatment pathways within a single model, from preclinical disease through to diagnosis and referral, adjuvant treatment, follow-up, potential recurrence, palliative treatment, end-of-life care and eventual death. A methodological framework has been developed based on three key principles: 1) the model boundary and breadth should capture all relevant aspects of the disease and its treatment; 2) the model should be developed such that the decision node is conceptually transferable across the pathway; and 3) the costs and consequences of service elements should be structurally related. **RESULTS:** Case study applications in colorectal cancer services suggest that Whole Disease Modelling is feasible and may provide a consistent platform for economic analysis at virtually any point in a disease pathway using multiple economic decision rules. **CONCLUSIONS:** The value of the approach may be realised when: multiple decision problems require formal economic analysis at a single timepoint; services are subject to rapid innovation and the model can be re-used; a substantial proportion of currently provided service elements have not previously been subjected to economic analysis, and; standard cost-utility decision rules fail to reflect the complexity of the decision-makers' objectives.

MO4

OUTCOMES BEYOND HEALTH

Joore MA[1], Dellaert B[2], Spijkers L[1], Severens JL[3], Krabbe P[4], Dirksen C[5]
[1]*MUMC, Maastricht, The Netherlands,* [2]*EUR, Rotterdam, The Netherlands,* [3]*Erasmus University Rotterdam, Rotterdam, The Netherlands,* [4]*RUG, Groningen, The Netherlands,* [5]*MUMC, maastricht, The Netherlands*

OBJECTIVES: The aim of this study was to investigate whether broadening the evaluative space in an economic evaluation would lead to other outcomes, and hence policy recommendations. **METHODS:** Two discrete choice experiments (DCE) were conducted in a population of patients who had been treated for varicose vein disease (N=390) either by foam sclerotherapy or surgical stripping. In the Health DCE the treatments were described in terms of health outcomes attributes only (based on the EQ5D dimensions). In the Extended DCE the treatments were described in terms of the same health outcomes attributes and other aspects (Waiting time, Probability of retreatment and Nature of treatment). The differences in the levels were collected in a clinical trial and entered into the preference models to calculate the differnce in utility between those treatments. The ΔU in both models was standardised on a [-1,1] scale. The incremental costs of foamsclerotherapy versus surgical stripping, as observed in the clinical trial, amounted to -€1123. **RESULTS:** All attributes were statistically significant, except for Waiting time and Probability of retreatment. The relative importances and the ranks of the health attributes differed between the models. The patients preferred surgical treatment if only health outcomes were considered, while the patients preferred dermatological treatment if also aspects beyond health outcomes were considered in the choice: ΔUhealth=-0.0109; ΔUextended=0.3971. When incremental utility was based on health outcomes only alone, the incremental cost-utility ratio was €103,027. When incremental utility was based broader outcomes, the incremental utility ratio indicated dominance. **CONCLUSIONS:** The results suggest that recommendation for policy would changed if not only health outcomes but also broader outcomes are considered. The results confirm that a restriction to health outcomes in the (economic) evaluation of health care leads to the maximization of health, but not necessarily to the maximization of benefit in a broader sense.

PODIUM SESSION III:
FLOATING THRESHOLDS AND BY PASSES: RISK SHARING AND PATIENT ACCESS

RS1

LITERATURE REVIEW ON PATIENT ACCESS SCHEMES, FLEXIBLE PRICING SCHEMES AND RISK SHARING AGREEMENTS FOR MEDICINES

Puig-Peiró R, Mestre-Ferrandiz J, Sussex J, Towse A
Office of Health Economics, London, UK

OBJECTIVES: To identify existing knowledge about the costs and benefits, assessed either quantitatively or qualitatively, of performance based reimbursement, risk sharing schemes, patient access schemes, and flexible pricing schemes for pharmaceuticals. **METHODS:** A systematic literature review was conducted using PubMed for the period January 2008 - April 2011. The terms "risk sharing", "flexible pricing", "patient access schemes", and "performance-based reimbursement" were searched in titles and abstracts. **RESULTS:** The search provided 62 records and after screening the number was reduced to 31. After full assessments of these studies, a total of 24 formed the basis of the review. More than 40 per cent of the publications referred to the Multiple Sclerosis Risk Sharing Scheme implemented in the UK since 2002. The review did not identify any cost benefit analysis evaluating the overall economic impact of schemes in monetary terms. All studies discussed costs and benefits qualitatively and in some cases, when known, some costs were reported. Schemes' key stakeholders – health service employees, companies, regulators –bear different costs and benefits and conflicting incentives may arise. Costs and benefits widely vary depending on the characteristics of the scheme. **CONCLUSIONS:** There is lack of consensus on the welfare consequences of the schemes and their social desirability. Identified benefits are countered by significant costs and the overall balance remains unclear. Further research is necessary: a) to assess in a transparent way to what extent the transactional costs and administrative burden are shared between payers and pharmaceutical companies, as they constitute an important barrier for the implementation of the schemes, and b) to aid design of a successful Value Based Pricing system for new medicines in the UK, given the similar principles that underpin outcome-based schemes where prices are set to match "real world" NHS value in practice.

RS2

COST-EFFECTIVENESS OF END-OF-LIFE, LIFE-EXTENDING INTERVENTIONS: NICE'S COST-EFFECTIVENESS THRESHOLD EXPLORED

Hamerslag L, Haynes S, Kusel J, Costello S
Costello Medical Consulting Ltd, Cambridge, UK

OBJECTIVES: It is widely recognised that the National Institute for Health and Clinical Excellence (NICE) in the UK employs cost-effectiveness thresholds in health technology appraisal decision-making. This incremental cost-effectiveness ratio (ICER) threshold has been topic of much debate and is estimated to lie around £30,000 per quality-adjusted life-year (QALY) gained. In December 2008, NICE approved supplementary advice to reconsider this threshold for life-extending, end-of-life interventions. This policy applies to treatments indicated for small patient populations with life expectancies of usually under 24 months, that typically prolong survival by at least 3 months. The aim of this study was to explore NICE's increased ICER threshold when end-of-life conditions are taken into account. **METHODS:** All NICE technology appraisals issued between December 2008 and June 2011 were reviewed. The appraisals in which end-of-life considerations applied were identified and ICERs from these appraisals were extracted. **RESULTS:** In total, 53 single technology appraisals were published in the timeframe considered; of these, only 13 fulfilled the end-of-life criteria, all concerning treatments for cancer. The final ICERs of these 13 interventions ranged from £31,800 to £68,000, although 10 out of 13 manufacturers employed patient access schemes to lower these values. Both the highest ICER that was approved and the lowest ICER that was not approved were £49,300 per QALY gained. Interestingly, both of these appraisals concerned interventions for the treatment of advanced renal cell carcinoma, implying that other factors must have been taken into account by NICE to reach this judgement. **CONCLUSIONS:** Cost-effectiveness seems to be the most important criterion for NICE in their health technology appraisals. For end-of-life, life-extending treatments, the cost-effectiveness threshold appears to lie around £50,000 per QALY. However, review of individual appraisals shows that other factors such as uncertainty in the estimates and unmet need are also taken into account in NICE's decision-making.

RS3

EVIDENCE, PROCESS OR CONTEXT? EXAMINING THE FACTORS THAT DRIVE COVERAGE DECISIONS OF PHARMACEUTICALS BY HEALTH TECHNOLOGY ASSESSMENT BODIES IN EUROPE

Cerri K, Fernández JL, Knapp M
London School of Economics and Political Science, London , UK

OBJECTIVES: In Europe, Health Technology Assessment (HTA) bodies produce coverage decisions that guide public funding of pharmaceuticals. This analysis examines and weights those factors that drive HTA coverage decisions, focusing on the National Institute for Health and Clinical Excellence (NICE) in England and Wales, the Scottish Medicines Consortium (SMC), the Dutch College voor Zorgverzekeringen (CVZ), and the French Haute Autorité de Sante (HAS). **METHODS:** A dataset of approximately 1000 HTA coverage decisions by NICE, SMC, CVZ and HAS from the period 2004-2009 was created, containing more than 30 clinical, economic, process and socio-economic factors extracted from published HTA reports. A three-cate-

gory outcome variable was used, defined as the decision to 'recommend', 'restrict' or 'not recommend' a technology. Multivariate analyses were conducted to assess the relative contribution of the explanatory variables on coverage decisions both within and between HTA bodies. **RESULTS:** Different combinations of clinical/economic evidence, process and socio-economic factors drive HTA coverage decisions by NICE, SMC, CVZ and HAS. In addition, the same factor may behave differently according to the nature of the coverage decision. The analysis further suggests there is a significant difference between HTA bodies in the probability of reaching a 'restrict' or 'not recommend' decision outcome relative to a 'recommend' outcome, adjusted for evidence, process and context factors. **CONCLUSIONS:** This analysis contributes to the understanding of factors driving HTA coverage decisions by examining multiple European HTA bodies, enhancing the comprehensiveness of the factors examined through descriptive and multivariate analyses and by identifying and weighting the key drivers of the coverage decisions made by the four HTA bodies between 2004 and 2009. This research further provides relevant insights to variation among HTA bodies in the determination of patient access to pharmaceuticals, and implications for collaboration between European HTA bodies.

RS4

THE INTERIM CANCER DRUGS FUND - HOW TO NOT SPEND £50 MILLION

Timm B, Brooks-Rooney C, Hamerslag L, Costello S
Costello Medical Consulting, Cambridge, UK

OBJECTIVES: The Cancer Drugs Fund (CDF) was established in April 2011 by the UK government, with a pledge of £200 million additional funding for each of the next 3 years to increase patient access to high cost oncology drugs in England. As an interim measure, £50 million was distributed between the 10 strategic health authorities (SHAs) in England to cover the 6 months from October 2010 to March 2011. This research aims to identify how the interim CDF (ICDF) was spent, and to discuss how this could impact utilization of the CDF. **METHODS:** Data regarding the total funding allocated to each SHA from the ICDF and how much of this money had been spent by March 31, 2011 were obtained from SHA websites. Missing data were accessed through freedom of information requests. **RESULTS:** Overall, there were over 2700 applications to the fund, with an average approval rate of 91%. Over the 6 month period covered by the ICDF, approximately £21 million was spent across the 10 SHAs in England; this constituted 42% of the £50 million allocated. There was significant variation in the amount spent by each SHA; the highest under-spend was in the South West, where 75% of funds remained unallocated. Several SHAs reported the forecasted costs for continuing treatment beyond March 2011; these costs were incurred in the 2011/12 financial year and therefore were not covered by the ICDF. Remaining budget is expected to be reclaimed by the Department of Health. **CONCLUSIONS:** It is clear that there was a significant under-spend of the ICDF by all SHAs. It is concerning that many funding applications were rejected, despite the fact that almost half of the funds remained unallocated. Steps need to be taken to ensure more effective use of the CDF and to minimise the risk of regional variations in drug access.

POSTER SESSION I
SELECTED HEALTH CARE TREATMENT STUDIES

Medical Device/Diagnostics – Clinical Outcomes Studies

PMD1

ND-YAG LASER INCIDENCE RATE COMPARISON OF THREE MONOFOCAL INTRAOCULAR LENSES (IOL) 36 MONTHS AFTER CATARACT SURGERY IN FRANCE

Lafuma A[1], Coulomb S[2], Robert J[2], Berdeaux G[3]
[1]*CEMKA-EVAL, Bourg la Reine, France,* [2]*Cemka Eval, Bourg la Reine, France,* [3]*Alcon France, Rueil-Malmaison, France*

OBJECTIVES: The aim of this study was to compare the 36-month Nd-Yag laser (a treatment of posterior capsular opacification, the most frequent complication of cataract surgery) incidence rate of three monofocal IOLs: Acrysof SN60WF (Alcon), Akreos AO-MI-60 (Baush&Lomb) and Hoya YA-60BB (Hoya). **METHODS:** This is a retrospective study conducted at 3 French sites. Each centre implanted at least two of the above IOLs. Patients had to have uncomplicated cataract surgery with at least 2 years of follow-up. Patients implanted with one of the above IOLs were picked up at random from the surgery theatre registry. Medical data were retrieved from patient charts. 36-months post surgical data were obtained from the surgeon's medical files and from other ophthalmologists, if involved in post-surgical care. Time to Nd:Yag laser analysis was carried out using Kaplan-Meier survival curves. Confounding variable imbalances were adjusted with a stepwise Cox model. The statistical unit is the eye. **RESULTS:** 126 eyes were implanted with Acrysof, 89 with Akreos and 85 with Hoya. Patients with Acrysof were younger (72.1, 76.4 and 75.2 years; P=0.0007). The sex ratio was 4 males: 6 females. Patient follow-up was longer in the Hoya eyes (27.8, 20.3 and 32.1 months; P=0.002). Eyes implanted with Acrysof had 1.68 times less Nd-Yag laser than Hoya (P=0.06) and 3.43 times less than Akreos (P<0.0001). The results remained unchanged when the analysis was restricted to the events occurring during the first 36 months (HR=2.20; P=0.009; HR=3.67; P<0.0001, respectively). Adjusting for confounding variable unbalances did not change the results. **CONCLUSIONS:** This analysis conducted at 36 months suggests that following usual surgical practice, Acrysof eyes had significantly less Nd-Yag laser capsulotomy than those implanted with Hoya and Akreos. Consequently, Acrysof eyes were less exposed to Nd-YAG laser complications and experienced lower post-surgical treatment costs.

PMD2

CLINICAL DECISION RULES FOR ADULTS WITH MINOR HEAD INJURY: A SYSTEMATIC REVIEW

Harnan SE, Pickering A, Pandor A, Goodacre SW
The University of Sheffield, Sheffield, South Yorkshire, UK

OBJECTIVES: A small number of cases of minor head injury deteriorate, resulting in serious injury or death. Computed Tomography (CT) identify intracranial injuries, but because it carries a cost and its own health risk, it should be limited to those most likely to have an injury. Clinical decision rules aim to identify these patients. There are many such rules, but it is unclear how their diagnostic accuracy compare. This study aimed to systematically identify clinical decision rules for adults with minor head injury and compare the estimated diagnostic accuracy. **METHODS:** Several key electronic bibliographic databases (biomedical, scientific and grey literature), were searched from inception to March 2010. Retrieved citations were considered for inclusion by at least two independent reviewers. Cohort studies that described a clinical decision rule to identify adults with minor head injury (GCS 13-15) at risk of intracranial injury or injury requiring neurosurgical intervention were included in the review. Data was extracted by one reviewer and checked by a second. Studies were quality assessed using the QuADAS tool. **RESULTS:** Twenty-two relevant studies were identified. No study satisfied all quality assessment items. Heterogeneity amongst patient selection criteria, outcome definitions, and reference standards was identified. The Canadian CT Head Rule (CCHR) high-risk criteria had sensitivity of 99-100% with specificity of 48-77% for injury requiring neurosurgical intervention. Other rules, such as New Orleans criteria, NEXUS II, NCWFNS and SIGN produce similar sensitivities but with lower and more variable specificity values. **CONCLUSIONS:** The most widely researched decision rule is the CCHR, which has consistently shown high sensitivity for identifying injury requiring neurosurgical intervention, with an acceptable specificity to allow considered use of cranial CT. No other decision rule has been validated as widely, or demonstrated similarly acceptable results. However, its exclusion criteria mean it may make it difficult to apply universally.

PMD3

BIOCHEMICAL MARKERS FOR THE IDENTIFICATION OF INTRACRANIAL INJURY FOLLOWING MINOR HEAD INJURY: A SYSTEMATIC REVIEW AND META-ANALYSIS

Pickering A, Fitzgerald P, Harnan SE, Pandor A, Goodacre SW
The University of Sheffield, Sheffield, South Yorkshire, UK

OBJECTIVES: Minor head injury (MHI) can lead to deterioration, severe injury and death in a small number of cases. Using Computed Tomography (CT) scans on all those with MHI would result in large numbers receiving an unnecessary dose of radiation. Biochemical markers may be useful in reducing the number of scans. This study aimed to systematically identify and synthesize data estimating the diagnostic accuracy of biochemical markers for intracranial injury on CT in patients with MHI. **METHODS:** Key databases including MEDLINE, EMBASE & CINAHL were searched for potentially relevant literature. Studies reporting a cohort of more than 20 patients, with more than 50% having suffered a MHI (GCS 13-15), and which tested the diagnostic accuracy of a biochemical marker for intracranial or neurosurgical injury were included. Quality was assessed using the QUality Assessment of Diagnostic Accuracy Studies (QUADAS) checklist. Meta-analysis was used to estimate pooled sensitivity, specificity and likelihood ratios. **RESULTS:** Of the 12 included papers, nine provided diagnostic data on protein S100B only, one for Neuron-Specific Enolase (NSE) only, one for other markers and one study for both S100B and NSE levels. Data was only extracted and synthesized from S100B studies. Bayesian meta-analysis of these pooled data for 2442 adult subjects gave sensitivity of 96.8% (95% High Density Region (HDR), 93.8 to 98.6%) and specificity of 42.5% (95% HDR, 31.0 to 54.2%) with a negative likelihood ratio of 0.076 (95% HDR, 0.031 to 0.156). **CONCLUSIONS:** Evidence to support the addition of protein S100B as a triage tool for CT in MHI patients within three hours of injury is promising. Whilst the quality of studies is good, results are heterogeneous. S100B has the potential to be used in conjunction with a clinical decision rule. The marker therefore needs further testing as a component within such a diagnostic pathway.

PMD4

EXPERT ELICITATION TO POPULATE EARLY HEALTH ECONOMIC MODELS OF MEDICAL DIAGNOSTIC DEVICES IN DEVELOPMENT

Haakma W[1], Bojke L[2], Steuten L[1], Ijzerman M[1]
[1]*University of Twente, Enschede, The Netherlands,* [2]*University of York, York, Heslington, UK*

OBJECTIVES: During the development of new diagnostic and therapeutic devices, it is desirable to indicate their cost-effectiveness and to establish their potential clinical value to guide further research. In these early stages of development, however, there are usually limited or no clinical data available. In this study, expert elicitation was used to estimate uncertain priors of the diagnostic performance of a new imaging technology, i.e. Photo Acoustic Mammography (PAM). We compared PAM to Magnetic Resonance Imaging (MRI), in the detection of breast cancer. **METHODS:** Expert elicitation was used as a method to formulate the knowledge and beliefs of experts about the future performance of PAM and to quantify this information into probability distributions. 18 radiologists estimated the true positive rate and true negative rate based on existing MRI data and specified the mode, the lower, and the upper boundaries (95% credible interval). An overall probability density function (PDF) was determined using the linear opinion pooling method in which weighting is applied to reflect the performance of individual experts. **RESULTS:** The overall PDF indicated a sensitivity ranging from 58.9% to 85.1%, with a mode of 73.3%. The specificity ranges from 52.2% to 77.6%, with a mode of 66.5%. Experts expressed difficulties making the estimations, as there is not sufficient

data about the manner in which PAM visualizes different tumor types. **CONCLUSIONS:** Using expert elicitation prior distributions for sensitivity and specificity of PAM were obtained. This evidence could be used in early health economic models to establish cost-effectiveness. However, experts expressed difficulties estimating the performance based on limited data. The expression of uncertainty surrounding their beliefs reflects the infancy of the diagnostic method, however further clinical trials should be commissioned to indicate whether these results are valid. Before that, the use of the elicited priors in health economic models requires careful consideration.

PMD5

DIAGNOSTIC ACCURACY OF CLINICAL CHARACTERISTICS FOLLOWING MINOR HEAD INJURY: A SYSTEMATIC REVIEW AND META-ANALYSIS

Pandor A, Harnan SE, Goodacre SW, Pickering A, Fitzgerald P, Rees AC
The University of Sheffield, Sheffield, South Yorkshire, UK

OBJECTIVES: A small number of patients with minor head injury deteriorate, resulting in serious injury or death. Clinical features are often used to identify which patients with minor head injury are likely to deteriorate and therefore need CT scanning. To estimate the value of these characteristics for diagnosing intracranial injury (including the need for neurosurgery) in adults, children and infants, a systematic review and meta-analysis of diagnostic accuracy was undertaken. **METHODS:** Citations were identified through electronic searches of several key databases, including MEDLINE, from inception to March 2010. Cohort studies of patients with minor head injury (Glasgow Coma Score [GCS], 13-15) were selected if they reported data on the diagnostic accuracy of individual clinical characteristics for intracranial or neurosurgical injury. Study selection, quality assessment and data extraction were performed by one reviewer and checked by at least another. Where results allowed, pooled sensitivity, specificity and likelihood ratios were estimated through meta-analysis. **RESULTS:** Data were extracted from 71 studies (with cohort sizes ranging from 39 to 31694 patients). The most useful clinical characteristics for identifying those with intracranial injury were depressed or basal skull fracture in both adults and children (positive likelihood ratio [PLR], >10). Other useful characteristics in adults or children included focal neurological deficit, post traumatic seizure (PLR >5), persistent vomiting, and coagulopathy (PLR 2 to 5). Characteristics that had limited diagnostic value included loss of consciousness and headache in adults and scalp haematoma and scalp laceration in children. Few studies were undertaken in children and even fewer reported data for neurosurgical injuries. **CONCLUSIONS:** Amongst other characteristics, depressed or basal skull fracture indicated increased risk of intracranial injury and the need for CT scanning in adults and children. Other characteristics, such as headache in adults and scalp laceration of haematoma in children, do not reliably indicate increased risk.

PMD6

EFFICACY AND SAFETY OF ARTIFICIAL DISC ARTHROPLASTY COMPARED TO SURGICAL FUSION FOR SINGLE LEVEL CERVICAL AND LUMBAR DEGENERATIVE DISC DISEASE: A BAYESIAN META-ANALYSIS

Stam W[1], Alvares L[2], Birinyi-strachan L[3], Maetzel A[4]
[1]*Stam Consulting, Houten, The Netherlands,* [2]*Medtronic International, Tolochenaz, VD, Switzerland,* [3]*Medtronic Australasia, Sydney, NSW, Australia,* [4]*University of Toronto, Toronto, ON, Canada*

OBJECTIVES: Randomized clinical trial (RCT) evidence comparing cervical and lumbar total disc arthroplasty (TDA) with interbody fusion for degenerative disc disease (DDD) has been provided for different devices by FDA Investigational Device Exemption (IDE) studies. A synthesis of this evidence is needed for decision makers to select the appropriate intervention. This study aims to synthesize current clinical evidence on TDA and evaluate its relative efficacy and safety to interbody fusion. **METHODS:** A systematic search of Medline and Cochrane library identified 6 RCTs comparing TDA with fusion. These FDA IDE studies on lumbar (3) and cervical TDA (3), had similar designs and patient characteristics and allowed for pooling the outcomes. Efficacy was assessed by the FDA agreed outcomes: 1) > 15 points improvement in neck disability index (NDI, cervical) or Oswestry disability index (ODI, lumbar); 2) neurological success; 3) no subsequent surgery or intervention classified as "failure;" and 4) overall success: a composite measure of the previous outcomes and the absence of major adverse events. Comparative data were synthesised using a Bayesian meta-analytical approach. In contrast to a frequentist analysis, a Bayesian approach allows for calculating the probability of which intervention is the best and is therefore more intuitive for decision making. As a base case scenario a random effects analysis was performed on the intention to treat (ITT) data. **RESULTS:** The probability of lumbar and cervical TDA of having better outcomes than fusion at 2 years was 91% and 96% for overall success; 76% for ODI and 89% for NDI; 89% and 96% for neurological success; and 61% and 97% for secondary surgery, respectively. **CONCLUSIONS:** Based on this analysis, both lumbar and cervical TDA are likely to provide a greater net improvement relative to their respective interbody fusion techniques for single level DDD within 2 years in the elective patients.

PMD7

EFFECTIVENESS AND SELF-MONITORING OF BLOOD GLUCOSE (SMBG) FREQUENCIES IN POORLY-CONTROLLED PATIENTS WITH NON-INSULIN-TREATED DIABETES (NITDM) WHO WERE NOT ACTIVE TESTERS PRIOR TO THE STEP STUDY

Berndt K[1], Jelsovsky Z[2], Rees C[3], Mast O[4]
[1]*Roche Diagnostics, Mannheim, Baden-Würtemberg, Germany,* [2]*BioStat International Inc., Tampa, FL, USA,* [3]*Roche Diagnostics Operations, Inc., Indianapolis, IN, USA,* [4]*Roche Diagnostics GmbH, Mannheim, Germany*

OBJECTIVES: In poorly-controlled patients with NITDM the Structured Testing Protocol (STeP) study has shown improved HbA1c outcomes of a structured testing group (STG) versus enhanced usual care that included unstructured SMBG (active control group (ACG)) at overall cost neutrality over one year. This work analyzes HbA1c and testing frequencies in previously non active testers. **METHODS:** The underlying assumption of this exploratory analysis is that not active testers (STG: n=80; ACG: n=61) - the study participants who did not test in the week before the study – do in general not test systematically and might be particularly responsive to structured SMBG. For both groups HbA1c and the testing frequencies were calculated based on meter download data. **RESULTS:** At baseline both groups did not differ in any characteristic. Baseline HbA1c was 9.1 (Standard deviation1.2)%. In not active testers ITT analysis revealed a 0.59% (95%-CI: 0.07 to 1.11; p<0.03) larger HbA1c difference in STG than in ACG (STG: −1.71% (−2.06, −1.37); ACG: −1.12% (−1.51, −0.73)). STG performed significantly fewer tests/day than ACG (mean = 0.72 vs. 0.96, p=0.04). This equates to a −25% difference in annual test strip consumption between the STG (263 tests/year) and ACG (350 tests/year). While a relatively high test frequency was imposed by the study protocol in the beginning of the STeP study, in last study quarter average testing was 0.63 per day in STG and 0.79 per day in ACG (n.s.) (equivalent to 230 vs. 288 per year). **CONCLUSIONS:** Structured SMBG in not active testers was associated with higher reductions in HbA1c compared to standard SMBG use and compared to the overall STeP population. The use of structured SMBG may be especially cost-effective in terms of HbA1c reduction per test strips used in patients with poorly controlled NITDM who do not show a history of consistent SMBG use.

PMD8

SYSTEMATIC REVIEW OF THE IMPACT DIFFERENT METAL FEMORAL STEMS (MFSS) HAVE ON PATIENT OUTCOMES IN TOTAL HIP REPLACEMENT (THR) DUE TO OSTEOARTHRITIS (OA)

Edwards SJ, Hamilton V, Nherera L, Arber M
BMJ Technology Assessment Group, London, UK

OBJECTIVES: Commonly used metals for MFSs are titanium (T), stainless steel (SS) and cobalt-chrome (CC). There is no consensus on the best type of MFSs in THR. This research sought to identify which metal would achieve better patient outcomes. **METHODS:** Systematic review of MEDLINE and CENTRAL for randomised controlled trials (RCTs) and comparative observational studies (OS) in adult patients with OA undergoing THR reporting any of the following: failure/revision surgery, implant loosening, patient pain. Searching was restricted to English-language and was completed in June 2011. Identified studies were assessed for quality using the Cochrane Risk of Bias Tool. Meta-analysis was conducted using Peto odds ratio (OR), which performs better than other approaches at estimating ORs when there are several studies with no events in one or both arms. **RESULTS:** Of the 1,934 papers identified, 13 studies were included in the analysis: 2 RCTs and 11 OS. Direct comparison demonstrated outcomes were more likely with TvsCC: failure/revision (OR3.10, 95% Confidence Interval [95%CI]: 2.24-4.29); loosening (OR3.49, 95%CI: 2.35-5.17); pain (OR1.88, 95%CI: 1.43-2.46). Direct comparison of SS was only reported in one study with CC and only with revision where SS had increased risk (OR1.32, 95%CI: 1.13-1.55. Adjusted indirect comparison of TvsSS demonstrated increased risk with T for failure/revision (OR2.35, 95%CI: 1.64-3.36). Significant heterogeneity was identified in the direct comparison of TvsCC for failure/revision (I^2=65%, p=0.004) and pain (I^2=80%, p=0.002), with none identified for loosening (I^2=0%, p=0.34). Exploratory subgroup analyses by region where studies were conducted, cemented or uncemented stems, patient age, and study size, failed to generate a hypothesis for the potential cause of the heterogeneity. **CONCLUSIONS:** The available evidence suggests that stems made from cobalt-chrome are likely to perform better and put the patient at less risk of requiring a revision procedure than stems made from titanium or stainless steel.

PMD9

A1CNOW® AS AMBULATORY MONITORING OF GLYCATED HEMOGLOBIN IN DIABETIC TYPE 2 (DM2) PATIENTS: SYSTEMATIC REVIEW

Silva AP[1], Santoni NB[1], Pepe C[2], Laranjeira F[2]
[1]*Bayer Brazil, São Paulo, São Paulo, Brazil,* [2]*MedInsight, São Paulo, São Paulo, Brazil*

OBJECTIVES: To analyze the best available scientific evidence on the accuracy and usefulness of ambulatory monitoring of glycated hemoglobin in diabetic patients with A1CNow® and laboratory test. **METHODS:** We performed searches in medical literature databases and the best results were obtained with a search in Medline (via Pubmed), with the keywords: ("Point-of-Care Systems" [Mesh] AND ("Diabetes Mellitus" [Mesh] OR " Diabetes Mellitus, Type 2" [Mesh] OR "Diabetes Mellitus, Type 1" [Mesh] OR "Diabetes Complications" [Mesh] OR "Diabetes, Gestational" [Mesh])) AND "The Hemoglobin, glycosylated" [Mesh] AND ("humans" [MeSH Terms] AND (Português ⟨ OR Spanish ⟨)). We selected two studies on accuracy and five trials on the usefulness of the test. **RESULTS:** Related to the accuracy, A1CNow® proved to be accurate compared with laboratory tests, being the best correlation between the methods established between A1C values between 7 and 8.5%. Related to the usefulness, studies showed that the availability of HbA1c results during the visit improves the decision-making by physicians. In one clinical trial that specifically investigated the usefulness of A1CNow®, active titration of insulin based on weekly visit and monitoring of A1c by A1CNow® led to a greater percentage of patients achieving A1C<7% at the end of follow-up compared to the group which was based on laboratory tests (41% vs. 36%, p <0.0001). **CONCLUSIONS:** Based on the best evidence available (evidence level: 1B and intensity of recommendation: A), the use of A1CNow® for ambulatory monitoring of glycated hemoglobin in diabetic patients is accurate and reliable compared to the alternative diagnostic laboratory and useful in relation to the improvement of HbA1c levels.

Medical Device/Diagnostics – Cost Studies

PMD10

IMPACT ANALYSES OF FRACTIONAL FLOW RESERVE-GUIDED PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH MULTIVESSEL DISEASE IN FRANCE AND BELGIUM

Arvandi M[1], Bornschein B[1], Gothe RM[1], Rioufol G[2], De bruyne B[3], De pouvourville G[4], Desmet W[5], Lefevre T[6], Fearon WF[7], Pijls NHJ[8], Siebert U[9]
[1]UMIT - University for Health Sciences, Medical Informatics and Technology, Hall i. Tirol, Tirol, Austria, [2]Cardiovascular hospital – Hospices Civils de Lyon, Lyon, France, [3]OLV-Clinic-Aalst, Aalst, Belgium, [4]ESSEC Business School, Cergy, France, [5]University Hospitals Leuven, Leuven, Belgium, [6]Hopital Privé Jacques Cartier, Massy, France, [7]Stanford University Medical Center, Stanford, CA, USA, [8]Catharina Hospital, Eindhoven, The Netherlands, [9]UMIT/Harvard University, Hall i.Tirol, Austria

OBJECTIVES: The FAME Study is an international multicenter randomized clinical trial (n=1,005), which proved a significant improvement in health outcomes for patients undergoing multivessel percutaneous coronary intervention (PCI) guided by fractional flow reserve (FFR) measurement compared to PCI guided by angiography alone (ANGIO). The objective of this study is to estimate the impact of FFR-guided PCI on public health and on healthcare budget in France and Belgium and to compare these results with those of other European countries. **METHODS:** We used original patient-level data of the FAME Study (Tonino et al., NEJM 2009) to estimate health effects for France and Belgium. Utilities were measured with EQ-5D using French (time trade-off based) and Belgian Torrance transformed (visual analogue scale based) weights. Costs were based on French and Belgian prices and DRG catalogues. The size of the population eligible for the intervention was taken from national PCI registries to calculate number of major adverse cardiac events (MACE) avoided, quality-adjusted life years (QALYs) gained, and cost savings during a 2-year budget period (2011-2012) from the payer's perspective. We estimated ranges based on best and worst case scenarios regarding benefits, costs and FFR uptake. **RESULTS:** For both countries, FFR led to more QALYs, less MACE and lower costs under different scenarios within 2-year time horizon. The public health impact of implementing FFR-guided PCI ranged from 6 to 44 QALYs gained in France and 12 to 234 in Belgium. MACEs avoided ranged from 284 to 2108 and from 23 to 467, respectively. Cost savings ranged from 4.8 to 28.9 and from 0.43 to 7.7 million EUR, respectively. **CONCLUSIONS:** Our impact study shows that FFR-guided PCI in patients with multivessel coronary disease is dominant and leads to considerably reduced numbers of MACE, more QALYs and substantial cost savings in the French and Belgian health care systems.

PMD11

TREATMENT OF OVERACTIVE BLADDER AND FECAL INCONTINENCE PATIENTS FROM THE CANARY ISLANDS WITH SACRAL NEUROMODULATION: IS IT WORTH TO HAVE REGIONAL CENTERS OF EXCELLENCE?

Castro Díaz D[1], Canal Fontcuberta C[2], González García P[3], López Bastida J[4]
[1]Hospital Universitario de Canarias, La Laguna, S/C de Tenerife, Spain, [2]Medtronc Ibérica, SA, Madrid, Madrid, Spain, [3]Medtronic Ibérica SA, Madrid, Madrid, Spain, [4]Servicio Canario de Salud, S/C de Tenerife, Spain

OBJECTIVES: Sacral Neuromodulation (SNM) has proven to be an effective, safe and cost-effective therapy that should be available for refractory Overactive Bladder (OAB) and Fecal Incontinence (FI) patients. Canary Islands are divided into two provinces: Las Palmas and Santa Cruz de Tenerife. Refractory OAB and FI patients from Las Palmas are referred to other Spanish regions to receive SNM. This Budget Impact Analysis (BIA) approaches two possible referral programs from the perspective of Canary Islands Health Service (CHS): the treatment of these patients in Tenerife in a regional Center of Excellence or in Madrid as representative of the mainland. **METHODS:** A BIA was developed to analyze the different direct costs related to each of the options for a refractory population of 11 OAB and 4 FI patients during 1 year. The net economic impact caused by the treatment of patients from Las Palmas with SNM therapy was calculated based on two previous cost-effectiveness models and was assumed to be similar in both cases. Costs related to hospitalization, travelling, and living expenses for the patient and the caregiver were also considered, as these costs are reimbursed by the CHS to the patients and caregivers. **RESULTS:** The net economic impact for the CHS of treating 15 new patients from Las Palmas with SNM in Madrid would be €118,871 for the first year of the therapy, while treating these patients in Tenerife's Center of Excellence would be related to a net impact of €50,780. The savings provided by a referral program inside the Region would amount to €68,091; driven by differences in hospitalization, travelling and living expenses. **CONCLUSIONS:** In Canary Islands, the designation of Regional Centers of Excellence for specialized and effective treatments, such as SNM, would lead to important savings for the CHS, driven by differences in hospitalization, travelling and living expenses due to referral programs.

PMD12

ECONOMIC IMPACT ANALYSIS OF STERILIZATION OF RIGID ENDOSCOPES WITH STERRADTM VERSUS STEAM IN SPAIN

Busutil R[1], Espallardo O[1], Emmermann A[2]
[1]Johnson & Johnson Medical, Madrid, Madrid, Spain, [2]Ethicon Endo-Surgery (Europe) GmbH, Norderstedt, Germany

OBJECTIVES: The increasing penetration of endoscopic techniques in surgical procedures has resulted in a more frequent use of rigid endoscopes (RE). Several studies have reported significant reductions in the number of damaged RE and repairs when reprocessed with Sterrad™ instead of Steam. The aim of this study was to analyze the economic consequences of RE sterilization with Sterrad™ versus Steam from a hospital perspective. **METHODS:** A dynamic excel-based decision-analytic model was developed. Published literature was used to estimate the two key variables (% of RE damage with Steam as well as with Sterrad™). A two-way sensitivity analysis was conducted (varying the two key variables up to ±25%, thus generating 121 different scenarios). Input data for the model collected as an average from four Spanish hospitals were: 1000 RE sterilization units (StU) annually, 2000€ cost for every RE repair and 0,56€ in consumables/StU with Steam. 11,99€ in consumables/StU with Sterrad™ was calculated based on list prices and an average of 2.5 RE per sterilization cycle. The analysis covered a one year time horizon and assumed 100% utilization for each sterilization technology. **RESULTS:** A 21% budget impact decrease was achieved with Sterrad™ versus Steam, leading to 11,870€ in annual savings. The more costly sterilization process (11,986€ versus 560€ per year) was clearly more than compensated by the reduction of 23,296€ in RE repair costs. The sensitivity analysis showed in 100% of the scenarios that Sterrad™ was cost-saving compared to Steam. **CONCLUSIONS:** This analysis adds a new component of support for the sterilization of rigid endoscopes with Sterrad™ by demonstrating that it is cost-saving compared to reprocessing with Steam. Despite the conservative approach of the model which may be in favour of Steam, use of Sterrad™ led to savings of 21% in the hospital budget.

PMD13

COST ANALYSIS OF VASCULAR CLOSURE DEVICES (VCD) IN THE UNITED STATES

Nazareth T[1], Saadi R[2], Thompson M[2], Ferko N[2], Spaulding C[1]
[1]Cordis Corporation, Bridgewater Township, NJ, USA, [2]Cornerstone Research Group, Burlington, ON, Canada,

OBJECTIVES: Recent literature suggests complication rates associated with current VCDs are comparable or reduced when compared to manual compression (MC). However, well-documented differences exist among VCDs regarding the type and magnitude of complications. An indirect comparison was conducted to estimate the cost savings associated with use of novel VCD EXOSEAL™ vs. VCDs ANGIOSEAL™, MYNX™, PERCLOSE™ and STARCLOSE™ from the US hospital system perspective. **METHODS:** Crude VCD-specific complication rates were calculated for occlusion, access-site infection (ASI), femoral pseudoaneurysm (FAP), retroperitoneal hemorrhage (RPH), other access-site bleeds (OASB), and arteriovenous fistula (AVF) using prospective clinical studies identified in the most recent VCD instructions for use. A literature review (i.e., 2005 to current) was conducted to identify rates of complication consequences (i.e., amputation, vascular surgery, endovascular procedure, transfusion, ultrasound-guided intervention) and associated US costs were then applied to clinical consequence rates. The one-year budget impact was estimated assuming 100% use of EXOSEAL™ vs. current VCD market-share for percutaneous coronary intervention (PCI) procedures. Device costs were assumed identical. **RESULTS:** Complication rates for occlusion, ASI, RPH, FAP, OASB, and AVF were calculated for each VCD as follows: EXOSEAL™ [0.00%, 0.00%, 0.56%, 0.00%, 0.00%, 0.00%], ANGIOSEAL™ [0.33%, 0.00%, 0.33%, 0.00%, 0.00%, 0.33%], MYNX™ [0.00%, 0.00%, 0.00%, 0.53%, 0.53%, 0.00%], PERCLOSE™ [0.00%, 0.78%, 0.52%, 0.26%, 0.52%, 0.00%] and STARCLOSE™ [0.20%, 0.00%, 0.00%, 0.20%, 0.41%, 0.00%]. Results predicted that 100% use of EXOSEAL™ vs. combined use of VCDs could save approximately $70 USD per procedure and approximately $70,240 USD per 1,000 annual PCI procedures (i.e., typical hospital). Assuming 550,000 PCIs that use VCDs annually in the US, this translates to a predicted yearly cost-savings of $38,631,949 USD for the US hospital system. **CONCLUSIONS:** This analysis suggests use of EXOSEAL™ in patients undergoing PCI procedures may result in important cost-savings for US hospitals. Additional data will be required to confirm low complication rates with EXOSEAL™.

PMD14

BUDGET IMPACT ANALYSIS OF TWO DRUG-ELUTING STENTS FOR DIABETIC PATIENTS IN SPAIN

Busutil R[1], Ferko N[2], Espallardo O[1], Saadi R[3]
[1]Johnson & Johnson Medical, Madrid, Madrid, Spain, [2]Cornerstone Research Group, Burlington, ON, Canada, [3]Cordis Corporation, Bridgewater, NJ, USA

OBJECTIVES: The presence of diabetes in patients needing percutaneous coronary intervention (PCI) is associated with increased risk of adverse outcomes, such as target lesion revascularization (TLR), and thus an additional cost burden. A recent indirect treatment comparison (ITC) showed that the drug-eluting stent (DES) CYPHER™ improved clinical outcomes vs other DES resulting in cost-savings in diabetic patients. Based on this ITC, the objective is to conduct an adaptation to Spain and compare CYPHER vs. XIENCE™ from a hospital perspective with global annual budget. **METHODS:** A global budget-impact model was adapted to Spain using a previously reported ITC of DES in diabetic patients. In brief, the ITC included pair-wise meta-analyses of randomized trials with a common comparator to obtain relative treatment effects for different DES and absolute TLR risk. These reported clinical estimates were added to the Spain model, along with reported use and reimbursement rates for diagnosis-related groups (DRGs) of index procedures and re-interventions in Spain. Budget-impact was estimated for 100 annual PCIs with DES for diabetic patients in a typical Spanish hospital, assuming 100% utilization for each stent and identical stent acquisition cost. Analyses were conducted using two methods for estimating TLR risk. **RESULTS:** Results predicted that CYPHER, if used instead of XIENCE, could save approximately 320€ to 407€ per diabetic patient annually depending on TLR risk estimation method. Assuming 100 annual PCIs in diabetic patients, this translates to cost-savings varying from 32,048€ to 40,710€. These savings are driven by reduction in secondary interventions achieved by choosing the DES with the best TLR outcomes. **CONCLUSIONS:** This analysis indicates that use of CYPHER versus XIENCE in diabetic patients undergoing PCI can produce important savings for hospitals. Further cost research and clinical expert validation are needed to confirm results of this local adaptation.

PMD15

SOCIETAL COSTS OF ROUTINE FOLLOW-UP SERVICES FOR CARDIAC IMPLANTABLE ELECTRICAL DEVICES IN GERMANY AND THE UNITED KINGDOM - AND THE IMPACT OF REMOTE MONITORING

Smala A[1], Gessler M[2], Stoepel C[3]
[1]Biotronik SE & Co KG, Global Reimbursement and Health Economics, Berlin, Germany, [2]Biotronik SE & Co KG, Global Sales Strategy, Berlin, Germany, [3]Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Medizinische Klinik I, Neuss, Germany

OBJECTIVES: Expert consensus recommends calendar based in-office follow-up (FU) for pacemakers (PM) twice annually, for internal cardioverter defibrillator (ICD) or cardiac resynchronisation therapy devices (CRT) four times a year. To estimate the societal costs of these FUs in Germany and the UK (UK). To estimate potential cost savings from switching from conventional to a BIOTRONIK Home Monitoring FU (remote monitoring) regimen. **METHODS:** Prevalence-based estimates on the number of in-office FU visits were combined with data on private and ambulance transport and hospital services, with costs projected until 2015. **RESULTS:** Annual cost of routine FU in Germany are estimated to climb from EURO 106 mio (2010) to 142 mio (2015). For the UK, costs are forecast to rapidly increase from EURO 31 mio (2010) to 49 mio (2015). In Germany, patients bear the majority of the costs (61%), followed by hospital service costs (31%). In the UK, the situation is reversed with hospital costs contributing the most (84%), followed by patient travel costs (12%). The remainder is health insurance costs for ambulance transport. If 50% of all patients would attend one in-office visit annually and have their other FUs performed with Home Monitoring, annual cost savings in 2015 could reach EURO 43.9 mio in Germany, and EURO 14.7 mio in the UK. **CONCLUSIONS:** For the first time, costs of FU for PM and ICD/CRT in Germany and the UK are presented. As modern devices are capable to self-declare parameter deviations indicative for malfunctions or worsening disease, remote monitoring can help eliminating unnecessary visits. The presented savings are expected to be heavily underestimated due to not considering the impact of earlier event detection and improved disease outcomes. Savings could be invested in remote monitoring technologies, and freed medical specialist capacities be re-directed to CIED patients in real need of FU visits.

PMD16

THE ECONOMIC AND EFFICIENCY GAINS ASSOCIATED WITH THE USE OF A STANDARDISED, AUTOMATED BCR-ABL MONITORING TEST (SBAT): RESULTS FROM A BUDGET IMPACT ANALYSIS FOR THE USA

Ratcliffe AE[1], Ratcliffe M[1], O'Hanlon H[2], Hegarty L[3], Ossa D[4]
[1]PHMR Associates, London, UK, [2]Medaxial Group, London, UK, [3]Account Manager Medaxial Group, London, UK, [4]Novartis Pharma AG, Basle, Switzerland

OBJECTIVES: In the US the monitoring of patients with Chronic Myeloid Leukaemia (CML) presents extensive intra- and inter-lab variability, thus a standardised, automated test should allow for improvement in patient management and health outcomes. The aim of the study was to estimate the budget impact and improved testing accuracy associated with a the use of a standardised, automated BCR-ABL monitoring test (SBAT) when compared to laboratory developed tests (LDTs) for newly diagnosed CML patients over a 5-year period in the US. **METHODS:** Epidemiology data regarding the incidence of Philadelphia positive (Ph+) CML patients who would be treated with a tyrosine kinase inhibitor (TKI) were combined with workflow cost and accuracy (sensitivity and specificity) data associated with the sequential testing and monitoring of newly diagnosed CML patients. A survey of US laboratories was conducted to determine the labour and materials costs associated with the SBAT versus LDTs. A testing algorithm based on NCCN guidelines was used to capture a number of different tests including testing for major molecular response (SBAT versus LDTs), complete cytogenetic response (routine and FISH-fluorescence in situ hybridisation), and mutation analysis. **RESULTS:** Results indicate that the SBAT is both less resource- and labour- intensive, and can be carried out at a cost that is lower than when an LDT is used. In addition, overall test accuracy increases when the SBAT is used instead of an LDT. For example, for every 100 patients who follow BCR-ABL monitoring according to NCCN guidelines, savings of approximately $386,180 and approximately 327 more accurate test results could be achieved over 5 years. **CONCLUSIONS:** The benefits from a SBAT when compared to LDTs are not only from the reduction of intra- and inter-lab variability (increased accuracy) but also in economic terms due to lower overall costs. Therefore, a SBAT represents a cost-saving alternative versus LDTs.

PMD17

NOBLE METAL ALLOY-COATED URETHRAL CATHETER: A BUDGET IMPACT ANALYSIS IN THE VENETO REGION OF ITALY

Fantelli V[1], Van de Vooren K[2], Curto A[2], Filippi C[1], Bassotto F[1], Garattini L[2], Scroccaro G[1]
[1]UVEF - Drug effectiveness evaluation unit of the Regional Coordination for pharmaceutical agents - Department of Pharmacy, Verona, Italy, [2]CESAV - Center for Health Economics "Angelo & Angela Valenti", Ranica, Bergamo, Italy

OBJECTIVES: The aim of this paper is to illustrate a methodology to develop a BIA, assisting the decision maker in answering the question on financial sustainability. **METHODS:** The analysis compared the new coated urethral catheter (alternative A) to the long-term catheter currently in use in the region (alternative B). The study, built on efficacy data including "asymptomatic bacteriuria" solely, adopted the perspective of the Regional Health Service. A survey was conducted in seven local health authorities (LHAs) within the Region to obtain consumption data and the average price of respectively the new and currently used long-term catheters. The estimate of regional consumption of alternative B was obtained by projecting the consumption of 7 LHAs on the basis of the percentage of total inpatient admissions. The analysis included technology costs and the costs of additional hospitalization days due to Catheter Associated Urinary Tract Infections (CAUTI). Sensitivity analyses were conducted to test the robustness of the results in the "base case". **RESULTS:** In 2010 approximately 25.000 long-term catheters with an average price of 3.57 € were consumed. The regional estimate of annual consumption is about 221.560 catheters, with a total cost of € 791.000 per year. In the case of adopting alternative A, the base case analysis estimated savings of around € 200.000 per year. The one-way sensitivity analysis confirmed the extreme variability of the final result as a function of the confidence interval of the clinical efficacy. A more favorable result for the new catheter can be reached using a "two-way" analysis, combining a higher CAUTI incidence and a higher level of effectiveness (€2.045.866). **CONCLUSIONS:** The results are strongly influenced by the effectiveness of the new technology: a slight clinical benefit is enough to make the new catheter economically viable.

PMD18

MAST (MINIMAL ACCESS SPINAL TECHNOLOGIES) VERSUS OPEN SURGERY: ACTIVITY-BASED COST ANALYSIS OF SPINAL FUSION PROCEDURE FROM HOSPITAL PERSPECTIVE

Corbo M[1], Marchese E[2], Ihara Z[3]
[1]Medtronic Italia, Sesto San Giovanni, Milano, Italy, [2]IMS Health Italy, Milan, Italy, Italy, [3]Medtronic International, Tolochenaz, Switzerland

OBJECTIVES: Open spine surgery (OS) is associated with significant muscle trauma leading to delayed recovery, prolonged pain, and significant medical resource utilization. Minimal Access Spinal Technologies (MAST™) aim at minimizing muscle trauma, reduce blood loss, decrease postoperative pain, reduce length of stay in hospital (LoS), and expedite return to normal activities for the patient. The objective of this study is to determine and compare the resource consumption associated with open vs. minimal invasive surgery in patients with degenerative spinal disorder. **METHODS:** This activity-based cost-analysis was conducted in two Italian hospitals where patient flow and resource utilization were mapped and segmented through interviews with medical staff. Unit costs were retrieved from public sources and hospital data for the following categories 1) staff time; 2) tests; 3) drugs/consumables; 4) operating room (OR); 5) spinal implants/instrumentation; and 6) general costs. Costs were compared between pathways (open vs. MAST™) and for each phase (pre-hospitalization, hospitalization, surgery, post-surgery and follow-up. **RESULTS:** Both surgery and post-surgery were the most resource intense episodes: on average post-surgery accounted for 14% of the total costs in MAST™, and 24% in OS. MAST™ was associated with less overall resource use in both hospitals, mainly driven by shorter LoS post surgery (2 vs. 4 days), less blood loss and less demanding wound care. Total hospitalization costs were €6970-8310 for MAST™ and €8021- 8760 for OS. **CONCLUSIONS:** The study confirms published evidence on the shorter LoS with MAST™ and the economic benefits of a less invasive procedure. Despite initial higher investments (instrumentation, learning curve) MAST™ may be an effective and cost-saving alternative to OS. Further cost savings may be incurred due to faster return to work, not investigated in this study.

PMD19

COST-EFFECTIVENESS OF IMPLANTABLE DEFIBRILLATORS AFTER MYOCARDIAL INFARCTION BASED ON 8-YEAR FOLLOW-UP DATA (MADIT II)

Gandjour A[1], Holler A[2], Adarkwah CC[3]
[1]Pennington Biomedical Research Center/Louisiana State University, Baton Rouge, LA, USA, [2]University of Cologne, Köln, Germany, [3]Maastricht University, Maastricht, The Netherlands

OBJECTIVES: About 190,000 Germans suffer a myocardial infarction (MI) each year. Of these, 25% may be eligible for an implantable cardioverter defibrillator (ICD) due to low left ventricular ejection fraction. Given the high costs of implantation, the purpose of this study was to assess the cost-effectiveness of ICDs compared to conventional therapy in patients with an ejection fraction ≤ 30% after MI in Germany. **METHODS:** The economic evaluation was performed from the perspective of the German statutory health insurance (SHI). In order to simulate costs and effectiveness over lifetime, a Markov model was constructed with 7 health states. The model was based on 8-year follow-up data for ICD implantation after MI (MADIT II), which were published recently. **RESULTS:** The analysis shows that ICD implantation compared to conventional therapy in patients fulfilling MADIT-II criteria has a cost-effectiveness ratio of €44 736 per quality-adjusted life year gained. If every patient insured by the SHI and fulfilling the MADIT-II criteria would receive an ICD, the model suggests expenditures between €173 million and €1.7 billion per year. **CONCLUSIONS:** ICD therapy cannot be considered clearly cost-effective when compared to many well-accepted interventions. If policy makers decide to reimburse ICDs in the MADIT-II population, they will need to either raise premiums or abandon coverage for other currently funded medical interventions.

PMD20

COST ANALYSIS OF RECHARGEABLE DEEP BRAIN STIMULATOR IN DYSTONIA

Pr Coubes P[1], Fluck L[2], Topouchian A[2]
[1]Hôpital Gui De Chauliac, Montpellier, France, [2]Medtronic, Boulogne-Billancourt, France

OBJECTIVES: Deep brain stimulation (DBS) use in dystonia is associated with high energy needs and as such frequent replacement of the device. The first rechargeable DBS device (Activa®RC) offers a guaranteed 9 years longevity. Our objective is to perform a cost analysis of Activa®RC compared to the non rechargeable neurostimulators in dystonia patients in France. **METHODS:** A retrospective data collection was performed in a Neurosurgery Department (Pr. Ph. Coubes - Montpellier Public Hospital) with significant experience in DBS for dystonia. The cost analysis was based on direct medical costs, from a national insurance perspective. The evaluation concerns the device and hospitalization tariffs, the procedure cost being included in the hospitalization tariffs, in France, for the public hospitals. We compared the time to replacement with non-rechargeable devices versus rechargeable device, extrapolated over 9 years. A sensitivity analysis was performed using time-to-replacement variable. **RESULTS:** The cohort included 63 consecutive dystonia

patients, implanted with a non-rechargeable device (Kinetra™, Soletra™, Itrel®2) between 1996 and 2010. Overall, 117 implantations were performed (primo-implantation and replacement). The mediane time to replacement of the non-rechargeable devices was 2.9 years, ranging between 0.4 and 7.8 years. When extrapolated to the cohort population, the use of the rechargeable device would have avoided a total number of 215 hospitalizations over 9 years. The number of days of hospitalization avoided per patient was 10 days. The direct medical cost (device and hospitalization tariffs) avoided per patient was 27 886€. **CONCLUSIONS:** Over 9 years, the rechargeable DBS device allows to avoid 2 device replacements per patient. This is associated with a 40 % reduction of the total number of days in hospital, and 43% reduction in the direct medical cost. The rechargeable neurostimulator Activa®RC is adapted to patients with high energy needs like dystonia patients, with a time to replacement of 5 years or less.

PMD21

THE CLINICAL AND ECONOMIC BENEFITS OF SPINAL CORD STIMULATION IN THE TREATMENT OF FAILED BACK SURGERY SYNDROME (PRECISE STUDY)

Beccagutti G[1], Zucco F[2], Lavano A[3], De rose M[4], Poli P[5], Fortini G[6], Demartini L[7], De simone E[8], Menardo V[9], Cisotto P[10], Meglio M[11], Grifi M[12], De santo T[13], Costantini A[14]
[1]*Medtronic Italia, Sesto San Giovanni, Milan, Italy,* [2]*Azienda Ospedaliera Salvini, Garbagnate Milanese, Italy,* [3]*Centro di Neurochirurgia Funzionale e Stereotassica e della Cattedra di Neurochirurgia dell'Università Magna Grecia, Catanzaro, Italy,* [4]*Università Magna Grecia, Catanzaro, Italy,* [5]*Azienda Ospedaliera Universitaria Pisana, Pisa, Italy,* [6]*Azienda Ospedaliero Universitaria Ospedale di Circolo e Fondazione Macchi, Varese, Italy,* [7]*IRCCS Fondazione Salvatore Maugeri, Pavia, Italy,* [8]*A.O.R.N. "S.G. Moscati", Avellino, Italy,* [9]*A.S.O. "S. Croce e Carle, Cuneo, Italy,* [10]*Ospedale "S. Maria di Cà Foncello", Treviso, Italy,* [11]*Policlinico Gemelli, Roma, Italy,* [12]*Medtronic Italia, Sesto San Giovanni, Italy,* [13]*Medtronic Italia, Roma, Italy,* [14]*Ospedale Clinicizzato "SS Annunziata", Chieti, Italy*

OBJECTIVES: PRECISE study aims to assess the costs and the clinical benefits of Spinal Cord Stimulation (SCS) (plus conventional medical management, CMM) in the treatment of Failed Back Surgery Syndrome (FBSS) patients not adequately responding to CMM alone. Being the study closed, we report the preliminary clinical and resource consumption final results. **METHODS:** An observational, pre-post data collection with a 24-months follow-up (FU) was developed in 9 Italian Hospitals. Resource consumption, clinical outcomes (Pain Numerical Rating Scale - NRS, Oswestry Disability Index - ODI) and HR-QoL data (SF-36, EQ-5D) were collected before and after the SCS system implantation in order to be compared. **RESULTS:** Fifty-five of the 72 patients implanted (out of the 80 enrolled for the SCS screening) completed the study. Seventeen discontinued the therapy due to: consent withdrawal (24%), loss to FU (24%), SCS-related issues (29%), non-SCS related reasons (24%). Mean pain intensity decreased from 7.4±1.4 to 4.2±2.6 in the first 12 months, remaining consistent through the second year of FU (4.1±2.5). A continuous improvement in function measured with ODI was appreciated: 47 (85%) patients improved in the first year and 33 (60%) during the second, for a total of 41 (82%) patients improved at 24-month FU if compared to the baseline. EQ-VAS increased from 37 to 60 (12-months) to 63 (24-months). All SF-36 domains significantly improved, and especially "Bodily Pain", "Social Functioning", "Role Emotional". With respect to the baseline, the monthly per-patient resource consumption decreased: considering the second year of follow-up, both pain-related hospitalizations and GP visits experienced a 70% reduction in number, diagnostic exams diminished by the 82%. Monthly caregivers' days off from work dropped by the 80% (from 45 to 9). **CONCLUSIONS:** SCS allows a better and sustained pain control and HR-QoL improvement. If compared with CMM alone, SCS permits a reduction in resource consumption and productivity losses.

PMD22

ECONOMIC EVALUATION OF AMINO-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) TEST IN PATIENTS WITH DYSPNEA ATTENDING TO EMERGENCY DEPARTMENT (ED) IN SPAIN

Llorens P[1], Moreu J[2], Rodríguez J[3], Pérez Alcántara F[4]
[1]*Hospital General Universitario, Alicante, Spain,* [2]*Hospital Virgen de la Salud, Toledo, Spain,* [3]*Johnson & Johnson, Madrid, Spain,* [4]*Oblikue Consulting, Barcelona, Spain*

OBJECTIVES: Diagnosis of patients with dyspnea and suspected acute heart failure (HF) using NT-proBNP testing has been studied internationally. We aimed to analyze the efficiency of NT-proBNP compared to standard clinical evaluation alone use in Spanish Emergency Departments. **METHODS:** A decision-analytic model was developed to evaluate the clinical and economic outcomes of both diagnostic alternatives. Model's time horizon started at patient ED visits and ended after 60 days of follow-up (taking into account differences between hospitalized and non-hospitalized patients). Clinical parameters were mainly extracted from the PRIDE study and were validated by expert opinion (ED and cardiology doctors). We assumed that 65% of patients with dyspnea had HF based on Spanish published data. Resource use was obtained through expert opinion and examined under a National Healthcare System (NHS) perspective. We considered a 900 pg/ml cut-point for NT-proBNP test (sensitivity of 90% and specificity of 85%). Our model compared final diagnostic result with the initial diagnostic before ED discharge. A probabilistic sensitivity analysis was carried out in order to handle uncertainty. **RESULTS:** Diagnosis using NT-proBNP testing was correct in 91.96% of patients (59.09% true positive cases and 32.87% true negative cases) versus 85.53% with the standard clinical evaluation alone (50.79% of true positive cases and 34.74% of true negative cases). Besides, NT-proBNP testing involved less costs (4,045€ versus 5,405€) mainly due to less hospitalizations and a shorter length of stay. Robustness of results was confirmed through a sensitivity analysis. **CONCLUSIONS:** NT-proBNP test is less costly per correctly diagnosed patient than standard clinical evaluation alone in the assessment and management of patients with dyspnea at ED rooms from Spanish NHS perspective.

PMD23

CHARACTERIZATION OF FOCAL LIVER LESIONS BY CONTRAST-ENHANCED ULTRASOUND IN THE NETHERLANDS: AN ECONOMIC EVALUATION

Zaim R[1], Taimr P[2], De knegt R[2], Redekop W[1], Uyl-de Groot C[1]
[1]*Institute for Medical Technology Assessment, Erasmus University, Rotterdam, The Netherlands,* [2]*Department of Gastroenterology and Hepatology, Erasmus MC University Hospital, Rotterdam, The Netherlands*

OBJECTIVES: Liver imaging techniques aim to correctly characterize focal lesions and influence choices of therapeutic strategies. The objective of this study was to compare diagnostic efficacy and direct medical costs of contrast-enhanced ultrasound (CEUS) to magnetic resonance imaging (MRI) or computed tomography (CT) in the characterization of focal liver lesions in the The Netherlands. **METHODS:** This prospective study enrolled 170 patients at an academic hospital in the The Netherlands. A decision model was designed to compare two diagnostic algorithms based on the results of the study: 1) a typical patient work-up, which included ultrasound (US), followed by an MRI or CT examination, and 2) a new patient work-up in which CEUS was performed after US. The perspective of the healthcare sector in the The Netherlands was used. Clinical outcomes were 'correctly characterizedx benign and malignant liver lesions and life-years (LY). Model inputs were taken from the hospital database, literature and publicly available sources. Time horizon was two years. One-way and probabilistic sensitivity analyses were performed to assess uncertainty in the results. **RESULTS:** CEUS was able to identify benign and malignant focal liver lesions with a sensitivity of 96.9% and specificity of 92.3%. For correct tumor subgroup characterization, sensitivity and specificity were 86.2% and 85.6% respectively. Base-case results revealed that the CEUS strategy had similar effectiveness compared to the MRI/CT strategy (incremental effects of 0.002 LYs) and resulted in cost-savings of €452. The cost-savings for diagnostic phase and treatment phase were €160 and €292 respectively. The results were sensitive to specificity, sensitivity and cost of the diagnostic tests. Robustness of the results was confirmed by probabilistic sensitivity analysis. **CONCLUSIONS:** This study demonstrates that CEUS is a cost-saving alternative compared to the traditional diagnostic procedures and should be considered as one of the 'first stepx options in the front-line characterization of focal liver lesions in the The Netherlands.

PMD24

COST-EFFETIVENESS OF 3M ™ COBAN 2 ™ COMPRESSION SYSTEM IN THE TREATMENT OF LYMPHOEDEMA

Purwins S, Herberger K, Rustenbach SJ, Augustin M
University Clinics of Hamburg, Hamburg, Germany

OBJECTIVES: The treatment of chronic lymphoedema (CL) is of particular health economic interest since, due to its chronic nature and continuous need for treatment, it is associated with high costs and considerable patient burden. The objective of this study was to assess the cost-effectiveness of 3M™ Coban 2™ compression system in the treatment of CL compared to Comprilan® short-stretch bandage compression therapy. **METHODS:** In the UK and the United States a multi-center, prospective, open-label study was conducted, including patients with CL of the legs (n=40) and the arms (n=42). Patients were randomly assigned to the four treatment arms (3M™ Coban 2™ compression treatment either daily, 2x/wk or 3x/wk, and daily compression therapy with Comprilan® bandages). Cost analysis from the UK payors' perspective was based on material costs and personal resource utilization for bandage changes and for manual lymphtherapy. Clinical outcomes in the cost-effectiveness analysis was defined as mean volume reduction at the end of therapy (19 days). **RESULTS:** On average, 3 weeks treatment for a patient with lymphoedema added to 1,297.96 € for the health service comissioners and up to 576,54 € for the physiotherapists across all groups. Lymphoedema treatment with 3M™ Coban 2™ compression system twice a week was more cost-effective than the other treatments (ICER 37.65 € per % reduction of circumference vs. 146.60 € (daily), 145.67 € (3x/wk) and 147.53 € (daily compression therapy with Comprilan® bandages)). Results were comparable for patients with CL of the upper and lower extremities, respecitvely. Sensitivity analysis provided stable results after variation of costs, utilization rates and clinical outcomes. **CONCLUSIONS:** Treatment of lymphoedema with 3M™ Coban 2™ compression system twice a week is more efficient than treatments applied daily or three times per week.

PMD25

COST-EFFECTIVENESS OF TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) IN HIGH-RISK OR INOPERABLE PATIENTS WITH SYMPTOMATIC AORTIC VALVE STENOSIS IN SPAIN

Ferreira-González I[1], Serra V[2], Abdul O[2], Lizan L[3], Paz S[3], Banz K[4], Sureda C[2], Igual A[2], Garcia del Blanco B[2], Angel J[2], Garcia-dorado D[2], Tornos P[2], Ribera A[2]
[1]*Vall d'Hebron Hospital, Barcelona, Barcelona, Spain,* [2]*Vall d'Hebron Hospital, Barcelona, Barcelona, Spain,* [3]*Outcomes'10, Castellon, Castellon, Spain,* [4]*Outcomes International, Basel, Basel, Switzerland*

OBJECTIVES: Transcatheter aortic valve implantation (TAVI) represents an innovative technology superior to medical management (PARTNER study, US) in inoperable patients with severe aortic valve stenosis (AVS). This study aims to estimate the cost-effectiveness of TAVI compared to conservative medical management in symptomatic AVS patients in Spain. **METHODS:** A economic longitudinal cohort model was used to predict clinical and economic outcomes of symptomatic AVS patients treated with either transapical (TA) or transfemoral (TF) TAVI, or medical management alone (MEDICAL). Clinical model input data for TAVI was derived from the real-world SOURCE registry, and for MEDICAL from literature and a registry of 60 untreated Spanish AVS patients followed up for 336 days. Health utilities as well as resource use and unit costs utilized for modelling are representative for Spain. Missing information was substituted by expert estimates. Economic results

are expressed as cost per quality adjusted life year (QALY) gained. Perspective is that of the national health system (NHS). Benefits and costs were discounted with 3% per year. **RESULTS:** Over the 3 year analysis period, 2.12 life years per patient were achieved with TA TAVI, 2.31 with TF TAVI and 1.51 with conservative medical care, representing. 1.24, 1.38 and 0.74 QALYs, respectively. Cumulative direct costs were predicted to amount to €37,311 and €35,689 with TA and TF TAVI, respectively and to €23,103 with conservative care. Cost/QALY gained was €28,003 for TA TAVI and €19,499 for TF TAVI, both ratios remaining well below the accepted willingness-to-pay threshold for Spain. The substantial cost of the TAVI procedure was largely offset over time mainly by savings related to prevented hospital readmissions for cardiac reasons. Sensitivity analyses indicated these findings to be robust. **CONCLUSIONS:** Compared to conservative management, TAVI is a life-saving and cost-effective treatment for high-risk or inoperable patients with symptomatic aortic valve stenosis in Spain.

PMD27

COST-EFFECTIVENESS ANALYSIS OF CARDIAC RESYNCHRONIZATION THERAPY IN PATIENTS WITH ASYMPTOMATIC TO MILD HEART FAILURE BASED ON THE EUROPEAN COHORT OF THE REVERSE STUDY FROM THE SPANISH HEALTH SYSTEM PERSPECTIVE

Quesada A[1], Almenar L[2], Díaz Molina B[3], Crespo C[4], Marti B[5], Mealing S[6], Linde C[7], Daubert C[8]
[1]*Hospital General de Valencia, Valencia, Spain,* [2]*Hospital Universitario La Fe, Valencia, Spain,* [3]*Hospital Universitario Central de Asturias, Oviedo, Spain,* [4]*Oblikue Consulting, Barcelona, Spain,* [5]*Medtronic Iberia, Madrid, Spain,* [6]*Oxford Outcomes Ltd, Oxford, UK,* [7]*Karolinska University Hospital, Solna, Sweden,* [8]*Centre Hospitalier Universitaire, Rennes, France*

OBJECTIVES: The aim of this study was to combine clinical results from the REVERSE study (Resynchronisation reverses Remodelling in Systolic Left Ventricular Dysfunction) and costs associated with the addition of cardiac resynchronization therapy (CRT) to optimal medical therapy (OMT) in patients with mild symptomatic (NYHA I-II) or asymptomatic left ventricular dysfunction and markers of cardiac dyssynchrony in Spain. **METHODS:** We developed a Markov model of CRT + OMT (CRT-ON group) vs. OMT alone (CRT-OFF group) based on a retrospective cost-effectiveness analysis. Raw data from the model was derived from literature and expert opinion, reflecting clinical and economic consequences of patient's management in Spain. Time horizon was 10 years, and costs were expressed in Euro 2010. Both costs and effects were discounted at 3% per annum. **RESULTS:** CRT-ON group showed higher total costs than CRT-OFF, however patients with CRT reduced 94% the length of hospitalization in the ICU (0.006 vs. 0.091 days) and 34% in general ward (0.705 vs. 1.076 days). Surviving patients with CRT-ON (88.2% vs. 77.5%) remained in slighter functional class longer and they achieved an improvement of 0.9 life years (LYGs) and 0.77 years quality-adjusted life years (QALYs). In terms of cost per LYGs, the results were €40,782 (5 years) and €18,431 (10 years), and in terms of costs per QALYs gained were €39,800 and €21,500 at 5 and 10 years respectively. Probabilistic sensitivity analysis showed that the probability of CRT-ON was cost-effective is 65.54% at 10 years. **CONCLUSIONS:** The use of CRT added to OMT represents an efficient use of resources in patients suffering from heart failure in NYHA functional class I and II, with cost-effectiveness ratios below the Spanish threshold at 10 years.

PMD28

COST-EFFECTIVENESS ANALYSIS OF THREE LEPROSY CASE DETECTION METHODS IN NORTHERN NIGERIA

Ezenduka CC
University of Nigeria, Enugu, Enugu, Nigeria

OBJECTIVES: Case detection is key to identifying leprosy disease early in its development for more effective prevention of progression to permanent disability. The study evaluated the costs and cost-effectiveness of three leprosy case detection methods in Nigeria's north-eastern states of Adamawa and Gombe; namely Rapid Village Survey (RVS), Household Contact Examination (HCE) and Traditional Healer's (THs) incentive approach **METHODS:** The study was cross-sectional and explorative, undertaken in routine practice setting, targeting endemic and non-endemic communities selected randomly. Primary and secondary data were collected from routine practice records and the Nigerian Leprosy Elimination Programme 2009. All costs were measured from both providers' and patients' perspectives. Effectiveness was measured as new cases detected and outcome expressed as cost per case detected. Incremental approach, using routine passive case detection method as a reference was used to estimate the costs and effects by comparing each method against the routine practise; to measure additional cost per new case detected, as incremental cost-effectiveness ratio (ICER). Univariate sensitivity analysis was carried out to evaluate uncertainties around the ICER. All costs were converted to US Dollars at the 2010 exchange rate. **RESULTS:** HCE generated a total of $2416 at the lowest rate of $142 per additional case detected at all contact levels, as the most cost-effective method while the RVS was dominated by THs method which generated a total of $4447 at $193 per new case detected.Variation of diagnostic accuracy and subsistent wage for valuing unpaid time did not significantly change the results. **CONCLUSIONS:** From both perspectives and at all contact levels, the Household Contact Examination, complementing routine practice demonstrated the most cost-effective approach to identifying new leprosy cases for effective prevention and control of leprosy in Nigeria. It will be necessary to carry out implementation studies to establish the feasibility and acceptability of the method in other leprosy areas.

PMD29

A1CNOW® AS AMBULATORY MONITORING OF GLYCATED HEMOGLOBIN IN DIABETIC TYPE 2 (DM2) PATIENTS: BRAZILIAN ECONOMIC MODELING

Silva AP[1], Santoni NB[1], Pepe C[2], Laranjeira F[2]
[1]*Bayer Brazil, São Paulo, São Paulo, Brazil,* [2]*MedInsight, São Paulo, São Paulo, Brazil*

OBJECTIVES: To determine the cost-effectiveness of measuring glycated hemoglobin with A1CNow ® compared with standard exam (SE) for DM2 patients, from the Brazilian Private Healthcare System perspective. **METHODS:** The study was a cost-effectiveness analysis based on Markov modeling to estimate costs and consequences of treatments. Epidemiological and efficacy data derived from a critical appraisal of the scientific literature. Only direct medical costs were considered. If available, costs of clinical events (CE) were obtained from burden of disease studies. If not, Brazilian official guidelines were obtained to determine the resources used to treat the CE. Drugs, hospital daily admission rates, procedures and laboratory tests unit costs were obtained from Brazilian official databases. Costs and benefits were discounted at 5% yearly. Outcomes were expressed as CE avoided. Probability sensitivity analysis (PSA) was conducted to assess model robustness. Life time horizon was analyzed. **RESULTS:** Through the systematic review of the literature the studies were selected to form the body of clinical data for the analyses. The systematic review showed that although the absence of studies directly evaluating the impact of A1CNow on cardiovascular events, their favorable influence on cardiovascular disease intermediate markers suggests that A1CNow may have clinically relevant effect in patients at risk. The analysis showed higher clinical benefits and lower costs for A1CNow. Considering 100 patients, 99.8 and 146.1 CE happen in A1CNow and SE arms, respectively. The average time-horizon cost per patient was R$25,444(€11,108) and R$29,278(€12,782) for A1CNow and SE, respectively, showing the dominance of A1CNow compared to SE. PSA demonstrated that in 95.3% of the simulations A1CNow was dominant (more effective with lower cost) compared to SE. **CONCLUSIONS:** Our study demonstrated that A1CNow have clinically relevant effect in reducing CE being dominant for monitoring of glycated hemoglobin in DM2 patients. PSA confirmed this determinist result.

PMD30

COST-EFFECTIVENESS ANALYSIS OF PULMONARY VEIN ISOLATION (PVI) USING A NOVEL CRYO ENERGY-BASED BALLOON CATHETER: A HIGH-VALUE PROCEDURE FOR PAYERS?

Tsintzos S, Eggington S
Medtronic International Trading Sarl, Tolochenaz, Vaud, Switzerland

OBJECTIVES: Atrial Fibrillation (AF) is the most common arrhythmia among the elderly. It has dire consequences, stroke being the most catastrophic. Its burden is highly significant; changing demographics lead to more patients impacted. Managing AF encompasses arrhythmia control and stroke prevention – with new technologies being developed for both. For Paroxysmal AF (PAF) – which terminates spontaneously within 7 days – electrical Pulmonary Vein Isolation (PVI) has advanced as the cornerstone treatment in patients unresponsive to pharmaceuticals. PAF accounts for 75% of patients, and half are medicated with sub-optimal outcomes. We sought to evaluate the cost-effectiveness of PVI when using a new balloon-based catheter using cooling energy for lesion creation (Arctic Front, Medtronic). **METHODS:** A Markov Microsimulation Model compared treatment with Arctic Front vs. conventional drugs. STOP-AF Pivotal Trial Data were used to estimate PVI efficacy and complication rates. A literature review identified data for long-term PVI and drug therapy outcomes. The model incorporated Arctic Front specific complication rates (e.g. stroke, tamponade and phrenic nerve paralysis) and drug toxicities and impact on stroke risk was included. Utility weights were assigned for various health states. and a range of time horizons was used, with a UK perspective adopted for costs and benefits. One-way and probabilistic sensitivity analyses were undertaken. **RESULTS:** Depending on the time horizon, the ICER ranged from £3,200/QALY to £15,700/QALY gained. Results were sensitive to assumptions regarding long-term outcomes and the quality of life benefit of remaining free of PAF. **CONCLUSIONS:** PVI can be highly cost-effective in treating PAF – a highly prevalent and burdensome disease. Results are consistent with similar technology economic evaluations, and reinforce the evidence base for PVI as a cost-effective therapy for PAF.

PMD31

ECONOMIC EVALUATION OF PRIMOVIST VERSUS EXTRACELLULAR CONTRAST IN IMAGING OF LIVER METASTASES OF COLORECTAL ORIGIN

Castell J[1], Bernal C[1], De Marcos JÁ[2], Cugat E[2], Ramón E[3], Tellado JM[3]
[1]*Hospital Universitario Virgen del Rocío, Seville, Spain,* [2]*Hospital Universitari Mútua de Terrassa, Barcelona, Spain,* [3]*Hospital G. U. Gregorio Marañón, Madrid, Spain*

OBJECTIVES: The main purpose of this study was to conduct an economic evaluation of Primovist enhanced MRI (PV-MRI) compared to extracellular contrast-media-enhanced MRI (ECC-MRI) in patients suffering from liver metastases of colorectal origin in Spain. **METHODS:** An analytic model previously implemented in three European countries (Germany, Italy and Sweden) was adapted in Spain to estimate all aggregated costs of both diagnosis options compared. Probabilities of needing further imaging and of needing surgical plans modification or confirmation were adjusted by Spanish clinical experts (surgeons and radiologists). Contrasts cost was estimated from PTR (weighting the different EECs prices for sales in Spain for this option), and tests (MRI and CT) and different surgery procedures (high or low risk, modification or confirmation of surgical plans, etc.) costs were extracted from official fees of different Spanish Autonomous Communities (CCAA). **RESULTS:** PV-MRI was associated with a reduced need for extra imaging tests (6% vs. 9%). Taking into account the costs of diagnosis tests and surgery procedures (including modification of surgical plans during intervention), PV-MRI option was a cost-neutral strategy, with total costs similar to ECC-MRI (576 € vs. € 578, PV-MRI vs ECC-MRI respectively). **CONCLUSIONS:** Additional costs associated with colorectal liver metastases diagnosis with PV-MRI regarding to ECC-MRI are offset by lower

costs in intraoperative changes of the surgical plan and reductions in unnecessary surgery associated with the use of PV-MRI. Results from the previous study VALUE, which showed that no patient with PV required additional imaging tests as part of a Phase IV, confirm the results obtained in the present analysis (resulting in even slightly lower cost than the total cost of diagnosis using PV-MRI).

PMD32

COST EFFECTIVENESS OF CERVICAL CANCER SCREENING IN SERBIA: A COMPARISON OF SCREENING POLICIES

Mihajlović J[1], Pechlivanoglou P[1], Postma MJ[2]
[1]*University of Groningen, Groningen, The Netherlands,* [2]*University of Groningen, Groningen, Groningen, The Netherlands*

OBJECTIVES: Cervical cancer incidence in Serbia has been identified as one of the highest in Europe, showing slow but steady increase during the last decade. Despite the National Programme for Prevention of Cervical Cancer that has recently been established, an organised Pap screening is far from full implementation. This study aims to assess the effectiveness and cost effectiveness of absolute adherence to the proposed policy compared to the current practice. **METHODS:** A Markov model simulating the natural history of cervical cancer was developed. Calibration was performed using country specific data, sourcing incidence and mortality from Serbian cancer registries. Accordingly, the screening algorithm incorporated in the model was based on the local guidelines. We followed a hypothetical cohort of 100,000 15-year old girls until the end of their lifetime. Subsequently, the actual cytological screening practice covering only 20% of the targeted population was compared to a scenario of absolute adherence to the national screening programme. A discount rate of 1.5% for health and 4% for cost outcomes was applied. **RESULTS:** The natural history model showed that limited benefit is currently being achieved from cytological screening. The hypothetical cohort analysis indicated that absolute guidelines adherence would result in 422 deaths averted and an incremental cost effectiveness ratio (ICER) of 3272 €/LYG. The ICER estimate did not exceed the national annual GDP (3857 €/capita) - a commonly used informal threshold. **CONCLUSIONS:** This research identified that full adherence to the screening policy is very likely to be cost effective. In general, the low screening coverage that has been observed appeared as the most serious obstacle to the prevention of cervical cancer. The new methods in cervical cancer prevention, however, such as HPV vaccination and HPV testing, require further pharmacoeconomic assessment.

PMD33

ECONOMIC EVALUATION OF TWO WOUND DRESSINGS FOR CHILDREN WITH PARTIAL-THICKNESS SCALDS FROM THE PUBLIC PAYER PERSPECTIVE

Tolentino ACM, Takemoto MLS, Fernandes RA, Cukier FN, Takemoto MMS, Cruz RB, Ribeiro ACP, Fernandes RRA, Santos PML, Moretti AIP
ANOVA - Knowledge Translation, Rio de Janeiro, Brazil

OBJECTIVES: This study aimed to develop cost-effectiveness analysis of Soft Silicone Wound-Contact Dressing (SS) versus Silver Sulphadiazine (SSD) in children with partial-thickness scalds (PTS), under the perspective of Brazilian public payers. **METHODS:** A literature search was conducted to gather efficacy data for SS and SSD and identified one randomized controlled trial that compared median time to 100% epithelialization (MTH) for SS and SSD. These data were used to estimate clinical benefits in terms of "inpatient days avoided". The model assumed that SSD is the current practice in Brazilian public hospitals and patients are discharged at the time their wound heals. Resource use was estimated through expert panel, only direct medical costs were included in the analysis and unit costs were obtained from Brazilian official price lists. **RESULTS:** The randomized trial observed MTH of 10.5 and 27.6 days for SS and SSD, respectively (incremental effectiveness of -17.1 days). Evidence from smaller observational studies have reported intervals to SS change of up to 14 days, while SSD requires two changes per day. Thus, the model estimated costs for the inpatient period assuming one dressing change for SS and 28 changes for SSD. The cost per dressing change was estimated as 33BRL for SS and 23BRL for SSD and the overall treatment costs were 1,261BRL and 23BRL. SS-related incremental costs were -1228BRL indicating a cost-saving profile. Benefits in terms of reduction in length of stay were not accounted in the base case scenario. If average public hospital daily charges were included in the cost estimation, savings would reach -2209BRL. **CONCLUSIONS:** SS dressing has shown higher efficacy when compared to SSD, with fewer overall costs. The significant reduction in the median time to healing offset the higher unit cost by lowering the number of required changes and the total length of stay.

PMD34

COST EFFECTIVNESS OF AMBULATORY CARDIAC MONITOR VERSUS HOLTER

Gregg ML[1], Guo N[1], Schwenger S[2], Goeree R[1]
[1]*McMaster University, Hamilton, ON, Canada,* [2]*M-health Solutions, burlington, ON, Canada*

OBJECTIVES: A new ambulatory electrocardiogram (loop recorder) has been introduced in Canada to detect arrhythmias, overcoming issues of previous recorders with its capability of automatically detecting/sending electrocardiograph data and simultaneously patient activation of device during symptoms. The loop recorder is expected to have a higher diagnostic yield due to its recording capabilities and longer test period (14days) however the cost is greater than the standard of care (Holter). Cost-effectiveness was estimated for Holter versus the loop recorder for diagnosing paroxysmal or persistent atrial fibrillation in primary physician care in Ontario, Canada, from a health payer's perspective. **METHODS:** A probabilistic decision analytic model was constructed to estimate cost, number of cases correctly detected, and number of strokes averted due to correct detection and treatment over a 19 month period. Direct medical costs included diagnostic testing, treatment of atrial fibrillation, prevention of stroke, and treatment of stroke. Costs were expressed in 2011 Canadian dollars. One-way, multi-way and probabilistic analyses of uncertainty were conducted. Model inputs were from various sources including primary data, published literature and expert opinion. **RESULTS:** Average cost was estimated at $490 for Holter, and $612 for loop recorder. Average cases of atrial fibrillation correctly detected were 0.032 for Holter, and 0.058 for loop recorder. Average number of strokes averted were 0.010 for Holter and 0.018 for loop recorder. The probabilistic mean incremental cost-effectiveness ratio of loop recorder versus Holter was $2430 per additional case correctly detected and $698 per additional stroke averted. At a $20,000 willingness-to-pay threshold the probability of the loop recorder being cost effective for cases detected and strokes averted were 95.5% and 60.4% respectively. Cases detected and strokes averted were 99.3% and 92% respectively for a willingness-to-pay of $50,000. **CONCLUSIONS:** Cost-effectiveness analysis favours the new loop recorder compared to Holter.

PMD35

COST-EFFECTIVENESS ANALYSIS OF THE CORAIL HIP SYSTEM FOR PRIMARY TOTAL HIP ARTHROPLASTY IN SPAIN

Crespo C[1], Espallardo O[2], Graefenhain De Codes R[3], Nieves D[4]
[1]*Oblikue Consulting, Barcelona, Spain,* [2]*Johnson & Johnson Medical, Madrid, Madrid, Spain,* [3]*Johnson & Johnson Medical Iberia, Madrid, Madrid, Spain,* [4]*Oblikue Consulting, Barcelona, Barcelona, Spain*

OBJECTIVES: The Corail™ Hip System, a hydroxyapatite coated cementless implant, has demonstrated its high efficacy and safety for primary total hip arthroplasty (THA) for over 20 years. The objective of this work was to evaluate the cost-effectiveness of the Corail™ Hip System in comparison with other cementless hip designs (standard) in Spain. **METHODS:** An analytical decision-making model was constructed as a Markov model for patients who were candidates to THA. The study perspective was from the viewpoint of the Spanish National Health System (NHS). Time horizons included in the model were 10 or 20 years and lifetime. Healthcare costs associated with the compared interventions and their consequences were expressed in euro 2011. Data came from a review of the literature and was validated by local clinical experts. A discount rate of 3% was applied on costs and efficacy data. **RESULTS:** The use of the Corail™ Hip System for THA compared with the standard resulted in €4317 per revision avoided and €5812 per QALY gained considering a time horizon of 10 years. The result was dominant in favour of Corail™ when a time horizon of 20 years or lifetime was considered for all the scores. Corail™ provided a gain of 0.075 QALY and saved €279 versus the standard (lifetime). There were no significant differences between sexes. In the sensitivity analysis was built the best scenario for Corail™ including the worse efficacy data available for the standard and Corail™ resulted in a gain of 0.388 QALY and saved €2226 (lifetime). The probabilistic sensitivity analysis showed that Corail™ was cost-effective in 76% of cases (threshold of €30,000/QALY). **CONCLUSIONS:** Preliminary results showed that the Corail™ Hip System is a cost-effective option in THA compared with the rest of cementless hip trademarks available in Spain.

PMD36

COST-EFFECTIVENESS OF THE EX-PRESS GLAUCOMA FILTRATION DEVICE IN THE NETHERLANDS

De jong L[1], Lafuma A[2], Aguade AS[3], Clément O[3], Berdeaux G[4]
[1]*Amsterdam Medical Center, Amsterdam, The Netherlands,* [2]*CEMKA-EVAL, Bourg la Reine, France,* [3]*Cemka Eval, Bourg la Reine, France,* [4]*Alcon France, Rueil-Malmaison, France*

OBJECTIVES: To compare the costs and effectiveness of the EX-PRESS glaucoma filtration device (Alcon Inc, TX) to trabeculectomy, 5 years after surgery, in primary open angle glaucoma (POAG). **METHODS:** Seventy-eight patients with POAG uncontrolled despite maximally-tolerated medical therapies were randomized to receive either the EX-PRESS or undergo a trabeculectomy, realized by a single surgeon. Outcomes captured over 5 years included intraocular pressure (IOP a surrogate endpoint of glaucoma progression), use of IOP lowering medications and additional eye surgeries. The economic perspective was the one of the Dutch National Health System. Patients were considered a success if they had an IOP less than or equal to the success thresholds of 15 or 18 mmHg, without IOP lowering medications, and without having undergone further glaucoma surgery. Time to failure was analyzed using a log rank test. Costs were discounted at a 4% rate. EX-PRESS cost was not included. **RESULTS:** The 5-year failure rate was 41% for EX-PRESS versus 69% for trabeculectomy (P=0.005) using an 18 mmHg IOP target and 46% versus 77% (P=0.001) for 15 mmHg. EX-PRESS patients were less likely to use medications, and among the medically treated patients, required fewer drugs. EX-PRESS eyes required less needling (2 vs 5) and less cataract surgery (5 vs. 8). Without discounting, drug savings with EX-PRESS equaled €333.86 and €107.79 for eye surgery /laser, a total of €441.65. With a 4% discounting, the figures became €310.45, €132.78 and €443.23, respectively. **CONCLUSIONS:** At 5 years after surgery, EX-PRESS demonstrated that it better controls IOP than trabeculectomy, resulting in savings in both IOP lowering drugs and eye surgeries. Economic benefits of the better IOP control (less disease progression, i.e. a better vision) and saving according to a lifelong time horizon will be estimated in future modelling exercises.

PMD37

COST-EFFECTIVENESS OF THE EX-PRESS GLAUCOMA FILTRATION DEVICE IN FRANCE

De jong L[1], Lafuma A[2], Clément O[3], Aguade AS[3], Berdeaux G[4]
[1]*Amsterdam Medical Center, Amsterdam, The Netherlands,* [2]*CEMKA-EVAL, Bourg la Reine, France,* [3]*Cemka Eval, Bourg la Reine, France,* [4]*Alcon France, Rueil-Malmaison, France*

OBJECTIVES: EX-PRESS glaucoma filtration device (Alcon Inc, TX) is an alternative treatment to trabeculectomy, a surgery realized in advanced primary open angle glaucoma (POAG). This analysis reports the incremental cost and benefits of EX-PRESS. **METHODS:** Patients with POAG uncontrolled by maximally-tolerated

medical therapies were randomized to receive either the EX-PRESS or a trabeculectomy. Clinical outcomes included intraocular pressure (IOP), use of IOP lowering medications and post-operative eye surgeries. The study follow-up was 5 years. The economic perspective was the one of the French society. EX-PRESS cost was not included. Patients were considered a success if they had an IOP less than or equal to the success thresholds of 15 or 18 mmHg, without IOP lowering medications, and without having undergone further glaucoma surgery. Time to failure was analyzed using a log rank test. Costs were discounted at a 3% rate. **RESULTS:** 78 patients were analyzed, 39 in each arm. EX-PRESS eyes had better IOP control at 1 (12.0 vs 13.9 mmHg; P=0.02), 2 (11.9 vs 13.8 mmHg; P=0.01) and 3 years (12.0 vs 13.5 mmHg; P=0.04). The five-year failure rate was 41% for EX-PRESS versus 69% for trabeculectomy (P=0.005) using an 18 mmHg IOP target and 46% versus 77% (P=0.001) for 15 mmHg. At year 5, 41.0% of the EX-PRESS patients had an IOP lowering drug prescription versus 53.9% for the trabeculectomy patients. EX-PRESS patients received 0.85 IOP lowering medications versus 1.10 in the trabeculectomy group. EX-PRESS patients required less needling (2 versus 5) and had fewer cataract surgeries (5 versus 8). Without discounting, drug savings with EX-PRESS equaled €277.00, €331.02 as a total. With a 3% discounting, the figures became €260.00 and €342.97, respectively. **CONCLUSIONS:** At 5 years after surgery, EX-PRESS demonstrated that it better controls IOP than trabeculectomy, resulting in post-operative savings.

PMD38

COST-EFFECTIVENESS OF THE CARDIOVASCULAR MARKER ST2 IN PROVIDING RISK STRATIFICATION AFTER ACUTE HEART FAILURE

Rinde H[1], Rubin A[2]
[1]*BioBridge Strategies, Binningen, BL, Switzerland,* [2]*Critical Diagnostics, San Diego, CA, USA*

OBJECTIVES: ST2 is a blood test that accurately risk stratifies patients with heart failure (HF). This enables physicians to select high risk patients for intensive disease management (DM) programs. We evaluated the cost-effectiveness of ST2 in patients discharged from hospital after an acute heart failure event. **METHODS:** We developed a decision-analytic model to explore the 30-day mortality and cost outcomes. A horizon of 30 days was used as a recognized hospital quality metric. We compared two clinical scenarios: 1) HF patients did not enter DM programs; 2) only patients with ST2 >35 ng/ml entered DM programs. The clinical data came from the Basel study, a prospective, blinded study of 591 HF subjects. We modeled the mortality, the hypothetical reimbursement of ST2 testing, costs of DM and hospitalizations. A US health care system perspective was taken. A range of sensitivity analyses and scenario analyses were performed. **RESULTS:** We simulated a cohort of patients with a mean age of 78 years old over the 30-day period post discharge. During that period there was 11.8% mortality and 20.1% all cause re-hospitalization rates. We assumed a 26% reduction in mortality and a 21% reduction in re-hospitalization from intensive DM based on a peer-reviewed meta-analysis. The base case showed that the ST2 strategy reduces lost life years by 0.217 with cost saving of $1079 per tested patient when compared to no DM. Sensitivity analyses suggest that the model is most sensitive to the cost of re-hospitalization and the cost and effectiveness of the intensive DM program. **CONCLUSIONS:** Under a variety of scenarios, prediction of 30-day HF risk with ST2, in order to select high risk patients for enrollment into intensive DM programs, reduces mortality and is cost saving.

PMD39

COST EFFECTIVENESS ANALYSIS OF INTRATHECAL BACLOFEN THERAPY (TRICUMED™) VERSUS MEDICAL TREATMENTS FOR SEVERE SPASTICITY IN TURKEY

Malhan S[1], Oksuz E[2], Ozsezer Y[3]
[1]*Baskent University, Ankara, Turkey,* [2]*Baskent University, Ankara, Turkey,* [3]*Neuromodulation Group, Ýstanbul, Turkey*

OBJECTIVES: The objective was from a Turkish perspective to analyse the incremental cost-effectiveness of Intrathecal baclofen therapy (Tricumed™) compared with medical treatment in adults for severe spasticity in Turkey. **METHODS:** We compared the costs and health effects of intrathecal baclofen therapy with standard treatment only, from the health care perspective for a 1-year period. Health effects were expressed in terms of an "ashworth score" as a year. The ashworth score data was collected from the literature for both Intrathecal Baclofen Therapy and medical treatment for severe spasticity. The cost of the treatments were calculated based on the treatment guidelines for Turkish patient from the Turkish health care payer's perspectives. **RESULTS:** The annual average cost of Intrathecal Baclofen Therapy per patient has been estimated to be €10357,27. On the other hand, the yearly average cost of medical treatment per patient has been found as €6080,16. The incremental cost effectiveness ratio (ICER) for Intrathecal Baclofen Therapy versus Medical Treatment for severe spasticity analysed as 89,33€ per "ashworth score". **CONCLUSIONS:** Intrathecal Baclofen Therapy is a cost-effective technology for the severe spasticity patients compared to the medical treatment for severe spasticity in Turkey.

PMD40

COST EFFECTIVENESS OF FRACTIONAL FLOW RESERVE MEASUREMENT IN MULTIVESSEL CORONARY ARTERY DISEASE IN BELGIUM AND FRANCE

Bornschein B[1], Arvandi M[1], Gothe R[1], Rioufol G[2], De bruyne B[3], De pouvourville G[4], Desmet W[5], Lefevre T[6], Fearon WF[7], Pijls NHJ[8], Siebert U[9]
[1]*UMIT - University for Health Sciences, Medical Informatics and Technology, Hall i. Tirol, Austria,* [2]*Cardiovascular hospital - Hospices Civils de Lyon, Lyon, France,* [3]*OLV-Clinic-Aalst, Cardiovascular Center Aalst, Aalst, Belgium,* [4]*ESSEC Business School, Cergy, France,* [5]*University Hospitals Leuven, Leuven, Belgium,* [6]*Hopital Privé Jacques Cartier, Massy, France,* [7]*Stanford University Medical Center, Stanford, CA, USA,* [8]*Catharina Hospital, Eindhoven, The Netherlands,* [9]*UMIT/Oncotyrol/Harvard University, Hall i.T.;Innsbruck, Tyrol, Austria*

OBJECTIVES: The FAME Study is an international multicenter randomized clinical trial (n=1,005), which demonstrated a significant improvement in health outcomes for patients with multivessel coronary artery disease undergoing percutaneous coronary intervention (PCI) guided by fractional flow reserve measurement (FFR) compared to PCI guided by angiography alone. We performed a cost-effectiveness analysis along the FAME trial to estimate the cost effectiveness of FFR in France and Belgium and compared the results with those of other European countries. **METHODS:** We used original patient-level data of the FAME study (Tonino et al., NEJM 2009) to estimate resource consumption, which was valued using prices from French and Belgian price lists and DRG catalogues (2010 values). Utilities were measured with EQ-5D based on French time trade-off and Torrance-transformed Belgian visual analogue scale (VAS) weights. We adopted a societal perspective and a one-year time horizon (i.e., follow-up of the FAME Study). Variability was examined using one-way sensitivity analysis and bootstrap resampling (n=5000). Results are expressed in incremental costs (EUR) and incremental QALYs. **RESULTS:** In both countries, FFR slightly improved QALYs ($p>0.05$) at significantly lower costs ($p<0.05$). Cost savings reached approximately 900 EUR/patient for both countries. For both countries, bootstrap analysis showed that FFR was cost saving in >50% of all bootstrap samples and cost effective in >90% when using a cost-effectiveness threshold of 50,000 EUR/QALY. The most influential cost components were prices for DES and FFR pressure wires. Cost-savings in France and Belgium are higher than recently presented results for Germany, the UK and Italy, where FFR is cost saving with savings ranging from 300-600 EUR/patient. **CONCLUSIONS:** In the context of the health care systems of Belgium and France, FFR-guided PCI is cost saving (dominant) in patients with multivessel coronary artery disease. These results are robust and in line with those of other European countries.

PMD41

DRUG ELUTING STENT (DES) VERSUS BARE METAL STENT (BMS) ON CLINICAL, HUMANISTIC AND ECONOMIC OUTCOMES: A 12-MONTH PROSPECTIVE OBSERVATIONAL STUDY

Lee V[1], Yan B[2], Lau JC[1], Tang WK[1], Yu CM[2]
[1]*The Chinese University of Hong Kong, Shatin, N.T Hong Kong, Hong Kong,* [2]*The Chinese University of Hong Kong, Shatin, Hong Kong*

OBJECTIVES: An ongoing 2-year local prospective study to compare clinical, humanistic and economic outcomes of Drug Eluting Stents (DES) and Bare Metal Stents (BMS). **METHODS:** All patients receiving DES or BMS placement in Prince of Wales Hospital in Hong Kong within the period of September 2009 to March 2010 were recruited and followed for 12 months. Clinical outcome was measured by occurrence of major adverse cardiac events (MACE). EQ-5D questionnaire, with visual analog scale (VAS), was used to assess patients' health-related quality of life. The questionnaire was administered by patients before procedure, at 6 month and 12 month. Cost of index procedure and follow-up were recorded and cost per QALY of DES over BMS was used to evaluate cost-effectiveness of DES. Subgroup analysis was performed on patients with diabetes mellitus (DM). **RESULTS:** 325 patients were enrolled (n=210 for DES and n=115 for BMS), with balanced baseline characteristics. MACE was significantly less common in DES group (n=10, 4.8% vs n=14, 12.2%; OR=0.361, 95% Cl=0.155 to 0.841). The increase in utility score at 12 month was 0.22 for DES group and 0.17 for BMS group (p=0.294). Aggregate 12-month cost was higher in DES group (HK$110,640 68,706 vs HK$99,802 93,420; p=0.235). Cost per QALY gained for DES was HK$184,564. Subgroup analysis showed that cost per QALY was HK$15,303 in DM patients. Subsidizing DM patients to use DES, instead of BMS, could save up to HK$6,370,000 annually for Hospital Authority. (1US$ = 7.8 HK$) **CONCLUSIONS:** DES was shown to be superior to BMS in clinical outcome. Even with higher procedural cost in DES group, the lower follow-up cost resulted in gradually smaller difference in aggregate cost. DES was more cost-effective than BMS, especially in DM patients. Subsidizing DM patients to use DES would be cost-saving and lead to better clinical outcome.

PMD42

COST-EFFECTIVENESS OF USING THE UGT1A1 PHARMACOGENETIC TEST TO REDUCE THE INCIDENCE OF IRINOTECAN CHEMOTHERAPY-RELATED FEBRILE NEUTROPAENIA

Shabaruddin FH[1], Elliott RA[2], Tappenden P[3], Payne K[4]
[1]*University of Malaya, Kuala Lumpur, Malaysia,* [2]*University of Nottingham, Nottingham, UK,* [3]*University of Sheffield, Sheffield, UK,* [4]*University of Manchester, Manchester, UK*

OBJECTIVES: Neutropaenia, a chemotherapy-related adverse event, is graded in terms of severity and can have different relative effects on health and resource use. For advanced colorectal cancer (CRC) patients on irinotecan-based chemotherapy, UGT1A1 testing can stratify populations into different risk groups to potentially reduce the incidence of febrile neutropaenia, which may also impact on healthcare resources. High-risk patients can be prescribed lower irinotecan doses to reduce febrile neutropaenia. Two previous economic evaluations of UGT1A1 testing focussed on reducing grade 3&4 neutropaenia. This study aimed to assess the cost-effectiveness of UGT1A1 testing to reduce the incidence of irinotecan-related febrile neutropaenia. **METHODS:** An economic model of UGT1A1 testing to predict febrile neutropaenia compared to standard care was developed over a lifetime horizon from the UK NHS perspective. Treatment pathways were informed by a national survey of CRC experts (n=44). Model inputs were identified from: a micro-costing observational study (n=48 patients), CRC expert (n=55) elicitation and published literature. **RESULTS:** UGT1A1 testing was cost-saving and resulted in lower incidence of febrile neutropaenia. For a cohort of 100 patients, the test was estimated to save £17,700, avoid 0.4 febrile neutropaenic episodes, gain 0.006 life-years and 0.007 QALYs. The likelihood that the test was cost-effective was 94% at a threshold of £25,000 per QALY gained. Sensitivity analysis (probabilistic and one-

way) suggested the largest driver of cost-effectiveness was the effect of irinotecan dose reduction on survival. Value of information analysis indicated a low value of future research to reduce parameter uncertainty (5 year population EVPI: £31,564). However, assumptions affecting model structure had a relatively higher impact on cost-effectiveness. **CONCLUSIONS:** This is the first economic evaluation of UGT1A1 testing to reduce the incidence of febrile neutropaenia. This study illustrated the importance of considering febrile neutropaenia in addition to grade 3 and 4 neutropaenia in evaluations of UGT1A1 testing.

PMD43

AN EVIDENCE-BASED MICROSIMULATION MODEL FOR CHRONIC GRAFT VERSUS HOST DISEASE IN SPAIN

Sierra J[1], Perez-Simon J[2], Crespo C[3], Rodríguez J[4], Brosa M[3]
[1]*Hospital de la Santa Creu i Sant Pau, Barcelona, Spain,* [2]*Hospital Virgen del Rocio, Sevilla, Spain,* [3]*Oblikue Consulting, Barcelona, Spain,* [4]*Johnson & Johnson, Madrid, Spain*

OBJECTIVES: Rituximab (Rmb), Imatinib (Imt) and extra-corporeal photopheresis (ECP) are some of the strategies used as rescue therapy among patients with chronic graft-versus-host disease (cGVHD) who failes previous lines of treatment. The purpose of the study was to assess the cost-effectiveness of ECP in patients with cGVHD in Spain. **METHODS:** A Microsimulation model was built to estimate the clinical and economic consequences of ECP versus Rmb or Imt for 1000 hypothetical patients. Model probabilities concerning the efficacy of ECP, Rtm and Imt and severity degree per organ affected were obtained from literature. Treatment pathways and adverse events were evaluated taking into consideration expert opinion. Local data on costs (Euros 2010) and use of health resources were also validated by clinical experts. An annual 3% discount rate was applied to costs and outcomes. The perspective was the Spanish National Health System and time horizon was 5 years. **RESULTS:** Differences in improvement when ECP is used showed a gain at first year of 6.2% and of 6.7% against Rmb and Imt, respectively. The higher efficacy of ECP leads to a gain of 0.011–0.024 Quality Adjusted Life Year in the first year and 0.062-0.094 at year five compared to Rmb or Imt. Results showed than higher acquisition cost of ECP vs Imt was compensated at 9 months by higher efficacy and vs Rmb was partially compensated (517€ year 5). After 9 months, ECP was dominant vs Imt. The incremental cost-effectiveness ratio of ECP versus Rmb was 29,646€ per LY gained and 24,442 € per QALY gained at year 2.5. The probabilistic sensitivity analysis show robustness of results, being the ECP cost-effective in 70% of the simulated cases at year 5 (threshold of €30,000 per QALY gained). **CONCLUSIONS:** ECP as third-line therapy for cGVHD is a more cost-effective compared to Rmb or Imt.

PMD44

ECONOMIC EVALUATION OF THE UGT1A1 PHARMACOGENETIC TEST TO INFORM DOSE SELECTION OF IRINOTECAN-BASED CHEMOTHERAPY

Shabaruddin FH[1], Elliott RA[2], Tappenden P[3], Payne K[4]
[1]*University of Malaya, Kuala Lumpur, Malaysia,* [2]*University of Nottingham, Nottingham, UK,* [3]*University of Sheffield, Sheffield, UK,* [4]*University of Manchester, Manchester, UK*

OBJECTIVES: The UGT1A1 pharmacogenetic test can potentially inform irinotecan dose selection and reduce the incidence of neutropaenia, a key adverse event of irinotecan-based chemotherapy in advanced colorectal cancer (CRC). Neutropaenia has a negative impact on health and its management uses healthcare resources. The UGT1A1 test identifies patients at low-, intermediate- or high-risk of grade 3&4 neutropaenia. High-risk patients can be prescribed lower doses to reduce the incidence of neutropaenia. This study aimed to assess the cost-effectiveness of UGT1A1 testing and identify key parameters driving cost-effectiveness. **METHODS:** An economic model of UGT1A1 testing to predict grade 3&4 neutropaenia compared to standard care was developed over a lifetime horizon from the UK NHS perspective. Treatment pathways were informed by a national survey of CRC experts (n=44). The model was populated with data from: systematic reviews of the effectiveness and utility literature; a micro-costing observational study (n=48 patients) and CRC expert (n=55) elicitation. **RESULTS:** UGT1A1 testing was cost-saving and resulted in lower incidence of grade 3&4 neutropaenia. For a cohort of 100 patients, the test was estimated to save £14,500, avoid 4.4 neutropaenic episodes, gain 0.06 life-years and 0.05 QALYs. The probability that the test was cost-effective at willingness-to-pay thresholds between £20,000 and £30,000 per QALY gained was above 95%. These findings were specific to model assumptions and specifications. Sensitivity analysis (probabilistic and one-way) suggested that the main driver of cost-effectiveness was the effect of irinotecan dose reduction on survival. Value of information analysis indicated a low value of future research to reduce parameter uncertainty (5 year population EVPI: £13,116). In contrast, assumptions affecting model structure had a comparatively greater impact on cost-effectiveness. **CONCLUSIONS:** This analysis modelled NHS-relevant clinical treatment pathways and provided potentially useful evidence for UK decision-makers. Structural model assumptions rather than parameter inputs had a larger impact on cost-effectiveness.

PMD45

OPTAR STUDY: TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) VERSUS OPTIMAL MEDICAL TREATMENT (OMT) IN PROHIBITIVE SURGICAL RISK PATIENTS WITH SEVERE AORTIC STENOSIS (AS) – AN EXPLORATORY COST-EFFECTIVENESS ANALYSIS

Teles RC[1], Almeida M[1], Eaton JN[2], Watt M[2], Busca MR[3], Farinha S[4], Mendes M[1]
[1]*Hospital Santa Cruz, Lisbon, Portugal,* [2]*Oxford Outcomes Ltd, Oxford, Oxon, UK,* [3]*Medtronic International Trading Sàrl, Tolochenaz, Switzerland,* [4]*Medtronic Portugal, Lisbon, Portugal*

OBJECTIVES: Aortic valve stenosis is a chronic and progressive valvular heart disease. The standard treatment of this condition involves a major open surgery. For patients currently ineligible for surgery, medical management is the only option available. Transcatheter aortic valve implantation (TAVI) devices recently appeared as a new less invasive treatment option. The objective of this study was to develop an exploratory cost-effectiveness analysis of TAVI vs Optimal Medical Treatment (OMT) in the Portuguese Setting. **METHODS:** This analysis used a Markov model developed by Oxford Outcomes to assess costs and benefits of TAVI vs OMT. A short term sub-model represents the first 30 days after TAVI (cycle length of one day), whereas a long term model (cycle length of one month) considers a 10-year time horizon. For TAVI patients the health states considered are ICU, General Wards, Home, Re-operation and Death. OMT patients are in either Home or Dead health states, receiving medication until death and at risk of co-morbidity-related hospitalisations. Portuguese NHS healthcare resource consumption was retrospectively collected at Hospital de Santa Cruz in Lisbon for a cohort of 44 high risk AS patients (21 TAVI; 23 OMT), over a period of 11 months. Clinical parameters, transition probabilities and utility values were derived from relevant literature. Costs were taken from the official Portuguese published tables and hospital reports. Costs and benefits were discounted at 5% p.a. Probabilistic and one-way sensitivity analysis were performed. **RESULTS:** Treatment with TAVI compared to OMT increased life years by 1.7 (3.13 vs. 1.46) and quality-adjusted life years (QALYs) by 1.4 (2.23 vs. 0.80). Direct costs were 32,067€ with TAVI and 4,662€ with OMT. Incremental Cost Effectiveness Ratios (ICERs) estimated are 16,375 €/LYG and 19,180 € /QALY. **CONCLUSIONS:** TAVI is highly likely to be a cost-effective intervention for the treatment of AS in patients who are currently ineligible for surgery.

PMD46

DEVELOPMENT OF A STANDARD REIMBURSEMENT DOSSIER FOR THE EVALUATION OF EFFECTIVENESS AND COST-EFFECTIVENESS OF A NEW MEDICAL DEVICE (NEBULIZER MINI-PLUS)

Dózsa C[1], Borcsek B[2]
[1]*University of Miskolc, Miskolc, Hungary,* [2]*Med-Econ Ltd, Verõce, Hungary*

OBJECTIVES: In Hungary the re-regulated, transparent coverage system of medical aids was put into force in 2007 (after the re-regulation of coverage policy of drugs /2004/). Until 2010 287 reimbursement applications were evaluated by the Office of HTA of the National Institute for Strategic Health Research. The aim of the study was to develop a standard reimbursement dossier, which evidenced the effectiveness and cost-effectiveness of a new medical device (Nebulizer Mini-Plus). **METHODS:** According to a recommendation of the above mentioned HTA Office the combined assessment of technical functions and prices was suggested as eligible filter for the coverage of products with sufficient price-value rate. Hence the base of the study was: to compare the technical parameters of nebulizers and to use the cost-minimization analysis (CM). The study had payer's perspective, but aspect of equity (burden of disease) was taken into consideration because of the high significance of diseases of respiratory system. After the literature review and comparison of technical parameters of nebulizers, the 2009-2010 turnover of nebulizers were analysed and the budget impact was estimated for 2011-2012, considering the business risks. **RESULTS:** Taking into consideration that several technical parameters (lung deposition, particle size) of Mini-Plus exceeded other devices and its price was lower than the cheapest reimbursed device: it was expressed as the dominant alternative of compression nebulizer therapies. By its coverage the payer can reach almost 15.000 USD saving and minimally 3685 USD burden loss (reducing of co-payment) for patients until 2012. There are additionally cost-saving potentials in reduction of drug consumption and hospitalization. **CONCLUSIONS:** The combined assessment of technical functions and prices (supported by CM) was a successful and eligible strategy for the evaluation of the effectiveness and cost-effectiveness of a new medical device, and can be adapted for other types of medical aids.

PMD48

AN ECONOMIC EVALUATION OF THE HEARTWARE VENTRICULAR ASSIST DEVICE IN THE NHS

Craig J[1], Saxby RC[1], Homer T[2], Swartz MT[2]
[1]*University of York, Heslington, York, UK,* [2]*HeartWare Inc., Framingham, MA, USA*

OBJECTIVES: End-stage heart failure is a leading cause of death; patients have a poor prognosis and low quality of life. Managing the limiting and distressing symptoms places significant costs on the NHS. Therapy options are few; primarily combination medical therapy and, for a few patients, transplantation using a donor heart. Left ventricular assist devices (LVADs) are mechanical pumps that support the heart function. Use is increasing worldwide as more studies demonstrate clinical effectiveness, primarily from improved patient survival and quality of life. However, there are no published cost effectiveness studies. This pilot evaluates the cost effectiveness of the HeartWare LVAD as destination therapy for patients with end-stage heart failure. **METHODS:** A cost-utility model compared the outcomes and costs of patients who were medically managed without a transplant (n=15) with those who received a HeartWare LVAD and no subsequent transplant (n=17). Clinical data were from a multicentre trial evaluating the safety and efficacy of the HeartWare LVAD [1] and outcomes for patients listed on the NHS Blood and Transplant Registry [2]. Utility values were from a Health Technology Assessment [3] and derived using the EQ-5D tool. Cost data came mainly from published sources. **RESULTS:** The results from this evaluation were patients managed with the HeartWare device had higher costs but better outcomes than those who were medically managed. At 5 years the additional cost was about £20,500 per patient and a QALY gain of 1.05, giving an incremental cost per QALY of under £20,000, below the threshold commonly adopted of £25,000 per QALY. **CONCLUSIONS:** The results are encouraging and suggest it is plausible that using LVADs as long-term support in patients with end-stage heart failure could be a cost-effective use of healthcare provider resources. Further research is needed to refine the clinical and cost data.

PMD49

THE POTENTIAL ROLE OF MAGNETIC RESONANCE IMAGING (MRI) IN AXILLARY NODE ASSESSMENT OF EARLY BREAST CANCER: AN ECONOMIC EVALUATION

Meng Y[1], Ward SE[1], Cooper K[1], Harnan SE[1], Wyld L[2]
[1]*University of Sheffield, Sheffield, UK,* [2]*Royal Hallamshire Hospital, Sheffield, UK*

OBJECTIVES: Surgical techniques including sentinel lymph node biopsy (SLNB) and 4-node sampling (4-NS) are currently used for axillary nodal assessment of early breast cancer (EBC) in the UK. Such procedures are associated with adverse effects, (AEs), in particular scarring, pain, general anaesthesia and occasional lymphoedema which may impact on long term quality of life. Magnetic resonance imaging (MRI) is a non-invasive technique offering the potential to avoid such AEs. A range of MRI techniques, including USPIO (ultrasmall superparamagnetic iron oxide contrast agent)-enhanced and gadolinium-enhanced MRI exist, however diagnostic accuracy of these techniques may be lower than for surgical techniques. An economic evaluation was undertaken to compare MRI with surgical techniques for assessment of axillary lymph node metastases in patients with EBC. **METHODS:** The costs and benefits of replacing SLNB or 4-NS with MRI (replacement strategy) or adding MRI before the surgical techniques (addition strategy) were modelled using discrete-event simulation in SIMUL8®. A systematic review was undertaken to obtain effectiveness outcomes of the MRI techniques, whilst resource use data and health related utilities were obtained from the literature. **RESULTS:** Our results predict that a replacement strategy for MRI, based on the pooled estimate of all MRI techniques, dominates the baseline SLNB and 4-NS strategies, as a result of avoiding AEs from surgical techniques. However this strategy leads to more false-positive and false-negative cases. The MRI addition strategy may also be cost-effective, but is subject to greater uncertainty. USPIO-enhanced MRI produces the most favourable cost effectiveness ratio, but the evidence is based on studies with small patient numbers. **CONCLUSIONS:** These results suggest that there is a potential role for MRI in axillary node assessment of EBC. Based on current evidence USPIO-enhanced MRI offers the most cost effective option, but further large studies are required to obtain high quality evidence on diagnostic accuracy.

PMD50

COST-EFFECTIVENESS OF CARDIAC RESYNCHRONISATION THERAPY FOR PATIENTS WITH MODERATE-TO-SEVERE HEART FAILURE

Neyt M, Stroobandt S, Obyn C, Camberlin C, Devriese S, De Laet C, Van Brabandt H
Belgian Health Care Knowledge Centre, Brussels, Belgium

OBJECTIVES: To assess the cost-effectiveness of cardiac resynchronisation therapy (CRT) both with CRT-P (biventricular pacemaker only) and CRT-D (biventricular pacemaker with defibrillator) in patients with New York Heart Association (NYHA) functional class III/IV from a Belgian health care payer perspective. **METHODS:** A lifetime Markov model was designed to calculate the cost-utility of both interventions. In the reference case, the treatment effect is based on the COMPANION trial. Costs are based on real-world data. Pharmacoeconomic guidelines were applied, including probabilistic modelling and sensitivity analyses. **RESULTS:** Compared with optimal medical treatment, on average 1.31 quality-adjusted life-years (QALY) are gained with CRT-P at an additional cost of €14,700, resulting in an incremental cost-effectiveness ratio (ICER) of about €11,200/QALY. As compared to CRT-P, CRT-D treatment adds on average an additional 0.55 QALYs at an extra cost of €30,900 resulting in an ICER of €57,000/QALY. This result was very sensitive to the incremental clinical benefit of the defibrillator function on top of CRT. **CONCLUSIONS:** Based on efficiency arguments, CRT-P can be recommended for NYHA class III and IV patients if there is a willingness to pay more than €11,000/QALY. Even though CRT-D may offer a survival benefit over CRT-P, the incremental clinical benefit appears to be too marginal to warrant a three times higher device price for CRT-D. Further clinical research should focus on the added value of CRT-D over CRT-P.

PMD51

COST SAVINGS AND IMPROVED UTILITY THROUGH THE USE OF FLORBETABEN BETA-AMYLOID PET IMAGING IN DEMENTIA DIAGNOSIS

Pastätter R[1], Uhl-hochgräber K[2], Blankenburg M[2]
[1]*Karolinska Institute, Stockholm, Sweden,* [2]*Bayer HealthCare Pharmaceuticals, Berlin, Germany*

OBJECTIVES: Early diagnosis of Alzheimer's disease may allow for early appropriate treatment, delayed symptom aggravation, delayed nursing home placement, and reduced care costs. The use of Amyloid-specific Positron Emission Tomography (PET) scanning might complement routine clinical diagnostic procedures and lead to earlier and more accurate differential diagnosis than presently possible. The aim of this study is to estimate cost-effectiveness of Florbetaben PET imaging. **METHODS:** A decision-analytic model using Markov cohorts to simulate Alzheimer's disease (AD) management compares, from a societal perspective, three strategies after routine clinical assessment: 1) use of Florbetaben PET to direct treatment decisions; 2) "treat all" approach; 3) "wait and see" approach. **RESULTS:** Florbetaben PET appears to be cost-effective and strictly dominant: both comparator strategies result in higher long-term costs at lower health outcomes. Values of incremental costs saved (US$2340 – without considering cost of Florbetaben tracer) and health outcomes gained (0.028 QALYs) to the nearest comparator strategy are small. However, the results prove to be robust in sensitivity analyses. **CONCLUSIONS:** Although Florbetaben PET imaging has significant upfront costs, identifying and treating patients with AD early and correctly results in overall cost savings and QALYs gained. This analysis may underestimate the true benefit of Florbetaben PET imaging because the value of knowing early about the underlying pathology from the perspective of patients and caregivers is not implemented in the model – apart from medical and economic value, even emotional aspects and the opportunity for future planning should be considered. This could be subject of further research.

PMD52

WORKLOAD IN GERMAN HOSPITALS CAUSED BY ROUTINE FOLLOW-UP SERVICES FOR CARDIAC IMPLANTABLE ELECTRICAL DEVICES (CIED)

Smala A[1], Vogtmann T[2]
[1]*Biotronik SE & Co KG, Global Reimbursement and Health Economics, Berlin, Germany,* [2]*Kardiologische Gemeinschaftspraxis "Am Park Sanssouci", Potsdam, Germany*

OBJECTIVES: Regular follow-up (FU) of CIED patients is mandatory to monitor device functionality and disease status. Demand for this highly specialised service increases continuously. However, most calendar based visits do not need further action and could safely be replaced by remote monitoring. This model aims 1) to quantify hospital workload associated with calendar based FU between 2011 and 2015, and 2) to identify opportunity costs if monitoring services would be performed remotely. **METHODS:** The estimated number of prevalent CIED patients in Germany was combined with recently published data on healthcare personnel resource burden related to FU. Opportunity costs were identified considering 2011 DRG payments for frequent cardiology procedures. **RESULTS:** Assuming in-office FU twice annually for pacemaker patients, and four times annually for implantable cardioverter defibrillator or cardiac resynchronisation therapy patients, hospitals will have to provide about 2.23 mio FU services in 2015, to about 856,000 patients. These services will bind about 411,000 physician hours, 392,000 nurse hours and 280,000 technician hours, at total costs of EURO 44.8 mio to hospitals. Using remote monitoring to replace all but one in-office FU visit per year could free up to 126,700 physician hours (2015). In theory, this physician time would allow for about 50'600 bypass surgeries (worth EURO 596 mio), or 84,400 dual-chamber pacemaker implantations (EURO 434 mio), or 63,300 dual chamber ICD implantations (EURO 1.1 billion). Possible cost overestimation due to not considering unscheduled FU visits is explored in scenario analyses. **CONCLUSIONS:** The ability of BIOTRONIK Home Monitoring to safely replace in-office FU visits has been proven in clinical trials. While continuously monitoring all patients, it is possible to identify patients in need to attend in clinic FU in person. Remote monitoring technologies can support hospitals with focussing their available staff and room capacities and optimise operative income while providing patient care at potentially improved outcomes.

PMD53

PULMONARY VEIN ISOLATION FOR THE TREATMENT OF PAROXYSMAL AF: TIME REDUCTION AND PRODUCTIVITY GAIN WITH "ANATOMICALLY-DESIGNED" CATHETHERS COMPARED TO "POINT BY POINT" CATHETERS

Fagnani F[1], Coulomb S[1], Marcaud N[2], Bouchet M[2], Bonté J[1]
[1]*Cemka, Bourg la Reine, France,* [2]*Medtronic France SAS, Boulogne Billancourt, France*

OBJECTIVES: Electrical Pulmonary Vein (PV) Isolation (PVI) is regarded as effective treatment of Symptomatic Drug-Refractory Paroxysmal Atrial Fibrillation (PAF). Traditionally, appropriate circumferential lesions were created point-by-point, using single tip catheters guided by navigation systems, and generally employing radiofrequency (RF) source. "Anatomically-Designed" catheters were introduced recently and are pre-shaped to create the appropriate lesions with a single application on each PV. We hypothesised that the shape of these catheters is associated with reduced procedure times and Operating Room (OR) productivity gains. In this study, catheters employing cryo (Arctic Front, Medtronic) and duty cycled bipolar radiofrequency (PVAC, Medtronic) energy sources were examined. **METHODS:** Using a chart review approach, 158 procedures were included (85 with "anatomically-designed" catheters, 73 "point-by point") across 7 diversified French centres. Selection criteria were used to ensure comparability of procedures. In parallel an economic analysis was performed to estimate the budgetary impact in terms of DRG case-mix for hospitals, resulting from potential increased OR activity. **RESULTS:** Reduced procedure time was observed in six out of seven participating centres. The difference in median times was 35 minutes (p=0.0192). There was significant variability of procedures times depending on hospital status (public or private), the experience of electrophysiologists involved and the annual activity. Based on the DRG casemix produced in the rythmology OR and the current tariffs, the mean revenue for the centre was estimated between 1100€ (private) and, 400 € (public) per hour of total OR time. **CONCLUSIONS:** Use of "Anatomically-Designed" PVI Catheters has the potential to substantially reduce procedure time and increase procedure capacity of rythmology labs. Shorter procedure times allow better management of OR and treatment of more patients with potential productivity gains to hospitals that may offset the extra cost of the new techniques.

PMD54

RESOURCE UTILISATION RELATED TO CATHETER-ASSOCIATED URINARY TRACT INFECTIONS IN SWEDISH SPINAL INJURY PATIENTS

Bruce S[1], Löfroth E[1], Knutsson B[2], Börstell T[2], Myrén KJ[1]
[1]*IMS Health, Stockholm, Sweden,* [2]*AstraTech, Mölndal, Sweden*

OBJECTIVES: To collect real-life data on costs and resource use, in order to understand the economic burden and treatment patterns of urinary tract infection (UTI) amongst people with spinal injury, who are in need of chronic, intermittent catheterisation. **METHODS:** We used the CEBRxA database, which combines data from a public claims database for the South-West region of Sweden, comprising around 1.5 million individuals, with national Swedish registers on drug utilisation and mortality. We identified a population of spinal injury patients (ICD-10 S14.0, S24.0, S34.0, and T91.31) who in addition had received a diagnosis of neurogenic bladder (ICD-10 N31*), anytime during the years 2000 to 2009. UTIs were identified through the following ICD-10 codes: N11.0, N30*, N39.0*, N39.X*, N12.-P, and N30.-P. A cost per UTI was calculated through considering UTI-related care contacts that occurred within 14 days from each other (from 2005-07-01 onwards). **RESULTS:** We

identified 295 spinal injury patients, with a mean age at index of 44 years, an average follow-up time of 6 years, and of which 79% were males. For 67% of the population we observed at least one UTI, which resulted in a care contact. Interestingly, a quarter of the population used prophylactic antibiotics (J01XX05), corresponding to an average of 235 DDDs per year, amongst users. A majority of UTIs were handled in primary care, while over 90% of costs were contributed by UTI-related hospitalisations. The mean cost per UTI was 43,500 SEK, while estimates varied considerably, with costs ranging from an average of 1,800 SEK for UTIs handled in primary care to 177,200 SEK for inpatient care. **CONCLUSIONS:** In a population of spinal injury patients, costs for catheter-associated urinary tract infections are to a large extent driven by outlier, expensive hospitalisation. There would be a large potential for cost savings if these hospitalisations could be avoided.

PMD55

RESOURCE UTILISATION RELATED TO URINARY TRACT INFECTIONS IN SWEDISH SELF-CATHETERISATION PATIENTS

Löfroth E[1], Bruce S[1], Knutsson B[2], Börstell T[2], Myrén KJ[1]
[1]*IMS Health, Stockholm, Sweden,* [2]*AstraTech, Mölndal, Sweden*

OBJECTIVES: To collect real-life data on costs and resource use, in order to understand the economic burden of urinary tract infection (UTI) amongst a population who has received self- catheterisation training. **METHODS:** We used the CEBRxA database, which combines data from a public claims database for the South-West region of Sweden, comprising around 1.5 million individuals, with national Swedish registers on drug utilisation and mortality. We identified a population of patients who had received self-catheterisation training anytime between 2006 and 2009(procedure code GB005). UTIs were identified through the following ICD-10 codes: N11.0, N30*, N39.0*, N39.X*, N12.-P, and N30.-P. A cost per UTI was calculated through considering UTI-related care contacts that occurred within 14 days from each other. **RESULTS:** We identified 989 patients, with a high mean age at index of 65 years, 79% males, and an average follow-up time of 1.5 years. The disease burden of this population was mainly related to the genitourinary system, like retention of urine, benign prostate hyperplasia, cystitis, and neurogenic bladder, although essential hypertonia emerged as the third most common comorbidity. We observed an average frequency of one UTI every two years, while around one-fifth of patients had a yearly UTI-frequency of one or above. A majority of UTIs were handled in primary care, while around 80% of costs were contributed by UTI-related hospitalisations. However, among female patients, inpatient care only contributed to 60% of total costs. The mean cost per UTI was 10,500 SEK, while estimates varied, with average costs ranging from 2,100 SEK in primary care, to 32,000 SEK for inpatient care. **CONCLUSIONS:** Patients having received self-catheterisation training were on average of higher age and male. UTI-related hospitalisation was a clear driver of costs, although this effect was less pronounced for women.

PMD56

A SYSTEMATIC LITERATURE REVIEW ON THE CLINICAL AND ECONOMIC OUTCOMES ATTRIBUTABLE TO THE USE OF HEMOSTATIC MATRIX DURING TONSILLECTOMY AND ADENOIDECTOMY

Williams EN[1], Kreuwel H[2], Krishnan S[2]
[1]*Marinus Consulting, LLC, Life Sciences Group, Mountain View, CA, USA,* [2]*Baxter Healthcare, Westlake Village, CA, USA*

OBJECTIVES: Approximately 880,000 tonsillectomy/adenoidectomy procedures are performed in the US annually. Hemostatic matrix (FLOSEAL) is used for adjunctive hemostasis in a variety of surgeries, but the health economic rationale supporting its application in tonsillectomy and adenoidectomy has yet to be established. A systematic literature review was conducted in order to examine the evidence for hemostatic matrix and to consider its value in reducing the burden of these procedures. **METHODS:** Applying keywords and inclusion criteria, the PubMed, EMBASE, and Centre for Reviews and Dissemination databases were queried for studies published in English up to March 1, 2011. Reference lists and the American Academy of Otolaryngology-Head and Neck Surgery database were also manually searched. Data on costs, resource utilization, and health outcomes were extracted and summarized. **RESULTS:** Four prospective, randomized controlled trials provided data on 187 patients treated with hemostatic matrix. In the two studies utilizing crossover design, no patients in the hemostatic matrix groups required electrocautery, whereas 3 of 35 (9%) and 4 of 34 (12%) patients, respectively, required adjunctive hemostatic matrix intraoperatively after failing electrocautery. In all three studies measuring operating room time, use of hemostatic matrix resulted in significantly shorter mean durations (range, 0.93 to 24.6 minutes) compared to electrocautery (range, 9.53 to 32.6 minutes) (all studies, $P<0.05$). Although postoperative bleeding rates did not differ, hemostatic matrix-treated patients in three of four studies reported significant reductions in postoperative pain scores and narcotic consumption compared to electrocautery-treated patients ($P<0.05$). **CONCLUSIONS:** Published evidence suggests that hemostatic matrix is effective in achieving intraoperative hemostasis during tonsillectomy/adenoidectomy. Given the high volume of procedures, using hemostatic matrix during tonsillectomy and adenoidectomy may be potentially cost saving due to resulting reductions in operating time and postoperative narcotic consumption. Further research may identify patients who are more likely to benefit from hemostatic matrix in this indication.

PMD57

DATA VISUALIZATION FOR BUSINESS INTELLIGENCE: ASSESSING AN ONLINE TOOL USED FOR BENCHMARKING HOSPITAL PROCEDURE COSTS TO REIMBURSMENT IN CARDIAC CATHETERIZATION AND ELECTOPHYSIOLOGY PROCEDURES

Cload P[1], Mallow P[2], Mako J[2], Gunnarsson C[3]
[1]*GE HealthCare, Chalfont St Giles, UK,* [2]*s2 Statistical Solutions, Inc., Cincinnati, OH, USA,* [3]*S2 Statistical Solutions, Inc., Cincinnati, OH, USA*

OBJECTIVES: Data visualization as a form of business intelligence and knowledge discovery will democratize the use of large scale payer/claims and electronic medical records databases. The goal of this analysis was to assess the feasibility of utilizing Tableau Software™ to create a data visualization tool that would augment data mining and analytic methods for understanding hospital costs and reimbursement patterns in cardiac catheterization and electrophysiology procedures. **METHODS:** The Premier Perspective® database was utilized for this analysis. The Premier Perspective® database houses data from over 600 hospitals and ambulatory surgery centers across the United States. Eligible procedures were those that occurred during the year 2010 with the associated ICD-9 or CPT codes for either cardiac catheterization or electrophysiology procedures. All data were imported into Tableau Software™ and dashboards were created to visualize the data by procedure costs and department costs. Summary statistics of hospital utilization, total costs, components of costs, and hospital charges for both inpatient and outpatient settings are available for exploration in a dynamic manner by each quarter in 2010. Each dashboard is hosted in a secure online environment and fully interactive allowing for dozens of different filters to be applied. **RESULTS:** For the year 2010 there were 1,104,936 visits of cardiac related procedures With 164,210 unique cardiac catheterization procedures and 22,263 cardiac electrophysiology procedures. Custom developed dashboards show procedures (and associated volumes) by in- and out- patient status, by ICD-9 or CPT code, department, costs and CMS reimbursement levels. This data visualization tool makes it possible to quickly see hospital cost breakdowns on dozens of different dimensions. **CONCLUSIONS:** Tableau Software™ is a powerful tool to enable the health outcomes researcher to have insights into complex multilevel data. Business intelligence tools developed in this manner enable visual interaction and exploration of data for rapid hypothesis generation and business intelligence.

Medical Device/Diagnostics – Patient-Reported Outcomes & Preference-Based Studies

PMD58

PROVISION AND FINANCING OF MEDICAL AIDS IN THE MANAGEMENT OF RARE DISEASES: THE CASE OF AMYOTROPHIC LATERAL SCLEROSIS (ALS)

Henschke C
Berlin University of Technology, Berlin, Berlin, Germany

OBJECTIVES: Patients suffering from ALS have a need for a multitude of medical aids. Existing (bureaucratic) hurdles might create plenty of problems for people with rare diseases. Uncertainty about provision of medical aids and substantial waiting times limit patient's ability to participate in the activities of daily living. This study aims 1) to analyze problems in financing and provision of medical aids; 2) to explore differences in reimbursement decisions of private and social health insurance (SHI); and 3) to explore patient satisfaction according to the type of health insurance. **METHODS:** First, published and grey literature was used to analyse payment flows and supply chain activities of the various actors involved in the provision and payment of medical aids. Second, a survey of ALS patients (n=20) based on semi-standardized questionnaires was conducted . Gathered information included patients' demographic characteristics, information on coverage decisions and problems in the provision of medical aids. Based on patient satisfaction, analysis of variance tests were performed to investigate differences in satisfaction between SHI and privately insured persons. **RESULTS:** A majority of patients experienced problems in reimbursement decisions, particularly in the case of expensive or individually customized technologies. These reimbursement problems were more common among SHI insured persons. Both SHI insured and privately insured persons complain about long duration processes of individual requests for meeting the cost. Nonetheless, most patients stated that they were satisfied with the actual provision of medical aids, including product and service quality. **CONCLUSIONS:** Our results suggest that difficulties with medical aids' reimbursement decision processes are a common problem among SHI and private insured ALS patients. Although the patient's insurance type has an impact on these time-consuming process. Consequently, there is a need for an interdisciplinary approach in the provision of medical aids. Case managers might be a solution to overcome these problems.

PMD59

COMPLICATED PARKINSON'S DISEASE: DISCRETE CHOICE ANALYSIS TO ASSESS PATIENTS' PREFERENCES. A PILOT STUDY

Lloyd AJ[1], Herdman M[2], Gonzalez P[3]
[1]*Oxford Outcomes, an ICON plc Company, Oxford, Oxon, UK,* [2]*Insight Consulting & Research, Mataro, Spain,* [3]*Medtronic Iberia, Madrid, Spain*

OBJECTIVES: In advanced or complicated Parkinson's disease (CPD), among other treatment alternatives, patients can receive deep brain stimulation (DBS) or continuous duodenal levodopa-carbidopa infusion (CDLCI). This pilot study was designed to understand the preferences of patients who face these treatment choices. **METHODS:** Treatment attributes were identified based on a literature review, focus groups with patients, caregivers, and interviews with clinicians. A discrete choice experiment survey was developed, reviewed by clinicians and piloted with patients. Patients (potentially considering DBS or CDLCI) in Spain (n=30) and the UK (n=10) completed the survey . Treatment attributes included surgery type, impact on daily life, medication need, speech difficulties, movement control, dyskinesia, and off-periods. Data were analyzed using a multi-level hierarchical logistic model. **RESULTS:** Surgery type (DBS electric lead insertion in the brain vs CDLCI intraduodenal tube placement) was the most powerful predictor in the model, with a pref-

erence for DBS over CDLCI (OR= 8.02, 95% CI=6.17-10.38). Avoiding deterioration in movement was also important in determining treatment choice (OR=0.67; 95%CI=0.57-0.79) as was avoiding limitations on daily activities; (OR=0.69; 95%CI=0.54-0.88). **CONCLUSIONS:** CPD patients were able to engage in this quite complex task to indicate their views regarding treatments. Participants had a preference for DBS surgery type. Maintaining movement and daily activities were also important attributes. As the surgery attribute was a composite of both surgical procedure and daily maintenance, further study is needed to identify which of these aspects is the strongest predictor of patient preferences. Finally, a larger study is needed to understand the importance of attributes for all the treatment alternatives that can be offered to CPD patients

PMD60

DEVELOPMENT AND CONTENT VALIDITY OF THE COPD DEVICE PREFERENCE QUESTIONNAIRE

Clark M[1], Hofmann A[2], Tabberer M[3], Martin S[1]
[1]*RTI Health Solutions, Ann Arbor, MI, USA,* [2]*GlaxoSmithKline, Research Triangle Park, NC, USA,* [3]*GlaxoSmithKline, Uxbridge, Middlesex, UK*

OBJECTIVES: To develop and subsequently evaluate content validity of questions assessing patient preference between two dry powder inhaler (DPI) devices (the Handihaler and the Novel DPI) for the treatment of chronic obstructive pulmonary disease (COPD), based on ease of use. **METHODS:** Initial COPD Device Preference Questionnaire (CDPQ) items were designed to assess inhaler device preference based on aspects of ease of use identified as important by COPD patients and physicians during previous research. Two iterative rounds of semistructured, in-depth interviews were conducted in adult patients currently receiving COPD medication via the Handihaler. Initially, patients were asked to describe the actuation of the Handihaler. Next, the features and steps required to operate the Novel DPI were described, and participants were asked to demonstrate using an empty device. Cognitive debriefing of the CDPQ was then conducted. Patients completed and evaluated five items, each phrased two different ways (beginning with "which. . ." or "thinking. . ."). Round 1 interviews (n = 8) gathered feedback on preferred phrasing and modifications required to improve the CDPQ. Round 2 interviews (n = 8) assessed modifications and gathered additional input to confirm content validity. All interviews were recorded and transcribed for analysis. **RESULTS:** Round 1 interviews resulted in addition of instruction detail, modification of questions based on a clear preference for the "which" phrasing, and removal of two items (i.e., understanding how to use the device and number of steps involved in preparing the device) deemed duplicative. Round 2 interviews did not result in additional changes. Participants found instructions, items, and response wording easy to understand and complete. An item-tracking grid was constructed to summarize item changes and their rationales. **CONCLUSIONS:** Participant feedback indicates that the concepts of greatest importance in determining COPD inhaler device preference related to ease of use were reflected in the final CDPQ items.

PMD61

THE EFFECTS OF SUBJECTIVE INSOMNIA PATTERN ON THE QUALITY OF LIFE OF THE CLIMACTERIC WOMEN IN TAIWAN

Wu HC[1], Lai JN[2], Hwang JS[3]
[1]*Buddist Tzu-Chi General Hosipital, New Taipei, Taiwan,* [2]*National Yang-Ming University, Taipei, Taiwan,* [3]*Academia Sinica, Taipei, Taiwan*

OBJECTIVES: Sleep issues are relevant to women across their whole lifespan and this is especially true during the climacteric period. Previous studies have demonstrated that insomnia influences quality of life (QOL) across various different domains. However, the different characteristics of the insomnia that influences the QOL remain unclear. Our study was designed to investigate which type of insomnia influences the health-related quality of life amongst women. **METHODS:** A total of 1098 women age between 40-60 years seeking medical advice were drawn from two hospital, with a further 314 healthy referents of the same age, range and gender, with no history of hormone replacement therapy and living in the same municipality, also being recruited from a national health survey sample for comparison. Each one was asked to fill out a brief questionnaire, the Taiwan version of the World Health Organization Quality of life (WHOQOL-BREF), which assesses quality of life based on 26 items in four domains (physical, psychological, social and environmental). In addition, the Pittsburgh sleep quality index (PSQI) was used to evaluate the sleep quality and insomnia pattern of the subjects. Multiple regression analyses were conducted to control variables such as age, marital status, religion, educational attainment and menopausal status. **RESULTS:** The mean total score of the PSQI was 7.5 ± 3.8 with a range from 0-20. In the 1098 participants, 65.3% (n=717) were confirmed to be poor sleepers, and 34.7% (n=381) were good sleepers. After controlling for the demographic factors, it was found that subjective poor sleep quality and daytime dysfunction were the major determinants of the scores in the different domains. **CONCLUSIONS:** A high incidence of poor sleep quality exists among climacteric women in the urban area of Taiwan and subjective poor sleep quality and poor daytime function should be taken into consideration in the management of climacteric women seeking medical advice.

PMD62

VALIDATION OF A PATIENT-REPORTED OUTCOME (PRO) MEASURE AND A CLINICIAN-REPORTED OUTCOME (CRO) MEASURE TO ASSESS SATISFACTION AND PREFERENCE WITH PHARMACOLOGICAL STRESS AGENTS FOR SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT) MYOCARDIAL PERFUSION IMAGING (MPI)

Hudgens S[1], Kothari S[2]
[1]*Mapi Values, Boston, MA, USA,* [2]*Astellas Pharma US, Deerfield, IL, USA*

OBJECTIVES: The objective of this study was to validate clinician and patient measures of satisfaction and preference for pharmacological stress agents (PSAs) used in Single Photon Emission Computed Tomography (SPECT) Myocardial perfusion imaging (MPI) procedures using classical and novel psychometric methods. **METHODS:** Psychometric validation of the Clinician Satisfaction and Preference Questionnaire (CSPQ) and the Patient Satisfaction and Preference Questionnaire (PSPQ) was conducted in a sample of 90 patients and 15 clinicians. Due to the small sample size, a Bayesian Item Response Theory was utilized to validate the initial parameter estimates. Specifically, item difficulty was evaluated using patient characteristics as the known prior distributions. **RESULTS:** The CSPQ demonstrated strong internal consistency (alpha=0.99) and moderate point-biserial correlations between PSA satisfaction scores and agent preference (range 0.63-0.65). The PSPQ 'preparation' and 'reaction to agent' scales demonstrated strong internal consistency (alpha=0.90 and 0.87 respectively). Test-retest reliability was acceptable for all PSPQ scales (ICC range=0.73 to 0.86). Concurrent validity with the Treatment Satisfaction Questionnaire for Medication (TSQM) indicate low to moderate correlations between the Effectiveness, Convenience and Global Satisfaction scales of the TSQM with the PSPQ Satisfaction with Administration, Satisfaction with Effects and Overall Satisfaction items (range 0.46 to 0.78). The results of the Bayesian analysis indicated consistency between the two approaches. Specifically, item difficulty was invariant across the various patient demographics. **CONCLUSIONS:** The CSPQ and PSPQ were developed and validated using rigorous, gold standard methodology. The resulting instruments sufficiently represents meaningful domains demonstrate strong internal consistency, good test-retest reliability, and predictive validity associated with clinician and patient measures of satisfaction and preference for pharmacological stress agents (PSAs) used in Single Photon Emission Computed Tomography (SPECT) Myocardial perfusion imaging (MPI) procedures. The variance in the item parameters were fully explained by the summary demographic information on the patients and physicians as supported by the Bayesian analysis.

Medical Device/Diagnostics – Health Care Use & Policy Studies

PMD63

COST-BENEFIT ANALYSIS OF CT CONTRAST MEDIA (IOPROMIDE) WITH PREFILLED CARTRIDGE TYPE COMPARED TO GLASS BOTTLE TYPE

Kim J[1], Park S[1], Boo Y[2], Lee E[1], Tang J[1], Jeong S[1]
[1]*Seoul National University, Seoul, South Korea,* [2]*Eulji University, Gyeonggi-do, South Korea*

OBJECTIVES: In CT imaging, as preparation procedure for contrast media (Iopromide), the use of prefilled cartridge (PFC) is simpler compared to glass bottle (GB). There are several benefits such as infection control and time saving. This study examined the benefits of contrast media with PFC compared to GB. **METHODS:** The benefits are defined as the cost savings which can occur when used in various situations. A decision analytic model was created to evaluate the effectiveness according to the type. The use of each type could finally lead to local infection and blood stream infection (BSI). We estimated the benefits using the probability of infection from decision model and treatment costs from insurance claims data. To estimate the benefits of time saving, we measured the preparation time repeatedly in general hospitals. Assuming that the reduced time was replaced with CT scan in new patients, we estimated the time saving benefits by multiplying the result to the cost of CT scan. **RESULTS:** The material cost of GB was $74.8 which is higher than $72.9 of PFC. In contrast, in case of GB, the probability of contamination, local infection and BSI were 3.3%, 1.25%, 0.060% respectively, which were higher than PFC (0%, 1.22%, 0.058%). The benefit in reduction of infection was estimated at $0.20 per case in PFC. The reduced time from using PFC has an average of 51.9 seconds based on 113 observations from 3 general hospitals. The time saving benefit was estimated at $7.16 per case. Therefore, the total benefit was estimated at $7.36. **CONCLUSIONS:** This study showed that PFC dominated GB (lower costs, and higher benefits). This was driven by lower material cost, lower infection risk and administration time for PFC compared to GB. Findings of this study suggest that the use of PFC contrast media is an efficient utilization of resources in Korea.

PMD64

THE EFFECT OF SUPPLEMENTARY FEES ON THE DIFFUSION OF MEDICAL DEVICES IN THE GERMAN SYSTEM OF DIAGNOSIS RELATED GROUPS (G-DRG): THE CASE OF DRUG-ELUTING STENTS IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION

Bäumler M
Berlin University of Technology, Berlin, Germany

OBJECTIVES: The aim of the study was to measure the effect of supplementary fees on the use of drug-eluting stents (DES) in AMI patients instead of conventional bare-metal stents (BMS). German DRG fees do not distinguish between different types of coronary stents. To compensate hospitals for higher costs of DES, supplementary payments could be negotiated between the hospital and the sickness funds. **METHODS:** Administrative data of one of the largest German sickness funds was used to identify the determinants of DES use in AMI patients. The dataset contained information on demographic characteristics and co-morbidities on patient level. Information on hospital and regional level including the supplementary fee for the use of DES was merged. 9.453 patients with an admission due to an AMI and the implantation of a BMS or DES between 2004 through to 2006 were included in the analysis. For analyzing the data, a logistic multilevel regression approach was used; the dependent variable was binary, taking the value of 1 if a DES was implanted and 0 if a BMS was implanted. In the regression, a comprehensive set of covariates on patient level as well as variables on hospital and regional level were included. To test robustness of the estimation, several models were estimated.

RESULTS: A substantial share of the variance (around 20%) was related to the hospital level. Preliminary results suggest that supplementary fees had a borderline significant positive impact on DES use. Further hospital characteristics also had a significant impact on the use of DES ($p<0.05$), as well as area characteristics. **CONCLUSIONS:** Although there seems to be a small influence of supplementary fees on the use of DES, further hospitals' and area characteristics might be of higher importance than reimbursement incentives. Attributing the diffusion of technologies to financial incentives only would fall too short.

PMD65

SYSTEMATIC REVIEW OF STUDIES OF THE EFFICIENCY OF NEGATIVE PRESSURE THERAPY FOR COMPLEX FOOT WOUNDS IN DIABETIC PATIENTS

Quecedo L[1], Del llano J[2]
[1]fundación Gaspar Casal, madrid, Spain, [2]Fundación gaspar casal, Madrid, Spain

OBJECTIVES: Systematic analysis of the available studies of the clinical effectiveness and safety of negative pressure therapy, as compared with traditional courses of treatment, in complex foot wounds in diabetic patients. **METHODS:** A bibliographical search was performed in the following databases: Embase.com, Medline and Cochrane Library, covering from 2000 until the present. The following descriptors and key words were used: diabetic foot, negative-pressure wound, vacuum-assisted closure and diabetic ulcers. The Jaddad criteria were used to determine the quality of the clinical trials. The studies selected were randomized clinical trials that featured patients older tan 18 years, with complex ulcers, postoperative wounds, or wounds resulting from the amputation of the foot, with a control group comparing negative pressure therapy with conventional therapies (saline solution, alginates or hydrophilic substances. The treatments were applied every 48 hours. A total of 12 studies, of which only 7 were pertinent, were selected. Two independent reviewers extracted the information and determined the methodological quality of the selected studies. **RESULTS:** Of the 7 studies selected (539 patients), 5 involved patients with postoperative wounds and 2 used the same group of patients. One of the two studies involving ulcers of the foot was limited by its simple size (N=10). The methodological quality of the studies is moderate-low. **CONCLUSIONS:** The evidence supports the effectiveness and security of negative pressure wound therapy in complex foot ulcers in diabetic patients. Given that it is unlikely that further research will change this positive appraisal (despite the moderate-low quality of the studies analyzed, its cost profile and the absence of adverse effects) it is possible to make a strong recommendation in favor of the therapy.

PMD66

DEMAND FOR ROUTINE IN OFFICE FOLLOW-UP VISITS FOR CARDIAC IMPLANTABLE ELECTRICAL DEVICES (CIED) IN GERMANY AND THE UNITED KINGDOM

Smala A[1], Gessler M[2], Stoepel C[3]
[1]Biotronik SE & Co KG, Global Reimbursement and Health Economics, Berlin, Germany, [2]Biotronik SE & Co KG, Global Sales Strategy, Berlin, Germany, [3]Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Medizinische Klinik I, Neuss, Germany

OBJECTIVES: Based on clinical trial evidence, remote follow-up (FU) has been recommended for replacing in office visits routinely scheduled to monitor device functionality and health status of patients with CIED. No data exist on the actual demand for such visits. To estimate the total number of calendar based in-office FU visits in Germany and the UK (UK) by 2015. **METHODS:** Official national sales data for implantable pacemakers (PM), cardioverter defibrillators (ICD) and cardiac resynchronisation therapy (CRT) devices were combined with published replacement rates and estimates for patient mortality and device longevity. Following HRS/EHRA guidelines on FU frequency, demand for FU consultations until 2015 was modelled. **RESULTS:** For 2010, the model estimates about 677'800 prevalent patients with a CIED in Germany and 225,000 in the UK. The growth in CIED patients recently seen in the UK is expected to slow down but to continue to be higher than in Germany (+8.3% per annum until 2015 versus 4.8%). Assuming two annual visits for PM patients and four visits for ICD and CRT patients, the total number of routine FU visits is estimated to increase from 1.66 mio in Germany (2010) to 2.23 mio (2015). For the UK, service numbers will increase from 538,000 (2010) to 836,000 (2015). These estimates do not include unscheduled FU visits. **CONCLUSIONS:** Regular FU services for CIEDs are mandatory to ensure device functionality and monitor disease status. Increasing patient volumes will push demand for these services, placing a potentially unmanageable burden on cardiology service providers, payers and patients, unless infrastructure investments occur. High demand for services and low actionability of routine visits may result in inappropriate guideline adherence with potentially negative impact on patient safety and device longevity. Clinics need to become aware of this situation and adopt strategies for handling the expected workload in the future.

PMD67

THE COST-EFFECTIVENESS OF TRANSCATHETER AORTIC VALVE IMPLANTATION IN ELDERLY PATIENTS WITH SEVERE AORTIC STENOSIS WHO ARE CONTRAINDICATED FOR CONVENTIONAL SURGICAL AORTIC VALVE REPLACEMENT IN THE UNITED KINGDOM

Campbell J[1], Faivre P[2], Kumar P[2], Drummond M[3]
[1]OptumInsight, Medford, MA, USA, [2]OptumInsight, Uxbridge, UK, [3]University of York, Heslington, York, UK

OBJECTIVES: To assess the cost-effectiveness of transcatheter aortic valve implantation (TAVI) versus medical management (MM) for severe aortic stenosis (AS) in elderly patients with excessive surgical risk. **METHODS:** A Markov model was developed of survival, quality-adjusted life-years (QALYs) and medical costs, in elderly patients in the UK with severe AS and excessive risk for conventional aortic valve replacement (cAVR). Incremental cost-effectiveness ratios (ICERs) were estimated as cost per QALY-gained, from the National Health Service (NHS) perspective, over 3 years. Clinical and utility outcomes over the first year were derived from published results of a head-to-head randomized controlled trial comparing [transfemoral] TAVI and MM. Base-case analyses assumed no additional procedure-related adverse events after the first year—not including re-hospitalizations due to cardiovascular events—and constant treatment-specific mortality after the first month. Costs of procedures, adverse events, re-hospitalizations and long-term health care utilization were estimated using NHS tariff and reference cost schedules, National Institute of Health and Clinical Excellence reports, peer-reviewed literature and clinical experts. Outcomes and costs (2010£) were discounted at 3.5% per annum. **RESULTS:** Under conservative assumptions, treatment with transfemoral TAVI is estimated to result in better survival (35% vs. 13% at three years) and more QALYs (1.17 vs. 0.76) than MM. TAVI is also associated with higher costs of initial treatment and procedure-related adverse events, partially offset by lower costs of re-hospitalizations (net costs of £34,500 vs. £23,700). The base-case ICER of £26,100 is sensitive to variation in assumptions about long-term mortality for MM and long-term cardiovascular events for TAVI but remains below £30,000; the model is also sensitive to assumptions on long-term care use. **CONCLUSIONS:** In elderly patients who are contraindicated for cAVR, TAVI is estimated to result in better survival and fewer re-hospitalizations over a three-year period compared with MM, and can be considered cost-effective at 3 years with a base-case ICER of ~£26,000.

PMD68

PURCHASING AND ADOPTING CARDIOVASCULAR DEVICES: A GLOBAL SURVEY

Menzin J[1], Neumann P[2], Duczakowski C[1], Woodward RM[1], Friedman M[1], Outlaw JJ[3], Durtschi A[3]
[1]Boston Health Economics, Inc., Waltham, MA, USA, [2]Tufts University School of Medicine, Boston, MA, USA, [3]Abbott Vascular, Santa Clara, CA, USA

OBJECTIVES: The objectives of this study were to: 1) evaluate, from a global perspective, the decision-making processes, roles of individuals involved, and physicians' and administrators' beliefs about future decision making for the adoption of cardiovascular devices and medical technologies; and 2) determine which clinical and health economic factors decision makers consider the most influential and what types of data they use when making decisions. **METHODS:** We surveyed cardiovascular physicians and hospital administrators in the US, UK, Australia, France, Germany, and Japan using a web-based questionnaire. Respondents were asked about their involvement in and opinions on the decision-making process in their institutions, and the role that clinical and economic data play in influencing decisions. Chi-squared tests were used to test for statistical differences between physicians and hospital administrators (all countries combined) and across countries. **RESULTS:** The questionnaire was completed by 151 physicians and 154 administrators across the six countries with roughly 25 physicians and 25 hospital administrators responding from each. Physicians, followed by hospital committees, were most frequently responsible for making decisions, but respondents believed influence would shift towards committees in the future. Physicians (78%) and administrators (81%) believed costs would more heavily influence decisions in the next 5 years. Approximately half of hospital administrators consulted economic data often when making device adoption decisions. Use varied somewhat by country with most frequent use by both physicians and hospital administrators in the U.S., U.K., and Australia. **CONCLUSIONS:** Physicians' and hospital administrators' roles in decision making for cardiovascular devices appear to be changing in many countries, with committees and administrators assuming more important roles. While clinical data is most influential to the decision process, the impact of health economic data seems to be growing.

PMD69

TREATMENT OF URINARY TRACT INFECTIONS IS COMMON AMONGST SWEDISH PATIENTS IN NEED OF CHRONIC CATHETERISATION

Bruce S[1], Löfroth E[1], Knutsson B[2], Börstell T[2], Myrén KJ[1]
[1]IMS Health, Stockholm, Sweden, [2]AstraTech, Mölndal, Sweden

OBJECTIVES: To collect real-life data from a Swedish setting on treatment patterns and frequency of urinary tract infection (UTI), amongst patients in presumed need of chronic, intermittent catheterisation. **METHODS:** We used the CEBRxA database, which combines data from a public claims database for the South-West region of Sweden, comprising around 1.5 million individuals, with national Swedish registers on drug utilisation and mortality. We identified two sets of patients; Population I: spinal injury, in addition to neurogenic bladder, and Population II: self-catheterisation training (GB005). A list of antibiotics, known for their frequent use in treating UTIs was used to evaluate treatment patterns. In addition, a prophylactic treatment for UTI was evaluated (J01AXX05). An antibiotic regime was defined through considering all dispatches that occurred within 14 days from each other, simultaneously (data available from 2005-07-01 until 2009-12-31). **RESULTS:** We identified 295 and 989 patients for Population I and II, respectively. Both populations consisted primarily of males, while Population I was on average much younger (44 vs. 65 years). For Population I, we observed an average frequency of 2.5 UTI-related antibiotic regimes per year. For Population II, an average rate of 1.9 UTIs per year was observed, while females showed an elevated rate of 2.5. Interestingly, prophylactic use of antibiotics was widespread in Population I, with usage in 25% of patients, while for Population II, only 3% of patients had dispatched J01AXX05. An evaluation of the prescribed dose for Population I prophylaxis users, pointed to an almost continuous use, at an average 235 DDD per patient and year. **CONCLUSIONS:** Through studying UTI-related antibiotic treatment patterns we demonstrated a high disease burden for UTIs in two, primarily male, populations, in presumed catheterisation need. The frequent use of prophylactic treatment in the spinal injury population pointed to an even larger disease burden for these patients.

PMD70

A REVIEW OF THE GEOGRAPHIC VARIATIONS IN THE IMPLANT RATE OF TRANSCATHETER AORTIC VALVES IN 14 EUROPEAN COUNTRIES

Busca R[1], Brasseur P[1], Hull M[2], Mealing S[3]
[1]Medtronic International Trading Sàrl, Tolochenaz, Switzerland, [2]Medtronic Structural Heart, Minneapolis, MN, USA, [3]Oxford Outcomes Ltd, Oxford, UK

OBJECTIVES: Multiple medical reimbursement systems exist in Europe, which may create unequal dissemination and coverage of innovative medical devices. Even in the setting of regularly revised systems, uptake of new technology may be delayed leading to unequal reimbursement. **METHODS:** This study analyzed the 2010 geographical trends of transcatheter aortic valve implantation (TAVI) rates in 14 countries (Medtronic CoreValve System and Edwards Sapien). Implant data were gathered from BIBA Medical Ltd, a UK-based provider of consulting and market analysis services for the medical device industry. In addition demographic and economic data were gathered from Eurostat, a statistical office of the European Union. Regression techniques were used to explore the relationship between implant rate and a number of key variables. **RESULTS:** In 2010, a total of 14,400 TAVI procedures were documented providing an average country-based implant rate of 36.2 per million/Inhabitants. A seven-fold difference in implantation rate existed between the highest and lowest implanting countries (Germany, 77 per million/inhabitants vs. Norway 12 per million/inhabitants). Implant rates were correlated with per-capita GDP (r^2=0,015), health expenditure (r^2=0.15) and number of implanting centers in the country (r^2=0.18). At this time, only two European countries have a dedicated tariff for TAVI that is applicable nationwide and covers both the device and the procedure (Germany – €34,900, France - €28,477). Differences between country-specific tariffs depend on the method of DRG calculation. In Austria, the TAVI tariff was made to equal that of surgical aortic valve replacement. Countries such the UK and Italy have adopted case-by-case funding. In countries such as Belgium and the The Netherlands TAVI is funded by the hospital-based budget. **CONCLUSIONS:** Significant differences in TAVI rates exist among European countries. These observations may help us to better understand unequal patterns of dissemination and coverage of innovative medical devices such as TAVI.

PMD71

RESOURCE USE CAUSED BY IN-OFFICE FOLLOW-UP VISITS FOR CARDIAC IMPLANTABLE ELECTRICAL DEVICES (CIED) IN GERMANY AND THE UNITED KINGDOM

Smala A[1], Gessler M[2], Vogtmann T[3]
[1]Biotronik SE & Co KG, Global Reimbursement and Health Economics, Berlin, Germany, [2]Biotronik SE & Co KG, Global Sales Strategy, Berlin, Germany, [3]Kardiologische Gemeinschaftspraxis "Am Park Sanssouci", Potsdam, Germany

OBJECTIVES: Expert consensus recommends follow-up (FU) for patients with pacemakers to be performed twice annually, with implantable cardioverter defibrillators or cardiac resynchronization therapy devices four times annually. Most of the routinely scheduled calendar based FU in-office visits do not require further action but contribute to the consumption of limited health care resources. This model estimates the resource use associated with in-office FU visits in Germany and the UK (UK). **METHODS:** Own estimates on the number of FU visits were combined with previously published data on frequency and distance of private and public transport. Recently published data on healthcare personnel resource use were considered to model hospital resource use. Data were modeled until 2015. **RESULTS:** If service providers continue the current service model of routine calendar based in-office visits for CIED patients, about 2.23 mio visits will be needed in Germany, and 836'000 in the UK in 2015. These visits would consume approximately 1.11 mio hours of time in consulting rooms in Germany, and 418,000 hours in the UK. More than 87,000 ambulance transports in Germany and 33,000 in the UK will be required for patients attending FU visits. Patients able to use their own transport will drive about 287 mio kilometers in Germany and 28 mio kilometers in the UK. Workload for physicians, nurses and technicians will reach 1.1 mio hours in Germany, and 406,000 hours in the UK, most of them being provided by physicians. These estimates do not yet include unscheduled and emergency services for CIED patients. **CONCLUSIONS:** The increasing number of in-office FU visits will continue to place a heavy burden on primarily cardiology service providers but also on patients. Technologies such as BIOTRONIK's Home Monitoring can assist hospitals in handling the increasing service demand, free patients from unnecessary travel burden, and ensure adherence to FU.

PMD72

MAMMA CARCINOMA – DATA ANALYSES AND CLASSIFICATION OF TREATMENT IN AUSTRIA

Schiller-frühwirth I[1], Zauner G[2], Einzinger P[3], Breitenecker F[4]
[1]Main Association of Austrian Social Security Institutions, Vienna, Austria, [2]Dwh Simulation Services, Vienna, Austria, [3]Dwh Simulation Services, Vienna, Vienna, Austria, [4]Vienna University of Technology, Vienna, Austria

OBJECTIVES: Cost of illness analysis of breast cancer in Austria using mainly Austrian billing data from intramural and extramural medical treatment based on data from 2006/07 for treatment and degree of severity evaluation. Regarding this project a detailed treatment course classification has to be realized to evaluate the costs and patient ways in Austrian health system. **METHODS:** Main strategy of the project is the combination of data samples detected by Austrian cancer registry and billing data of intramural and extramural single person datasets in combination with intake data of medication for each patient. By combining the recorded data from national statistics, including TNM-classification of each new breast cancer case, and the ICD10-diagnoses, as well as medical individual services, results in classification of breast carcinoma on single person level are achieved. For separation of drug treatment concerning chronical diseases versus cancer indicated drug administration, the half year time span before the first mamma carcinoma detection and the year afterwards is analyzed separately. Special medication groups are assessed in detail and inclusion/exclusion – criteria for costs and treatment are defined. **RESULTS:** Based on this identification an alternative subsumption of new detected carcinoma in six groups (hormone receptor positive, Her 2 positive, hormone receptor positive and Her 2 positive, triple negative, metastasizing mamma carcinoma, early stage mamma carcinoma without chemo therapy in course of treatment) is defined. **CONCLUSIONS:** This classification leads to better insights for cost evaluation representing the state of the art in Austria. This strategy also leads to better overall reliability because the margin of uncertainty of the parameters can be reduced significantly.

PMD73

COMPARISONS OF ANAPHYLACTOID REACTIONS ASSOCIATED WITH DIFFERENT GADOLINIUM PRODUCTS AND IODINATED CONTAST MEDIA USING THE FDA'S ADVERSE EVENT REPORTING SYSTEM

Raisch DW[1], Garg V[2], Samaras AT[3], Saddleton EE[3], Lauman AE[3], Mckoy J[3], Belknap SM[3], West D[3]
[1]University of New Mexico College of Pharmacy, Albuquerque, NM, USA, [2]University of New Mexico, Albuquerque, NM, USA, [3]Northwestern University, Chicago, IL, USA

OBJECTIVES: To review reports of anaphylactoid reactions from gadolinium products (GPs) and iodinated contrast media (ICMs) and to compare events, outcomes, and signals associated with different GPs. **METHODS:** We reviewed ARs in the FDA Adverse Event Reporting System (AERS) and compared reports for GPs and ICMs. We searched FDA-AERS using all reaction terms for ARs linked with GPs and, separately, ICMs. We compared demographics, outcomes, and types of reactions between GPs and ICMs. We compared signal detection results for each GP using proportional reporting ratios (PRRs) and 95% confidence intervals (CI). **RESULTS:** Through March 2010, there were 494 and 2,533 reports for GPs and ICMs, respectively. The data are not confluent since ICM usage preceded GP usage (first ICM event date: 1943, received by FDA: 1969; first GP event date: 1969, received by FDA 1998). Mean ages (± standard deviation) were 49.1±18.0, and 57±18.5, and % male/female were 38%/59% and 40%/43% for GPs and ICMs, respectively. The ARs for GPs and ICMs were serious in 91.7%/97.5% and fatal in 7.5%/13.9%, respectively. Proportions of reports and PRRs (CI) for linear GPs were: gadopentetate dimeglumine = 45.3%, 5.03 (4.34-5.71), gadobenate dimeglumine = 25.9%, 11.41 (9.67-13.46). For the other linear GPs, gadodiamide was reported in 7.9% and gadoversetamide in 0.1%, but the number of cases of use of the agents alone were too small to determine PRR. Gadoteridol, a cyclic GP, was reported in 18.2% of cases with a PRR of 5.27 (4.30-6.45). Overall, PRRs were indicative of safety signals for both GPs and ICMs, 5.9, (5.4-6.4), 7.4 (CI: 7.1-7.7), respectively. **CONCLUSIONS:** FDA-AERS data indicate that GP-associated ARs generate a safety signal comparable to ICMs. Although over 80% of GP-associated ARs were with linear GPs, there was a significant safety signal for one macrocyclic structure GP as well as two linear structure GPs.

PMD74

HOME DIALYSIS MODALITIES: THE DEVELOPMENT OF A FRAMEWORK TO IDENTIFY AND QUANTIFY FAVOURABLE RENAL POLICY AND REIMBURSEMENT FACTORS

Laplante S[1], Vanovertveld PG[2]
[1]Baxter Healthcare Corporation, Braine l'Alleud, Belgium, [2]Baxter Healthcare Corporation, Zurich, Switzerland

OBJECTIVES: The use of home dialysis modalities such as peritoneal dialysis and home haemodialysis varies across Europe and North America from today <5% in Germany to 28% in Denmark. These differences have often been attributed to reimbursement and renal care organization factors. This analysis was undertaken to quantify the strength of association of potential factors influencing usage of home dialysis modalities with the intent to later facilitate evidence based policy choices. **METHODS:** A 4-pillar framework including 8 different factors (home target, reimbursement level, payment flow, pre-dialysis education, assisted dialysis, home guideline/policy, incentives for home, monitoring/planning tool) was postulated to explain the variation in home dialysis usage across countries. A semi-quantitative scoring algorithm was developed and used to rate the renal care organization of 12 European countries, Canada, and the USA based on publicly available information. A regression analysis was used to explore the relationship between the score and the use of home dialysis modalities as retrieved from the latest available renal registry reports. The most significant factors were identified by analysis of variance. **RESULTS:** A significant (r^2=0.694; $p<0.001$) correlation was found between the total score and home dialysis usage. Countries like Denmark and Sweden achieving a score of 5 have a 26-28% usage of home modalities. In comparison, Germany had a score of −2 and <5% of dialysis patients are on home modalities. Three factors were especially significant: well funded and independent pre-dialysis education ($p<0.001$), clinical guideline/policy favouring home modalities ($p=0.002$), and (absence of) provider-driven demand ($p=0.035$). **CONCLUSIONS:** The 4-pillar framework appears to be useful to identify gaps in a country renal care policy and decide on further actions to be taken when intending to increase usage of home dialysis modalities. Actions to implement/correct pre-dialysis education, clinical guideline/policy favouring home modalities and (absence of) provider-driven demand should probably be prioritized.

PMD75

PATIENT SELF-TESTING OF ORAL ANTICOAGULATION THERAPY BY COAGUCHEK® XS SYSTEM. RAPID HEALTH TECHNOLOGY ASSESSMENT IN SLOVAK HEALTH CARE ENVIRONMENT

Visnansky M[1], Mesaros S[2]
[1]SLOVAHTA, Bratislava, Slovak Republic, [2]SMs Consulting, Ltd., Bratislava, Slovak Republic

OBJECTIVES: to explore the effects of patient self-testing (PST) of oral anticoagulation therapy (OAT) by CoaguChek® XS System compared to standard available care (laboratory testing) for selected group of patients. **METHODS:** Health Economy Model (HECON), using Cost-Effectiveness Analysis (CEA), complemented by Budget-Impact Analysis (BIA) on public health insurance coverage in Slovakia. We searched MEDLINE, Cochrane and available grey literature (Industrial Sources and Expert Opinions) for meta analyses, systematic reviews, economic evaluation studies and health technology reports on PST of OAT. Outcomes analyzed were feasibility and accuracy of PST, thromboembolic events, hemorrhagic complications and mortality. Real-world data from General Health Insurance, Inc. were used for costs associated with corresponding diagnoses, complications and management of patients on OAT, including full cohort of patients (n=100, average age of 63 years) on PST. Markov Model (life time horizon) for OAT patient management was developed, comparing PST with standard care. Outcomes observed were major thromboembolic events, major hemorrhagic complications and mortality. Payer perspective and direct healthcare costs only, associated with OAT management were considered in CEA and BIA for diagnosis subgroups. Discount rate of 5% was used for costs as well as outcomes. Sensitivity analysis for major complications was performed. **RESULTS:** CEA for PST vs. standard care associated with OAT shows that intervention is cost-effective (dominant) for all diagnosis subgroups. Net costs (BIA) associated with PST for expanding the existing cohort of patients 10 times (n=1000) are 1.596 mil. € in Year 1 (up to 3.579 € in Year 5). **CONCLUSIONS:** PST of OAT is considered cost-effective in terms of International Normalized Ratio (INR) regulation and safer in terms of complications. Moreover, analysis of selected subpopulations (mitral and/or aortic mechanical heart valve implantation, aortic and/or other aneurysm and congenital cardiovascular malformations) shows that PST brings the most significant cost-savings especially for those OAT patient segments.

PMD76

ARE HEALTH TECHNOLOGY ASSESSMENTS OF MEDICAL DEVICES CATCHING UP WITH PHARMACEUTICALS?

Sweeney N, Andreykiv M, Wiebinga C
Quintiles Consulting, Hoofddorp, The Netherlands

OBJECTIVES: To evaluate how HTA is applied to medical devices (MD) and to assess whether established HTA agencies have similar influences over MD coverage and reimbursement decisions compared to pharmaceuticals. **METHODS:** Manual search of 69 HTA agencies' websites was conducted to determine whether they undertake MD HTAs. Of the agencies that reported MD assessments, we evaluated the HTA process in respect to methodological approaches and influence on market access decisions. **RESULTS:** The majority (49 out of 69) of HTA agencies conduct MD assessments and make these appraisals publically available. Thirty-five of these agencies provide reimbursement advice in their reports. In most cases recommendations serve as non-mandatory guidance, aimed at helping local and national stakeholders make informed decisions about the use of the device within their health care system. Despite widespread use of MD evaluations, the number of completed reviews is relatively low. Sixty percent of the agencies that performed MD HTAs (29 out of 49) applied similar methodologies to both MD and drug assessments. **CONCLUSIONS:** While the majority of HTA agencies are adding MD assessments to their work plans, procedural pathways are not as transparent and robust as those for pharmaceuticals. Combined with the low output of publications this currently leads to limited application of MD HTAs to market access decisions. However, a new system is emerging which recognizes the unique features of MD and the distinctive level of evidence needed for regulatory approval. In future we anticipate that market access of medical devices will be centralized under the umbrella of existing HTA agencies. Thus, following the example of NICE, HAS and CVZ which have established one national HTA process, with independent pathways within their agencies for both drug and MDs.

PMD77

COMPONENTS OF HEALTH TECHNOLOGY ASSESSMENT FOR RADIOLOGY IN CHILE

Cuenca D[1], Leisewitz T[2], Bryon A[1], Rascovsky S[3], Strappa V[4]
[1]*HEORT, Bogota, Colombia,* [2]*HEORT, Santiago de Chile, Chile,* [3]*Instituto de Alta Tecnología Médica, Medellín, Colombia,* [4]*Ministerio de Salud, Santiago de Chile, Chile*

OBJECTIVES: The objectives of this paper are to present the current status of HTA in the field of radiology and describe the role played by Chilean Health System governmental institutions and private agents in the decision-making process in order to allocate resources for the incorporation of new technology. **METHODS:** A bibliographical review was made based on the opinions of local experts, and a review of the available local literature. **RESULTS:** The decision-making process of acquiring a new technology in radiology is different depending on whether the provider is public or private. For public providers, first, the hospital solicits to include the purchase of the equipment in the budget for the year immediately following. Then, the decision is taken by the Ministry of Health (MINSAL). It is a centralized decision, but not subdue to a formal economic assessment. For private providers, the decision usually comes from the clinical need. An economic assessment for viability is carried out, expected demand and budgeted costs of examination are calculated in order to calculate the payback time on investment and finally decision to purchase is made. **CONCLUSIONS:** Data on health economics are increasingly important to the Chilean health authorities, even though, they are not considered essential to make decisions. At present, there is more awareness of the importance of implementing methods of analysis. Therefore, it is advisable to continue providing such information. On the whole, the decision to purchase a new technology in radiology depends on whether the provider is public or private. It does not involve variables derived from complex economic or structured studies, but depends on the need of the equipment and market availability.

PMD78

BENEFIT-RISK ANALYSIS IN ABSENCE OF CLINICAL EVIDENCE: DECIDING FOR TREATMENT OF SKULL DEFORMITY IN BABIES AGED 5 MONTHS

Van Til JA[1], van der Maas EW[1], Boere-Boonekamp MM[1], Van Vlimmeren L[2], Ijzerman MJ[1]
[1]*University of Twente, Enschede, Overijssel, The Netherlands,* [2]*Radboud University Nijmegen, Nijmegen, Gelderland, The Netherlands*

OBJECTIVES: Skull Deformaty (SD) is a flattening of the head as a result of pressure on the malleable skull in infants in the first months of life. Presently, a RCT is conducted to compare the effect of an orthotic helmet to the natural recovery of skull shape in the first three years of life. Burden of treatment is considerable; the helmet has to be worn 23 hours a day for at least 6 months. Possible harms include acceptation problems, pressure wounds and severe skin rash or eczema. The harms of treatment are perceived as an important reason for low adherence to and parental refusal of helmet treatment. The objective of this study is to estimate the risk-benefit trade-off in SD management in pediatric physiotherapists. **METHODS:** A discrete choice experiment was performed with the most important attributes of SD management. A total of 267 pediatric physiotherapists stated their preference for treatment of a 5 month old child with SD. A three scenario design was chosen Each scenario was characterized by its effect, its burden and the harms of treatment. Logistical regression analysis was performed to analyze the results of the discrete choice experiment. **RESULTS:** Not surprisingly, child physiotherapists' ideal treatment has a high probability of timely success with low burden and minimal harms. At present, most attributes indicate a strong preference for awaiting natural recovery. Risk benefit assessment favoring the helmet will only be attained if the helmet can show highly significant clinical benefit. **CONCLUSIONS:** This study shows that risk benefit analysis can give early indications on the potential of a treatment, by estimating the effectiveness at which the treatment becomes more favorable than its comparator. Whether the risk-benefit analysis will be in favor of helmet treatment in the case of SD, is questionable, as earlier studies have not demonstrated superiority of the helmet.

PMD79

AN EVALUATION OF THE NON-INVASIVE IMAGING TESTS USED IN CURRENT CARE OF TIA AND MINOR ISCHEMIC STROKE IN THE NETHERLANDS: HOW MUCH PRACTICE VARIATION IS THERE?

Buisman L, Silitonga A, Rijnsburger A, Redekop W
Erasmus University Rotterdam, Rotterdam, The Netherlands

OBJECTIVES: There is increasing interest in estimating the health and economic impact of a new technology in the early phases of its development. However, this requires knowledge about current care. We examined how non-invasive imaging is currently used to assess carotid stenosis in patients with a recent TIA or minor ischemic stroke, as a first step in an early economic evaluation of new imaging technologies which will be used for the prediction of the risk of plaque rupture. **METHODS:** We first examined the current guidelines in the The Netherlands, Europe and US regarding the use of non-invasive imaging tests (i.e. CT angiography (CTA), duplex ultrasonography (DUS), MR angiography (MRA)) in the assessment of carotid stenosis in patients with a TIA or minor ischemic stroke. In addition, semi-structured interviews were conducted with neurologists in several Dutch hospitals to determine how patients are actually diagnosed in daily clinical practice. **RESULTS:** Current guidelines differ in the use of non-invasive imaging tests in assessing carotid stenosis in patients with a recent TIA or minor ischemic stroke. In addition, practice variation is high, since hospitals use different (combinations of) tests. According to the neurologists, these differences are probably caused by capacity problems, degree of expertise in performing certain tests and lack of evidence regarding effectiveness and cost-effectiveness of the imaging tests in assessing carotid stenosis. **CONCLUSIONS:** The observed practice variation is high, and has implications for assessing the health and economic impact of the new technology, since estimating impact requires comparison with current care. The choice of just one comparator representing current care is therefore meaningless, since choice of comparator may strongly affect the estimated health and economic impact of the new technology. The final impact of a new technology will be hospital-dependent, and therefore multiple comparisons and scenario analyses are needed.

Medical Device/Diagnostics – Research On Methods

PMD80

PATIENT DEMOGRAPHICS AND SURGICAL EXPENDITURE IN HERNIA REPAIR SURGICAL COHORTS USING A RETROSPECTIVE NATIONWIDE PATIENT DATABASE

Hargreaves JA[1], Nair KV[2], Ghushchyan VH[2], Allen RR[3], Mcqueen RB[3], Robinson T[4]
[1]*ETHICON Product UK, Livingston, UK,* [2]*University of Colorado, Denver, Aurora, CO, USA,* [3]*University of Colorado, Aurora, CO, USA,* [4]*School of Medicine, Aurora, CO, USA*

OBJECTIVES: Several observational studies have examined the epidemiological and social characteristics of patients undergoing hernia surgery, but conclusions drawn from these studies are generally limited due to the small sample population. Here we describe patient demographics of hernia repair patients and surgical expenditure using a population-based approach with a retrospective nationwide database. **METHODS:** Premier Inc has established one of the largest hospital databases worldwide. It collects patient data from around 500 hospitals in the US. Hernia surgery was stratified by inpatient or outpatient treatment, hernia repair surgery type (inguinal, incisional or umbilical), surgical procedure (laparoscopic or open), and the type of mesh used (flat, tissue-separating or device). Patient demographics were recorded and are presented for every cohort of patients. Surgical

costs across hernia repair and mesh type cohorts are also presented. **RESULTS:** Across treatment groups the majority of patients were white (~70%) with a mean age of 54 years. Inguinal and umbilical hernia repair groups were both predominantly male with low to moderate incidences of obesity and diabetes. Incisional hernia repair patients had the highest incidence of obesity (19.0%) and diabetes (18.5%) and could be equally either male (42.0%) or female (58.0%). Tissue-separating mesh (TSM) was used mainly in incisional hernia repairs, whilst other meshes were used in all surgical cohorts. TSM was used more frequently in females (60.1%) and in patients with a high incidence of obesity (22.7%) and diabetes (22.1%). No striking differences in surgical costs across the hernia repair or mesh type cohorts were observed, with average surgical costs between $2199 and $4099. **CONCLUSIONS:** This is the first example of extracting hernia repair patient demographics from a nationwide database. Although there are limitations to the interpretation of this data, these results are encouraging. Further development of the management, analysis and interpretation of such data is ongoing.

PMD81

DECISION ANALYTIC MODELS USED IN ESTIMATING THE COST-EFFECTIVENESS OF DRUG-ELUTING STENTS VERSUS BARE-METAL STENTS

Burgers LT, Redekop W, Severens JL
Erasmus University Rotterdam, Rotterdam, The Netherlands

OBJECTIVES: Drug-eluting stents (DES) and bare-metal stents (BMS) are both used widely in percutaneous coronary interventions (PCI). However, the incremental cost-effectiveness of DES versus BMS varies considerably between studies. A systematic review is performed to gain insight how modeling influences the cost-effectiveness of DES versus BMS. **METHODS:** We reviewed modeling studies published until February 2011 that studied the cost-effectiveness of DES versus BMS. We then extracted various parameters (e.g., model type, time horizon, data sources, choice of disease states) and explored the influence of these parameters on the cost-effectiveness outcomes. **RESULTS:** The incremental cost-effectiveness ratios (ICER) from the 22 eligible studies ranged from DES being dominated by BMS to DES being dominant. Different parameters can contribute to these differences, including time horizon, assumptions concerning stent efficacy, study perspective, stent cost prices and the specific type of stents being compared. Almost half of the studies used a time horizon ≤12 months, assuming that differences in clinical events between the two stents occur in the first year. However, published literature contradicts this assumption since DES can induce very late in-stent thrombosis. Moreover, many studies base restenosis rates on angiographic follow-up. Since angiography overestimates the difference in restenosis rate between DES and BMS, its use leads to an overestimate of quality-adjusted life-years gained and number of avoided reinterventions and an underestimate of the costs of the DES strategy. The price premium of DES versus BMS differs considerably between studies (€900-€3300) and this difference also affects the ICER. **CONCLUSIONS:** Choices made in cost-effectiveness models to compare DES with BMS lead to wide variation in cost-effectiveness estimates, making it difficult to conclude that DES is more cost-effective than BMS. Since 80,000 PCIs are performed per year in the UK, it is very important to obtain valid estimates of the cost-effectiveness of DES versus BMS.

PMD82

DRUG ELUTING BALLOON FOR THE TREATMENT OF PERIPHERAL ARTERY DISEASE: A COST-EFFECTIVENESS ANALYSIS IN ITALY

Giardina S[1], Brasseur P[2], Busca R[2], Micari A[3]
[1]*Medtronic Italy SPA, Sesto San Giovanni, Italy,* [2]*Medtronic International Trading Sàrl, Tolochenaz, Switzerland,* [3]*Villa Maria Eleonora Hospital, Palermo, Italy*

OBJECTIVES: Conventional balloon angioplasty for treatment of femoropopliteal arterial disease is associated with a high restenosis rates 12 months post-procedure. Recent clinical data have showed that use of DEBs may substantially reduce restenosis. This suggests that DEB may decrease number of revascularizations and therefore be a cost-effectiveness treatment for peripheral artery disease (PAD). This study evaluated the economic impact of using a drug-eluting balloon (DEB) for treatment of femoropoliteal arterial disease. **METHODS:** A decisional tree model has been developed to compare two alternative treatment strategies for superficial femoral artery disease (SFA): standard balloon angioplasty (PTA) and provisional stenting versus DEB. Cost for initial hospital care and the long term management of the disease, including reintervention, has been accounted for according to National Health Care Service and societal perspectives. Probabilities have been retrieved by available literature review of RCT and from an observational study on DEB that evaluated risk of target lesion revascularization (TLR) at 1 year. Uncertainty around the model inputs was tested using unvaried and multivariate sensitivity analyses **RESULTS:** Specific procedure costs (including angioplasty balloon, DEB, stent, contrast medium) were 1500€ in both group because incremental cost for use of DEB was offset by reduction of number of stents used in the DEB arm. No difference has been noted also for initial hospitalization. Given a 1 year TLR rate of 8.7% and 14% for DEB and stenting respectively, DEB resulted a cost-saving strategy for the treatment of superficial femoral artery disease. Results were sensitive to hypothesis on number of stents and DEB used and their relative cost. **CONCLUSIONS:** PTA of femoropopliteal arterial disease using DEB appears to be a clinical improvement for treatment of PAD and a potentially cost saving strategy compared to use of stents in the Italian Health Care System.

PMD83

USING FIVE EXISTING MODELS TO COMPREHENSIVELY MODEL THE COST-EFFECTIVENESS OF A HIGH DEFINITION CT SCANNER IN A CORONARY ARTERY DISEASE POPULATION: A NICE DIAGNOSTIC GUIDANCE PROJECT

Burgers LT[1], Redekop W[1], Westwood M[2], Lhachimi S[1], Severens JL[1], Armstrong N[2], Sculpher MJ[3], Walker S[3], Mckenna C[3], Al MJ[1]
[1]*Erasmus University Rotterdam, Rotterdam, The Netherlands,* [2]*Kleijnen Systematic Reviews Ltd, York, UK,* [3]*The University of York, York, UK*

OBJECTIVES: Cost-effectiveness analysis (CEA) of a medical test can require extensive modeling if test results influence treatment decisions and disease progression. We applied the assessment hierarchy of Schaafsma et al. (2009) to a CEA of a high definition CT-scanner (one of the first assessments in the NICE/UK Diagnostics Guidance Programme). **METHODS:** Schaafsma presents four steps to evaluate the value of diagnostic tests: 1:accuracy assessment, 2:evaluation of added value, 3:clinical outcome assessment and 4:cost-effectiveness analysis. **RESULTS:** In the assessment of diagnostic tests in coronary artery disease (CAD) modeling was unavoidable, since a major problem in CEAs is the unavailability of randomized controlled trials (RCT) that capture diagnosis, prognosis and treatment. Moreover, most RCTs in the field of diagnostic test yield only information about sensitivity, specificity, and short-term complication rates. When the evaluation is limited to the added value of the high definition CT-scanner, one model, estimating the proportions correctly diagnosed and complications associated with the CT-scanner, is sufficient. However, since incorrect test results can result in major health loss through incorrect or delayed treatment this method is inappropriate. Most tests aim to improve prognosis thus, step 3 and 4 were applied in our assessment. Therefore, five existing models were combined (diagnosis, CAD management, stroke complication, radiation, non-CAD mortality) to create a meta-model that estimates the cost-effectiveness. **CONCLUSIONS:** CEAs of a medical test can be performed in various ways described by Schaafsma. If the aim is to conduct a comprehensive analysis that includes various economic and health impacts, a synthesis of existing models to create a meta-model is one way to achieve this. These models need to be grafted together carefully to avoid invalid or irrelevant results; literature and expert opinion can assist in that endeavour. One critical pitfall is the use of models created for dissimilar patient populations.

PMD84

ASSESSING COST EFFECTIVENESS AND VALUE OF FURTHER RESEARCH WHEN DATA ARE SPARSE: NEGATIVE PRESSURE WOUND THERAPY FOR SEVERE PRESSURE ULCERS

Soares MO
University of York, york, UK

OBJECTIVES: Health care resources are scarce and decisions have to be made about how to allocate funds. Often these decisions are based on sparse or imperfect evidence. One such example is negative pressure wound therapy (NPWT), which is a widely used treatment for severe pressure ulcers; however, there is currently no robust evidence that it is effective or cost effective. **METHODS:** This work considers the decision to adopt NPWT given a range of alternative treatments, using a decision analytic modelling approach. Literature searches were conducted to identify existing evidence on model parameters. Given the limited evidence base, a second source of evidence, beliefs elicited from experts, was used. Judgements from experts on relevant (uncertain) quantities were obtained through a formal elicitation exercise. Additionally, data derived from a pilot trial were also used to inform the model. The three sources of evidence were collated, and the impact of each on cost effectiveness was evaluated. **RESULTS:** Negative pressure wound therapy was expected to be less costly and more effective than any other treatments. The decision to adopt NPWT was however very uncertain (probability of being cost effective of 0.55). The expected value of perfect information for the relevant UK population was approximately £98 million. Specifically, the results suggest that a study evaluating the effectiveness of NPWT might be worthwhile. The trial design that offered most value was a three armed trial, with follow-up of at least 1 year and approximately 500 participants per arm. **CONCLUSIONS:** The analyses presented demonstrate how allocation decisions about medical technologies can be explicitly informed when data are sparse and, how this kind of analyses can be used to guide future research prioritisation, not only indicating whether further research is worthwhile but what type of research is needed and how it should be designed.

PMD85

SLEEP QUESTIONNAIRES DISCRIMINATE BETWEEN PARTICIPANTS WITH AND WITHOUT OVERACTIVE BLADDER SYMPTOMS

Margolis MK[1], Coyne K[1], Jumadilova Z[2]
[1]*United BioSource Corporation, Bethesda, MD, USA,* [2]*Pfizer Inc., New York, NY, USA*

OBJECTIVES: Nighttime urinary frequency (nocturia), common in patients with overactive bladder (OAB), negatively impacts sleep quality. Three sleep-related patient-reported questionnaires were assessed with regard to ability to discriminate between patients with and without OAB. **METHODS:** Adult men and women with OAB symptoms for at least 3 months (≥8 micturitions per day; ≥2 micturitions per night; and ≥6 urgency episodes over 3 days per bladder diary) and without OAB symptoms (control group) completed several sleep questionnaires: Stanford Sleepiness Scale (morning and evening for 5 days), Epworth Sleepiness Scale, and Nocturia Quality of Life Questionnaire (N-QoL); t tests were performed between groups. **RESULTS:** A total of 43 participants with OAB and 10 healthy controls were enrolled. Mean age and proportion of men were similar in the OAB and control groups (63.7 vs. 55.6 years old [P=0.31], and 46.2% vs 40.0% male [P=0.53], respectively). Race, employment status, and education level were also similar between groups (all P>0.25). Mean scores on the Stanford Sleepiness Scale across the 5 days were significantly higher in the OAB group than the control group at time of awakening (3.0 vs. 2.0; P=0.0030) and at 7:00 pm (3.5 vs. 1.9; P=0.0006), indicating greater sleepiness. Epworth Sleepiness Scale mean scores were also significantly higher in the OAB group than the control group (10.5 vs 4.1, respectively; P<0.0001), indicating greater daytime sleepiness. On the N-QoL, participants with OAB had signifi-

cantly lower mean Total scores than controls (54.7 vs. 99.2; P<0.0001), Sleep/energy scores (55.9 vs. 100.0; P<0.0001), and Bother/concern scores (54.0 vs. 98.3; P<0.0001), indicating greater health-related quality of life impairment because of nighttime urination. **CONCLUSIONS:** The Stanford Sleepiness Scale, Epworth Sleepiness Scale, and N-QoL all effectively discriminate between participants with OAB symptoms and those without OAB symptoms.

PMD86

A SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS CONDUCTED FOR ASSESSMENT OF GENETIC TESTING TECHNOLOGIES

Assasi N, Schwartz L, Tarride JE, Goeree R, Xie F
McMaster University, Hamilton, ON, Canada

OBJECTIVES: The conventional economic evaluations (EE) methods may be challenging within the context of genetic testing technologies (GTTs), because: the main outcome a GTT is information, benefits may occur many years after taking the test, non-medical harms might be associated with GTTs, and GTTs may also provide information about the genetic status of the family members of affected individuals. This study was performed to systematically review the methods used in EEs included in Health Technology Assessments (HTAs) of GTTs. **METHODS:** A systematic search of literature was undertaken to identify HTA reports on GTTs that included EEs in addition to clinical effectiveness results. Studies were reviewed in terms of methods (e.g. type of EE, analytic perspective, cost-effectiveness analysis), and quality (using QHES instrument). **RESULTS:** Of 342 identified citations, 13 HTAs consisting of 10 model-based and 3 trial-based EEs were included. More than 50% of the included studies had moderate to low quality scores mainly due to not reporting information on basic elements of a standard EE and inadequate management of uncertainty. Cost-effectiveness analysis (CEA) accounted for 62% of included studies. 65% of the studies adopted a third party payer perspective, and 60% used a lifelong time horizon. 75% of CEAs reported intermediate outcomes (e.g. cases-detected). The majority of studies exclusively included technical costs of testing (100%) and therapeutic or preventive interventions (62%). The most frequent variables tested in univariate sensitivity analysis included costs (62%), effects (46%) and transition probabilities (54%). Probabilistic sensitivity analysis was conducted in 31% of studies. **CONCLUSIONS:** We found several methodological challenges in the reviewed EEs, including: identification of a proper analytical perspective, inclusion of wider range of outcomes and costs, allowing for long-term psychological, ethical and social impacts of genetic tests, and sufficient management of uncertainty. These issues should be carefully considered in future EEs of GTTs.

Surgery – Clinical Outcomes Studies

PSU1

SUPRAPUBIC TUBE PLACEMENT RELATED BOWEL INJURY: PROPOSED GUIDELINES FOR OPEN PLACEMENT

Ellsworth P[1], Tompkins A[1], Lasser M[2]
[1]*Brown University, Providence, RI, USA,* [2]*Brown University, providence, RI, USA*

OBJECTIVES: Suprapubic catheterization (SPT) is a common urologic procedure performed on an elective and urgent basis. Percutaneous approaches have developed in an effort to circumvent the need for general/spinal anesthesia, but are not without risk. Rates of SPT-related bowel injury range from 0.3% to 2.7%. We experienced 4 cases and reviewed the literature to determine identifiable risk factors for bowel injury. **METHODS:** A literature review was performed of all English language articles listed in PubMed and articles reporting percutaneous SPT placement related bowel injury were selected. Included in our review are 4 cases in our institution. Data from articles and our cases was extracted to determine the technique of SPT placement utilized, underlying risk factors, and nature of bowel injury. **RESULTS:** Nineteen papers reported 22 cases of bowel injury as a result of percutaneous SPT placement, 2 of which were excluded for insufficient data. Additionally, the 4 cases at our institution were included in the analysis. Small capacity or thick-walled neurogenic bladders (4/24, 17%), prior abdominal surgery (13/24, 54%), and pelvic radiation (5/24, 21%) were associated with bowel injury during SPT placement. Diagnosis of bowel injury was based on history, physical examination and imaging modalities. Bowel injury had a bimodal presentation, at initial placement (14/24, 58%) and at initial SPT change (10/24, 42%). **CONCLUSIONS:** Based on this review we advocate consideration of open SPT placement in patients with small capacity or thick-walled neurogenic bladders, those in whom the bladder cannot be distended adequately, prior abdominal/pelvic surgery or radiation, ascites. If percutaneous SPT is planned, Trendelenburg positioning and use of ultrasound and/or fluoroscopy at time of SPT placement is supported by the literature.

PSU2

COMPARISON OF SEIZURE AND HYDROCEPHALUS AND OTHER CLINICAL CONDITIONS BEFORE AND AFTER SUBEPENDYMAL GIANT CELL ASTROCYTOMA SURGERY IN PATIENTS WITH TUBEROUS SCLEROSIS COMPLEX

Sun P[1], Liu Z[2], Rogerio J[2], Guo A[2], Garay C[2], Kohrman M[3]
[1]*Kailo Research Group, Fishers, IN, USA,* [2]*Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA,* [3]*University of Chicago, Chicago, IL, USA*

OBJECTIVES: To compare the prevalence rates of seizure, hydrocephalus and other clinical conditions before and after a surgical removal of subependymal giant cell astrocytoma (SEGA) in patients with tuberous sclerosis complex (TSC). **METHODS:** A pre-post comparative longitudinal cohort study was conducted based on 3 large US national healthcare claims databases (2000-2009). TSC patients with a first observed SEGA surgery at age 35 or younger and with continuous health insurance coverage 1 year before and 1 year after the surgery were selected. The prevalence rates of seizure, hydrocephalus, and other TSC related clinical conditions, such as vision disorders, coma, speechlessness, headache, stroke or hemiparesis, cognitive difficulties, muscle weakness, papillodema, balance disorders, loss of sensation, nausea and vomiting, depression, anxiety, attention deficit disorders, autism, and sleep disorders, were estimated and compared between a period of the last 6 preoperative months and the first two postoperative periods (the 2nd to 6th postoperative months; 7th to 12th postoperative months). Repeated measures analysis with bootstrapping re-sampling approach was used for the cross-period comparisons. **RESULTS:** The mean age of the select patients (N=47) was 11.6 year at their first observed SEGA surgery; the majority of the patients were male (66%). Statistically significant postoperative increases in the prevalence rates of seizure (23~ 26%, p<0.05), hydrocephalus (21~26%, p<0.05), headache (17~19%, p<0.05), stroke and hemiparesis (6~9%, p<0.05), and autism (9%, p<0.05) were observed. **CONCLUSIONS:** This real-world claim data showed an increase in the risk of some clinical conditions including seizure and hydrocephalus after a SEGA surgery in patients with TSC. Further research to explore any possible causal relationship between these risk increases and SEGA surgery through prospective studies or registries is needed.

PSU3

PREVALENCE RATES OF SURGICAL COMPLICATIONS AMONG TUBEROUS SCLEROSIS COMPLEX PATIENTS WITH SURGICAL REMOVAL OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA: A REAL-WORLD NATIONAL RETROSPECTIVE COHORT STUDY

Sun P[1], Liu Z[2], Rogerio J[2], Guo A[2], Garay C[2], Kohrman M[3]
[1]*Kailo Research Group, Fishers, IN, USA,* [2]*Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA,* [3]*University of Chicago, Chicago, IL, USA*

OBJECTIVES: To examine the prevalence rates of surgical complications among tuberous sclerosis complex (TSC) patients with surgical removal of subpendymal giant cell astrocytoma (SEGA). **METHODS:** Based on 3 US national health care claims databases (2000~2009), a retrospective cohort study was conducted in TSC patients who had a SEGA surgery at age 35 or younger, and were under continuous health insurance coverage 1 year before and 1 year after the surgery. A SEGA surgery was identified by a healthcare claim that simultaneously had a TSC diagnosis code, a benign brain tumor diagnosis code and a procedure code of removing a benign tumor from cerebral ventricle system. The surgical complications examined in the study included surgical procedure complications, nervous system complications, surgical misadventures, postoperative infection, subdural empyemas, and epidural abscess. The prevalence rates of these conditions were estimated for the first postoperative year. **RESULTS:** Approximately 47 TSC patients had at least one SEGA surgery. The mean age of patients at their 1st observed SEGA surgery was 11.6 years. The majority of patients (66%) were male. The prevalence rates of surgical complications in the 1st postoperative year were 34% for surgical procedure complications, 17% for subdural empyemas, 12.8% for nervous system complications, 6% for postoperative infection, 2% for epidural abscess, and 0% for surgical misadventures respectively. **CONCLUSIONS:** In this real-world claim database analysis, we observed that a portion of TSC patients experienced surgical complications within first year after their SEGA surgeries. Further research is needed to better understand the causes of this surgical outcome.

PSU4

POSTOPERATIVE PREVALENCE RATE OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) DIAGNOSIS AND REPEATED SEGA SURGERY IN PATIENTS WITH TUBEROUS SCLEROSIS COMPLEX: A REAL-WORLD NATIONAL RETROSPECTIVE COHORT STUDY

Sun P[1], Liu Z[2], Rogerio J[2], Guo A[2], Garay C[2], Kohrman M[3]
[1]*Kailo Research Group, Fishers, IN, USA,* [2]*Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA,* [3]*University of Chicago, Chicago, IL, USA*

OBJECTIVES: To examine the postoperative prevalence of subependymal giant cell astrocytoma (SEGA) diagnosis and repeated SEGA surgeries among patients with tuberous sclerosis complex (TSC) who had an initial SEGA surgery. **METHODS:** Based on three US national health claims databases (2000~2009), we conducted a retrospective cohort study with TSC patients who had a first observed SEGA surgery at age 35 or younger and were under continuous health insurance coverage 1 year before and 1 year after their 1st SEGA surgery. A SEGA surgery was defined as having 1) a TSC diagnosis code, 2) a benign brain tumor diagnosis code, and 3) a procedure code for removing a benign tumor from cerebral ventricle system. A SEGA diagnosis is defined as 1) and 2). The prevalence rates of postoperative SEGA diagnosis and repeated SEGA surgery were estimated for a period from the 3rd through 6th postoperative month and a period from the 7th through 12th postoperative month respectively. **RESULTS:** The select patients (N=47) had mean age of 11.6 years (at the 1st SEGA surgery) with 66% males. After the 1st observed SEGA surgery, postoperative prevalence rates of SEGA diagnosis was 34% in the period from the 3rd to 6th postoperative month and 26% in the period from the 7th to 12th postoperative month. About 4~9% patients had a repeated SEGA surgery in their 1st postoperative year. **CONCLUSIONS:** In the real-world setting, TSC patients with SEGA surgery may experience repeated SEGA surgeries or/and still have SEGA diagnoses within the first postoperative year. Further research on the effectiveness of SEGA surgery via prospective studies or registries is needed to improve care in TSC patients with SEGA.

PSU5

RISK OF ARTHRITIS AS A PREDICTOR FOR THE MISDIAGNOSIS OF CHONDROLYSIS: AN INTERNATIONAL ANALYSIS OF CLINICAL OUTCOMES

Smith JC[1], Provencher MT[2], Solomon DJ[3], Navaie M[4]
[1]*Advance Health Solutions, La Jolla, CA, USA,* [2]*Naval Medical Center San Diego, San Diego, CA, USA,* [3]*Marin Orthopedics and Sports Medicine, Novato, CA, USA,* [4]*Advance Health Solutions, LLC, La Jolla, CA, USA*

OBJECTIVES: Chondrolysis is defined as the rapid and diffuse loss of articular cartilage, typically within 12 months after surgery. Although described in nearly all diarthroidial joints, recent studies have shown that chondrolysis has been misdiagnosed in numerous case reports. This study aimed to determine contributing factors associated with the misdiagnosis of chondrolysis to help improve accurate diagnostication and clinical decision making. **METHODS:** A systematic literature review identified 128 publications on 783 joints (626 hips, 128 shoulders, and 29 knees) diagnosed as chondrolysis. Among these, 72 joints (48% knees, 9% shoulders, and 7% hips) were determined to be misdiagnosed by consensus across five orthopaedic surgeons. A broad range of data was examined in relation to misdiagnosis. For all cases, the presenting diagnosis and surgical procedure(s) as well as other potential contributors including chemical, thermal, and mechanical factors were examined to estimate the differential risk of rapidly developing osteoarthritis which was categorized as low, moderate, or high. Descriptive statistics, bivariate comparisons, and multivariate regression analyses were performed, with $p<0.05$ denoting significance. **RESULTS:** Misdiagnosis of chondrolysis was neither associated with arthroscopic procedures nor chemical, thermal, or mechanical factors during surgery. Among correctly diagnosed cases, the risk of developing rapid osteoarthritis was considered low among 94.4% (671/711), moderate among 1.0% (7/711), and high among 4.6% (33/711). In contrast, among misdiagnosed cases, 13.9% (10/72) of presenting diagnoses were considered low risk for osteoarthritis, 19.4% (14/72) moderate, and 66.7% (48/72) high. After adjusting for potential confounders, the single most significant predictor associated with misdiagnosis of chondrolysis was a presenting medical condition that increased the risk of developing rapid osteoarthritis ($p<0.01$). **CONCLUSIONS:** Misdiagnosis of chondrolysis appears to be strongly correlated with the risk of rapidly developing osteoarthritis, a pathology that is characterized by chronic and focal degeneration of cartilage rather than rapid and diffuse cartilage loss that signify chondrolysis.

PSU6
LONG TERM EFFECTIVENESS OF LIMBAL RELAXING INCISION (LRI) DURING CATARACT SURGERY TO CORRECT ASTIGMATISM

Gauthier L[1], Lafuma A[2], Robert J[3], Kunisk-Joinville O[3], Berdeaux G[4]
[1]*Polyclinique côte Basque Sud, SAINT JEAN DE LUZ, France,* [2]*CEMKA-EVAL, Bourg la Reine, France,* [3]*Cemka Eval, Bourg la Reine, France,* [4]*Alcon France, Rueil-Malmaison, France*

OBJECTIVES: Correction of astigmatism during cataract surgery is important to free the patient from distance vision spectacles. Several techniques are available: Laser, Toric intraocular lenses and LRI. This abstract reports on the long term effectiveness of LRI. **METHODS:** The charts of all patients having had LRI during cataract surgery done by LG were extracted. The LRI consisted of a 6 mm length contra-lateral limbal incision with a 600μm depth calibrated lancet. The main outcome was objective keratometry. Vector analysis was conducted according to Alpins and Goggin. Success was defined as at least one diopter cylinder reduction in its axis (+/− 22.5°), independent of the pre-operative astigmatism (emmetropia was not the objective). Keratometries performed before 3 months were not taken into account in the survival analyses (Kaplan-Meyer). **RESULTS:** A total of 129 eyes were included in the analysis. Patients mean age was 68.3 and the sex ratio was 47 males: 53 females. Average follow-up was 2.0 years. On average, the cylinder was 1.8D (1.1) before surgery and 1.4D (0.9) at one year. No major axis shift was observed on average (from -1.6° at week 4 to 2.9° after 2 years) while its standard deviation was high (from 73° at week 4 to 62° after 2 years). Success rates were 78% at week 50, 48% at week 100 and 23% at week 250. **CONCLUSIONS:** A 6 mm length contra-lateral limbal incision does not allow a 1D cylinder correction. The predictability of correcting astigmatism along the cylinder axis is low. Consequently, the success rate is low at week 50 and declining over the long term. The probability to be free of distance vision glasses and to realize the associated savings is uncertain with LRI. Lastly, interpreting effectiveness results of LRI based on vector analysis parameter averages is misleading.

PSU7
IMPLICATIONS OF ALLOARTHROPLASTIC INFECTIONS IN HIP AND KNEE SURGERY

Letsch R[1], Juelicher P[2], Letsch J[3], Graf J[3]
[1]*Vivantes Humboldt Klinikum, Berlin, Germany,* [2]*Johnson & Johnson Medical, Norderstedt, Germany,* [3]*Charité, Berlin, Germany*

OBJECTIVES: Evaluation of diagnostic, epidemiological, microbiological, surgical, and economic parameters of periprosthetic hip and knee infections. **METHODS:** Data of a large Berlin hospital group (>5000 beds) were analysed over 3 years for the above mentioned criteria. **RESULTS:** A total of 7524 arthroplasties from January 1, 2007 - December 2009 were performed because of femoral neck fractures and arthritis of hip/knee; 18.1% of them were revisions, 319 of these (259 patients) due to infection. All received major revision surgery; i.e. 208 patients underwent 1 revision, 43 patients 2, 7 patients 3, and 1 patient 4. Pathogen organisms were 57 x coag-neg. Staphylococci, 54 x Staph. aureus, 21 x Enterococci, and 19 x Streptococci, with a wide variety of further bacteria in fewer numbers. 72 SSI-infections were multibacterial. MRSA was encountered 8 x. In 99 specimen bacteriology was negative. Most revisions were performed as two-stage procedures. Pre-op joint puncture was carried out 92 x, with a positive result in 59 cases. Antibiotic treatment was more effective, when pre-op bacterial diagnosis permitted a targeted drug application. Age and ASA classification played no role in the prevalence of periprosthetic infections. There were differences between hospitals, septic surgery ranging from 4.5% up to 40.9% of all operative revisions (specialized departments). Length and frequency of hospital stay were extended grossly, when infection occurred, as well as the number of diagnostic and therapeutic measures. Besides the individual disaster this resulted in a large increase in total cost for septic revision surgery. **CONCLUSIONS:** Periprosthetic infections represent a catastrophe for the patient, a burden for the therapeutic team and an economical hazard for society. Methods to avoid this complication are high hygienic standards, early clinical detection of infection, meticulous, repeated bacterial diagnostics, radical surgery, and specific antibiotic treatment. The present study confirms these recommendations by analysis of >300 surgical revisions of alloarthroplastic infections.

PSU8
RISKS AND BENEFITS OF ACRYSOF® CACHET™ IMPLANTATION IN HIGH MYOPIA (≥-6 DIOPTRE): A SYSTEMATIC LITERATURE REVIEW

Siddiqui MK[1], Mann K[1], Vonmaltzahn R[2], Ternouth AM[2], Verboven Y[3], Berdeaux G[4]
[1]*Heron Health Private Ltd, Chandigarh, Chandigarh, India,* [2]*HERON Evidence Development Ltd, Luton, UK,* [3]*Alcon Research Ltd, Puurs, Belgium,* [4]*Alcon Research Ltd, Rueil-Malmaison, France*

OBJECTIVES: To assess risks and benefits associated with AcrySof® Cachet™, other marketed phakic intraocular lenses (PIOLs) in Europe, and laser refractive surgery (RS) in patients with high myopia (HM). **METHODS:** MEDLINE, Embase, and Cochrane databases were searched for randomised controlled trials and observational studies conducted in HM patients. Two reviewers undertook data extraction followed by reconciliation of included studies. Meta-analysis was performed to combine comparative data; weighted means were calculated for single arm studies. The quality of single arm studies was assessed using Downs and Black checklist (score ≥12: excellent quality). **RESULTS:** Of 1853 abstracts screened, 51 studies (23 comparative, 28 single arm studies) were included. Results were statistically significant in favour (OR, 95% CI) of PIOLs compared to RS for manifest refractive spherical equivalent (MRSE) within ±0.50D (3.42, 1.19–9.90), gain of ≥1 lines of best spectacles corrected visual acuity (BSCVA) (5.28, 1.26-21.97), and fewer secondary refractive procedures (0.18, 0.10–0.33). Mean quality index score was 15.04. Baseline characteristics including myopia severity and anterior chamber depth were comparable across studies. AcrySof® Cachet™ showed favourable efficacy for uncorrected distance visual acuity of 20/20 in 46.2% eyes at 3 years post-operative (Artisan and Visian had 40.8% and 31.0% eyes respectively). Percentage of eyes needing spectacles (criteria: MRSE not within ±0.50D) were 43.45%, 17.19%, and 6.14% for Visian, Artisan, and AcrySof® Cachet™ respectively. For safety, the loss of ≥1 lines of BSCVA was 0.56% in AcrySof® Cachet™ and 2.25%, 13.16% for Artisan and Visian respectively. Annualized post 6 month endothelial cell loss (0.41%) was within the expected rate of natural loss (0.6%±0.5%). **CONCLUSIONS:** PIOLs were associated with proven favourable efficacy and safety compared to RS. Amongst PIOLs, within the first 3 years AcrySof® Cachet™ has shown favourable efficacy and safety. Comparative trials are required to confirm the robustness of results.

PSU9
INCIDENCE OF MAJOR SURGERIES IN PATIENTS WITH METASTATIC COLORECTAL CANCER

Wang S, Gao SK, Barber B, Wagner V, Zhao Z
Amgen, Inc., Thousand Oaks, CA, USA

OBJECTIVES: Surgical procedures may potentially interfere with anticancer drug therapy for metastatic colorectal cancer (mCRC). The objective of this study was to examine the proportion of patients with mCRC who underwent major surgeries. **METHODS:** Using a large US medical claims database from a nationally commercially-insured population, patients with diagnosed mCRC between January 2004 and March 2010 were identified. The first metastasis diagnosis date served as the index date. Patients were followed from the index date to death, disenrollment, or end of the study period, whichever occurred first. Major surgery was defined according to the list of major surgeries developed by the National Committee for Quality Assurance using Current Procedural Terminology procedure codes. Major surgeries were examined by anatomic locations: 1) colon or rectum; 2) liver or lung; and 3) all other anatomic sites. Major surgeries on colon or rectum were assessed separately, since they likely include a high percentage of interventions to remove primary tumors. The proportion of major surgeries was descriptively analyzed. **RESULTS:** The study sample included 4768 mCRC patients who met the study inclusion and exclusion criteria between January 2004 and March 2010. Mean age was 60.0 years old and 45.9% of patients were female. Mean length of follow-up observation period was over one year (414 days). Overall, 42.3% of patients had at least one major surgery on anatomic sites other than colon/rectum after mCRC diagnosis. By anatomic locations, 17.6% of patients had major surgeries on liver or lung (13.4% on liver and 4.9% on lung); and 32.3% had major surgeries on all other anatomic sites. Major surgeries on colon or rectum occurred in 35.9% of patients (32.9% on colon and 4.1% on rectum). **CONCLUSIONS:** Major surgeries are highly prevalent in patients with mCRC from this commercially insured population after mCRC diagnosis. This might have implications for anticancer drug therapy in mCRC patients.

Surgery – Cost Studies

PSU10
ECONOMIC EVALUATION OF MAGNETIC RESONANCE GUIDED FOCUSED ULTRASOUND IN PATIENTS WITH UTERINE FIBROIDS IN GERMANY

Alvarez-Ossorio L[1], Burkowitz J[1], Nackunstz I[2], Brueggenjuergen B[1]
[1]*Alpha Care GmbH, Celle, Germany,* [2]*Philips GmbH, Hamburg, Germany*

OBJECTIVES: Costs related to Magnetic Resonance Guided Focused Ultrasound (MR-HIFU) for uterine fibroids have not been compared to alternative treatments being performed in Germany up to now. Hence, the purpose of this analysis was to identify the cost-consequences of hysterectomy, myomectomy, uterine artery embolization (UAE) and MR-HIFU in the first year of therapy. In addtition the budget impact of the MR-HIFU from the perspective of the NHS (direct costs) and social perspective (indirect costs) should be analysed. **METHODS:** The cost of leiomyoma-

related hospitalization and patient follow-up was calculated based on data from statistics of the Hospital Remuneration System, the G-DRG hospital payment scheme and the office-based doctors' fee scale. The cost caused due to recovery and disability was estimated based on information from the Federal Statistical Office and data of the Federal Health Reporting. Experts were interviewed to provide follow-up resource use information. **RESULTS:** A total of 78,229 hospitalized leiomyoma-related cases were treated in year 2009. 80% were hysterectomies, 14% myomectomies and 6% were related to other therapies. Concerning the therapy cost per patient, hysterectomy reveals the highest therapy cost, (€5913) followed by myomectomy (€5793), UAE (€4675) and MR-HIFU (€4311). In a scenario without MR-HIFU the cost per case accrued to a total of €5840. The budget impact analyse targeting a patient group between 30 and 45 years of age, reveals a potential cost-benefit of €1529 per patient if MR-HIFU would be introduced in the SHI system. **CONCLUSIONS:** Our results suggest that MR-HIFU due to the administration in the outpatient sector, the low complication rate and the low disability cost should be considered as a cost-favourable alternative for the therapy of uterine fibroids.

PSU11

MEDICO-ECONOMIC ANALYSIS OF THE IMPACT OF MALNUTRITION ON THE POST-OPERATIVE COURSE OF COLORECTAL CANCER PATIENTS

Preaud E[1], Melchior JC[2], Carles J[3], Brami M[4], Duru G[5], Fontaine E[6], Hébuterne X[7], Lukacs B[8], Zazzo JF[9], Panis Y[10], Nitenberg G[11]
[1]*Mapi Values, Lyon, France,* [2]*R. Poincaré Hospital, APHP, Garches, France,* [3]*JNB-Développement, Paris, France,* [4]*Technical Agency for Information about Hospitalization, Paris, France,* [5]*Cyklad Group, Rilleux la Pape, France,* [6]*University Hospital Center, Grenoble, France,* [7]*University Hospital Center, Nice, France,* [8]*Tenon Hospital, APHP, Paris, France,* [9]*Antoine-Béclère Hospital, APHP, CLAMART , France,* [10]*Beaujon Hospital, APHP, Clichy, France, Paris* [11]*University, Paris, France*

OBJECTIVES: The aim of this study was to assess the clinical and economic impact of malnutrition in post-surgery colorectal cancer patients. **METHODS:** We performed post-hoc analyses of the data collected in the Alves and al* prospective study. The following criteria for malnutrition were used: weight loss >10% in the 6 months pre-surgery and/or BMI<18.5 (pts <70 years) or <21 (pts ≥70 years). 2 groups (gps) were created a posteriori: Well-Nourished (WN) and Malnourished (MN) pts. Postoperative morbidity, mortality, hospital length-of-stay (LOS), and hospital discharge setting were compared between the 2 gps. Individual costs were valued using the French National Cost Study. We defined 3 scenarios: the most accurate estimate and the upper and lower possible limits of this estimate. The economic impact of malnutrition was assessed by calculating the difference in cost per hospital stay between MN and WN pts. **RESULTS:** A total of 762 pts were included in the analyses. Gps had the same characteristics, except more MN pts underwent emergent surgery. Complication rate was not significantly different between the 2 gps; mortality was higher in MN pts (7.4% vs. 4.1%, p=0.056) and MN pts had a mean LOS 3.1 days longer than WN pts (p=0.004). A greater proportion of MN pts could not be discharged and were referred to another facility (69.6% vs. 54.2%, p=0.027). Malnutrition impacts the cost per hospital stay by about 3154€ per patient (most accurate estimate), creating an annual impact of 9,572,770€ for French public hospitals. **CONCLUSIONS:** Malnutrition in colorectal cancer surgical pts is associated with a significant increase of LOS and delays returning home following hospitalization; both have significant budget impact. Prospective studies are needed to further investigate this impact and related cost-benefit of (specialized) nutritional support in this homogeneous category of patients.

PSU12

ESTIMATING COST AND RESOURCE USE FOR WHOLE BRAIN RADIATION VERSUS STEREOTACTIC RADIOSURGERY TREATMENTS AMONG BRAIN METASTASIS PATIENTS

Ganguli A[1], Dacosta Byfield S[2], Teitelbaum A[3], Ray S[1]
[1]*Abbott Laboratories, Abbott Park, IL, USA,* [2]*OptumInsight, Eden Prairie, MN, USA,* [3]*i3 Innovus, Eden Prairie, MN, USA*

OBJECTIVES: To examine real world health care utilization (HCU) and costs associated with whole brain radiation therapy (WBRT) or stereotactic radiosurgery (SRS) as the initial or only treatment of brain metastasis (BrMets). **METHODS:** A retrospective longitudinal analysis utilized claims data from a national health insurer, identifying patients ≥18 yrs with ≥2 claims ≥7 days apart for BrMets (ICD-9 198.3x) from 1/2004-4/2010. The index date was first BrMts claim date. Pre-index period of ≥6 months and ≥1 month post-index enrollment (<1 month was permitted if due to death). Patients with primary brain cancers were excluded. HCU and all-cause per-patient per-month (PPPM) costs were examined. **RESULTS:** The study included 1,901 and 303 patients who received WBRT or SRS as first or only treatment, with 179d vs. 306d follow-up, respectively. Baseline Charlson comorbidity scores were similar. Mean age at BrMets diagnosis was higher for WBRT (59yrs) vs. SRS (57yr) [p-value=0.002]. Rates of HCU (events/person-month) were higher among WBRT vs. SRS patients for office visits (5.29 vs. 3.69), ER visits (0.25 vs. 0.17), and inpatient stays (0.26 vs. 0.17); rates of outpatient visits were lower among WBRT patients (2.31 vs. 3.24) [p-value<0.001]. Total costs PPPM were higher for the SRS ($20,682) vs. WBRT cohort ($16,909) [p-value=0.005]. Outpatient costs PPPM was the major cost-driver among the SRS cohort ($8,936, 43% of total) vs. $3,192 (19% of total) for WBRT. Office costs PPPM contributed most to overall cost among WBRT ($3,428, 20% of total) vs. $3,053 (18% of total) for SRS. Pharmacy costs PPPM were higher for the SRS ($1,232) vs. WBRT cohort ($692) [p-value <0.001]. **CONCLUSIONS:** BrMets patients with SRS incurred higher cost compared to WBRT patients. SRS is recommended for BrMets patients with ≤3 lesions and WBRT in >3 lesions may explain longer survival among SRS patients. Additional studies are augmented to understand differences.

PSU13

HEALTHCARE RESOURCES UTILIZATION AND ASSOCIATED COSTS WITH SURGICAL TREATMENT OF DUPUYTRENXS DISEASE IN SPAIN

de Salas-Cansado M[1], Ramírez E[2], Pérez-de la Campa C[3], Ruiz-Antorán MB[4], Muñoz R[2], Barroso V[3], Centeno GA[4]
[1]*Pfizer Spain, Alcobendas, Madrid, Spain,* [2]*Hospital La Paz, Madrid, Spain,* [3]*Hospital Universitario de la Princesa, Madrid, Spain,* [4]*Hospital Puerta de Hierro, Majadahonda, Madrid, Spain*

OBJECTIVES: To estimate the healthcare resource utilization and their associated costs secondary to fasciectomy of Dupuytren's disease treated according with usual medical practice in public hospital centers in Spain. **METHODS:** This multicenter, observational, retrospective cohort study, extracted data through the revision of medical records of three tertiary public hospitals. Each center should recruit 40 patients which were operated for Dupuytren's disease, as principal diagnose of Minimum Data Set, in which the surgical procedure conducted was fasciectomy, during 2007-2009. To collect all the resources consumed during surgery, a healthcare resource utilization form was designed. Demographic (age, gender, occupational status), clinical (time of evolution of the pathology and comorbilities) and healthcare utilization (hospitalizations, medical visits, test, and drugs) data were collected under medical routine. Unitary costs were provided by e-SALUD and BOT data base. **RESULTS:** A total of 123 subjects (86.2% men; 35.8% active workers) were identified. 17.8% of subjects were diagnose of Dupuytren before year 2000; 8.4% between 2000-2005 and 73.8% after 2006. 81.3% of patients had at least one comorbidity, being hypertension (45%) the most frequent. 71.6% of patients were hospitalized in orthopedist (75%) and plastic surgery unit. Mean(SD) length of hospital stay was 1.5(1.1) days. 28.4% there were operated in ambulatory surgery. All the patients had follow-up visits after surgery, 27% needed physical therapy, 88% performed preoperative tests and 8% visit the emergency room after surgery. Healthcare mean costs were as follows: fasciectomy €1074(0); hospitalizations €978(743); ambulatory €186(10); follow-up visits €260(173); emergency rooms €13(53); tests €132(121); drugs €7(9); physical therapy €46(134). Total cost for patients with Dupuytren's disease treated with surgery was €2304(825). There were no significant differences between the three centers analyzed; p=0.181. **CONCLUSIONS:** This evaluation suggest that healthcare resources utilization for surgical treatment for patients with Dupuytren's disease may cost €2,304(825) per surgery (fasciectomy) treated under usual medical practice in Spain.

PSU14

COMPLICATIONS AND COSTS ASSOCIATED WITH TUBAL LIGATIONS

Brewster C[1], Howard B[2], Lage M[3]
[1]*Teva Pharmaceuticals, Kansas City, MO, USA,* [2]*Teva Branded Pharmaceutical Products R&D, Inc., Horsham , PA, USA,* [3]*HealthMetrics Outcomes Research, Groton, CT, USA*

OBJECTIVES: To examine changes in post-tubal ligation complications and their associated costs over time. **METHODS:** Data were obtained from the US i3 Invision™ Data Mart. Data collected spanned the period from January, 2006 through March, 2010. CPT and ICD-9 codes were used to identify patients who received a tubal ligation as well as a post-tubal ligation complication. Patients were also subcategorized based upon year of tubal ligation (2007, 2008, or 2009) in order to examine if there were any noticeable trends over time. **RESULTS:** There were 15,169 women under age 50 who received a tubal ligation and had continuous insurance coverage in the 1 year post-tubal ligation. The mean age at tubal ligation was 35.26 years (SD=5.46) with 10.46% having tubal ligation at the time of a pregnancy. Overall, 21.68% (n=3,288) of women experienced at least 1 complication, with the most common being heavy menstrual bleeding (n=2,190, 14.44%) and surgical complications (n=729, 4.81%). When assessing changes in complications from 2007-2009, diagnoses of heavy menstrual bleeding (p=0.0003), sepsis (p=0.0392), surgical complications (p=0.0240), and any complication (p<0.0001) all showed statistically significant increases over time. Of all women who had a tubal ligation, charges associated with the tubal ligation did not increase significantly from 2007-2009; however, the charge associated with complications did show a statistically significant increase over the same time period. The average charge for women who experienced a complication (n=3,228) was $37,425 (SD=$68,249). **CONCLUSIONS:** A substantial number of women experience post-tubal ligation complications and the charges associated with these complications have increased significantly over time.

PSU15

THE ECONOMIC BURDEN OF POST-TRANSPLANT EVENTS IN RENAL TRANSPLANT PATIENTS IN UK, ITALY, NETHERLANDS, POLAND AND BELGIUM

Sennfalt K[1], Ling C[2], Pericleous L[3], Sbarigia U[4], Gatta F[5], Kolasa K[6], Zagorska A[6], Chamberlain G[2], Pandit P[7]
[1]*Bristol-Myers Squibb International Corporation, Rueil-Malmaison, France,* [2]*Cardiff Research Consortium Ltd, Cardiff, UK,* [3]*Bristol-Myers Squibb UK, Middlesex, UK,* [4]*Bristol-Myers Squibb International Corporation, Braine - L'Alleud, Belgium,* [5]*Bristol-Myers Squibb Italy, Rome, Italy,* [6]*Bristol-Myers Squibb Poland, Warszawa, Poland,* [7]*Cardiff Research Consortium, Capita India, Mumbai, India*

OBJECTIVES: There are limited data currently available regarding the prevalence of post-transplant events and associated resource utilization in renal transplant patients in clinical practice. This study aims to describe the healthcare resource utilization and costs of managing patients after renal transplantation, stratified by relative graft functioning status, using observational data from relevant databases and physician questionnaires from transplant centres across Europe. **METHODS:** Data from renal databases in Cardiff and Leuven University Hospitals have been analysed to assess 3-year post-transplant resource use in the UK and Belgium, respectively. Similar data have been derived from questionnaires administered in

multiple centres in UK, Italy, The Netherlands and Poland. For each country, published local costs have been applied to the resource use. Results have been stratified by glomerular filtration rate (GFR) at one-year post-transplant. **RESULTS:** Across these countries, the total three-year cost of post-transplant care varies depending on local treatment practices, from a minimum of €36,000 per patient in Poland to a maximum of €77,000 in the The Netherlands. Consistently across all countries, the average three-year costs decrease as a result of improved graft functioning status (increased GFR) at one year. The average three-year costs for a patient with a GFR≥45 at one year are 29% lower than those with <30GFR in the The Netherlands, 40% lower in Italy, 43% lower in Belgium, 50% lower in the UK, and 51% lower in Poland. **CONCLUSIONS:** This study demonstrates that in five European countries, worsening post-transplant renal function contributes to substantive increases in resource use, with some variation across regions. Therefore management strategies that promote renal function after transplantation are likely to provide important resource savings. Additional analyses are ongoing in Spain, Czech Republic, Hungary, Germany and Sweden to further confirm these observations.

PSU16

MINIMALLY INVASIVE SURGERY IN TOTAL HIP ARTHROPLASTY: A COST-EFFECTIVENESS ANALYSIS

Navarro espigares JL[1], Hernandez torres E[1], Ruiz arranz JL[2]
[1]*Hospital Universitario Virgen De Las Nieves, Granada, Spain,* [2]*Area Sanitaria Serrania De Ronda, Ronda, Spain*

OBJECTIVES: The main objective of this study is to evaluate the cost-effectiveness of total hip arthroplasty through anterolateral minimally invasive surgery (MIS) and compare it with the traditional approach. **METHODS:** A study was conducted to compare traditional and minimally invasive surgical techniques for total hip arthroplasty in a population of 340 patients at two Spanish hospitals (the Virgen de las Nieves University Hospital of Granada and the Serranía de Ronda Hospital) during the year 2007. The design of the study was a prospective stochastic cost-effectiveness analysis, where effectiveness data were collected over a one-year period at individual patient levels and costs were gathered from the analytical accounting system of Virgen de las Nieves University Hospital. Effectiveness was measured in functional terms (clinical) and self-perceived quality of life (SF-12 survey) during the first 6 postoperative weeks. **RESULTS:** After 6 postoperative weeks, in comparison with the conventional technique, a pattern in improvements for MIS was observed for length of hospital stay (hospitalization time was 4.97 days shorter); for operative time (an average of 83.3 minutes for MIS patients and 97.8 minutes for the control group); and for average length of skin incision (9.83 cm. for the MIS group and 16.2 cm. for the control group). The total cost of THA with MIS was lower (4519.19 €) than the cost of traditional hip replacement (6722.46 €). Incremental effectiveness value in terms of quality of life was 0.11 points in the SF-12 survey for MIS. The cost-effectiveness analysis reveals a strong dominance of MIS versus traditional THA. **CONCLUSIONS:** The study showed that the minimally invasive technique reduces inpatient resource utilization and improves self perceived quality of life of patients compared with the traditional approach. The more beneficial incremental effectiveness ratio of MIS versus traditional THA supports the recommendation for expanded use of minimally invasive surgery.

PSU17

COST-EFFECTIVENESS OF DSAEK VERSUS PK FOR CORNEAL ENDOTHELIALDISEASE

Patel S, Kaakeh R, Shtein R, Smith D
University of Michigan, Ann Arbor, MI, USA

OBJECTIVES: To perform a comparative cost-effectiveness analysis of Descemet's stripping automated endothelial keratoplasty (DSAEK) and penetrating keratoplasty (PK) for corneal endothelial disease. **METHODS:** Systematic review of the peer-reviewed English literature through a search of PubMed to populate a 5 year model of a) quality adjusted life years (QALYs) associated with clinical outcomes of the relatively new DSAEK procedure and the long-established PK procedure, and b) third party payer (US Medicare 2010) costs associated with associated medical, surgical and pharmaceutical services. **RESULTS:** Five year follow-up focusing on standard therapy and complications yeilds 2.99 QALYs associated with DSEAK and 1.94 QALYs with PK, a difference of 1.05. Following slightly higher sugical costs of $US7925 for DSEAK and $US7544 for PK, total five year costs are $US10,104 associated with DSEAK and $US9840 with PK, a difference of $US264. The ICUR is $US251. Sensitivity analyses of differeing disc dislocation rates, astigmtism complication rates and cost parameters yield ICURs in the range of $US0 to $US500. **CONCLUSIONS:** Using the literature on outcomes and costs for treatments of corneal endothelial disease, a five year model yields robust results siggesting that DSEAK is slightly more expensive procedure than PK to third party payers, but with favorable quality adjusted life year resulting making DSEAK a cost-effective option under all scenarios considered.

PSU18

COST-UTILITY ANALYSIS OF LAPAROSCOPIC VERSUS OPEN SURGERY FOR COLORECTAL CANCER

Callejo D, Guerra M, Reza M, Maeso S, Blasco JA
Agencia Laín Entralgo, Madrid, Spain

OBJECTIVES: To assess the comparative efficiency of laparoscopic versus open surgery in colorectal cancer patients. **METHODS:** To establish relative efficacy of laparoscopic versus open surgery in all measures that could have clinical or economic relevance. Using previous systematic reviews and updating their contents with the new information published after. Meta-analysis technique is used to summarize the information. A Markov model is developed to estimate progress in time of health and resource use obtained with these two alternatives. Measures of health outcomes used in the model were life years and quality adjusted life years. Probabilistic sensitivity analysis was performed to assess uncertainty in the parameters included in the Markov model. **RESULTS:** Preliminary results show that cost of laparoscopic-assisted surgery is higher than open surgery in close to 750 €. This difference decreased slightly in the immediate postoperative period due to the lower readmission rate. The difference in costs, coupled with the equivalence in long-term results obtained by the two techniques makes that any of them can be considered efficient for our health system. Since considering a willingness to pay between 20,000 and 30,000 € per quality-adjusted life year gained, none of the alternatives have above 60% chance to be the best option. **CONCLUSIONS:** The laparoscopic-assisted resection has shown results in terms of overall survival and recurrence similar to those achieved by open surgery in colorectal surgery patients. The estimated cost for laparoscopic intervention is slightly higher than open surgery, but seems to accelerate the postoperative recovery time. This implies that none of the two alternatives is clearly superior to the other in terms of efficiency. Therefore, each decision maker at hospital level will assess available human and material resources, and its cost structure to use resources more efficiently.

PSU19

THE DOORS-STUDY OF ON-PUMP VERSUS OFF-PUMP CORONARY ARTERY BYPASS GRAFTING: A POST HOC ANALYSIS OF METHODS FOR MULTIPLE IMPUTATION OF MISSING DATA IN ECONOMIC EVALUATION

Ehlers L[1], Fenger-grøn M[2], Beck SS[3], Houlind K[4], Lauridsen J[5]
[1]*Department of Business Studies, Aalborg, Denmark,* [2]*Department of Clinical Epidemiology, Aarhus University Hospital, Denmark & Research Unit for General Practice, Aarhus University, Aarhus, Denmark,* [3]*HTA & Health Services Research, Centre for Public Health, Central Denmark Region, Aarhus, Denmark,* [4]*Dept. of Cardiothoracic and Vascular Surgery, Aarhus University Hospital, Denmark, Aarhus, Denmark,* [5]*The Research Unit of Health Economics, University of Southern Denmark, Denmark, Odense, Denmark*

OBJECTIVES: A cost-utility analysis was conducted alongside the Danish On-pump Off-pump Randomization Study (DOORS) based on the intention to treat principle. **METHODS:** A post hoc analysis of the problem of missing data was addressed by multiple imputation using the conditional Gaussian as well as the chained equation approach. Both methods where applied using two different models (representing a data-driven respectively a clinical reasoning selection strategy). **RESULTS:** The cost-effectiveness acceptability curve for the complete case analysis (n=779) showed 88 % probability of OPCAB being cost-effective at a threshold value of £30.000 per QALY. In analyses based on the conditional Gaussians approach and the chained equations approach to multiple imputation the results was 73-75 %. **CONCLUSIONS:** The result of the previously published complete-case analysis of the cost-effectiveness of OPCAB versus CCABG was reinforced by this post hoc analysis of the uncertainty due to missing data. The analysis showed that the conditional Gaussian approach and the chained equations approach produced similar results Evidence about the long term cost-effectiveness of OPCAB versus CCABG is warranted.

Surgery – Patient-Reported Outcomes & Preference-Based Studies

PSU20

ESTIMATING PREFERENCES FOR ECONOMIC EVALUATION IN PATIENTS WITH LOCALIZED PROSTATE CANCER

Avila MM[1], Becerra V[1], Cunillera O[1], Pardo Y[2], Ferrer M[3]
[1]*IMIM (Institut de Recerca Hospital del Mar), Barcelona, Catalunya, Spain,* [2]*IMIM (Institut de Recerca Hospital del Mar), Barcelona, Barcelona, Spain,* [3]*IMIM-Hospital del Mar, Barcelona, Barcelona, Spain*

OBJECTIVES: The high variability on preferences estimates for prostate cancer could be explained by differences in methods, techniques and obtaining populations. Our aim was to estimate the preferences and willingness to pay of patients in the "Spanish Multicenter Study of Localized Prostate Cancer" at 5 years of follow-up, according to the treatment received (radical prostatectomy, external radiotherapy and brachytherapy). **METHODS:** Data analyzed were from the 5-year follow-up evaluation of the "Spanish Multicenter Study of Localized Prostate Cancer", in which patients completed the preference questionnaire. The estimation of preferences was conducted using the indirect method (from the SF-6D index), and the direct method using the Standard Gamble (SG) and Time Trade-Off (TTO) techniques. We also assessed the patients' Willingness-to Pay (WTP). The three treatment groups were compared using the Kruskall Wallis test. **RESULTS:** Of the 441 patients enrolled, 105 were treated with radical prostatectomy, 137 with external radiotherapy and 199 with prostate brachytherapy. Most patients were married or living with a partner (89.6%), were retired (76%) and had completed primary or secondary studies (53.5%). Utilities measured with the SF-6D showed no statistically significant differences by treatment group ($p = 0.356$). The utilities measured by TTO presented the greatest differences according to treatment: mean of 0.94 in the radical prostatectomy group, 0.99 in external radiotherapy and 0.98 in brachytherapy ($p < 0.001$). The willingness to pay also showed significant differences: mean of 58.4 € in the radical prostatectomy group, 32.04 € in external radiotherapy and 28.8 € in brachytherapy ($p < 0.01$). **CONCLUSIONS:** The estimates of preferences vary according to the method and the technique used to obtain them. Both the utilities obtained by the direct method and the ones through willingness to pay indicate that radical prostatectomy is the worst valued treatment, prostate brachytherapy being the most valued by patients with localized prostate cancer.

PSU21

SPEECH PROBLEM AND HEALTH-RELATED QUALITY OF LIFE IN HEAD AND NECK CANCER SURVIVORS AFTER FIVE YEARS OF TREATMENTS

Payakachat N[1], Suen JY[2]

[1]University of Arkansas for Medical Sciences, College of Pharmacy Little Rock, Little Rock, AR, USA, [2]University of Arkansas for Medical Sciences, Little Rock, AR, USA

OBJECTIVES: Advanced head and neck cancer (HNC) survivors may have permanent alteration in their ability to communicate with others. Health-related quality of life (HrQOL) outcomes have been emphasized as an important issue in cancer survivors. This study compared HrQOL of the HNC survivors (five years after primary treatments) who had speech problem (SP) to who did not (NSP). We also explored sensitivity of HrQOL instruments relative to this problem. **METHODS:** This study was observational, mailed survey study. Target samples were individuals who received HNC treatments before 2005. We identified subjects through the Central Arkansas Radiation Therapy Institute Registry or recurited by phiysicinas of the university Head and Neck Surgery Unit. Self-perceived speech problem and HNC-specific HrQOL outcomes were determined using the University of Washington Quality of Life Questionnaire (UW-QOL) version 4. HrQOL outcomes were also described using the EQ-5D and the SF-6D. A rank analysis of covariance was performed to test for differences between the two groups on HrQOL outcomes, adjusted for years after treatment, treatment received, and cancer site. We expected that a sensitive HrQOL instrument would produce significant lower HrQOL scores for the SP group when compared to the NSP group at p-value < 0.05. **RESULTS:** Forty-seven HNC survivors' HrQOL were analyzed (78% response rate). Survivors' age averaged 65 years (SD=13) and the average years after the primary treatment was 8 years (SD=2). 16 (34%) reported having speech problems (SP group). The UW-QOL-Composite and the SF-6D scores in the SP group were significant lower than the NSP group (62±16 vs. 78±15, p=0.007; 0.66±0.12 vs. 0.78±0.16, p= 0.023). While there was no difference on the EQ-5D scores between the two groups (0.78±0.16 (SP) versus 0.84±0.14 (NSP), p=0.252). **CONCLUSIONS:** HNC survivors with self-perceived speech problem reported significant lower HrQOL. The UW-QOL and the SF-6D are sensitive to detect HrQOL difference relative to speech problem.

PSU22

PERFORMANCE OF THE FUNCTIONAL ASSESSMENT OF VISUAL TASKS (VISTAS-18) AMONG CATARACT PATIENTS RECEIVING MONOFOCAL AND MULTIFOCAL INTRAOCULAR LENS IMPLANTS

Heichel CW[1], Kozak I[2], Fellows I[3], Tally S[4], Atkinson MJ[4]
[1]Shiley Eye Center, University of California, San Diego, La Jolla, CA, USA, [2]Jacobs Retina Center, University of California, San Diego, La Jolla, CA, USA, [3]University of California, Los Angeles, Los Angeles, CA, USA, [4]University of California, San Diego (UCSD), San Diego, CA, USA

OBJECTIVES: This study was performed to examine the psychometric performance of the four VISTAS-18 scales (i.e., Near Function, Intermediate Function, Extended-Intermediate Function, Distant Function) to the known benefits of intraocular lens (IOL) surgery, and more subtle differences between monofocal and multifocal IOL types. **METHODS:** Subjects (Ss) were recruited from surgery clinics 2-8 weeks prior to receiving bilateral IOL implants. Visual assessments were conducted at the pre-surgical visit and then after recovery. Following both visits, Ss completed a self-report questionnaire and the VISTAS item pool. The four VISTAS-18 Function Scale scores were evaluated using change from baseline in visual acuity assessments, and as well the type of IOL implant. Responder analyses were conducted for each distance range. **RESULTS:** Ss (n=61) had a mean age of 69.0 years (SD= 9.5) were in good health prior to surgery, although with low satisfaction with their vision and very low satisfaction with their visual aids. Most Ss received monofocal (n=39) or multifocal (n=16) lenses. Uncorrected and corrected visual function improved significantly following surgery on all four VISTAS-18 scales. Greater improvements were observed on the Near (p=0.007) and Intermediate (p=0.017) Function Scales for recipients of multifocal versus monofocal lens. The responder analyses indicated that 10/15 (66%) individuals who received multifocal lenses reported a one or more point reduction in near range task difficulty, and 11/15 (73%) in the intermediate range, compared to only 10/35 (29%) and 16/30 (53%) of individuals receiving monofocal implants. **CONCLUSIONS:** The VISTAS-18 Function Scales performed well, both in terms of changes in visual acuity associated with IOL implantation, as well as in demonstration of responsiveness to more subtle differences in Near and Intermediate function associated with lens type. The clinical implications of reliable assessment of visual tasks in near, intermediate and distant ranges of vision are discussed.

PSU23

REHABILITATION NEEDS AND PREDICTIVE FACTORS OF HEALTH-RELATED QUALITY-OF-LIFE IN BREAST CANCER PATIENTS DURING TWO YEARS AFTER SURGERY - A MULTICENTER PROSPECTIVE STUDY

Shimozuma K[1], Taira N[2], Shiroiwa T[1], Ohsumi S[3], Kuroi K[4], Saito S[5]
[1]Ritsumeikan University, Kusatsu, Shiga, Japan, [2]Okayama University Hospital, Okayama, Okayama, Japan, [3]National Hospital Organization, National Shikoku Cancer Center, Matsushima, Ehime, Japan, [4]Tokyo Metropolitan Cancer and Infectious Diseases Center Komagome Hospital, Tokyo, Tokyo, Japan, [5]Okayama University, Okayama, Okayama, Japan

OBJECTIVES: Provision of psychosocial support and rehabilitation for patients after cancer treatment is important for long-term health-related quality-of-life (HRQOL). Effective use of healthcare resources requires identification of patients requiring rehabilitation. The objectives of this study were to clarify the patterns of physical and psychosocial recovery over time and to identify the significant baseline and treatment-related factors predicting HRQOL at 6 months, 1 and 2 years after breast cancer surgery. **METHODS:** A multicenter longitudinal study was performed to evaluate physical conditions, anxiety, depression and HRQOL at one month, 6 months, and 1 and 2 years after surgery in 196 breast cancer patients. Physical conditions were evaluated using a patient-reported symptom checklist. HRQOL was rated using the Functional Assessment of Cancer Therapy scale-General (FACT-G) and the Breast Cancer subscale. Anxiety and depression were rated using the Hospital Anxiety and Depression Scale (HADS). **RESULTS:** More than 50% of patients had local problems of "tightness", "arm weakness" and "arm lymphedema", and systemic problems of "reduced energy, fatigue, and general weakness" postoperatively. The HRQOL score significantly improved one year after surgery, and scores for physical, emotional and functional well-being also increased with time, whereas the score for social well-being was highest at baseline and decreased with time. Depression and anxiety significantly improved with time. Concomitant disease, marital status and the presence of a partner, anxiety and depression at baseline, pathological lymph node involvement, and adjuvant intravenous chemotherapy were significant factors predicting FACT-G scores at 6 months and 1 and 2 years after surgery. Depression at baseline was a strong predictor of HRQOL up to 2 years after surgery. **CONCLUSIONS:** These results suggest that physical rehabilitation is required for tightness and lymphedema, and a further study of psychosocial interventions is required to improve depression and social well-being.

PSU24

COMPARISON OF THE RESPONSIVENESS OF THE SF-36 AND THE RAW AND RASCH-BASED SCORES OF THE OXFORD KNEE SCORE IN PATIENTS UNDERGOING TOTAL KNEE REPLACEMENT

Ko Y[1], Lo NN[2], Yeo SJ[2], Yang KY[2], Chong HC[2], Yeo W[2], Thumboo J[2]
[1]National University of Singapore, Singapore, [2]Singapore General Hospital, Singapore

OBJECTIVES: To compare the responsiveness of the generic Short Form 36 (SF-36) and the raw and Rasch-based scores of the condition-specific Oxford Knee Score (OKS) in patients undergoing total knee replacement (TKR) **METHODS:** Adult patients undergoing TKR in a hospital of Singapore between 2001 and 2006 completed the SF-36 and OKS at baseline and at 6 and 24 months postoperatively. OKS data were fitted to the Rasch partial credit model using the Winsteps program. Responsiveness was assessed using effect size (ES), standardised response mean (SRM), and relative validity (RV). **RESULTS:** A total of 702 patients who had complete data at baseline and two follow-ups were included in the analysis. After removing items regarding limping and kneeling, the remaining OKS items fit the Rasch model. Bodily pain (BP) and Physical functioning (PF) were more responsive than the other SF-36 domains. In addition, the OKS raw scores (raw-OKS) and Rasch-based modified OKS (Rasch-OKS) were consistently more responsive than all eight SF-36 domains. At the 6-month follow-up, Rasch-OKS had the largest ES whereas raw-OKS had the largest SRM (2.7 and 1.9, respectively). When compared to raw-OKS, the RV of Rasch-OKS, BP, and PF were 1.5, 2.0, 2.8, respectively. Similar order was observed at the 24-month follow-up. **CONCLUSIONS:** The OKS is more responsive than the SF-36 in patients undergoing total knee replacement. The raw and Rasch-based scores of OKS have comparable responsiveness. Different responsiveness indices may give different results.

Surgery – Health Care Use & Policy Studies

PSU25

EFFECTIVENESS OF MINIMALLY INVASIVE SURGERY FOR TOTAL HIP ARTHROPLASTY

Navarro Espigares JL[1], Hernandez Torres E[1], Ruiz Arranz JL[2], Padial Ortiz MA[1], Aranda Villalobos P[3]
[1]Hospital Universitario Virgen De Las Nieves, Granada, Spain, [2]Area Sanitaria Serrania De Ronda, Ronda, Spain, [3]Hospital Universitario Virgen de las Nieves, Granada, Spain

OBJECTIVES: The main objective of this review is to determine the effectiveness of total hip arthroplasty with MIS compare to the traditional approach. Specifically, this appraisal aims to answer questions related to functionality, quality of life, and clinical results. **METHODS:** The bibliographic review was conducted in two phases: an initial phase of search for appropriate studies and a second phase of selection according to previously established criteria. The search for articles was carried out in major databases and subsequently in bibliographical references for the studies found. The databases reviewed were MEDLINE/PubMed/MeSH Database, EMBASE, Economic Evaluation Database/DARE/HTA, CSIC/EMI-Biomedicine, and ScienceDirect Collection. The search period was limited to the years 2003 to 2009. The selection of items was made at an early stage by screening article summaries followed by full texts. **RESULTS:** We initially selected more than 600 studies, 78 for detailed evaluation, and 32 final studies for inclusion in the review. The results of this review are presented in two sections. The first represents the main descriptive characteristics of the studies selected in favor of MIS (19), and the second presents the unfavorable studies (13). Among the main benefits we found a decrease of transfusion requirements, better mobilization and rehabilitation, low dislocation, reduced surgical time, shorter hospital stays, less soft tissue damage, and better short term results. The main drawbacks were increased risks of complications, malposition of prosthesis, healing problems, and irrelevant clinical incision size and functionality. **CONCLUSIONS:** The studies presented in this review show clear evidence of how MIS influences the effectiveness related to functional outcomes, hospital stays, and surgical aggressiveness of the intervention. In this regard, we found a greater number of comparable studies supporting minimally invasive surgery in terms of effectiveness than those that emphasize complications and disadvantages of this technique.

PSU26

TWO-YEAR CHANGES IN GENERIC AND OBESITY-SPECIFIC QUALITY OF LIFE AFTER GASTRIC BYPASS

Mar J[1], Arrospide A[1], Mar B[2], Martinez de Aragón G[3], Karlsson J[4]

[1]Hospital Alto Deba, Mondragon, Spain, [2]Donostia Hospital, Donostia-San Sebastian, Spain, [3]Txagorritxu Hospital, Vitoria-Gasteiz, Spain, [4]Göteborg University, Göteborg, Sweden

OBJECTIVES: The first objective was to assess the two-year changes in quality of life after gastric bypass in patients with severe obesity. Second, we analysed the effect of weight reduction on the different HRQL dimensions in the framework of the International Classification of Functioning, Disability and Health (ICF). **METHODS:** We carried out a prospective intervention study with consecutive patients referred to two bariatric surgical units in the Basque Country. We included generic (SF-36, EuroQuol 5D) and specific questionnaires (Moorehead-Ardelt, Obesity-related Problems scale). The SF-36 mental and physical dimensions and stigma theory, allowed us to apply an approach based on the ICF. We measured effect size (ES), standardized response mean (SRM) and ROC curves. **RESULTS:** Of 82 operated patients, 79 were tracked for 2 years. Average weight loss was 49 kg (28%) and BMI was reduced from 50.6 to 31.8. The initial problems and the final improvements were larger in the physical dimensions. The benefit of treatment was large for almost all HRQL domains as measured by EQ-5D, SF-36, OP and Moorehead-Ardelt. Only the improvements in some of the mental domains of the SF-36 were classified as small or moderate. ROC curves were not sensitive to change in BMI. **CONCLUSIONS:** We suggest that the negative impact of severe obesity on HRQL is mainly a cause of disability as described in the ICF. Two-year improvements in HRQL are related to recovery from disability after gastric bypass treatment. The primary focus on the physical dimension is not contradictory with evidence of the impact of weight-related stigmatization in obese individuals at the social level and its consequences in mental health. In the ICF framework,

Surgery – Research On Methods

PSU27

FRACTURE RELATED TREATMENTS AFTER PRIMARY SURGICAL INTERVENTIONS OF HIP FRACTURE EIGHT YEARS FOLLOW UP

Sebestyén A[1], Gresz M[2], Patczai B[3], Mintál T[3], Varga S[3], Molics B[3], Boncz I[3]
[1]South-Trasdanubian Regional Health Insurance Fund Administration, Pécs, Hungary, [2]National Health Insurance Fund Administration, Budapest, Hungary, [3]University of Pécs, Pécs, Hungary

OBJECTIVES: The aim of our retrospective study was to analyze the further fracture related treatment/complication after primary treatment of femur neck fracture according to most frequently used types of operation. **METHODS:** The data derive from the financial database of the Hungarian National Health Insurance Fund Administration, based on the 10th revision of the International Classification of Diseases (ICD) with ICD code S7200. The following patients were included into the study: having social insurance identification number, being discharged from hospitals in 2000 after primary treatment of femur neck fracture, over the age 60. The patients with polytrauma or high energy trauma patient were excluded from the study. During the 8 year follow up period the further fracture related treatment and complications were analyzed according to the most frequently used types of operation. **RESULTS:** Altogether 3783 patients were included into the study. The distribution of primary surgical intervention was: arthroplasty 12.5%, screw fixation 73.6%, dynamic hip screw (DHS) 5.1%, femoral neck nailing 5.0%, Ender nailing 1.8%, Gamma nailing 1%, others 1 %. The fracture related treatment rate was 14,5%. The main types of further fracture related treatments are listed: 5.7% hip replacement, metalwork removal 3.6%, replacement of implants 2.48%, aseptic and septic look: 1.7%, 0.7% resection arthroplasties. The further fracture related treatment rate according to the most frequently used types of operation: arthroplasty 4.8 %, screw fixation: 16.1 %, DHS: 7.8%, femoral neck nailing: 21.5%, Ender nailing: 19.4 %, Gamma nailing: 2.4%. **CONCLUSIONS:** The methods, providing quickly full weight bearing (Gamma nailing, DHS, hip arthroplasty) had lower complication rate, while the methods (screw fixation, Ender nailing, femoral neck nailing) providing partial weight bearing had higher complication rate. The backgrounds of fracture related treatments should be investigated in the future.

PSU28

ECONOMIC IMPACT OF STEREOTACTIC RADIOSURGERY FOR MALIGNANT INTRACRANIAL BRAIN TUMORS

Lal L[1], Franzini L[2], Panchal J[2], Chang E[3], Meyers CA[3], Swint JM[2]
[1]Ingenix Consulting, Missouri City, TX, USA, [2]University of Texas Health Science Center Houston, School of Public Health, Houston, TX, USA, [3]University of Texas M.D. Anderson Cancer Center, Houston, TX, USA

OBJECTIVES: Brain metastases occur in a majority of patients with malignant disease and result in decreased quantity and quality of life. Treatment alternatives range from whole brain radiation therapy (WBRT), neurosurgery, and the newest modality, stereotactic radiosurgery (SRS). This article reviews economic evaluations of SRS in the metastatic setting and compares to other treatment options. **METHODS:** Studies were included if they were published in peer reviewed journals, primarily in patients with malignant brain metastasis, and at least included a cost analysis between interventions **RESULTS:** Uncertainty surrounding the cost-effectiveness of SRS exits due to lack of efficacy information between treatment alternatives, methodological limitations, and design differences between the available studies. However, when cost –effectiveness ratios are available, SRS appears to be a reasonable option in resource limited settings, with incremental cost-effectiveness ratios (ICERS) just below the $50,000 range. **CONCLUSIONS:** Better designed economic analysis in the setting of randomized clinical trials or observational studies need to be conducted to fully understand the economic value of SRS.

DISEASE-SPECIFIC STUDIES

Infection – Clinical Outcomes Studies

PIN1

PHARMACIST PARTICIPATION IN ANTIRETROVIRAL DRUG MONITORING FOR THE PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV AT WARINCHUMRAB HOSPITAL, UBONRATCHATHANI, THAILAND

Choopan K
Chulalongkorn University, Muang , Ubonratchathani, Thailand

OBJECTIVES: Thailand has been one of the leading developing countries to implement a national program to prevent mother-to-child transmission (PMTCT) of HIV. The objective of this study was to determine the impact of pharmacist intervention to monitor HIV-infected pregnant women. Pharmacist provided medication and guideline information including phamacotherapeutic suggestion. **METHODS:** In this research, retrospective study was employed with descriptive statistics using average percentage frequency, making use of out-patients records of treatments in HIV-infected pregnant women who informed about the benefits of taking antiretroviral (ARV) drugs for PMTCT, side effects of ARV drugs, importance of adherence to drugs and the fact that HIV transmission to their infants can possibly occur despite ARV use by pharmacist. **RESULTS:** The HIV-infected pregnant women group of 24 cases, 4 were withdrawn due to unable to follow up, 20 cases have been followed-up and shown the effectiveness of medicine. There were 8 new patients (33.33%) firstly received ARV. The mean CD4 cell counts at baseline of all patients were 227+-69.28 cells/mm3. Most regimens for treatment was highly active antiretroviral therapy containing zidovudine (AZT)+lamivudine (3TC)+lopinavir/ritonavir (LPV/rtv) 41.67% where treated with AZT+3TC+nevirapine were secondly used (33.33%). It was found that 34.4% of patients had adverse drug reactions. The ADR incidence of ARV was 4.0 patients and 6.2 events per 1000 person-day. Gastrointestinal system such as nausea and vomiting were found at 12.50% and 8.33% were diarrhea were the most organ system affected. During the study period, 3 patients had to change ARV regimens because of ADRs. 16.67% were non-compliance but less than 7 days at early period. The rate of MTCT of HIV was 8.33% after monitoring for one year. **CONCLUSIONS:** The results indicated that a medication monitoring and evaluating process by pharmacist associated with improved rational used of drug in HIV-infected pregnant women. This project provides a foundation for future quality improvement.

PIN2

SAFETY AND EFFICACY OF TENOFOVIR AS COMPARED TO OTHER NUCLEOT(S)IDE ANALOGUES IN THE TREATMENT OF CHRONIC HEPATITIS B – A SYSTEMATIC REVIEW WITH MIXED TREATMENT COMPARISON

Wojciechowski P[1], Stozek A[1], Szmyd J[1], Gwiosda B[1], Mierzejewski P[2], Kazmierski M[2], Rys P[1], Wladysiuk M[1], Plisko R[1]
[1]HTA Consulting, Krakow, Poland, [2]Gilead Sciences Poland Sp. z o.o., Warszawa, Poland

OBJECTIVES: The aim of this study was to assess efficacy and safety of tenofovir (TDF) as compared to other nucleot(s)ide analogues (NAs), i.e. lamivudine (LAM), adefovir (ADV) and entecavir (ETV) in the treatment of chronic hepatitis B virus (HBV) infection. **METHODS:** Assessment was based on randomized controlled trials (RCTs) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines. Studies met the inclusion criteria if they directly compared at least two of following interventions: TDF, LAM, ADV, ETV or placebo. The electronic medical databases (EMBASE, MEDLINE, CENTRAL) were searched. Two reviewers independently selected trials, assessed their quality and extracted data. Mixed treatment comparison (MTC) was performed with WinBugs software. If feasible, subgroup analyses were performed according to hepatitis B antigen e (HBeAg) and or LAM resistance status. **RESULTS:** We identified 30 relevant studies (6674 patients) with 12-144 weeks of follow-up . MTC showed that TDF increased the chance of HBV DNA clearance at the end of treatment period as compared to ADV (OR = 13,16 [3,21; 54,20]), LAM (OR = 61,09 [11,10; 503,78]) and ETV (OR = 9,55 [1,53; 76,98]). Subgroup analysis in HBeAg-positive subjects revealed that TDV was more effective than ADV (OR = 21,60 [1,67; 285,40]) and LAM with respect to HBV DNA clearance but no difference were found between TDV and ETV (OR = 11,24 [0,53; 342,57). TDF showed similar efficacy to other NAs with respect to normalization of alanine aminotransferase activity (ALT) and histological improvement. TDF did not increase the risk of any and serious adverse events either in comparison with PLC or with other NAs. The rates of ALT flares were similar in all groups. **CONCLUSIONS:** TDF demonstrated the highest efficacy with respect to reduction of viral load in patients with chronic HBV and maintained a very good safety profile.

PIN3

COMPARING THE EFFICACY AND TOLERABILITY OF ANTI-RETROVIRAL THERAPY IN TREATMENT-NAÏVE HIV-1 INFECTED ADULTS: A SYSTEMATIC REVIEW OF RANDOMIZED CLINICAL TRIALS AND BAYESIAN MIXED TREATMENT COMPARISONS INCLUDING ATAZANAVIR/R, DARUNAVIR/R, LOPINAVIR/R, AND EFAVIRENZ

Verheggen B[1], Vandeloise E[2], Treur M[1], Thuresson PO[1], Lescrauwaet B[3]
[1]Pharmerit International, Rotterdam, The Netherlands, [2]Bristol-Myers Squibb, Braine-l'Alleud, Belgium, [3]Xintera Consulting BVBA, Leuven, Belgium

OBJECTIVES: A framework for comparative research is useful for health technology assessment (HTA) and clinical decision making. The objective was to systematically assess efficacy and tolerability of 3rd agents, atazanavir/r (ATV/r) compared to darunavir/r (DRV/r), lopinavir/r (LPV/r) and efavirenz (EFV), in treatment-naïve HIV-1 infected adults. **METHODS:** A systematic literature search was conducted to identify published randomized clinical trials (1-1-2000 to present), in which the four anti-retroviral (ARV) treatments were used for these patients. Pooled esti-

mates for virological response (VR; viral load levels <50 copies/ml), immunorecovery (change in CD4 cells/μl from baseline to week 96), incidence of diarrhea, nausea and rash were generated by Bayesian mixed treatment comparison (MTC). Point estimates were reported with corresponding 95% credible intervals. **RESULTS:** In total, 6 unique studies and 2 study extensions were included; consisting of 3 ATV/r, 1 DRV/r, 5 LPV/r, and 5 EFV treatment arms. Pooled MTC estimates for VR at week 48 were 77.7% (95%CrI: 74.1%-81.1%) for ATV/r, 76.4% (72.9%-79.7%) for EFV, 74.7% (67.2%-81.2%) for DRV/r, and 72.5% (69.9%-75.0%) for LPV/r. The ratio of the proportion of patients with VR at week 96 versus week 48 was estimated at ATV/r: 0.934 (0.872-0.999), DRV/r: 0.918 (0.807-1.041), EFV: 0.908 (0.834-0.981) and LPV/r: 0.878 (0.827-0.929). Immunorecovery was 254.9 (245.2-264.9) cells/μl for LPV/r, 238.1 (219.5-257.0), 225.2 (209.6-241.3), and 206.1 (190.3-222.4) for DRV/r, ATV/r and EFV respectively. The incidence of diarrhea was 10.7% (8.7%-12.8%) for LPV/r, compared to 4.5% (2.3%-7.4%), 2.3% (0.3%-7.0%), and 2.1% (1.0%-3.7%) for DRV/r, EFV, and ATV/r respectively. The incidence of nausea and rash did not differ markedly among the treatments. **CONCLUSIONS:** The estimates for efficacy and tolerability suggest all 4 ARV treatments are valuable options in treatment-naive HIV patients, with ATV/r's sustained viral response bringing added value. This MTC provides a useful framework for ARV treatment comparison for HTA and clinical decision making.

PIN4

CLINICAL AND ECONOMIC BURDEN OF INVASIVE FUNGAL INFECTION (IFI) IN EUROPE: A REVIEW OF THE LITERATURE

Khachatryan A[1], Stephens JM[2], Mays R[2], Haider S[3]
[1]*Pfizer Inc, New York, NY, USA,* [2]*Pharmerit International, Bethesda, MD, USA,* [3]*Pfizer Inc, New London, CT, USA*

OBJECTIVES: To systematically assess the clinical and economic burden of invasive fungal infection (IFI) in Europe and to understand the value and treatment outcomes of diagnostic and empirical therapeutic approaches. **METHODS:** A comprehensive literature review was conducted using PubMed/MEDLINE and EMBASE (past 10 years) and relevant clinical societies (last 5 years) to identify epidemiology, outcomes, and treatment trends focusing on invasive Aspergillus and Candida infections using a defined protocol for inclusion/exclusion and data collection metrics. Clinical and economic burden outcomes described were incidence, mortality, overall healthcare resource utilization, length of hospital stay, and costs for IFI. **RESULTS:** Of 370 abstracts screened, 57 primary literature articles and 18 clinical society abstracts met inclusion criteria providing data from 12 European countries. No studies were identified in Eastern Europe and only two randomized, controlled studies comparing pre-emptive to empirical treatment were found. IFI incidence ranged from 3%-8% in empirical vs 8%-9% in pre-emptive treatment. Overall (IFI attributable) mortality ranged from 5%-41% (0%-24%) and 2%-17% (0%-13%) for non-comparative vs comparative studies, respectively. The highest mortality was found among critically ill patients, pediatric, and those with hematologic malignancies. The cost of IFI ranged from €8,351-€11,821 when evaluating hospitalizations and antifungals to €26,596-€49,216 when all direct costs for management were included. Costs for antifungal therapy alone were €3,930-€7,314. The incremental cost burden of IFI ranged from €10,530-€51,033 depending on the certainty of infection (possible, probable, proven) and duration of follow up. **CONCLUSIONS:** IFI represents a substantial clinical and economic burden in critically ill and immunocompromised patients in Europe. IFI may account for up to 24% of mortality in these high risk populations and increase length of hospitalization by 20%. Differentiation of outcomes for pre-emptive and empirical treatment strategies have not been well defined and should be the focus of future clinical studies.

PIN5

PATIENT AND CLINICIAN PERCEIVED BENEFIT OF EARLY CONSUMPTION OF FAMCICLOVIR FOR THE TREATMENT OF HERPES OUTBREAKS

Twiss J[1], Mckenna S[2], Bloch M[3], Bonney MA[4]
[1]*Galen Research Ltd, Manchester, UK,* [2]*Galen Research Ltd, Manchester, UK, UK,* [3]*Holdsworth House Medical Practice, Darlinghurst, Australia,* [4]*Novartis Pharmaceuticals Australia, North ryde, NSW, Australia*

OBJECTIVES: The aim of the study was to conduct secondary analyses of trial data to determine whether taking famciclovir within 12 hours of first perceiving the symptoms of genital herpes was related to decreased outbreak severity and improved healing. **METHODS:** Data were derived from a double-blind, randomised, active-controlled study of patient-initiated therapy comparing a 2-day course of famciclovir with a 5-day course (total dose 1,50 mg in both courses) in adults with genital herpes. Patients completed the Herpes Symptoms Checklist (HSC) on each day of the five day study period. The proportion of patients healed (without lesions) at day 5 was also determined. **RESULTS:** Data were available for 501 patients (male = 58.5%; mean age (sd) = 39.2 (11.6) yrs). For the combined treatment groups, patients who took their medication within 12 hours had significantly lower HSC scores on day 1 (within 12 hours, median HSC=6; above 12 hours, median HSC=8; Mann-Whitney U=12,733.5, p<0.05). Patients who took their medication within 12 hours also had significantly lower HSC area under the curve scores for the 5 day study period (AUC; within 12 hours, median HSC=3.8; above 12 hours, median HSC=5.1; Mann-Whitney U=12,751.0, p<0.05). These differences were not apparent for the treatment groups separately. There was a significant association between the time at which the patients took their medication and whether or not they were healed at day 5 for the combined sample (Chi-square = 4.95, p<0.05). This finding was also observed for the 2-day treatment group (Chi-square=6.11, p <0.05) but not for the 5-day treatment group (Chi-square=0.49, p=0.48). **CONCLUSIONS:** Taking famciclovir within 12 hours of first becoming aware of genital herpes symptoms is associated with decreased symptom severity and speed of healing. The 2-day treatment, when taken within 12 hours, is associated with a higher rate of healing by day 5.

PIN6

CLINICAL OUTCOMES ANALYSIS COMPARING ENTECAVIR WITH LAMIVUDINE MONOTHERAPY AND LAMIVUDINE WITH "TENOFOVIR ADD-ON AS NEEDED" APPROACH IN THE TREATMENT OF CHRONIC HEPATITIS B INFECTION IN TURKEY

Ozdemir O[1], Saylan M[2], Yegnidemir N[3], Lescrauwaet B[4]
[1]*Yorum Consulting Ltd, ISTANBUL, Turkey,* [2]*Bristol-Myers Squibb, Istanbul, Turkey,* [3]*Bristol Myers Squibb, Istanbul, Turkey,* [4]*Xintera Consulting BVBA, Leuven, Belgium*

OBJECTIVES: In Turkey, lamivudine (LAM) is the only reimbursed antiviral (AV) agent for the treatment of chronic hepatitis B (CHB) patients with HBV-DNA level < 107 copies/mL. According to local reimbursement guideline, Tenofovir (TDF) should be added in case of non-response at week24, or when viral resistance is observed. This study aimed to compare the long-term clinical outcomes of entecavir (ETV) with the current reimbursement approach (LAM monotherapy or LAM with add-on TDF as rescue) in this patient subgroup. **METHODS:** Analysis population included patients (n=1000; 35% HBeAg-positive; 35 years old) without compensated or decompensated cirrhosis (CC or DC) or hepatocellular cancer (HCC) at model entry. Daily dose of AVs compared were (1) ETV 0.5mg, (2) LAM 100mg and (3) LAM 100mg + add-on TDF 300mg when non-response or viral resistance occurs. A decision-tree model with 5 parallel pathways for different levels of HBV-DNA with a time horizon of 10 years was built. Major clinical outcomes included mortality and life-years lost (LYL). **RESULTS:** Monotherapy with LAM during 10 years, resulted in 198CC, 8.9DC and 66HCC cases . Addition of TDF to LAM in case of non-response or viral resistance, reduced these cases to 78, 3.6 and 24 patients, respectively. ETV treatment resulted in 24, 0.9 and 7.5 avoided cases of CC, DC and HCC, respectively. While 108 deaths are estimated with LAM monotherapy (1,916LYL), in the LAM plus TDF approach, the number of death will decrease to 44 (794LYL). ETV treatment will further improve the results with additional avoidance of 15 deaths (275LYL). The advantage of ETV is more prominent in HBeAg-positive patients (444 avoided LYL). **CONCLUSIONS:** ETV was found to be superior to both LAM monotherapy and LAM add-on TDF approaches in the treatment of CHB. Better clinical outcomes may be expected with the introduction of ETV in this subgroup.

PIN7

THE COMPARATIVE EFFICACY OF TELAPREVIR VERSUS BOCEPREVIR IN TREATMENT-NAIVE AND TREATMENT-EXPERIENCED PATIENTS WITH GENOTYPE 1 CHRONIC HEPATITIS

Diels J[1], Cure S[2], Gavart S[3]
[1]*Janssen EMEA Health Economics and Market Access, Janssen Pharmaceutica NV, Beerse, Belgium,* [2]*i3 Innovus, Uxbridge, Middlesex, UK,* [3]*Worldwide Market Access, Janssen Global Services, Janssen Pharmaceutica NV, Beerse, Belgium*

OBJECTIVES: To indirectly compare the efficacy of telaprevir and boceprevir combined with peginterferon/ribavirin in achieving sustained viral response (SVR) in treatment-naïve and treatment-experienced patients with genotype 1 chronic hepatitis C virus (HCV). **METHODS:** A systematic review of literature was conducted in MEDLINE (January 2000-December 2010) to identify randomized controlled trials and comparative open-label studies on the efficacy of pegylated interferon (α-2a and α-2b)-ribavirin (PR)-based treatment in genotype 1 chronic HCV patients. A Bayesian mixed treatment comparison (MTC), enabling indirect comparisons of interventions while respecting randomization, was performed on the endpoint of SVR (HCV RNA undetectable at 24 weeks after end of treatment), assuming fixed study effects. For treatment-experienced patients, only previous relapsers and partial responders were included, as no clinical results in prior null-responders were available for boceprevir. **RESULTS:** Twelve publications were identified and included in the systematic review and MTC. In treatment-naïve patients, the odds ratio (OR) (posterior mean [95% credible interval]) for telaprevir (12 weeks + Response Guided Treatment (RGT) 24/48 weeks PR) and boceprevir (24 weeks + RGT 28/48 weeks PR) versus PR was respectively 3.76 [2.78-5.22] and 2.96 [2.23-4.01]. The OR for the indirect comparison of telaprevir versus boceprevir was 1.46 [0.89-2.25] (probability(OR>1)=0.931). In treatment-experienced patients, the OR of telaprevir (12 weeks + 48 weeks PR) and boceprevir (32 weeks + RGT 36/48 weeks PR) versus PR was respectively 12.56 [7.30-24.43] and 5.12 [2.90-10.30]. The OR for the indirect comparison of telaprevir versus boceprevir was 2.70 [1.02-5.80] (probability(OR>1)=0.978) for all patients, and 3.63 [1.12-8.97] and 1.39 [0.08-6.05] for prior relapsers and partial responders respectively. **CONCLUSIONS:** In the absence of direct comparative head-to-head studies between telaprevir versus boceprevir for the treatment of chronic HCV genotype 1 patients, MTC-based indirect comparison suggests better efficacy for telaprevir in both treatment-naïve and treatment-experienced patients compared to RGT boceprevir.

PIN8

A DECISION TREE MODEL COMPARING CLINICAL OUTCOMES OF TREATMENT WITH TELBIVUDINE WITH OR WITHOUT "TENOFOVIR ADD-ON AS NEEDED" AND LAMIVUDINE WITH OR WITHOUT "TENOFOVIR ADD-ON AS NEEDED" IN THE TREATMENT OF CHRONIC HEPATITIS B INFECTION IN TURKEY

Ozdemir O[1], Saylan M[2], Pakel H[3], Lescrauwaet B[4]
[1]*Yorum Consulting Ltd, ISTANBUL, Turkey,* [2]*Bristol-Myers Squibb, Istanbul, Turkey,* [3]*Bristol Myers Squibb, Istanbul, Turkey,* [4]*Xintera Consulting BVBA, Leuven, Belgium*

OBJECTIVES: In Turkey, lamivudine (LAM) is the only reimbursed antiviral (AV) agent for the treatment of chronic hepatitis B (CHB) patients with HBV-DNA level < 107 copies/mL. Tenofovir (TDF) can be added when the patient does not respond at week24, or viral resistance emerges. This study aimed to compare the long-term clinical outcomes of telbivudine (ldt) with or without TDF add-on and LAM with or

without TDF add-on in the treatment of CHB. **METHODS:** Analysis population consisted of patients (n=1000; 35% HBeAg-positive; 35 years old) without compensated or decompensated cirrhosis(CC, DC) or hepatocellular cancer(HCC). AVs compared were 1) Ldt 600mg/day; 2) Ldt + add-on TDF 300mg/day when non-response or viral resistance occurs; and 3)LAM 100mg/day (4)LAM + add-on TDF 300mg/day. A decision tree model with 5 parallel pathways for different levels of HBV-DNA was built using a 10-year time-horizon. Selected major clinical outcomes were mortality and life-years-lost (LYL). **RESULTS:** With LAM or Ldt monotherapy, 137CC, 5DC, 40 HCC cases and 70 dead versus 85CC, 3,5DC and 25HCC cases and 44 dead were expected to occur, respectively. With LAM or Ldt monotherapy, 1236 and 774 life-years will be lost, respectively. When a potent AV is added to LAM or Ldt, HBV complications were expected to decrease and avoided LYL were substantial (164 to 591 years, respectively). However, there is no important difference between starting with LAM or Ldt and adding TDF strategies: 1CC, 0 DC, 0HCC cases and 2 dead will be avoided. **CONCLUSIONS:** Ldt monotherapy was found to be superior to LAM monotherapy. However, Ldt +TDF does not seem a better approach than LAM+TDF in the treatment of CHB. This paradoxical finding might be explained due to marginally superior efficacy of Ldt versus LAM and a longer time-period before adding a potent antiviral to treatment.

PIN9

SYSTEMATIC REVIEW OF NON-INTERFERON BASED REGIMENS FOR CHRONIC HEPATITIS C TREATMENT

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Chronic Hepatitis C virus (HCV) infection is one of the silent global epidemics with significant unmet need and disease burden. One of the major limitations of current treatments is the need for 12 or 6 months of Interferon based therapy, which has tolerability and toxicity issues for many patients. During last 2-3 years several new agents have been tested in clinic, which have shown promising results as non-interferon based therapy. Goal of this study was to review the clinical efficacy and safety profile of non-interferon based therapies for HCV treatment. **METHODS:** We searched the MEDLINE, and abstracts from AASLD and EASL until May 2011. Studies were selected for clinical trials on direct acting agents for HCV. Primary endpoints reviewed were Sustained Viral Response (SVR). Toxicity was evaluated as secondary endpoint. Aggregated data were further analyzed to understand comparative safety and efficacy. **RESULTS:** Until May 2011, results of five eligible HCV clinical trials for interferon free regimens were available. Overall, treatment with combination of protease and polymerase inhibitor showed dramatic viral load reduction after 2 weeks of treatment. The combination of PSI-7977 and PSI-938 showed 93% viral clearance after 14 days (n=16). The combination of RG7227 and RG7128 demonstrated 5.1 log reduction in viral load in treatment naive, and 4.9 log reduction in null responder patients after 14 days of treatment. The combination of BMS-790052 and BMS 650032 showed 36.3% 24 week SVR in null responder patients. One study evaluating VX-222 and Telaprevir combination was discontinued due to viral breakthrough. Several studies are currently on-going whose data would be available in 2011-2012. **CONCLUSIONS:** Non-interferon based therapies have shown impressive viral load reduction in short term studies. However, more data for SVR, viral breakthrough and resistance is needed to confirm their safe use in HCV infected population.

PIN10

CLINICAL AND ECONOMIC BURDEN OF HOSPITAL ONSET HEALTH CARE FACILITY ACQUIRED CLOSTRIDIUM DIFFICILE INFECTION (HO-HCFA-CDI) IN EUROPE: A SYSTEMATIC REVIEW

Wiegand P[1], Nathwani D[2], Wilcox M[3], Stephens JM[1], Wan W[1], Shelbaya A[4], Haider S[5]
[1]*Pharmerit International, Bethesda, MD, USA,* [2]*Ninewells Hospital & Medical School, Dundee, UK,* [3]*Leeds General Infirmary, Leeds, UK,* [4]*Pfizer, New York, NY, USA,* [5]*Pfizer Inc., Groton, CT, USA*

OBJECTIVES: To describe the clinical and economic burden associated with hospital onset health care facility acquired *Clostridium difficile* infection (HO-HCFA-CDI) in European health care facilities (EHCF). **METHODS:** A systematic review of the PubMed, EMBASE and infectious disease societies was performed to capture clinical and economic burden of HO-HCFA-CDI in Europe. Included studies were published in English between 2000-2010 and had >20 patients with documented CDI acquired/treated in a EHCF. Data collection was completed by three un-blinded reviewers using Cochrane Handbook and PRISMA guidelines. The primary outcomes were mortality, recurrence, length of stay (LOS) and cost related to CDI. **RESULTS:** We identified 1138 primary articles and conference abstracts, which were narrowed to 38 and 30 studies, respectively, after applying eligibility criteria. Outcomes data were available from only 14 countries, with 47% of studies from UK institutions. CDI mortality at 30 days ranged from 2% in France to 42% in the UK. Mortality rates more than doubled from 1999-2004, and continued to rise until 2007, when reductions were noted in the UK. Recurrent CDI varied from 1% in France to 36% in Ireland; however, equivalent recurrence definitions were not used, which affects study outcomes. Median length of stay ranged from 8 days in Belgium to 124 days in the UK. The incremental cost of CDI was £4,577 in Ireland and £11,317 in Germany, after standardization to 2010 GBP. Country-specific averages, weighted by study sample sizes, ranged from 2.8% to 29.8% for 30-day mortality; 5.9% to 22.6% for recurrence; and, 16.1 to 37.9 days for LOS. **CONCLUSIONS:** Burden of CDI in Europe was most commonly described using 30-day mortality, recurrence, LOS and cost data. Country-specific reporting mandates partly influence the available data on CDI burden in EHCFs. The continued spread of CDI and resultant healthcare burden underscores the need for judicious antibiotic use.

PIN11

THE IMPACT OF DIRECTLY OBSERVED THERAPY (DOT) IN PATIENTS WITH TUBERCULOSIS

Sallum RH[1], Travers KU[1], Kalsekar A[2], Kleinman L[3]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Bristol Myers Squibb, Princeton, NJ, USA,* [3]*United BioSource Corporation, Bethesda, MD, USA*

OBJECTIVES: With adherence being a driver of treatment efficacy, we aimed to systematically assess treatment adherence and efficacy in a disease area impacted by the rapid emergence of multiple drug resistances as a result of non-adherence, tuberculosis. We systematically reviewed the literature to qualitatively assess the impact of directly observed therapy (DOT) versus other treatment modalities (non-DOT) on adherence and treatment efficacy in patients with tuberculosis. **METHODS:** English-language literature indexed in the MEDLINE database (accessed via PubMed) from January 1, 2000 through November 5, 2010 was systematically reviewed. Experimental and observational studies with at least 10 patients and one treatment group receiving a DOT were included and reviewed for adherence and efficacy outcomes. **RESULTS:** Thirty-seven tuberculosis studies were included. Twelve studies reported outcomes for both DOTs and non-DOTs. Six comparative studies reported treatment completion; DOT was numerically favored in 5/6 studies, with 3 studies showing significant treatment completion rate benefit in the DOT group. In Daneil et al., the DOT treatment completion benefit (61.6% DOT, 41.5% non-DOT) paralleled significantly less mortality (9.2% DOT, 19.8% non-DOT) and greater treatment success (61.6% DOT, 41.5% non-DOT) ($p<0.001$). In Chee et al., significantly greater treatment completion (89.2% vs. 70.7%) and fewer treatment interruptions (4.0% vs. 12.9%) in the DOT group paralleled fewer deaths (4.2% vs. 13.1%; $p<0.001$). Only one study showed lower treatment completion and more deaths for the DOT. However these results were juxtaposed with a higher cure rate and less treatment default. **CONCLUSIONS:** DOT has shown specific positive clinical impact by reducing mortality, and increasing treatment success and cure rate through increased adherence. This suggests the social pressure of health care professional involvement in observing therapy administration may be a driver of adherence. The association of both treatment adherence and positive clinical outcome with DOT may exist in other disease indications.

PIN12

EPIDEMIOLOGY, OUTCOMES, AND COSTS OF HOSPITALIZATION DUE TO PNEUMONIA, MENINGITIS, AND SEPTICEMIA IN CANADA FROM 2004 TO 2010

Qizilbash N[1], Mcneil S[2], Ye J[3], Gray S[3], Zanotti G[4], Todd M[3], Dartois N[5]
[1]*OXON Epidemiology Limited and Department of Primary Care and Public Health, Imperial College, London, UK,* [2]*Canadian Center for Vaccinology, Dalhousie University, Halifax, NS, Canada,* [3]*Pfizer, Collegeville, PA, USA,* [4]*Pfizer Canada, Kirkland, QC, Canada,* [5]*Pfizer, Paris, France*

OBJECTIVES: The hospital burden and costs of pneumonia, meningitis, and septicemia remain high. A retrospective database analysis was conducted for years 2004–2010 to quantify incidence, case-fatality, length of stay, and cost of hospitalization from all-cause pneumonia, meningitis, and septicemia in Canada (excluding Quebec). **METHODS:** Hospitalizations due to these conditions from 2004–2010 were identified from a national database in Canada using *International Classification of Diseases-10* codes. Statistics Canada provided the population at-risk data for incidence calculations. A costing model, devised using hospitalization data from Ontario, was used to estimate disease-specific costs. Results are reported for all age groups combined. **RESULTS:** From 2004–2010, hospitalized pneumonia incidence (cases per 1,000-persons) declined from 3.61 to 3.47, case-fatality rates declined from 12.3% to 11.6%, and average length of hospitalization increased from 9.99 to 10.54 days. Hospitalized meningitis incidence (cases per 100,000-persons) increased non-monotonically from 4.20 to 4.67, case-fatality rates increased from 5.5% to 6.6%, and average length of hospitalization increased from 12.36 to 12.88 days. Hospitalized septicemia incidence (cases per 100,000-persons) increased from 74.28 to 82.03, case-fatality rates remained at approximately 26%, and average length of hospitalization increased from 14.76 to 16.68 days. From 2004–2009, average total costs (Canadian $) increased from $12,195 to $15,742 for pneumonia, remained at approximately $19,000 for meningitis, and increased from $22,289 to $31,019 for septicemia. Incidence patterns for the three conditions differed by age and gender. **CONCLUSIONS:** The clinical and economic burden due to all-cause hospitalized pneumonia, meningitis, and septicemia across all ages combined have not demonstrated major reductions during the period reviewed and remain high, particularly for pneumonia. However, the pattern varied by age group. Substantial savings in costs and hospital resources may accompany prevention of these conditions by measures aimed at major underlying causes, such as influenza virus and *Streptococcus pneumoniae*.

PIN13

EPIDEMIOLOGY OF STAPHYLOCOCCUS AUREUS INFECTIONS IN CHILDREN: A LITERATURE REVIEW OF THE LAST 10 YEARS

Bricout H[1], Maier W[2], Mouchet J[3]
[1]*Sanofi Pasteur MSD, Lyon, France,* [2]*Registrat-Mapi, London, UK,* [3]*MAPI Research Trust, Lyon, France*

OBJECTIVES: To provide an overview on the epidemiology of *Staphylococcus aureus* (SA) infection in children from North America and Europe. **METHODS:** A literature review was conducted using Medline and based on 4 different search strategies to focus on a children population from birth to 18 years of age and to identify publications from the last 10 years. **RESULTS:** A total of 233 abstracts were retrieved, resulting in the selection of 21 publications. Findings suggest increased incidence rates of hospital-acquired (HA) SA infections worldwide over time. For instance in the USA, the increase in the overall incidence of SA infection among children is significant: from 20.8/1000 admissions in 2002 to 35.8/1000 admissions in 2007, as

well as in the incidence of Methicillin-Resistant SA (MRSA) infection among children: from 6.7/1000 admissions in 2002 to 21.2/1000 admissions in 2007. The most frequent clinical manifestations of SA infections include abscess and cellulitis, pneumonia, osteomyelitis and bacteremia. Children under the age of one year have a substantially higher rate of SA bloodstream (SAB) infections. Mortality rate due to SAB is up to 10% in neonates while approximately 2% among children. Rates of MRSA infections vary by geography: highest in the USA (31.4-59.5% of HA SA infections) and Southern Europe (28-63%), lower rates in Central Europe (6-22%) and the lowest rates in Northern Europe (<1%). MRSA infections are associated with higher rates of crude mortality than Methicillin-Sensible SA (MSSA) infection worldwide (OR: 1.93, 95%CI 1.54-2.12 – Shorr et al 2007). **CONCLUSIONS:** Serious SA infection represents a substantial and potential growing public health problem in the pediatric population. Given the difficulty of developing new classes of antibiotics and the increasing likelihood of resistance developing to all currently available antibiotics, a vaccine could help to prevent these infections in children and reduce associated morbidity and mortality.

PIN14

PRESCRIBING PATTERNS OF SEBIVO® (TELBIVUDINE): A SURVEY AMONG PHYSICIANS IN SELECTED EUROPEAN COUNTRIES

Aponte torres Z[1], Lara N[2], Primatesta P[3], Trylesinski A[4]
[1]*Novartis Pharma, Barcelona, Barcelona, Spain,* [2]*IMS Health, Barcelona, Barcelona, Spain,* [3]*Novartis, Basel, Basel, Switzerland,* [4]*Novartis, Basel, BAsel, Switzerland*

OBJECTIVES: To describe the initial decision to prescribe telbivudine and the prescription patterns in outpatient clinical settings in Europe. To assess the prescriber's knowledge regarding the safety profile of telbivudine. **METHODS:** This observational cross sectional study examined the initial decision to prescribe telbivudine and the prescribing patterns among 48 physicians randomly selected in Germany, Italy and Spain. Physicians were eligible to take part in the study if they had prescribed telbivudine in the 12 months before the survey. **RESULTS:** More than 96% of the participating physicians were prescribing entecavir, telbivudine and tenofovir disoproxil fumarate at the time of the survey. Physicians reported a varied frequency for monitoring HBV DNA and alanine transferase (ALT) levels after initiation of telbivudine treatment (94% monitor at least at 6 months and 6% monthly). Drug characteristics most frequently mentioned by physicians as the reason to initiate treatment with telbivudine were rapid viral suppression (70%), efficacy in treatment-naïve patients (69%), favorable safety profile (49%) and predictable clinical outcomes (41.8%). Considering the characteristics of the individual patient at treatment initiation, the most frequent reasons to prescribe telbivudine were the patient's viral load at start of treatment (77%), age (62%) and serum ALT level (41%). Physicians reported being aware of the requirement for monitoring possible side effects particularly muscle related events and changes in renal function. **CONCLUSIONS:** Overall, these results indicate that physicians in the EU who prescribe telbivudine are aware of the potential benefits and risks of telbivudine treatment and the prescription is based on the well validated management guidelines (roadmap concept).

PIN15

TRENDS IN VARICELLA-ZOSTER INCIDENCE IN THE NETHERLANDS & BOOSTING EFFECT WITHIN HOUSEHOLDS

Oostvogels AJJM[1], Gumbs P[2], Fortanier A[3], Van Steenwijk PC[4], Postma MJ[5]
[1]*University of Groningen, Groningen, The Netherlands,* [2]*GlaxoSmithKline, Zeist, The Netherlands,* [3]*GlaxoSmithKline, The Netherlands, Zeist, The Netherlands,* [4]*Zorggroep Almere, Almere, The Netherlands,* [5]*University of Groningen, Groningen, Groningen, The Netherlands*

OBJECTIVES: Vaccination against varicella is discussed in literature with regard to the possible effects on the incidence of herpes zoster, as both are caused by the varicella-zoster virus (VZV). We investigated whether temporal trends exist in the incidence of varicella and the incidence of herpes zoster. We also conducted a case-control study to investigate the boosting effect within families, based on our information on household situation. **METHODS:** Using Dutch general practitioner (GP) practices and pharmacies databases, longitudinal data, including free text fields, was collected about varicella and herpes zoster from approximately 165,000 patients over 7 years. Data included date of birth, date of diagnosis, gender and household situation. **RESULTS:** A seasonal trend for the incidence of varicella was found with a peak in spring, but no temporal trend was found for the incidence of herpes zoster. The results of the case-control study show the following: people living within the same households as varicella patients are less likely to develop herpes zoster within the period of +/− 2 months after exposure to varicella (mean age is 22.9 years; OR is 0.4; 95% CI: 0.3-0.5). However people within the same households as varicella patients are more likely to develop herpes zoster within 2 months to 7 years after exposure to varicella (mean age is 27.9 years; OR is 1.3; 95% CI: 1.1-1.5). **CONCLUSIONS:** The trend analyses show a seasonal trend in the incidence of varicella where the incidence of herpes zoster is more or less stable over time. The case-control study shows that people within the same household with varicella patients are less likely to develop herpes zoster immediately after exposure and more likely to develop herpes zoster later in life. As herpes zoster is positively correlated with age this is expected.

PIN16

RATES AND PREDICTORS OF GONORRHEA RE-SCREENING AMONG PRIVATELY INSURED PATIENTS WITH GONORRHEA IN 2007-2009

Shi L[1], Liu J[1], Kissinger P[1], Khan M[1], Wu EQ[2]
[1]*Tulane University, New Orleans, LA, USA,* [2]*Analysis Group, Inc., Boston, MA, USA*

OBJECTIVES: Gonorrhea is the second most commonly reported bacterial STD, most of which is diagnosed in the private sector. STD treatment guidelines suggest retesting people with gonorrhea 3 months post treatment. The objective was to examine the rate and predictors of re-testing within 3-6 months among privately insured patients (15-50 years) diagnosed with gonorrhea. **METHODS:** A commercial insurance database was used to extract patients with gonorrhea (ICD-9-CM codes: 98.xx) in year 2007-2009. The date of first gonorrhea diagnosis was used as the index date. Patients were required to have health insurance >= 6 months before and after the index date. We also defined the re-screening service for gonorrhea by using the CPT codes: 87081, 87205, 87590, 87591, 87492, 87800, and 87801 within 3-6 months after the index date. Logistic regression model was used to identify factors affecting the likelihood of gonorrhea retesting. **RESULTS:** Among 1016 persons diagnosed with gonorrhea, about 48% were in the age group 15-25 years, 36% in 25-40 years, and 16% in 40-50 years. The majority were women (61.4%). Only 110/1016 (10.8%) patients were rescreened within 3-6 months. The re-screening rates in 2007, 2008, and 2009 were 6.1%, 11.6%, and 13.7%, respectively. The re-screened individuals were more likely to be: women but not pregnant (OR=1.93, 95% CI: 1.20-3.12), pregnant women (OR=4.46, 95% CI: 2.17-9.19), compared to men; age 15-25 years old (OR=2.65, 95% CI=1.17-6.00) and 25-40 years old (OR=2.65, 95% CI: 1.15-6.09), compared to age 40-50 years old; and those diagnosed in 2008 (OR=2.11, 95% CI: 1.15-3.85) and 2009 (OR=2.44, 95% CI: 1.28-4.66), compared to 2007. **CONCLUSIONS:** While rescreening rates are increasing among privately insured patients diagnosed with gonorrhea, they are still very low. To improve rescreening rate, policy makers should urgently consider policy options including rescreening of all gonorrhea cases for effective control of the disease.

Infection – Cost Studies

PIN17

MODELLING BUDGET IMPACT (BI) OF VACCINATING AT-RISK ADULTS AND THE ELDERLY WITH 23-VALENT PNEUMOCOCCAL POLYSACCHARIDE VACCINE (PPV23) COMPARED TO 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE (PCV13) IN GERMANY

Jiang Y[1], Gauthier A[1], Annemans L[2], van der Linden M[3], Nicolas-Spony L[4], Bresse X[4]
[1]*Amaris Consulting UK, London, UK,* [2]*Ghent University, Ghent, Belgium,* [3]*National Reference Centre for Streptococci, Aachen, Germany,* [4]*Sanofi Pasteur MSD, Lyon, France*

OBJECTIVES: *Streptococcus pneumoniae* is a leading cause of life-threatening pneumococcal diseases (PDs). In Germany, PPV23 has been recommended in the elderly (aged 60 and over) since 1998. In 2006, the pneumococcal conjugate vaccine (PCV) was introduced in children and is expected to be launched in adults shortly. US experience showed that PCV vaccination of children led, ten years after its introduction, to a decrease in the incidence of invasive PD (IPD) caused by the PCV serotypes and to an increase in IPD caused by the non-PCV serotypes. This study aimed to assess the BI of vaccinating at-risk adults and the elderly (aged 60 and over) with PPV23 and/or PCV13 in Germany. **METHODS:** A multi-cohort, population-based Markov model was developed, consisting of five health states: no PD, IPD, NBPP (non-bacteraemic pneumococcal pneumonia), post-meningitis sequelae and death. Cohorts of individuals receiving initial vaccination, and the unvaccinated individuals were followed over time. All data were retrieved from published sources. German epidemiological trends were modelled according to US data. As vaccine effectiveness in adults against the vaccine-serotypes is not available for PCV13, optimistic and pessimistic hypotheses were defined. The net budget impact (NBI) was calculated for the 2012-2016 period. **RESULTS:** Vaccinating German at-risk adults and the elderly with PCV13 at current vaccine uptake resulted in an undiscounted NBI of €239 million in the base case, which is 22% higher than vaccinating with PPV23. No scenario was found in favour of PCV13. Results were sensitive to vaccination uptake, vaccine prices, vaccine effectiveness and epidemiological trends assumptions. **CONCLUSIONS:** Using a population-based approach, our model was designed to simulate the progression of PDs in a changing environment in terms of demographics, epidemiology and available vaccines. According to this analysis, PCV13 is likely to result in a significant impact on the healthcare budgets.

PIN18

BUDGET IMPACT ANALYSIS OF TENOFOVIR IN TREATMENT OF CHRONIC HEPATITIS B (CHB)

Gwiosda B[1], Krzystek J[1], Rys P[1], Wladysiuk M[1], Mierzejewski P[2], Kazmierski M[2], Plisko R[1]
[1]*HTA Consulting, Krakow, Poland,* [2]*Gilead Sciences Poland Sp. z o.o., Warszawa, Poland*

OBJECTIVES: To estimate the impact of tenofovir reimbursement in treatment of adults with chronic hepatitis B in Poland. **METHODS:** Analysis was performed from the public payer perspective in 5-year time horizon. Target population was defined as adults with chronic hepatitis B who are eligible for antiviral treatment. Size of the target population was estimated on the basis of Polish sales data obtained from IMS, including the sale of nucleoside analogues in the period January 2007-March 2010. In the analysis following cost categories were included: drugs (tenofovir, entecavir, adefovir, lamivudine), monitoring, hospitalizations and complications of hepatitis-B (cirrhosis, hepatocellular carcinoma). Reimbursement assumption was that tenofovir will be financed in heath therapeutic program on the basis of financing principles of entecavir and adefovir. It was assumed that tenofovir will be initial (first choice) therapy in population of patients who are eligible to tenofovir, entecavir or adefovir therapy and that in case of reimbursement tenofovir will be replacing entecavir and adefovir. **RESULTS:** The size of target population will be circa 4100 people in 2011 and increases to circa 6200 people in 2015. Forecast population of patients using tenofovir is ca 1500 patients in 2011 and will grow to ca 3200 patients in 2015. In current scenario (lack of tenofovir reimbursement) expenditures on antiviral drugs in target population will be ca 76,000,000 PLN in 2011 and will steadily increase to ca 120,000,000 PLN in 2015. Total expenditures in the target

population would be ca 130,000,000 PLN in 2011 and will steadily increase to ca 202,000,000 PLN in 2015. In case of tenofovir reimbursement estimated decrease in total expenditures will be ca 6,000,000 PLN in 2011 and ca 11,000,000 PLN in 2015. **CONCLUSIONS:** The decision for tenofovir reimbursement will cause decrease in public payer expenditures for patients with chronic hepatitis B.

PIN19

PHARMACOECONOMIC ANALYSIS OF PEGYLATED INTERFERON ALFA USE IN CHRONIC HEPATITIS C

Ryazhenov VV
I.M. Sechenov Moscow State Medical University No.1, Moscow,, Russia

OBJECTIVES: Budget impact analysis of chronic hepatitis (HCV) pharmacotherapy with pegylated interferon alfa-2a (PegIFN alfa-2a) and pegylated interferon alfa-2b (PegIFN alfa-2b). **METHODS:** The study used a Budget Impact Analysis method with the Rational Drug Use Indicator (RDUI), which allows to quantitatively describe the economic effectiveness of a particular drug taking into account its useful application potential. The modeling was based on the data collected in IDEAL clinical study. The model considered two groups of HCV genotype 1 patients, equal in number (1000 patients per group) and comparable in demographic, clinical, and virological characteristics: group 1 – patients receiving PegIFN alfa-2a, group 2 – PegIFN alfa-2b. Patients' age and weight, as well as the drug dose were taken into account. A sensitivity analysis was performed in modeling the number of patients treated with PegIFN alfa-2a and PegIFN alfa-2b. **RESULTS:** It is estimated that under the given model conditions the direct costs per patient in PegIFN alfa-2a treatment of hepatitis C for 48 weeks amounted to 419,199.36 rubles, and PegIFN alfa-2b – 422,637.12. The direct costs difference in the 1: 1 ratio of patients treated with PegIFN alfa-2a and PegIFN alfa-2b amounted to 1,718,880 rubles. As shown by the RDUI calculation, inefficient budget expenditure in the case of using PegIFN alfa-2b in 1,000 patients during the analyzed treatment period may reach 63,395,570 rubles. The results sensitivity analysis according to RDUI revealed a dependence of the budget losses on the share of patients receiving PegIFN alfa-2a and PegIFN alpha-2b. **CONCLUSIONS:** When comparing the budget impact by PegIFN alfa-2a and PegIFN alfa-2b HCV treatment strategies, the economic expediency of the strategy of using PegIFN alfa-2a in Russian patients was identified.

PIN20

CLINICAL AND ECONOMICAL IMPACT OF PNEUMOCOCCAL VACCINATION IN SPANISH ADULT POPULATION MEASURED BY A DYNAMIC MODEL

Pradas R[1], Gil de Miguel A[2], Alvaro A[2], Gil-Prieto R[2], Guijarro P[3], Lorente R[1], Antoñanzas F[1]
[1]*Universidad de la Rioja, Logroño, La Rioja, Spain,* [2]*Universidad Rey Juan Carlos, Alcorcon, Madrid, Spain,* [3]*Pfizer Spain, Alcobendas, Madrid, Spain*

OBJECTIVES: This study aimed to assess the efficiency of the 13-valent pneumococcal conjugate vaccine (PCV13) administered annually to 65-years-old cohort in Spain versus the alternative of not vaccinating and treating patients only when infected. **METHODS:** Infections avoided were calculated through a dynamic model based on Anderson and May work. 70% of the 65-years-old cohort was assumed as vaccinated with one PCV13 dose (318,000 subjects). Basecase estimated vaccine efficacy and serotype coverage were as follows (75% and 70% respectively). Disease cost was calculated based on CMBD database and published data. **RESULTS:** During the 5 years frame, a total of 83,844 infections would be avoided. Net savings of €62 million would be obtained. The distribution of the savings was not homogeneous, starting in the 3rd and increasing until the 5th year. To demonstrate model robustness, analyses of additional scenarios have been performed using extreme values of model parameters (vaccination programme coverage, vaccine efficacy, serotype coverage). Under those scenarios, the net savings results were always achieved. **CONCLUSIONS:** After three years, 65-year-cohort pneumococcal vaccination campaign appeared to be a cost saving intervention among Spanish population under different scenarios.

PIN21

CLINICO-ECONOMIC EVALUATION OF TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA (CAP) COMPLICATED BY SEPSIS WITH MOXIFLOXACIN COMPARED TO CEFTRIAXONE + AZITHROMYCIN

Zaitsev A[1], Tyrsin O[2], Morozov A[3]
[1]*The Main Military Clinical Burdenko Hospital, Moscow, Russia,* [2]*Bayer Healthcare Pharma, Moscow, Russia,* [3]*Bayer HealthCare Pharma, Moscow, Russia*

OBJECTIVES: Evaluation of comparative cost-effectiveness of treatment of CAP complicated by sepsis with moxifloxacin compared to ceftriaxone + azithromycin in adult patients. **METHODS:** literature search revealed prospective non-randomized comparative controlled clinical trial (n=87) where treatment efficacy of CAP complicated by sepsis was evaluated. MOX group received moxifloxacin (400 mg i.v.) 3-4 days with further switch to 400 mg per os daily. CEAZ group received combined therapy with ceftriaxone 2000 mg i.v. and azithromycin 5000 mg during 5 days. Efficacy criteria were length of antibacterial treatment, ICU and in-hospital days. Cost-effectiveness analysis was performed. **RESULTS:** Patients of MOX group spent 2.7±1.3 ICU days compared to 3.9±1.4 days ($p<0.05$) in CEAZ group. Antimicrobial treatment took 7.0±0.4 days in MOX and 10.0±0.5 days in CEAZ group ($p<0.05$). There was not statistically significant deference in hospital days. Costs of antibacterial treatment and ICU stay were 17,803 RUR (€447) per patient in MOX group and 19,020 (€478) in CEAZ group. **CONCLUSIONS:** treatment of CAP complicated by sepsis with moxifloxacin compared to combined therapy in adult patients leads to ICU stay reduction by 1.2 days and cost saving by 1216 RUB (€31).

PIN22

COMPARISON OF TWO DYNAMIC MODELS PREDICTING FUTURE BURDEN OF ILLNESS OF HEPATITIS C (HCV) IN THE EU-5 (FRANCE, GERMANY, ITALY, SPAIN, UK)

Kempel-Waibel A[1], Schwehm M[2]
[1]*Pharmametrics GmbH, Freiburg, Germany,* [2]*ExploSYS GmbH, Leinfelden-Echterdingen, Germany*

OBJECTIVES: The objective was to compare two modeling approaches to estimate the future burden of hepatitis C in selected countries. Due to varying efficacy depending on host factors such as viral load at baseline, disease duration, pre-treatment status, and disease severity more complex modeling is required. **METHODS:** Two models were developed. Model A was based on a classic Markov model with seven disease states modeling the impact of the new drugs based on response-guided therapy and efficacy. Drug acquisition cost, treatment management and annual health care cost were determined and the potential budget impact was assessed. Several "what if" analyses were performed. Model B is a dynamic, individual-based, stochastic model providing a powerful tool to perform sensitivity analysis on uncertain and disputed parameters. All input variables (incidence, prevalence, genotype distribution, cost, drug efficacy) were derived from a systematic literature and database review and analysis. **RESULTS:** In "what if" scenarios with varying treatment rates the time and cost to potential elimination of hepatitis C were modeled. Assuming all patients currently infected with hepatitis C would be treated from 2012 onwards, with efficacies (SVR) ranging between 70% and 80%, and assuming constant infection rates resulted in elimination of hepatitis C by the year 2030 in model A. In model B, in which individual-based host factors were taken into account, elimination was not achieved in the same time period. Different "what if" scenarios for non-responders, variations in baseline host factors, potential relapses and development of resistance were modeled more reliable with the individual-based model. **CONCLUSIONS:** Modeling "what if" scenarios on the basis of expected drug efficacy utilizing a dynamic, individual-based stochastic model results in a more comprehensive tool to estimate the distribution of expected future burden of HCV.

PIN23

TO ASSESS OR NOT TO ASSESS: THAT IS THE QUESTION! BUDGET, ETHICAL AND DECISIONAL IMPACT ASSESSMENT IN HIV: LOMBARDY REGION'S MOLO PROJECT

Restelli U[1], Lazzarin A[2], Galli M[3], Rizzardini G[3], Scolari F[1], Vanzago A[1], Croce D[1], Foglia E[1]
[1]*University Carlo Cattaneo - LIUC, Castellanza, Varese, Italy,* [2]*Specialist Clinic (IRCCS) San Raffaele del Monte Tabor Foundation, Milano, Milano, Italy,* [3]*"L. Sacco" Hospital Authority, Milano, Milano, Italy*

OBJECTIVES: The epidemiological transition for HIV-infection from a fatal condition to a chronic disease, has significant impact on decision-making process to ensure therapy appropriateness and to monitor the rising costs of antiretroviral (ARV) therapy. Starting from Lombardy Region's MOLO Project (MOnoterapia LOpinavir), this analysis aims to develop a methodological model based on treatment appropriateness, and to carry out an impact assessment of the simplification to monotherapy with lopinavir/ritonavir for HIV+ patients vs. standard therapy (NRTI backbone plus a third agent). **METHODS:** From the cohort of 23,721 HIV+ patients, according to eligibility criteria of 2010 Italian Guidelines, a static and dynamic (5ys) decisional model was produced to study the evolution of the disease, correlating clinical developments with total costs of population under assessment. The model provides 2 possible scenarios: monotherapy control or failure leading to re-induction. Cost of medicines, DRGs, lab tests and all other costs were inputted. The budget impact analysis was completed with an impact assessment comprehensive of: cost-effectiveness analysis, organizational, ethics and equity impact of treatment options. **RESULTS:** The analysis showed that the simplification to monotherapy with lopinavir/ritonavir could affect a significant sector of HIV+ patients, bringing economic benefits from 10.7 to 21.6MM€, in the first year. Analyzing the entire diagnostic clinical pathway, the analysis showed savings of 10.8 to 22.6MM€, and of 47.6 to 144.8 MM€ from 2,011 to 2,016. Monotherapy with lopinavir/ritonavir also ensures a better result vs. standard in terms of cost-effectiveness (14.007€ vs. 11.673€ in the most conservative hypothesis). Organizational impact doesn't show any differences between the two approaches, ethical impact is positive to the patients as regards long-term toxicity. **CONCLUSIONS:** The result of the analysis suggests that national and regional decision makers have considerable space for maneuver into a more appropriate position for resources management, without changing the efficacy and safety results of patients.

PIN24

POTENTIAL COSTS ASSOCIATED WITH NEW DIRECT ACTING ANTIVIRAL (DAAS) THERAPY FOR UNTREATED CHRONIC HEPATITIS C GENOTYPE 1 INFECTION IN THE VETERANS HEALTH ADMINISTRATION

Chan K[1], Lai MN[2], Groessl EJ[3], Hanchate A[1], Hernandez L[1], Wong JB[4], Clark JA[1], Asch S[5], Gifford AL[6], Ho S[7]
[1]*Boston University, Boston, MA, USA,* [2]*Veterans Affairs San Diego Healthcare System, San Diego, CA, USA,* [3]*University of California, San Diego, La Jolla, CA, USA,* [4]*Tufts University, Boston, MA, USA,* [5]*VA Greater Los Angeles Healthcare System (GLA), Los Angeles, CA, USA,* [6]*Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA, USA,* [7]*VA San Diego Healthcare System, San Diego, CA, USA*

OBJECTIVES: The Veterans Health Administration (VHA) is the largest single provider of hepatitis C (HCV) care in the United States. The newly approved direct acting antivirals (DAAs), Boceprevir (BOC) and Telaprevir (TEL) have significantly improved SVR rates for HCV Genotype 1 (GT1) patients. The objective was to project potential costs of DAAs on GT1 patients in the VHA. **METHODS:** A decision-analytic Markov model was developed to simulate the lifetime progression of HCV disease and to estimate the costs and clinical impacts of DAA in the current cohort of 103,331 GT1 treatment-naïve patients. Estimated federal pricing for drug costs and published response-guided antiviral efficacy data were used in the model. Treatment costs included drugs, inpatient/outpatient visits, and laboratory tests. We

estimated cost and effectiveness for four treatment strategies: 1) Standard dual therapy pegylated interferon alfa and ribavirin (PR); 2) BOC+PR triple therapy; 3) TEL+PR triple therapy; and 4) no treatment. **RESULTS:** In our model, patients received 1) PR for 48 weeks; 2) TEL for 12 weeks with PR for 34-36 weeks; or 3) BOC for 29 weeks with PR for 34-36 weeks. Estimated treatment cost associated with PR alone, BOC+PR, and TEL+PR are about $8,300, $31,000 and $45,000 per average patient, respectively. Total system-wide costs to adopt BOC+PR or TEL+PR would be $673 million and $971 million, respectively. Assuming continuation of the current 21% VHA treatment rates and optimal SVR results, the long term reduction in liver related death from treatment PR, Boc+PR, and Tel+PR are 7.9%, 13.1%, and 14.5%, respectively. **CONCLUSIONS:** Our model indicates upfront investments with BOC+PR, and TEL+PR are high, with the benefits of extending quality of life and lower costs due to liver-related morbidity. Though model projected potential cost under these assumptions, a clinical trial of comparative effectiveness would be needed to evaluate both costs and benefits of DAAs in veterans.

PIN26

ECONOMIC AND HEALTH RELATED QUALITY OF LIFE (HRQL) COMPARISON OF LOPINAVIR/RITONAVIR (LPV/R) AND ATAZANAVIR PLUS RITONAVIR (ATV+RTV)-BASED REGIMENS FOR ANTIRETROVIRAL (ARV) EXPERIENCED BRAZILIAN PATIENTS IN 2011

Simpson K[1], Baran R[2], Dietz B[3]
[1]*Medical University of South Carolina, Charleston, SC, USA,* [2]*Abbott Laboratories, Abbott Park, IL, USA,* [3]*Abbott GmbH & Co. KG, Ludwigshafen, Germany*

OBJECTIVES: In Brazil, switching to a protease inhibitor (PI) based ARV regimen is recommended as second line therapy for experienced patients failing non-nucleoside reverse transcriptase inhibitors. The BMS-045 study compared ATV+RTV and LPV/r regimens in ARV-experienced patients. Similar viral load (VL) suppression rates <400 copies were reported, but LPV/r provided greater suppression rate <50 copies. Total cholesterol (TC) levels improved to guideline levels in 23% of ATV+RTV patients and became elevated in 7% of LPV/r patients at 48 weeks. The long term clinical and cost impact of this difference is not yet clear. The objective of this study was to examine the long term HRQL and economic implications in Brazil for LPV/r versus ATV+RTV treatment of ARV-experienced patients. **METHODS:** A previously published HIV Markov model was adapted. Baseline assumptions: TC profile and CD4 cell distribution matching the BMS-045 population. HRQL and survival outcomes were measured in quality adjusted life years (QALYs). Costs in Brazilian Reale were indexed to 2011. ARV costs and HIV treatment patterns were based on Brazilian references. Lifetime costs/outcomes were discounted at 3% per annum. A national health services perspective was adopted. **RESULTS:** VL suppression differences favored LPV/r, driving a net improvement in survival (0.31 QALYs, 106 days). Five and 10 year cost savings (BRL1,816, BRL1,496 per patient) were projected for LPV/r. Lifetime costs were slightly higher for LPV/r due to improved survival. An incremental cost effectiveness ratio (ICER) of BRL2319 per QALY gained was estimated for the LPV/r regimen, which is highly acceptable by Brazilian threshold . **CONCLUSIONS:** Compared to ATV+RTV, an LPV/r based regimen is cost saving through the first 10 years of survival and is a cost effective use of public resources for ARV-experienced Brazilian patients. LPV/r implementation is supported by its improved viral suppression, short/long term cost savings and favorable ICER.

PIN27

COST ANALYSIS OF THE CONSUMED ORAL ANTIBIOTICS IN A TERTIARY CARE HOSPITAL IN GALLE, SRI LANKA

Subasinghe S[1], Hettihewa L[2], Cooray P[2], Kulathunga N[2]
[1]*University of Ruhuna, Faculty of Medicine, Galle, Sri Lanka,* [2]*University of Ruhuna, Galle, Sri Lanka*

OBJECTIVES: Research data on antibiotic usage pattern and cost comparison are scant in our country. Therefore we planned to identify oral antibiotic (OA) consumption and cost comparison for 2010 in tertiary care hospital in Sri Lanka. **METHODS:** Aggregate data for 2010 was collected from records of pharmacy and unit price was obtained from medical supplies division. Initial and final stocks of the OA, quantity received, quantities issued, quantity consumed and hospital data from VEN analysis were obtained. We identified the top ten for total cost (TTTC) and top ten for consumption (TTCS) OA. **RESULTS:** Ninethy-three percent of total cost for TTTC was utilized for the top seven highly consumed OA with low unit price. Seven percent of TTTC had been utilized for the drugs which were not in TTCS. In contrast three drugs in TTCS had not been included in TTTC but in the list of top 20. Low quota (2.5%) of the TTTC had been utilized for non essential drug in VEN which was not even in TTCS of OA. **CONCLUSIONS:** Ninety-three percent of the cost has been effectively utilized highly consumed low cost OA in this hospital for 2010. Seven percent of money in TTTC was spent for expensive OA. We suggest the authority to reconsider the change the drug ordering pattern with minimum cost and to suitable alternative low cost generics instead of expensive product.

PIN28

CONSUMPTION PATTERN AND THE COST ANALYSIS OF PARENTERAL ANTIBIOTICS IN A

Hettihewa LM, Subasinghe S, Nilakshi K, Cooray P
University of Ruhuna Faculty of Medicine, Galle, Sri Lanka

OBJECTIVES: We planned to identify the 2010 parenteral antibiotic (PA) consumption pattern and its cost effectiveness in government teaching hospital using aggregate data. **METHODS:** Aggregate data for 2010 was collected from pharmacy records and unit prize was obtained from medical supplies division. Initial and final stocks of the OA, quantity received, quantities issued and consumed per year were obtained. Data for VEN analysis was collected. Data was analyzed to identify the top ten for total cost (TTTC) and top ten for consumption (TTCS) PA according to the total cost and the consumption separately. **RESULTS:** Ninety-three perecent of TTTC was utilized for the top 7 highly consumed OA with low unit prize. Seven percent of expenditure of TTTC was utilized for drugs which were not included in TTCS. In contrast 3% of drugs (3 OA) in TTCS had not been included in TTTC. This indicates that these three OAs are cost effectively used. 2.5% of the TTTC had been used for a non essential drug in VEN which was not included even in TTCS of OA. **CONCLUSIONS:** We conclude that 93% of the cost has been effectively utilized highly consumed low cost OA in this hospital for 2010. Seven percent of the TTTC had been spent for expensive oral antibiotics. We suggest the authority to reconsider the change the drug orders to maximize the cost effectiveness and prioritize alternative low cost generics instead of expensive product orders.

PIN29

LINEZOLID VERSUS VANCOMYCIN FOR SKIN AND SOFT TISSUE INFECTIONS BY METHICILIN-RESISTANT STAPHYLOCOCCUS AUREUS: A COST COMPARISON ANALYSIS UNDER THE PRIVATE PAYER PERSPECTIVE IN BRAZIL

Fujii RK[1], Takemoto MLS[2], Mould JF[3], Lanzara G[4], Fernandes RA[5], Santos PML[5], Takemoto MMS[5]
[1]*Pfizer Pharmaceutics inc., São Paulo, São Paulo, Brazil,* [2]*ANOVA - Knowledge Translation, Rio de Janeiro, Rio de Janeiro, Brazil,* [3]*Pfizer, Inc., New York, NY, USA,* [4]*Pfizer Parmaceutics Inc., São Paulo, São Paulo, Brazil,* [5]*ANOVA - Knowledge Translation, Rio de Janeiro, Brazil*

OBJECTIVES: One third of skin and soft tissue infections (SSTI) are caused by methicilin-resistant staphylococcus aureus (MRSA). This study aims to compare SSTI-MRSA treatment costs with linezolid versus branded and generic vancomycin under the Brazilian private payer perspective. **METHODS:** A cost comparison study was performed to compare linezolid versus generic and branded vancomycin. As supported by clinical studies, overall treatment duration of 15 days with linezolid and 14 days with vancomycin was considered, using PO linezolid after a minimum 4-days cycle of IV infusion while vancomycin (1g bid) was entirely IV. A decision-tree model simulated SSTI-MRSA treatment assuming linezolid (600mg bid) IV can be switched to PO after 4-days and patients can be discharged if PO is implemented at physician discretion. Length of stay (LOS) and IV linezolid duration were ranged in one-way sensitivity analysis. Only direct medical costs were included in the analysis (hospital charges, medical visits, medical supplies and drug acquisition costs) and unit costs were obtained from Brazilian official price lists (2010 USD values). **RESULTS:** The linezolid scheme with 4-days IV (LOS=4 days) and 11-days PO resulted in overall costs per patient of 4089.58 USD, while branded and generic vancomycin exhibited 6657.33 USD and 6970,23 USD, respectively. The incremental cost of vancomycin-treated patients was driven by hospital daily charges, responsible for over 55% of the overall vancomycin costs. One-way sensitivity analysis revealed cost-savings for linezolid up to LOS ≥12 days, with overall costs per patient ranging from 4089.58 to 7428.84 USD if IV therapy was maintained throughout the inpatient period (LOS=15 days). **CONCLUSIONS:** Linezolid exhibited a cost-saving profile over branded or generic vancomycin for the treatment of SSTI-MRSA under the Brazilian public payer perspective. This economic benefit was a direct result of potential early discharge of patients receiving PO linezolid.

PIN30

COST ANALYSIS OF VORICONAZOLE VERSUS ITRACONAZOLE FOR PROPHYLAXIS OF INVASIVE FUNGAL INFECTION (IFI) IN ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) IN CANADA, FRANCE, GERMANY, AND THE UNITED STATES

Gao X[1], Ji X[2], Stephens JM[3], Schlamm H[4], Tarallo M[4]
[1]*Pharmerit North America LLC, Bethesda, MD, USA,* [2]*Pharmerit International, BETHESDA, MD, USA,* [3]*Pharmerit International, Bethesda, MD, USA,* [4]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: Voriconazole (VOR) demonstrated better tolerability with a longer treatment duration and less concomitant systemic antifungal drugs (con AF) compared to itraconazole (ITR). This study assessed key cost components associated with prophylaxis treatment of IFI after allogeneic HSCT across 4 countries (Canada, France, Germany, and US). **METHODS:** A prospective open-label multicenter clinical trial (IMPROVIT) for primary IFI prophylaxis after HSCT included patients>=12 years who were randomized to oral VOR or oral ITR from HSCT day for at least 100 and up to 180 days. Trial data on the key medical resource utilization (including hospital days and con AF use) for the first 100 days were analyzed and valued in 2010 costs. **RESULTS:** A total of 224 patients were in VOR and 241 in ITR group, with similar demographics (average age 43-year, 59% male, 92% Caucasian). VOR patients (vs. ITR) had longer study drug exposure (median: 96 vs. 68 days, p<0.0001; mean: 68 vs. 60 days, p=0.0162) and were 2 times less likely (P=0.0032) to use con AF. The average per-patient hospital cost for voriconazole (vs. itraconazole) was Can$27,674 (vs. Can$29,669), €13,277 (vs. €13,632), €15,185 (vs. €15,762), and $31,916 (vs. $33,521) in Canada, France, Germany, and the U.S., respectively. The average per-patient cost of con AF for voriconazole (vs. itraconazole) was Can$1028 (vs. Can$2290 p=0.0061), €2208 (vs. €4678, p=0.0095), €2422 (vs. €5033, p=0.0177), and $1,720 (vs. $3612, p=0.0146) in the study countries respectively. Total costs varied by country and were similar between treatment groups. The mean difference of 8 days in prophylaxis days between VOR and ITR was associated with 3.54%-4.55% reduction (depending on the country) in inpatient cost (all p<.0001) and 9.13%-11.82% reduction in con AF cost (all p<.01). **CONCLUSIONS:** Better tolerability of IFI prophylaxis after HSCT was associated with cost offsets due to reduced hospitalization and concomitant antifungal use.

PIN31

QUANTIFYING THE FINANCIAL AND DISEASE BURDEN ASSOCIATED WITH MOTHER TO CHILD TRANSMISSION OF HIV IN UGANDA

Kuznik A, Semeere A, Sempa J, Auerbach B, Lamorde M, Castelnuovo B, Hermans S, Ssewankambo F, Ssennono M, Mpanga Sebuyira L, Manabe YC
Infectious Diseases Institute, Kampala, Uganda

OBJECTIVES: In Uganda, mother to child transmission (MTCT) of HIV is responsible for approximately 25,000 infections among newborns annually and is the third leading cause of new infections. This analysis attempts to quantify the financial and disease burden associated with MTCT of HIV in Uganda. **METHODS:** Whereas HIV-negative infants have a life expectancy at birth ranging from 52.2 years for males and 54.3 years for females, the life expectancy of HIV-positive infants varies from 2 years in the absence of antiretroviral therapy (ART) to about 14.2 years with ART. Approximately 18% of eligible children in Uganda have access to ART, at an annual treatment cost of US$328. Lifetime health-care costs of HIV-positive untreated infants are assumed to be US$495. The model calculates years of life lost (YLL) as the difference in life-expectancy between HIV-positive and HIV-negative newborns and years of life lived with disability (YLD) by applying the relevant disability weights of 0.123 for each year lived with HIV and 0.5 for the last year of life with AIDS. All costs and life years are discounted at 3% annually. **RESULTS:** The total annual disease burden resulting from mother to child transmission of HIV is estimated at 592,480 disability adjusted life years (DALY's), which is defined as the sum of YLL: 572,662 and YLD: 19,818. The discounted net present value of future health care costs associated with mother to child transmission of HIV is estimated at US$27.3 Million. **CONCLUSIONS:** Mother to child transmission of HIV is associated with a substantial mortality and morbidity burden in Uganda. The financial burden is also worrisome in a country with annual health expenditures of US$24 per capita (circa US$ 830 Million total). Cost-effective strategies to reduce the incidence of MTCT that can be scaled-up nationally are urgently needed.

PIN32

ECONOMIC BURDEN OF NON-CF BRONCHIECTASIS ENROLLED IN A US MANAGED CARE PLAN

Joish VN[1], Boklage SF[1], Luong B[2], Operschall E[2], Spilsbury-Cantalupo M[1]
[1]*Bayer HealthCare Pharmaceuticals, Inc, Wayne, NJ, USA,* [2]*Bayer Schering Pharma, AG, Berlin, Berlin, Germany*

OBJECTIVES: To determine the cost of non-CF bronchiectasis patients enrolled in a managed care plan. **METHODS:** Data were obtained from a large employer-based claims database. A cohort of bronchiectasis patients (cases) with and without acute exacerbations was identified using *ICD-9* 494.0 and 494.1 codes and matched (1:3) on demographics to those without the disease (controls) from January 1, 2005-December 31, 2009. Index event for cases were defined as the first medical claim of bronchiectasis during the study period and controls were assigned the same index event to whom they were matched. Cases had no medical claim for cystic fibrosis and chronic obstructive pulmonary disorder 12 months prior (baseline) and post index event. Medical resource use and expenditures were estimated for 12 months before and after index event. All statistical tests were conducted using SAS 9.2. **RESULTS:** The final study sample included 9,146 cases and 27,438 matched controls. 64% and 50% of the sample was females and between 45-64 years of age at index date, respectively. 37%, 29%, and 27% of the sample was enrolled in a POS, HMO, or PPO type of health plan. Overall comorbidity burden as measured by the Charlson comorbidity score and respiratory conditions other than bronchiectasis were significantly ($p<.001$) greater at baseline among cases vs. controls. The incremental overall ($2,128 vs. $783) and respiratory-related ($896 vs. $100) costs were significantly ($p<.001$) greater among cases vs. controls. The difference was primarily driven by an increase in outpatient care visits (2.21 vs. 0.43), emergency room visits (0.31 vs. 0.08) and pharmacy scripts (3.58 vs. 0.83) in the post-index period vs. baseline in cases vs. controls. **CONCLUSIONS:** The study found that overall incremental economic impact of non-CF bronchiectasis to a health plan was $1345 per patient. Further research needs to identify the impact of current treatment on the burden of the disease.

PIN33

ECONOMIC IMPACT OF THE ANTIRETROVIRAL PHARMACOTHERAPY ON COST AND HIV/AIDS CONTROL IN BULGARIA

Dimitrova M[1], Manova M[2], Yancheva N[3], Tcherveniakova T[4], Stefanova M[2], Petrova G[5]
[1]*Faculty of Pharmacy, Medical University- Sofia, Bulgaria, Sofia, Bulgaria,* [2]*Medical University Sofia, Faculty of Pharmacy, Sofia, Bulgaria,* [3]*University Hospital for active treatment of infectious and parasitic diseases, , Sofia, Bulgaria,* [4]*Hospital for Infectious and Parasitic Diseases, Sofia, Bulgaria,* [5]*Medical University, Faculty of Pharmacy, Sofia, Bulgaria*

OBJECTIVES: To analyze the changes in the antiretroviral pharmacotherapy during 2006-2010 and its impact on cost and disease control of HIV/AIDS patients in Bulgaria. **METHODS:** Micro costing approach was used based on retrospective analysis of patients' records in major clinic for immunosuppressed patients at the University hospital of infectious and parasitic diseases in Sofia. Information was gathered for the way of diseases transmission, antiretroviral combinations and their cost, CD4 count and viral load per patient per year. It was evaluated the changes in the dosage regimes, cost of therapy and its influence on CD4 count and viral load. **RESULTS:** On total 162 patients were included in the study. Nearly 40 different dosage regimes were identified and all of them are combinations of 3 or 4 medicines. During the period were introduces 3 new antiretroviral medicines (tenofovir, emtricitabin, darunavir). The average yearly cost of pharmacotherapy (all regimes and patients) is increasing from 155 837.64 euro to 319 571.76 euro during 2006 - 2010 due to switch of the therapy for some of the patients to newer medicines because of drug toxicity, resistance or other reasons. All newly registered patients are treated with the new antiretroviral products and their yearly cost of therapy is 178251.12 euro. Introduction of the new medicines led to the increase in total pharmacotherapy cost with 291 89.64 euro, but also to better control measured with the increase in CD4 count (>500) and sustained suppression of vial load to <20 in 45.46% of patients. **CONCLUSIONS:** HIV/AIDS remain costly diseases for the Bulgarian population but new medicines led to better control on its progress and thus could save further hospital cost.

PIN34

COST-EFFECTIVENESS OF RESPIRATORY SYNCYTIAL VIRUS (RSV) VACCINATION OF DUTCH ELDERLY

Pouwels K[1], Meijboom M[1], Luytjes W[2], Hak E[1], Postma M[1]
[1]*University of Groningen, Groningen, Groningen, The Netherlands,* [2]*National Institute for Public Health and the Environment (RIVM), Bilthoven, Utrecht, The Netherlands*

OBJECTIVES: Respiratory syncytial virus (RSV) is increasingly recognized as an important cause of morbidity, mortality and health-care resource use in the elderly. Therefore we determined whether there are specific levels of vaccine cost and effectiveness for which a hypothetical RSV-vaccine for Dutch elderly could be cost-effective. **METHODS:** The annual excess RSV-associated age- and risk-specific burden was estimated using a rate-difference method. Different vaccination strategies were evaluated, for various levels of vaccine effectiveness and different levels of willingness to pay per quality-adjusted life year gained (QALY). Outcome measures included costs, QALYs, life years gained (LYGs), and the amount of money that can be spent per vaccination, while remaining cost-effective. **RESULTS:** Significant excess RSV-associated deaths, hospitalisations, GP-visits and antibiotic prescriptions were found. The burden of RSV increased with age and was higher for high-risk (HR) elderly than for low-risk (LR) elderly. For several scenarios vaccination of the Dutch elderly appeared to be cost-effective. Using base-case assumptions, the amount of money that can be spent per vaccination, while remaining cost-effective, ranged from €26 when vaccinating all 60+ elderly to €68 when vaccinating only 85+ elderly, for a willingness to pay of €50,000 per QALY and a vaccine effectiveness of 70%. For HR-elderly only these estimates ranged from €52 to €99. **CONCLUSIONS:** Vaccination of Dutch elderly with a hypothetical RSV vaccine was found cost-effective for several scenarios. Vaccination is more likely to be cost-effective when vaccinating only HR elderly than when vaccinating all elderly, despite a decreased life expectancy and quality of life and a decreased effectiveness of the vaccine assumed in HR-elderly in the model. This study shows the major burden of RSV in the Dutch elderly, potential cost-effectiveness of vaccination, stressing the need to have an effective vaccine available shortly.

PIN35

COSTS OF MANAGING GENITAL WARTS IN THE UK

Carroll S[1], Charman F[1], Lanitis T[2], Brown R[3]
[1]*Sanofi-Pasteur MSD, Maidenhead, Berkshire, UK,* [2]*United BioSource Corp, London, Middlesex, UK,* [3]*United BIosource Corp, Bethesda, MD, USA*

OBJECTIVES: Cases of genital warts (GW), caused by human papillomavirus (HPV), remains a significant problem in the UK. Costs to the National Health Service (NHS) to manage GW have been recently estimated, but studies excluded treatment by General Practitioners (GP) and costed resources without inclusion of full staff time and overheads thereby underestimating the full cost impact. This study estimates the cost of GW management taking account of all identified GW cases seeking care and applying the full NHS cost algorithm. **METHODS:** The number of GW cases obtained from the surveillance of Genitourinary Medicine (GUM) clinics by Health Protection Agency (HPA) and estimated number of GP visits (using THIN data) for GW were combined and projected to 2010. The number of visits and therapy required for GW management were estimated by GUM experts for standard and hard-to-treat patients. NHS payment by results (PbR) tariffs were applied to estimate GUM resource costs and GP visit and therapy costs estimated from PSSRU and BNF data. **RESULTS:** Extrapolating to 2010, there were 173,077 GUM clinic (33.5% recurrent, 11% persistent) and 16,882 primary care GW episodes excluding referrals to GUM. Approximately 2% of GUM cases were estimated to be hard-to-treat, requiring additional visits and resources. Resulting NHS costs were £52.4 million (average £273/female; £278/male patient). The proportion hard-to-treat was the most sensitive variable for overall national costs. **CONCLUSIONS:** The £52.4 million includes the full per patient costs for GUM clinics and costs for GP visits not previously estimated. This is higher than previous estimates and reflective of real NHS costs. The full cost of GW management is important to understand and quantify when considering the potential value of introducing a quadrivalent HPV vaccination in the UK. This is relevant from both a public health and health economic perspective.

PIN36

SURGICAL SITE INFECTION INCIDENCE AND BURDEN ASSESSMENT USING MULTI-INSTITUTIONAL REAL-WORLD DATA

Delissovoy G[1], Pan F[2], Patkar AD[3], Edmiston CE[4], Peng S[2]
[1]*Johns Hopkins Bloomberg School of Public Health, Baltimore , MD, USA,* [2]*United Biosource Corporation, Bethesda, MD, USA,* [3]*Ethicon, Inc, Somerville, NJ, USA,* [4]*Froedtert Hospital, Milwaukee, WI, USA*

OBJECTIVES: Surgical site infections (SSIs) are a significant burden to healthcare systems negatively affecting Medicare reimbursement, quality and hospital reputation. This study quantifies the economic impact of SSIs across multiple institutions in the United States (US) using more up-to-date real-world data **METHODS:** The economic impact of SSIs was evaluated in following surgeries (colon, hernia, CABG, shunt, abdominal and vaginal hysterectomy, c-section, hip and knee prosthesis, spinal fusion, abdominoplasty and breast surgery). The data source was the Premier Perspective™ Comparative Database, a national administrative discharge database (2007-2010) from about 500 hospitals throughout the US. The SSIs were identified by a combination of post-operative infection diagnosis codes, or postoperative prescription of selected antimicrobial drugs with treatment duration ≥5 days. The outcomes included rates of SSI by surgical category, the impact of SSI on

length of stay (LOS) and costs. Results were projected to the national level. Generalized linear models were used for the analysis. Covariates included the baseline patient-level surgical risk factors and hospital characteristics. **RESULTS:** SSI incidence was highest among colon surgery [12.0%, 95%CI:11.78-12.2%0)] and CABG [6.1%; 95%CI:5.88-6.2%)] cases, and lowest among C-section [0.3%; 95%CI:0.28-0.31%)] and vaginal hysterectomy [0.16%; 95%CI:0.13-0.2%)] cases. The projected national rates captured by Premier database were similar to the rates reported by the National Health Safety Network reported rates. Among all surgical procedures, health resource use associated with CABG and colon surgery cases were most affected by SSI. SSI resulted on an average 10.58 [SD 2.78; (95%CI:10.56-10.60)] days and 9.72 [SD 3.43; (95%CI:9.70-9.74)] days of additional LOS and $38,796 [SD $8,555; (95%CI:$38,741-$38,850)] and $19,349 [SD $5,720; (95%CI:$19,315-$19,383)] of additional costs in CABG and colon procedures respectively. **CONCLUSIONS:** Despite rise in infection control practices postoperative SSIs continue to remain associated with significant increases in LOS and hospitalization costs.

PIN37

THE COST OF MANAGING CHRONIC HEPATITIS C IN SWEDEN - MEDICAL RESOURCE UTILISATION IN DIFFERENT STAGES OF THE DISEASE

Orrskog S[1], Friberg S[1], Lenre M[2], Bäckman L[3], Duberg AS[4], Flamholc L[5], Friman S[6], Hollander A[7], Sangfelt P[3], Verbaan H[5], Oksanen A[7]
[1]*Heron Evidence Development AB, Stockholm, Sweden,* [2]*Janssen AB, Sollentuna, Sweden,* [3]*Uppsala University Hospital, Uppsala, Sweden,* [4]*Örebro University Hospital, Örebro, Sweden,* [5]*Skåne University Hospital, Malmö, Sweden,* [6]*Sahlgrenska University Hospital, Göteborg, Sweden,* [7]*Karolinska University Hospital Huddinge, Stockholm, Sweden*

OBJECTIVES: Approximately 3% of the global population is infected with the hepatitis C virus. 20% of the patients will develop cirrhosis within 20 years of infection, and these patients have a 1% to 5% risk per year of developing hepatocellular carcinoma (HCC). Standard treatment for hepatitis C is pegylated interferon combined with ribavirin. The objective of this study was to obtain an understanding of the resource utilisation and costs associated with chronic hepatitis C in Sweden. **METHODS:** A literature review was conducted to identify resource utilisation and costs of chronic hepatitis C in Sweden. The MEDLINE, EMBASE, NHS EED and Cochrane CCTR databases were searched. To validate the results of the literature review and fill gaps in the evidence base, interviews were conducted with eight clinicians and one nurse specialised in the areas of infection, gastroenterology or transplantation medicine. The Skåne price list was primarily used to obtain the unit costs. **RESULTS:** Twelve publications were relevant for inclusion in the review. There was a lack of resource utilisation data for certain disease stages, primarily decompensated cirrhosis and HCC, and for updated unit costs, in these publications. Also, no studies reported indirect costs associated with chronic hepatitis C in Sweden. The pooled data from the literature review and the interviews indicated a direct cost per year of EUR 300 for mild disease, EUR 400 for moderate disease, EUR 900 for compensated cirrhosis, EUR 13,000 for decompensated cirrhosis, EUR 20,000 for HCC and EUR 120,000 for liver transplantation (including one-year follow up). **CONCLUSIONS:** Chronic hepatitis C is associated with high rates of health care utilisation. The driver of the direct medical costs is the management of long-term consequences including cirrhosis, HCC and liver transplantation. More efficient therapies with higher cure rates could potentially result in long-term cost savings by reducing severe complications.

PIN38

GUIDELINE EVALUATION OF COSTS RELATED TO CHRONIC HEPATITIS C AND ANTIVIRAL TREATMENT STRATEGIES

Stahmeyer JT[1], Krauth C[1], Abdelfattah M[2], Bert F[2], Rossol S[2]
[1]*Hannover Medical School, Hannover, Germany,* [2]*Krankenhaus Nordwest, Frankfurt a.M., Germany*

OBJECTIVES: Treatment of chronic hepatitis C infection is well established and will be expanded to triple treatment with new drugs like hepatitis C virus (HCV) protease inhibitors in Germany in fall 2011. Costs related to the current HCV guidelines will be a basis for further health economic analyses needed for pricing strategies but are not available yet. The aim of this study is to analyse the costs associated with diagnosis, treatment and monitoring of HCV infected patients according to the 2010 German S3-consensus guideline considering HCV genotype and length of therapy. **METHODS:** Patients with chronic HCV infection were divided in patients with 1) normal transaminases; 2) elevated transaminases; 3) compensated cirrhosis; and 4) decompensated cirrhosis. Direct costs according to the actual 2010 HCV German guideline were analysed for basic diagnostic procedures, monitoring and treatment for patient groups 1-3. Costs were modelled according to treatment duration (16 to 72 weeks) depending on the sustained viral response and HCV genotype. Costs were calculated according to the German outpatient fee scale EBM-2010. **RESULTS:** Costs for basic diagnostics including determination of HCV genotype and diagnosis of potential hepatic comorbidities accounted for €401 per patient. Monitoring costs accounted for €596 – €1173 depending on length of therapy. Pharmaceutical costs accounted for the largest part of the costs (€7,709 – €34,692). The total costs of a 16-week treatment including basic diagnostics, monitoring and pharmaceutical costs accounted for €8,706, €12,734 for a 24-week treatment, €24,529 for a 48-week treatment and €36,266 for 72-week treatment. **CONCLUSIONS:** State of the art and guideline cost evaluation for treatment of HCV infection show high costs for optimal and viral response guided therapy. These data can be used for further investigation of real life costs and costs of new triple treatment strategies in HCV treatment.

PIN39

COST ANALYSIS OF ANTIBIOTIC THERAPY OF ACUTE PERITONITIS IN UKRAINE

Bezditko N, Gerasymova O, Mishchenko O
National University of Pharmacy, Kharkiv, Ukraine

OBJECTIVES: The cost analysis of ten schemes antibiotic therapy (AT) in patients with acute peritonitis was conducted. These schemes are recommended by the Clinical Protocol of acute peritonitis treatment (MHO of Ukraine, order 1297, 02.04.2010) for use in practice. **METHODS:** The schemes of antibacterial therapy are: I – ertapenem (1,0 gr intravenously (iv.) 1 time/day); II – cefotaxim (1,0 gr im. 3 times/day and metronidazol 100 ml (sol. 0,5%) iv. 2 times/day); III – amoxicillin clavulanate (1,2 gr 3 times/day); IV – moxifloxacin (400 mg 1 time/day); V – levofloxacin (500 mg iv. 1 time/day and metronidazol 100 ml (sol.0,5%) iv. 2 times/day); VI – cefepim (2,0 gr iv. 2 times/day and metronidazol 100 ml (sol.0,5%) iv. 2 times/day; VII – cefoperazone + sulbactam (2,0 gr 3 times/day); VIII – meropenem (500 mg iv. 4 times/day); IX – imipenem + cilastatin (500 mg/500 mg iv. 4 times/day); X – ciprofloxacin 400 mg iv. and metronidazol 100 ml (sol.0,5%) iv. 2 times/day. Three variants for each scheme were calculated: the schemes with original drugs, the schemes with generics and the schemes with ukrainian generics. Doses and duration of AT were calculated in accordance with the Clinical Protocol of acute peritonitis treatment. **RESULTS:** The costs range of treating one patient with acute peritonitis with original drugs is 3891 UAN (scheme I) - 7994 UAN (scheme VI). The costs range with generics of ukrainian production is 1924 UAN (scheme V) - 5413 UAN (scheme VIII) (1 EUR = 11,65 UAN). **CONCLUSIONS:** The costs of treatment schemes for patients with acute peritonitis with use of less expensive generic drugs are not always cheaper than the costs of original drugs using. The optimal schemes for treatment of patients with acute peritonitis were selected.

PIN40

LINEZOLID VERSUS VANCOMYCIN FOR SKIN AND SOFT TISSUE INFECTIONS BY METHICILIN-RESISTANT STAPHYLOCOCCUS AUREUS: A COST COMPARISON ANALYSIS UNDER THE PUBLIC HOSPITAL PERSPECTIVE IN BRAZIL

Fujii RK[1], Takemoto MLS[2], Mould JF[3], Fernandes RA[4], Santos PML[4], Takemoto MMS[4], Lanzara G[5]
[1]*Pfizer Pharmaceutics inc., São Paulo, São Paulo, Brazil,* [2]*ANOVA - Knowledge Translation, Rio de Janeiro, Rio de Janeiro, Brazil,* [3]*Pfizer, Inc., New York, NY, USA,* [4]*ANOVA - Knowledge Translation, Rio de Janeiro, Brazil,* [5]*Pfizer Parmaceutics Inc., São Paulo, São Paulo, Brazil*

OBJECTIVES: Seventy-nine percent of the skin and soft tissue infections (SSTI) are caused by staphylococcus aureus, from which 1/3 is methicilin-resistant staphylococcus aureus (MRSA). This study aims to compare SSTI-MRSA treatment costs with linezolid versus branded and generic vancomycin under the Brazilian public payer perspective. **METHODS:** A cost comparison study was performed to compare linezolid versus generic and branded vancomycin. As supported by clinical studies, overall treatment duration of 15 days with linezolid and 14 days with vancomycin was considered, using PO linezolid after a minimum 4-days cycle of IV infusion while vancomycin (1g bid) was entirely IV. A decision-tree model simulated SSTI-MRSA treatment assuming linezolid (600mg bid) IV can be switched to PO after 4-days and patients can be discharged if PO is implemented at physician discretion. Length of stay (LOS) and IV linezolid duration were ranged in one-way sensitivity analysis. Only direct medical costs were included in the analysis (hospital charges, medical visits, medical supplies and drug acquisition costs) and unit costs were obtained from Brazilian official price lists (2010 USD values). **RESULTS:** The linezolid scheme with 4-days IV (LOS=4 days) and 11-days PO resulted in overall costs per patient of 2,540 USD, while branded and generic vancomycin exhibited 3466 USD and 3663 USD, respectively. The incremental cost of vancomycin-treated patients was driven by hospital daily charges, responsible for over 60% of the overall vancomycin costs. One-way sensitivity analysis revealed cost-savings for linezolid up to LOS≥9 days, with overall costs per patient ranging from 2540-4548 USD even if IV therapy was maintained throughout the inpatient period (LOS=15 days). **CONCLUSIONS:** Linezolid exhibited a cost-saving profile over branded or generic vancomycin for the treatment of SSTI-MRSA under the Brazilian public payer perspective. This economic benefit was a direct result of potential early discharge of patients receiving PO linezolid.

PIN41

COST-BENEFIT ANALYSIS OF REGIONAL PROCURED ESSENTIAL MEDICINES IN THE SOUTHERN AFRICAN DEVELOPMENT COMMUNITY (SADC) WITH A FOCUS ON ACCESS TO ANTIRETROVIRAL DRUGS

Miller-Jansön HE, Stander M
HEXOR (Pty) Ltd, Johannesburg, Gauteng, South Africa

OBJECTIVES: SARPAM is a programme, designed to ensure the improvement of access to quality essential medicines in SADC. An economic appraisal was undertaken from a societal perspective to assess the economic feasibility of SARPAM's implementation. The evaluative framework considered elements linked to improved access to quality medicines which included regional procurement of ARVs. The objective was to report the positive impact of this initiative on access to health care. **METHODS:** Direct health care costs were estimated as the incremental investment needed to effectively implement regional cooperation processes over a 4 year period. Direct healthcare benefits were defined as the *"negative costs"* incurred due to monetary savings and rational drug use. These savings were based on the well-established advantages of regional procurement cooperation. Indirect health care benefits were estimated using the Human Capital Approach. **RESULTS:** In total, an investment of US$14 million in SARPAM (discounted at a rate of 4.5%) over a four-year period will result in overall benefits of between US$20 million to US$38 million. The resultant benefit-cost ratio ranges from 1.40: 1 to 2.72: 1. In terms of HIV/AIDS in South Africa in particular, the analysis estimated a *potential* maximum incremental benefit of US$147 million which could treat an additional 757,000 patients with first line treatment. These results confirm that major benefits might be derived from the SARPAM programme, including a regional procurement cooperation intervention of ARVs. **CONCLUSIONS:** There is compelling evidence that the

SARPAM programme, including a regional procurement cooperation intervention of ARVs, is both a cost beneficial and cost effective way of improving access to essential medicines in SADC. Specifically, this will have a significant impact on the access to healthcare of HIV AIDS patients where antiretroviral drug costs will be significantly reduced.

PIN42

METHODOLOGICAL DECISIONS IN ECONOMIC EVALUATIONS OF CHILDHOOD INFLUENZA VACCINATION: FINDINGS FROM A LITERATURE REVIEW

Newall AT[1], Jit M[2], Beutels P[3]
[1]University of New South Wales, Sydney , NSW, Australia, [2]Health Protection Agency, London, UK, [3]University of Antwerp, Antwerp, Belgium

OBJECTIVES: Influenza vaccination programs targeted at children have gained increasing attention in recent years. In the US, recommendations for influenza vaccination have expanded over the last decade to include all children aged 6 months to 18 years. However, in most other developed countries childhood influenza vaccination has been restricted to targeted programs for children at risk of influenza complications. **METHODS:** A literature search was conducted for English-language economic evaluations of influenza vaccination in those aged less than 18 years. Studies evaluating vaccination options exclusively targeted at specific risk groups were excluded. The literature search identified 20 relevant studies which were reviewed. **RESULTS:** The studies differed widely in terms of the costs and benefits that were included. All but one of the studies were conducted from a societal perspective. The majority of the studies included the value of lost productivity due to caregivers missing work to care for sick children. However, other forms of lost productivity were considered by some studies, including those resulting from being vaccinated, school absenteeism, premature death, and illness in caregivers. Only a small minority of studies also measured benefits in terms of non-monetised utilities such as quality-adjusted life years. Several evaluations, particularly those directly targeted at healthy children, did not include serious influenza complications. Only one of the reviewed studies used a dynamic transmission model able to fully incorporate the indirect herd protection to the wider population. **CONCLUSIONS:** The conclusions of the studies were generally favourable towards vaccination. Methodological decisions in terms of what costs and benefits to include appeared influential. Many studies applied a wider perspective (i.e. including productivity losses) than the reference case for economic evaluations used in many countries.

PIN43

THE TOTAL COST OF HIV PATIENTS TREATED WITH ARV THERAPY: REAL WORLD EVIDENCE FROM THREE ITALIAN ADMINISTRATIVE DATABASES

Degli Esposti L[1], Sangiorgi D[1], Soro M[2], Buda S[1]
[1]CliCon Srl, Ravenna, Italy, [2]Abbott Labs, ROME, RM, Italy

OBJECTIVES: To calculate the cost of Human Immunodeficiency Virus (HIV) patients treated with Anti-Retroviral therapy (ARV) including medications, hospitalizations, tests, and specialist visits over a 12 months follow-up period, 3 Italian Local Health Units databases were analysed. **METHODS:** All records (patients ≥18 years) between January 1, 2008 and December 31, 2009 associated with nucleoside analogue reverse-transcriptase inhibitor (NRTI), non-nucleoside analogue reverse-transcriptase inhibitor (NNRTI), protease inhibitor (PI), or other drugs in ATC J05A group, were included. Data and costs were collected for medications, hospitalizations, diagnostic tests, and specialist visits for the 12 months after the first ARV prescription (follow-up). Records of treatment for the 24 month prior to the first ARV prescription were classified as naïve or experienced. Costs-per-unit for resource use were collected from DRGs, National Tariffs and Drugs Formulary. **RESULTS:** A total of 779 records were analyzed 515 male (46.4±9.7years) and 264 female (42.0±9.2years). Records were classified as naïve (12,7%) and experienced (87,3%). The most prescribed regimens were Efavirenz+Tenofovir/Emtricitabine (TDF/FTC) (22.1%), Atazanavir±ritonavir(r)+ TDF/FTC (17.2%), and Lopinavir/r+TDF/FTC (11.2%). No switching of therapy during the follow-up was found in 78.2% of the records. Amid non-switcher records, the annual average total cost (medications, hospitalizations, tests, and specialist visits) was €9,103.82±5,302.11, including €7,099.70 for ARV therapy (77%), €631.65 for HIV-related hospitalizations (7%), and €551.49 for HIV-related diagnostic tests/specialist visits (6%). Total costs for Efavirenz+TDF/FTC, Atazanavir±r+TDF/FTC and Lopinavir/r+TDF/FTC regimens amounted to 7,637.40€, 11,257.00€ and 9,426.94€ respectively, with higher total costs being associated with Atazanavir±r+TDF/FTC. **CONCLUSIONS:** In this administrative databases analysis, the annual total average cost of HIV patients was significantly influenced by specific ARV medications, suggesting that total cost of therapies could differ significantly from drug acquisition cost of a single drug. A payer's perspective should include all direct costs and not only drug acquisition costs.

PIN44

COST-EFFECTIVENESS OF QUADRIVALENT HPV VACCINATION IN GERMANY USING A DYNAMIC TRANSMISSION MODEL

Schobert D[1], Remy V[2], Schöffski O[3]
[1]Universität Erlangen-Nürnberg, Nürnberg, Germany, [2]Sanofi Pasteur MSD, Lyon, France, [3]Friedrich-Alexander-Universität Erlangen-Nürnberg, Nuremberg, Germany

OBJECTIVES: Several health-economics models have evaluated cost-effectiveness of HPV vaccination in Germany. These static models do not consider the dynamics of infection or the herd immunity effect of vaccination on vaccinees' contacts. The objective of this study is to assess the epidemiological and economic impact of a prophylactic quadrivalent human papillomavirus vaccine (HPV6/11/16/18) in Germany with the help of a dynamic transmission model. **METHODS:** We adapted a previously published HPV6/11/16/18 dynamic transmission model to the German context. The model was populated with German-specific data where available and was manually calibrated to fit German epidemiological data. The base case analysis evaluated the current HPV vaccination programme for girls aged 12-17 years (cumulative coverage rate at 20 years of 45% and 55% for the 12-14 and 15-17 respectively), alongside current cervical cancer screening, versus screening only. **RESULTS:** At a steady state, the model projected that the vaccination strategy could reduce the number of HPV 6/11/16/18-related cervical cancer, CIN2/3, CIN1 and genital wart cases among women by 64.6%, 64.3%, 58.9% and 69.9% respectively. In addition, girls' vaccination could indirectly lead to a decrease of 48.2% of genital warts cases in males. The incremental cost-effectiveness ratio (ICER) of the current vaccination programme was estimated at €5,525 per QALY and €10,205 per LYG. Excluding vaccine's protection against HPV6/11 would increase the ICER to €10,296/QALY. An increase in girls' vaccination coverage rates would lead to a substantial disease reduction. **CONCLUSIONS:** In Germany, the current quadrivalent HPV vaccination programme can be regarded as a cost-effective strategy. An increase in vaccination coverage rate could lead to a more effective programme. Further public health benefits could be expected on other HPV-related diseases such as vulvar, vaginal and anal precancerous lesions on which the quadrivalent vaccine has demonstrated high efficacy.

PIN46

COST-EFFECTIVENESS AND PUBLIC HEALTH IMPACT OF PNEUMOCOCCAL VACCINATION IN MALAYSIA

Lee KK[1], Hong LW[2], Roberts CS[3], Lee VW[4], Hon E[5], Strutton DR[6]
[1]Monash University Sunway Campus, Bandar Sunway, Selangor, Malaysia, [2]Pfizer (Malaysia) Sdn Bhd, Shah Alam, Selangor, Malaysia, [3]Pfizer, Inc., New York, NY, USA, [4]Chineses University of Hong Kong, Hong Kong, China, [5]Chinese University of Hong Kong, Hong Kong, China, [6]Pfizer, Inc., Collegeville, PA, USA

OBJECTIVES: There are currently two pneumococcal conjugated vaccines in Malaysia. Pneumococcal vaccination is not currently part of the national immunization program (NIP). We studied the cost-effectiveness of population-wide pneumococcal vaccination in Malaysian children with the 13-valent pneumococcal conjugate vaccine (PCV13) versus the 10-valent pneumococcal conjugate vaccine (PCV10). **METHODS:** A 10-year Markov model was used to analyze the population level public health and economic impact of infant vaccination. Costs were considered from the payer's perspective. A 3% discount rate was applied to costs and outcomes. Local and regional epidemiology data were used when possible. PCV13 and PCV10 effectiveness was extrapolated from PCV7 data, taking into consideration the local serotype distribution. Medical and vaccine costs were obtained from local sources while lifetime medical costs of disability were estimated from US data. The analysis assumes a 3-dose vaccination series. Sensitivity analyses were performed to assess the robustness of the results. **RESULTS:** More cases of invasive pneumococcal disease (IPD) (8,671 cases), hospitalized pneumonia (346,716 cases), non-hospitalized pneumonia (897,729 cases) and acute otitis media (72,220 cases) are estimated to be avoided following vaccination with PCV13 vs PCV10. 1,952 IPD related deaths and 16,114 deaths from hospitalized pneumonia would additionally be prevented. Compared to PCV10, PCV13 saved an additional 489,916 life years and 447,681 QALYs. This resulted in a cost per life-year saved of RM18,011 and a cost per QALY gained of RM 19,710 for PCV13 vs PCV10. **CONCLUSIONS:** This analysis supports the cost-effectiveness of PCV13 vaccination compared with PCV10 in a potential NIP in Malaysia.

PIN47

COST-EFFECTIVENESS OF TELBIVUDINE IN FIRST LINE TREATMENT OF HBEAG-NEGATIVE PATIENTS WITH CHRONIC HEPATITIS B (CHB) IN THE TURKISH HEALTHCARE SETTING

Pala M[1], Sahin U[2]
[1]Novartis, Istanbul, Turkey, [2]Novartis, istanbul, Turkey

OBJECTIVES: The aim of this study is to analyze the cost-effectiveness over 6-year duration of first line telbivudine and lamivudine treatment in HBeAg-negative CHB patients with low viral load at baseline in line with the Turkish reimbursement guideline for oral CHB therapies. **METHODS:** Using a decision analytical model, cost-effectiveness of telbivudine was evaluated versus lamivudine in first-line use for HBeAg-negative patients with baseline serum HBV DNA levels <7 log10 copies/mL in Turkish healthcare setting from national payer's perspective in accordance with the local reimbursement guideline for oral CHB treatments based on roadmap concept. Primary measure of effectiveness was undetectable HBV DNA level by polymerase chain reaction (PCR) assay at model duration, while costs included only cost of oral CHB drugs incurred by the Payer. Probabilities of PCR negativity and resistance rates used in the model are derived from telbivudine's head-to-head study vs lamivudine subgroup analyses outcomes for week 24 and 104; and from respective pivotal clinical studies for second line therapies. **RESULTS:** In the CE model, total oral CHB treatment cost per negative patient treated with lamivudine and telbivudine arm over 6 years was estimated to be 9141€ and 7980€ respectively. Percentage of patients remaining on lamivudine at model duration was 29%, while 67% on telbivudine. The average cost-effectiveness ratio, cost per successfully treated patient at year 6, was calculated as 10,754€ for the lamivudine arm and 8,750€ for the telbivudine arm (difference is 2,004€) and the incremental cost-effectiveness ratio was -18,726€. **CONCLUSIONS:** First line CHB treatment with telbivudine in negative patients has been demonstrated as a dominant cost-effective option than lamivudine in the Turkish health care setting. Although telbivudine has higher reimbursement price, it has been offset by superior efficacy compared to lamivudine in HBeAg-negative patients with baseline serum HBV DNA levels <7 log10 copies/mL and less need for more costly second line treatments.

PIN48

COST-EFFECTIVENESS OF A PENTAVALENT HUMAN-BOVINE REASSORTANT ROTAVIRUS VACCINE (RV5) IN JAPAN

Yamabe K[1], Abe M[1], El khoury A[2], Itzler RF[3]
[1]MSD.K.K. Japan, Tokyo, Japan, [2]Merck Sharp & Dohme Corp., WHITEHOUSE STATION, NJ, USA, [3]Merck Sharp & Dohme Corp., UPPER GWYNEDD, PA, USA

OBJECTIVES: This study assesses the cost-effectiveness of universal vaccination with RV5 in a hypothetical cohort of 1,091,156 children in Japan during their first 5 years of life. **METHODS:** A Markov model was developed to evaluate the cost per quality-adjusted-life-year (QALY) from the healthcare and societal perspectives. The base case scenario assumes 94% of the vaccinated cohort received 3 doses of RV5 orally at 2, 4, and 6 months of age with the remaining children receiving only 1 or 2 doses. In the absence of a vaccination strategy, there is annually 1 death, 78,000 hospitalizations, and 739,874 outpatient visits. The efficacy of RV5 was based on the results of the Rotavirus Efficacy and Safety Trial (REST). The three dose efficacy in REST was similar to the one obtained from clinical trials conducted in Japan. **RESULTS:** Universal vaccination could reduce hospitalizations by 89% and all symptomatic episodes of rotavirus gastroenteritis by 59%. For the base case scenario, at a cost of JPY 5316 per dose and administration fee of JPY ,100 per dose, the cost per case avoided was JPY 22,704 and the cost per QALY saved was JPY 2,230,978 from the healthcare payer perspective. From the societal perspective, the cost per case avoided was JPY 8,934 and the cost per QALY saved was JPY 877,855. **CONCLUSIONS:** Using three times the GDP per capita as a threshold, universal vaccination with RV5 is likely to be cost-effective and to result in substantial reductions in rotavirus-related healthcare use in Japan.

PIN49

COST-EFFEECTIVENESS OF EARLIER INITIATION OF FIRST LINE COMBINATION ANTIRETROVIRAL THERAPY IN AN URBAN OUTPATIENT HIV CLINIC IN UGANDA

Kuznik A, Sempa J, Ssennono M, Hermans S, Castelnuovo B, Lamorde M, Semeere A, Auerbach B, Sowinski S, Ssewankambo F, Manabe YC
Infectious Diseases Institute, Kampala, Uganda

OBJECTIVES: According to national guidelines, HIV-positive patients in Uganda are to be initiated on combination antiretroviral therapy (cART) at a CD4+ T-cell (CD4) count below 250 cells/μl. However, cART initiation at higher CD4 counts increases survival, albeit at higher lifetime treatment cost. This analysis evaluates the cost-effectiveness of initiating cART at CD4 counts between 250 – 349 cells/μl vs. current guidelines. **METHODS:** The average CD4 decline in untreated patients with CD4 counts below 550 cells/μl occurs at a rate of 96.6 cells/μl annually. Life expectancy of cART-treated patients, conditional on baseline CD4 count, is modeled based on published literature. First line cART costs US$192 annually, with an additional US$113 per year for patient monitoring. Delay of cART until the CD4 count falls below 250 cells/μl incurs the cost of the bi-annual CD4 test and cost of routine maintenance care at US$85 annually. The analysis compares lifetime treatment costs and disability adjusted life-expectancy between early vs. delayed cART for ten baseline CD4 count ranges from 250-259 to 340-349 cells/μl. All costs and benefits are discounted at 3% annually. **RESULTS:** Treatment delay varies from 0.5 year (CD4: 250-299) – 1 year (CD4: 300-349). Early cART initiation increases life expectancy between 1.48 and 3.01 years and averts 1.31 – 2.67 disability adjusted life years (DALY's) per patient. Lifetime treatment costs are US$4255 – US$5210 for early initiation and US$3755 – US$4307 for delayed initiation. The cost/DALY averted of the early versus delayed start ranges from US$354 – US$362. **CONCLUSIONS:** In HIV-positive patients presenting with CD4 counts between 250-350 cells/μl, immediate initiation of cART is a highly cost-effective strategy using the recommended 1 time per capita GDP threshold of $460 reported for Uganda. Expanding the number of treatment slots to include patients with higher CD4 counts would constitute an efficient use of scarce health care dollars.

PIN50

THE CLINICAL EFFICACY AND COST-EFFECTIVENESS OF BOCEPREVIR IN COMBINATION WITH PEGYLATED INTERFERON- ALFA AND RIBAVIRIN FOR THE TREATMENT OF GENOTYPE 1 CHRONIC HEPATITIS C PATIENTS: A WITHIN TRIAL ANALYSIS FROM THE PERSPECTIVE OF THE SCOTTISH NATIONAL HEALTH SERVICE (NHS)

Nikoglou E[1], Humphreys S[1], El khoury A[2], Ferrante SA[3], O' Regan C[1]
[1]Merck Sharp and Dohme, Hertfordshire, UK, [2]Merck & Co, Whitehouse Station, NJ, USA, [3]Merck & Co, UPPER GWYNEDD, PA, USA

OBJECTIVES: Chronic infection with the hepatitis C virus (HCV), if not cleared, can cause severe liver damage and eventual death. Despite treatment with current standard of care (pegylated interferon-alfa and ribavirin (PR)), sustained virologic response (SVR) is achieved in less than half of genotype 1 HCV patients. This analysis evaluated the cost-effectiveness of boceprevir in combination with PR in treatment-naïve and previously treated genotype 1 HCV patients, based on results of the phase III clinical trials, and from the perspective of NHS Scotland. **METHODS:** A Markov model was created to simulate the three treatment strategies studied in the boceprevir phase III trials: boceprevir response guided therapy (RGT), where a shortened treatment duration was possible for early responders; a full duration boceprevir arm (4 weeks PR plus 44 weeks triple therapy); and a 48 week PR standard of care arm. Each treatment regimen including boceprevir was compared to the PR standard of care arm. The incremental cost-effectiveness ratio (ICER) was measured in terms of cost per quality adjusted life year. The efficacy values applied were taken from the boceprevir clinical trials. In treatment naïve patients, 63% and 66% patients achieved SVR in the boceprevir RGT and full duration arms respectively, compared to 38% in the control arm. In previously treated patients, 59% and 67% patients achieved SVR in the boceprevir RGT and full duration arms respectively, compared to 21% who received PR alone. **RESULTS:** The ICER over current standard of care lies between £6,462 and £13,299 for treatment naïve patients and between £5,248 and £6,684 for treatment experienced patients, depending on treatment duration. **CONCLUSIONS:** The addition of boceprevir to current standard of care for HCV genotype 1 patients is clinically efficacious and cost-effective, and comfortably below a threshold of £20,000 per QALY, irrespective of whether patients have been previously treated.

PIN51

A COST-EFFECTIVENESS ANALYSIS OF LINEZOLID VERSUS VANCOMYCIN FOR VENTILATOR-ASSOCIATED PNEUMONIA PATIENTS IN PANAMA

Lutz MA[1], Villalobos D[2], Morales G[3], Cuesta G[3]
[1]Pfizer S.A., Escazú, San Jose, Costa Rica, [2]Complejo Hospitalario Dr. Arnulfo Arias Madrid, Panama City, Panama City, Panama, [3]Pfizer Central America and the Caribbean, Escazú, San Jose, Costa Rica

OBJECTIVES: Ventilator-associated pneumonia (VAP) is the most common nosocomial infection in the intensive care unit (ICU). It's associated with significant morbidity, increasing the ICU and hospital length of stay (LOS), and raising overall costs. Panama's statistics are similar to those reported in developed countries. Literature suggests that costs could be reduced using the most efficient empiric therapy. The aim of this study was to assess the cost-effectiveness (CE) of linezolid against generic vancomycin as an empiric therapy for VAP patients, from the health care payer's perspective. **METHODS:** A decision-tree model was used to compare costs and effectiveness of linezolid (600mg/12 hours) and vancomycin (1g/12 hours) (comparator) for a cohort of patients with VAP. Effectiveness measures were: clinical and microbiological success rates, mortality rates, ICU LOS and overall costs. Effectiveness and epidemiologic data were collected from published literature. Local costs (2011 US$) were obtained from Panama's Social Security official databases. The model used a 12-week time horizon and only direct medical costs were considered (hospital LOS, medication costs, hematologic, gastrointestinal and skin adverse events and lab exams). Monte Carlo probabilistic sensitivity analysis (PSA) was constructed. **RESULTS:** Results showed linezolid as more effective and less expensive option for VAP. Clinical success rate was higher with linezolid (64%) against vancomicyn, (59.5%). Mortality was lower with linezolid (10.13% vs. 15.74%). Average ICU LOSs was 17.4 days with linezolid and 21.26 days with vancomycin. Overall medical costs per patient were $19,507 with linezolid and $20,411 with vancomycin. CE analyses showed linezolid is the dominant strategy. Acceptability curves showed that linezolid would be cost-effective within <3 GDP per capita threshold. PSA outcomes support the robustness of these findings. **CONCLUSIONS:** This is the first CE study for VAP developed in Panamá. Linezolid resulted as the cost-saving option for treating VAP patients in the Panamanian clinical environment.

PIN52

COST-EFFECTIVENESS OF RIFAMPICIN-BASED CONTINUATION PHASE OF TUBERCULOSIS TREATMENT IN UGANDA

Kuznik A, Hermans S, Castelnuovo B, Auerbach B, Ssewankambo F, Sempa J, Ssennono M, Lamorde M, Semeere A, Manabe YC
Infectious Diseases Institute, Kampala, Uganda

OBJECTIVES: Approximately 40,000 new TB cases are treated annually in Uganda, and 4,000 are reported to require re-treatment (category II treatment). Current tuberculosis (TB) treatment in Uganda is standard 4 drug therapy in intensive phase (2 months), followed by isoniazid and ethambutol for 6 months (6HE). However, the World Heath Organization recommends isoniazid and rifampicin for 4 months (4HR) in the continuation phase, which is associated with better efficacy. We sought to investigate the cost-effectiveness of 4HR vs. 6HE. **METHODS:** Randomized clinical trial evidence indicates a significant decrease in the rate of treatment failure and relapse associated with 6HE versus 4HR from 10.0% to 5.0%. The median international daily drug price is HR: US$0.115 and HE: US$0.069. When the initial regimen is not successful, re-treatment is associated with a mortality rate of up to 23% and involves an additional 8 month drug-regimen at a cost of US$39.25. A decision tree was used to calculate the expected total cost of TB treatment in the 4HR versus 6HE arm. **RESULTS:** The cost of TB treatment in the continuation phase is 4HR: US$13.82 and 6HE: US$12.46. However, once the cost of re-treatment is factored in, the average weighted treatment cost is 4HR: US$15.79 and 6HE: US$16.38. Replacing 6HE with 4HR nationally could decrease the annual cost of TB treatment by an estimated US$23,500 and prevent about 2,000 TB treatment failures and relapses per year. **CONCLUSIONS:** Combination therapy with 4HR in the continuation phase dominates 6HE, as it is associated with improved effectiveness and a lower average cost per patient. Since treatment failure or relapse is associated with worsened clinical outcomes in resource constrained settings, considerable gains to population health could be achieved at lower cost if 4HR became the new standard of care in the continuation phase of TB treatment in Uganda.

PIN53

COST-EFFECTIVENESS ANALYSIS OF PEGYLATED INTERFERON ALPHA-2A VERSUS PEGYLATED INTERFERON ALPHA-2B IN THE TREATMENT OF CHRONIC HEPATITIS C PATIENTS IN POLAND

Macioch T[1], Paweska J[1], Niewada M[1], Berak H[2], Szkultecka-Debek M[3], Russel-Szymczyk M[3]
[1]HealthQuest Sp.z o.o., Warsaw, Poland, [2]Hospital for Infectious Diseases, Warsaw, Poland, [3]Roche Polska Sp. z o.o., Warsaw, Poland

OBJECTIVES: To assess cost-effectiveness of pegylated interferon alpha-2a (PegIFNα2a) vs. pegylated interferon alpha-2b (PegIFNα2b) in the treatment of chronic hepatitis C (HCV) patients from Polish public payer perspective. **METHODS:** Systematic review assessed clinical efficacy and safety of the two treatment op-

tions. Seven state Markov model (chronic HCV, sustained virological response, compensated cirrhosis, hepatocellulare carcinoma, liver transplantation and death) was used to estimate clinical effects and costs in lifetime horizon, from Polish public payer perspective. Direct medical costs were considered. Separate analysis was done for genotypes 1,4 (48-week treatment) and genotypes 2,3 (24-week treatment). Clinical practice and cost data were gathered from clinical experts or based on the National Health Fund and Ministry of Health published price lists. Sensitivity analysis was conducted in order to assess the robustness of the results. **RESULTS:** Genotypes 1 and 4: total costs were 92 036 PLN (1 Euro=3.96 PLN) for PegIFNα2a and 87 793 PLN for PegIFNα2b. Average survival of HCV patient treated with PegIFNα2a was 27.9 life years (LY) and 14.83 quality adjusted life years (QALY) and treated with PegIFNα2b was 27.63 LYs and 14.61 QALYs. The incremental cost-effectiveness ratio was 15 878 PLN/LYG and incremental cost-utility ratio was 19 763 PLN/QALY. Values of both ratios fall below the cost-effectiveness threshold assumed in Poland (100 000 PLN/LYG or QALY). Genotypes 2 and 3: Total costs were 32 849 PLN for PegIFNα2a and 38 071 PLN for PegIFNα2b. Average survival of HCV patient treated with PegIFNα2a was 30.79 LYs and 17.15 QALYs and treated with PegIFNα2b was 30.20 LYs and 16.68 QALYs. The PegIFNα2a dominated PegIFNα2b. The results were confirmed in sensitivity analysis. **CONCLUSIONS:** PegIFNα2a is a clinically effective and safe treatment for HCV patients and is highly cost-effective (or dominant) from Polish public payer perspective.

PIN54

COST-EFFECTIVENESS OF 2+1 DOSING OF 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE COMPARED WITH 2+1 DOSING OF 10-VALENT CONJUGATE VACCINE IN PREVENTING PNEUMOCOCCAL DISEASE IN CANADA

Earnshaw S[1], Mcdade C[1], Zanotti G[2], Farkouh RA[3], Strutton D[4]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*Pfizer Canada Inc, Kirkland, QC, Canada,* [3]*Pfizer, Inc., Collegeville, PA, USA,* [4]*Pfizer Inc., Collegeville, PA, USA*

OBJECTIVES: Thirteen-valent pneumococcal conjugate vaccine (PCV13) and 10-valent pneumococcal conjugate vaccine (PCV10) are two approved vaccines for the active immunization against *Streptococcus pneumoniae*, causing invasive pneumococcal disease in infants and children. PCV13 offers broader protection against *Streptococcus pneumoniae*; however, PCV10 offers potential additional protection against non-typeable *Haemophilus influenzae*. We examined public health and economic impacts of a PCV10 and PCV13 pediatric national immunization programs (NIPs) in Canada. **METHODS:** A decision-analytic model was developed to examine the costs and outcomes associated with a 2+1 dosing of PCV10 and 2+1 dosing of PCV13 pediatric NIP. The model followed patients over the remainder of their lifetime. Recent disease incidence, serotype coverage, population data, percent vaccinated, costs, and utilities were obtained from the published literature. Direct and indirect effects were derived from 7-valent pneumococcal vaccine. Additional direct effect of 4% was attributed to PCV10 for moderate to severe AOM to account for potential non-typeable *Haemophilus influenzae* benefit. Annual number of disease cases and costs (2010 CAN$) were presented. **RESULTS:** In Canada, PCV13 prevented more cases of disease (7,465 when considering direct effects only and 49,340 when considering both direct and indirect effects) than PCV10. This translated to population gains of 80,565 to 94,134 more quality-adjusted life years when vaccinating with PCV13 versus PCV10. Use of PCV13 in children also reduced annual direct medical costs (including the cost of vaccination) by $5.8 to $132.8 million. Thus, PCV13 was found to dominate PCV10. One-way sensitivity analyses showed PCV13 to always be dominant or cost-effective versus PCV10. **CONCLUSIONS:** Considering the epidemiology of pneumococcal disease in Canada, 2+1 dosing of PCV13 is shown to be a cost saving immunization program as it provides substantial public health and economic benefits relative to 2+1 dosing of PCV10.

PIN55

COST-EFFECTIVENESS ANALYSIS OF PEGINTERFERON ALFA-2A (40KD) IN HBEAG-POSITIVE CHRONIC HEPATITIS B IN POLAND

Jakubczyk M[1], Pawęska J[2], Niewada M[2], Berak H[3], Szkultecka-Dębek M[4], Russel-Szymczyk M[4]
[1]*Warsaw School of Economics, Warsaw, Poland,* [2]*HealthQuest spółka z ograniczoną odpowiedzialnością Sp. K., Warsaw, Poland,* [3]*Hospital for Infection Disease, Warsaw, Poland,* [4]*Roche Polska Sp. z o.o., Warsaw, Poland*

OBJECTIVES: The analysis aimed to evaluate the cost-effectiveness of 48-week therapy with peginterferon alpha-2a (PegIFNα-2a) in HBeAg-positive chronic hepatitis B (CHB) patients versus 48-week (short-term analysis) or 4-year (long-term analysis) therapy with adefovir, entecavir or lamivudine from the public payer perspective in Poland. **METHODS:** A life-time Markov model based on previously published analysis was used. States encompassed treatment response (HBeAg seroconversion), relapse, complications (compensated/decompensated cirrhosis, hepatocellular carcinoma, liver transplantation) and death. Quality-adjusted life years (QALYs) were the measure of effectiveness. Short-term efficacy assessment was based on the results of randomized clinical trials (RCTs). Long-term efficacy data for nucleos(t)ide analogues (NAs) were derived from published models and RCTs extensions. Utilities and transition probabilities (spontaneous response, relapse, complications, death) were taken from published literature. Direct medical costs, i.e. costs of drugs and procedures used in the treatment of CHB and its complications were obtained using a survey conducted among Polish clinicians. In the base case analysis costs and benefits were discounted at a 5% and 3.5% annual rate, respectively. The robustness of the results was assessed using one-way, scenario and probabilistic sensitivity analyses. **RESULTS:** In both the short and long-term analysis PegIFNα-2a increased number of QALYs and life years gained (LYGs) compared to all investigated NAs. In the short-term model PegIFNα-2a decreased the costs of complications' treatment and increased the overall costs due to drug acquisition cost. ICER for PegIFNα-2a vs. lamivudine, adefovir and entecavir amounted to 50,809, 11,442 and 39,588 PLN/QALY, respectively (1€≈4 PLN). In the long-term model costs of NAs were higher. PegIFNα-2a was cost-saving and dominated adefovir and entecavir, while ICER versus lamivudine amounted to 27,431 PLN/QALY. Sensitivity analysis proved these results to be robust. **CONCLUSIONS:** Peginterferon alfa-2a is cost-effective when compared to adefovir, entecavir and lamivudine in Poland.

PIN56

COST-EFFECTIVENESS MODEL TO EVALUATE 200-DAY VS 100-DAY TREATMENT WITH VALGANCICLOVIR PROPHYLAXIS TO REDUCE CYTOMEGALOVIRUS DISEASE IN HIGH-RISK (D+/R-) KIDNEY TRANSPLANT RECIPIENT IN SPAIN

Fernández-Rivera C[1], Torre-Cisneros J[2], Guirado-Perich L[3], Oyagüez I[4], Ruiz-beato E[5]
[1]*Complexo Hospitalario Universitario, La Coruña, Spain,* [2]*Hospital Universitario Reina Sofía, Córdoba, Spain,* [3]*Fundación Puigvert, Barcelona, Spain,* [4]*Pharmacoeconomics & Outcomes Research Iberia, Pozuelo de Alarcón , Madrid, Spain,* [5]*Roche Farma, S.A, Madrid, Spain*

OBJECTIVES: IMPACT trial showed that prolonged prophylaxis of 200 days with valganciclovir (VGC 200) compared with 100 days (VGC 100) significantly decreases the incidence of cytomegalovirus (CMV) disease. Therefore, a cost-effectiveness model was developed to evaluate prolonged prophylaxis of 200 days with valganciclovir and its long term economic impact . **METHODS:** A Markov model was designed to simulate the CMV disease progression; costs and outcomes associated with the use of VGC 200 vs VGC 100 in a cohort of 10,000 patients over 10 years was examined. Data of the disease evolution were obtained from the IMPACT (Humar, Am J Transplant 2010) for year 1 and the available scientific evidence for years 2-10. The analysis was conducted from the perspective of the Spanish National Healthcare System (SNHS), considering direct medical costs. Unitary costs (€, 2010) were obtained from a Spanish database. Utility values were obtained from literature. The annual discount rate was 3% for costs and outcomes. **RESULTS:** Treatment with VGC 200 provides better results in health than VGC 100 (50,020.30 vs. 47,639.90 QALY/patient). The average overall cost per patient is €1,121,327 with VGC 200 and €1,131,187 with VGC 100. The savings per patient treated with VGC 200 in 10 years is €986. Sensitivity analysis confirms the stability of the results. **CONCLUSIONS:** Treatment of patients with prolonged prophylaxis valganciclovir reduces the incidence in high risk kidney transplant recipients and is a cost-saving strategy in CMV disease management from the perspective of the SNHS.

PIN57

COST-EFFECTIVENESS OF THE NEW GUIDELINES FOR THE PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV IN UGANDA

Kuznik A, Lamorde M, Semeere A, Castelnuovo B, Hermans S, Auerbach B, Ssewankambo F, Ssennono M, Sempa J, Mpanga Sebuyira L, Manabe YC
Infectious Diseases Institute, Kampala, Uganda

OBJECTIVES: In Uganda, 91,000 children are born annually to HIV-positive mothers, approximately 25,000 of which become HIV-infected. New guidelines recommend the use of combination antiretroviral therapy (cART) to prevent vertical transmission. We evaluate the cost-effectiveness of more costly cART relative to other or no preventative therapies. **METHODS:** Currently, about 48.4% of HIV-positive pregnant women do not receive any preventive therapies and therefore have a 40% risk of transmitting HIV to their child during pregnancy or breastfeeding. This risk can be reduced to 25.8% by single dose nevirapine (sdNVP; Cost: US$0.06), to 17.4% by dual therapy (3TC/AZT; Cost: US$16 for 7 weeks) and to 3.8% by cART (Cost: US$470 for 18 months). At CD4 counts below 350 cells/μl, lifetime cART is indicated for the mother (Cost: US$ 6,883), which reduces future transmission risk in an additional 3.49 pregnancies. The model calculates disability adjusted life years (DALY's) between therapies based on differences in HIV-transmission to children, which results in shortened life-expectancy. All costs and benefits are discounted at 3% annually. **RESULTS:** Replacing sdNVP and 3TC/AZT with cART could reduce annual HIV transmissions by 7,500 cases. Preventing one infection averts 23.7 DALY's. Hence, DALY's averted using 18 months cART versus sdNVP, 3TC/AZT, and no therapies are 5.21, 3.22, and 8.58, and yield a cost/DALY averted of US$46, US$99, and US$34, respectively. The corresponding figures for lifetime cART are 19.20, 11.87, and 31.60, resulting in a cost/DALY averted of US$205, US$354 and US$172, respectively. **CONCLUSIONS:** Using the 1 time per capita GDP threshold (US$460), cART as proposed in the new Ugandan guidelines is highly cost-effective relative to other drugs and would generate additional value if treatment could reach greater numbers of women. It remains highly cost-effective even if treatment is continued over the patients' lifetimes. It is imperative that these guidelines are rapidly implemented.

PIN58

COST-EFFECTIVENESS ANALYSIS OF PNEUMOCOCCAL 13-VALENTE CONJUGATE VACCINE VERSUS PNEUMOCOCCAL 10-VALENTE CONJUGATE VACCINE IN THE PEDIATRIC IMMUNIZATION ROUTINE, FROM THE SÃO PAULO STATE PUBLIC HEALTH CARE SYSTEM (BRAZIL)

Pepe C[1], Teich V[1], Mould JF[2]
[1]*MedInsight, São Paulo, São Paulo, Brazil,* [2]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: It is estimated that pneumococcal disease is responsible for more than a million deaths per year in children less than five years of age worldwide. This study aim to perform a cost-effectiveness analysis comparing pneumococcal 13-valent conjugate vaccine (PCV13) against pneumococcal 10-valent conjugate vaccine in prevention of invasive pneumococcal diseases (IPD), acute otitis media (AOM) and pneumonia, from the São Paulo Public Healthcare System perspective. **METHODS:** The type of study was cost-effectiveness analysis based on a decision tree model to estimate costs and consequences of prophylaxis. Epidemiological and efficacy data was collected from a critical appraisal of the scientific literature,

public databases information and clinical expert panel. The target population was a birth cohort in São Paulo followed for 5 years (598,474). The vaccination coverage rate was 90%, considering a four-dose schedule for 10-valent and tree-dose schedule for PCV13 as suggested by international guides. São Paulo costs and disease data was obtained from national official databases. A mandatory discounted price to the government, calculated by the ex-factory price minus 24.38% was considered to PCV13 and 10-valent. Costs and benefits were discounted at 5% annually. Outcomes were expressed as life years gained(LYG), deaths and number of disease cases avoided. Only the direct effect of vaccination and direct medical costs were considered. **RESULTS:** The analysis showed higher clinical benefits and lower costs for PCV13 prophylaxis; reduction of 7 deaths, 488 LYG and 17 cases of disease (sepsis and meningitis) and savings of BRL70,097,844(USD43,909,950) in 5 years. The total costs with events and vaccines were BRL113,902,160(USD72,576,883) and BRL137,914,893(USD87,877,465), respectively, for PCV13; and BRL113,999,789(USD71,410,542) and BRL207,915,109(USD130,239,983) for 10-valent. **CONCLUSIONS:** This study demonstrated that incorporating PCV13 in pediatric immunization routine results in reduction on mortality and morbidity with lower expected cost for São Paulo state healthcare system, showing the dominance of PCV13 regarding 10-valent.

PIN59

A COST-EFFECTIVENESS ANALYSIS OF VORICONAZOL, ANFOTERICINE B AND CASPOFUNGIN FOR INVASIVE ASPERGILOSIS PATIENTS IN PANAMA

Lutz MA[1], Trujillo JM[2], Morales G[3], Cuesta G[3]
[1]*Pfizer S.A., Escazú, San Jose, Costa Rica,* [2]*Hospital Oncológico Nacional, Panama City, Panama City, Panama,* [3]*Pfizer Central America and the Caribbean, Escazú, San Jose, Costa Rica*

OBJECTIVES: Invasive aspergilosis (IA) is a mycotic disease produce by Aspergillus sp and represents the second leading cause of invasive fungal infections. The mortality rate is about 50%. The aim of this study was to assess the cost-effectiveness (CE) of voriconazol, anfotericine B and caspofungin as first line treatments for IA adult patients in Panama, from the healthcare payer's perspective. **METHODS:** A decision-tree model was used to compare costs and effectiveness of anfotericine B (comparator), caspofungin and voriconazol for a cohort of patients with IA. Effectiveness measures were: clinical success rates, mortality rates, intensive care unit (ICU) length of stay (LOS), hospital ward LOS and overall costs. Effectiveness and epidemiologic data were collected from published literature. Local costs (2011 US$) were obtained from Panama's Social Security and Hospital Oncológico Nacional official databases. The model used a 12-week time horizon and only direct medical costs were considered. Monte Carlo probabilistic sensitivity analysis (PSA) was constructed. **RESULTS:** Results showed voriconazol as the most effective and least expensive option for IA. Clinical success rate was higher with voriconazol (56.6%) compared with anfotericine B (36.4%) and caspofungin (34.2%). Mortality rates were: 34.1% with voriconazol, 50.9% with anfotericine B and 44.7% with caspofungin. Average ICU LOSs was 7.59 days with voriconazol and 9.94 and 9.81 days with anfotericine B and caspofungin, respectively. Voriconazol also obtained the shortest ward LOS (15.96 days). Overall medical costs were $13,100 with voriconazol, $17,347 with anfotericine B and $13,716 with caspofungin. CE analyses showed voriconazol as the dominant strategy. Acceptability curves showed that voriconazol would be cost-effective within <3 GDP per capita threshold. PSA outcomes support the robustness of these findings. **CONCLUSIONS:** This is the first CE study for IA developed in Panamá. Voriconazol resulted as the cost-saving option for treating IA patients in the Panamanian clinical context.

PIN60

COST-EFFECTIVENESS OF TELBIVUDINE IN FIRST LINE TREATMENT OF HBEAG-POSITIVE PATIENTS WITH CHRONIC HEPATITIS B (CHB) IN THE TURKISH HEALTH CARE SETTING

Pala M, Sahin U
Novartis, Istanbul, Turkey

OBJECTIVES: The aim of this study is to analyze the cost-effectiveness over 6-year duration of first line telbivudine and lamivudine treatment in HBeAg-positive chronic hepatitis B patients with low viral load at baseline in line with the Turkish reimbursement guideline for oral CHB therapies. **METHODS:** Using a decision analytical model, cost-effectiveness of telbivudine was evaluated versus lamivudine in first-line use for HBeAg-positive patients with baseline HBV DNA levels <9 log10 copies/mL in Turkish healthcare setting from National Payer's perspective in accordance with the local reimbursement guideline for oral CHB treatments based on roadmap concept. Primary measure of effectiveness was undetectable HBV DNA level by polymerase chain reaction (PCR) assay at model duration, while costs included only cost of oral CHB drugs incurred by the Payer. Probabilities of PCR negativity and resistance rates used in the model are derived from telbivudine's head-to-head study versus lamivudine subgroup analyses outcomes for week 24 and 104; and from respective pivotal clinical studies for second line treatments. **RESULTS:** In the CE model, total oral CHB treatment cost per HBeAg-positive patient treated with lamivudine and telbivudine arm over 6 years was estimated to be 12,873€ and 11,435€ respectively. Percentage of patients remaining on lamivudine at model duration was 23%, while 50% on telbivudine. The average cost-effectiveness ratio, cost per successfully treated HBeAg-positive patient at year 6, was calculated as 15,362€ for the lamivudine arm and 13,053€ for the telbivudine arm (difference is 2,309€), and the incremental cost-effectiveness ratio was -37,859€. **CONCLUSIONS:** First line CHB treatment with telbivudine in HBeAg-positive patients has been demonstrated as a dominant cost-effective option than lamivudine in the Turkish healthcare setting. Although telbivudine has higher reimbursement price, it has been offset by superior efficacy compared to lamivudine in positive patients with baseline serum HBV DNA levels <9 log10 copies/mL and less need for more costly second line treatments.

PIN61

COST OF VIROLOGIC RESPONSE WITH TWO ACTIVE DRUGS IN THE OPTIMIZED BACKGROUND THERAPY WITH ETRAVIRINE, RALTEGRAVIR, AND MARAVIROC IN THE BRAZILIAN NATIONAL AIDS PROGRAM

Morais AD[1], Pereira ML[2], Azevedo H[3]
[1]*Janssen Cilag Farmaceutica, Sao Paulo, Sao Paulo, Brazil,* [2]*Janssen Cilag Farmaceutica, São Paulo, Brazil,* [3]*Janssen Cilag Farmaceutica, São Paulo, São Paulo, Brazil*

OBJECTIVES: To estimate the cost of virologic response at week 48 of treatment with etravirine (ETV), raltegravir (RAL) and maraviroc (MAV) for multi-experienced patients with 2 or more active drugs in the optimized background therapy (OBT) in the Brazilian National AIDS Program. **METHODS:** Treatment regimens of ETV and RAL were defined by the Brazilian national guidelines. Regimens with MAV were based in the same principles, although the drug is not yet reimbursed. Patients not achieving virologic response followed onto subsequent rescue treatments, defined by the guidelines. Re-treatment was not allowed. Treatment costs included cost of medication as published on the government website. The cost of MAV was defined by law. The number of multi-experienced patients receiving treatment was based on the dispensed capsules of RAL in the last 48 weeks. Virologic response was gathered from the phase III clinical trials of ETV, MAR and RAL, at week 48 for patients with two active drugs in the OBT defined by phenotypic susceptibility. **RESULTS:** The average cost of treatment at week 48 for multi-experienced patients with at least 2 active drugs in the OBT was R$ 27,243.14 with ETV, compared with R$ 27,702.91 with RAL, and R$ 31,220.72 with MAR. Given 5,627 multi-experienced patients received treatment, 862 patients failed with MAV, 544 failed treatment with RAL compared to 337 failed patients with ETV. For one third of the cohort (1.875), the total cost of treatment was R$ 58,565,276 for MAV, R$ 51,966,391 for RAL, and R$ 51,103,946 for ETV. **CONCLUSIONS:** Despite similar treatment costs, treatment with ETV compared to RAL and MAV is a more economic option for the treatment of multi-experienced patients with at least two active drugs in the OBT. At week 48, treatment with RAL and MAV was on average 2% and 15% more expensive compared to ETV, respectively.

PIN62

A MULTIDISCIPLINARY SUPPORT PROGRAM IN HEPATITIS C TREATMENT: AN ECONOMIC EVALUATION

Martín-Escudero V[1], Garcia-Retortillo M[2], Cirera I[2], Giménez M[2], Márquez C[2], Cañete N[2], Carrion J[2], Castellví P[2], Lázaro D[2], Navinés R[3], Castaño J[4], Urbina O[5], Salas E[5], Bory F[2], Martín-Santos R[3], Rubio-Terrés C[6], Solà R[2]
[1]*Roche Farma, Madrid, Spain,* [2]*Liver Section, Hospital del Mar.IMIM.Universitat Autònoma de Barcelona, Barcelona, Spain,* [3]*Dep.of Psychiatry and Psyc,Institute of Neurosciences, Hospital Clínic,Universitat de Barcelona, IDIBAPS. IMIM. Hospital del Mar, Barcelona, Spain,* [4]*Psychiatric Department,Hospital del Mar. IMIM, Barcelona, Spain,* [5]*Pharmacy Department,Hospital del Mar. Barcelona, Barcelona, Spain,* [6]*HealthValue, Madrid, Spain*

OBJECTIVES: To develop a cost-effectiveness analysis of a multidisciplinary support program (MSP) versus the conventional approach in the Hepatitis C (HC) treatment. **METHODS:** A total of 278 mono-infected naive HC patients were included: 131 in the MSP group and 147 patients were conventionally controlled (control group). All patients were treated with Peg-IFN-alfa-2a/ribavirin. The MSP team not only included hepatologists and nurses, but also, pharmacists, psychologists and assistants. Standard patient education, open and flexible visits scheduling, continued psychiatric evaluation and active medication control were carried out in the MSP. Treatment adherence, sustained virological response (SVR), and health resources use were evaluated. A Markov model for a lifetime horizon with seven health states and from the Spanish NHS perspective was developed. Transition probabilities and health states utilities were obtained from published literature. Costs were obtained from the Catalogue of Medicinal Products and from Spanish studies and databases (€-2010). 3.5% annual discount for costs and outcomes was applied. **RESULTS:** In the MSP group treatment compliance was higher than in the control group (94.6% vs 78.9%, p=0.0001). SVR was higher in the MSP group than in controls for all genotypes (77.1% vs. 61.9%, p=0.006), G-1/4 (67.7% vs 48.9%, p=0.02), and G-2/3 (87.7% vs. 81.4%, NS). For all genotypes, the cost per patient (including cost of drugs, health professionals and disease long-term complications) was €13,319 in MSP group and €16,184 in control group, furthermore, MSP group resulted more QALYs than controls (16.317 vs. 15.814), being MSP dominant (more effective, with lower costs) compared with the conventional approach. The MSP program was also dominant in G-1/4 patients (saving €2476, increasing 0.622 QALYs/patient) and G-2/3 (saving €1417, gaining 0.208 QALYs/patient). Results were stable for 95% CI of drug doses. **CONCLUSIONS:** HC treatment with Peg-IFN-alfa-2a/ribavirin in a MSP improves the compliance and is a cost-effective strategy compared with the conventional approach.

PIN63

COST-EFFECTIVENESS ANALYSIS OF ANTI-PNEUMOCOCCAL VACCINES IN PANAMA

Lutz MA[1], Luciani K[2], Morales G[1], Strutton DR[3], Roberts CS[4], Farkouh RA[3], Cuesta G[1]
[1]*Pfizer Central America and the Caribbean, Escazú, San Jose, Costa Rica,* [2]*Hospital de Especialidades Pediátricas, Panama City, Panama,* [3]*Pfizer, Inc., Collegeville, PA, USA,* [4]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: In 2010, there were more than 1500 illness related to Streptococcus pneumonia infections in pediatric population under 2 years old in Panamá. Currently, in Panamá, Prevenar 7 is the anti-pneumococcal vaccine (PCV) used. The aim of this study was to estimate the cost-effectiveness and cost-utility of immunization strategies based on pneumococcal conjugated vaccines (PCVs) in Panamá, from an institutional perspective. **METHODS:** A decision tree steady state model

was used to assess the population level public health and economic impact of infant anti-pneumococcal vaccination. The alternatives compared were: no vaccination (comparator), PCV-7, PCV-10 and PCV-13. The effectiveness measures were: child illness avoided, life years gained (LYs) and quality-adjusted life years (QALYs) gained. Effectiveness and utilities were obtained from literature. Local costs (expressed in 2011 $US) and epidemiology (data from 2009-2011) were obtained from Panamá's official databases. Univariate sensitivity analysis was performed. The time horizon for total costs was one year and for outcomes was lifetime with a discount rate of 3%. **RESULTS:** Results show that immunization is cost-saving against no-vaccination. PCV-13 gained the highest number of QALYs (305) against PCV-10 (191) and PCV-7 (168). PCV-13 prevented 629 illnesses and gained 334 LYs. PCV-10 and PCV-7 prevented 392 and 359 illnesses and gained 208 and 182 LY's, respectively. Total costs of illness with PCV-13, PCV-10, PCV-7 and no vaccination were $622,445, $777,878, $804,978 and $1,005,512, respectively. These results were robust to variations in herd immunity and impact adjustments of PCV-10 immunogenicity. **CONCLUSIONS:** This is the first cost-effectiveness study for anti-pneumococcal immunization in Panamá. Immunization strategies based on 7, 10 and 13-valent PCV's may be cost-saving interventions compared to no vaccination. PCV-13 dominates PCV-10 and PCV-7.

PIN64

COST-EFFECTIVENESS ANALYSIS OF ANTI-PNEUMOCOCCAL VACCINES IN GUATEMALA

Lutz MA[1], Grazioso C[2], Morales G[3], Strutton DR[4], Roberts CS[5], Farkouh RA[4], Cuesta G[3]
[1]*Pfizer S.A., Escazú, San Jose, Costa Rica,* [2]*Hospital General San Juan Dios, Guatemala City, Guatemala City, Guatemala,* [3]*Pfizer Central America and the Caribbean, Escazú, San Jose, Costa Rica,* [4]*Pfizer, Inc., Collegeville, PA, USA,* [5]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: . Pneumococcal bacteremia and pneumonia are priority diseases for public health in Guatemala since these are among the 10 most frequent causes of hospitalizations and mortality in children under 4 years old. The aim of this study was to estimate the cost-effectiveness of immunization strategies based on pneumococcal conjugate vaccines (PCVs) in Guatemala, from an institutional perspective. **METHODS:** . A decision tree steady state model was used to assess the population level public health and economic impact of infant anti-pneumococcal vaccination. The alternatives compared were: no vaccination (comparator), PCV-10 and PCV-13. The effectiveness measures were: illness avoided life years gained (LYs) and quality-adjusted life years (QALYs) gained. Effectiveness and utilities were obtained from literature. Local costs (expressed in 2011 $US) and epidemiology (data from 2009-2011) were obtained from Guatemala's official databases. Univariate sensitivity analysis was performed. The time horizon for total costs was one year and for outcomes was lifetime with a discount rate of 3%. **RESULTS:** . Results show that immunization is cost-saving against no-vaccination. PCV-13 gained more QALYs (7,569) against PCV-10 (5,824). PCV-13 prevented 5658 illnesses and gained 8404 LYs, while PCV-10 prevented 4140 illnesses and gained 6465 LYs. Total costs of illness with PCV-13, PCV-10 and no vaccination were $2,599,952, $3,071,811 and $5,534,657, respectively. These results were robust to variations in herd immunity and impact adjustments of PCV-10 immunogenicity. **CONCLUSIONS:** . This is the first cost-effectiveness study for anti-pneumococcal immunization developed in Guatemala. Immunization strategies based on 10 and 13-valent PCV's may be cost-saving interventions. PCV-13 dominates PCV-10.

PIN65

HEALTH ECONOMIC MODEL ON THE COSTS AND EFFECTS OF ROTA VIRUS VACCINATION IN GERMANY

Knoll S[1], Benter U[2], Standaert B[3]
[1]*GlaxoSmithKline GmbH & Co. KG, Munich, Bavaria, Germany,* [2]*Kendle GmbH, Munich, Bavaria, Germany,* [3]*GlaxoSmithKline Biologicals, Wavre, Belgium*

OBJECTIVES: Rotavirus gastroenteritis (RVGE) is one of the most frequent diseases among children aged 5 or younger. A general recommendation for rotavirus vaccination in Germany does not exist so far, leading to a vaccination rate of < 30%. This analysis simulates the cost-effectiveness of a general rotavirus vaccination in Germany using Rotarix™ from the perspective of the statutory health insurance (SHI). **METHODS:** An existing Markov model on rotavirus infection in children (published before) was adapted to the German situation. The model simulates costs and effects of rotavirus vaccination in a birth cohort of 699,301 children. In the model, vaccine efficacy rates from international clinical trials were combined with German epidemiology and cost data from the SHI perspective for 2011 (including SHI reimbursed productivity losses of parents). The model assumes a vaccination rate of 100% and discount rates of 3% for costs and effects. Results were tested for robustness using sensitivity analyses. **RESULTS:** A 100% vaccination with RotarixTM could avoid approximately 156,000 RVGE cases and associated physician visits as well as in-patient hospital stays. From the SHI perspective, this leads to cost savings of 13.6 Mio € in total. The main factors responsible for these savings are in-patient hospital stays avoided (64.1 Mio €), SHI reimbursed productivity losses of parents (19.0 Mio €) and physician visits avoided (5.4 Mio €). On the other hand, vaccination costs amount to additional 79.4 Mio €. Stability of results was most sensitive with respect to epidemiological parameters (number of RVGE cases, in-patient hospital cases) as well as productivity loss. **CONCLUSIONS:** A general™ vaccination against rotavirus in Germany can avoid severe diarrhea events in children aged 5 and younger. Additional vaccination costs for the SHI are more than outbalanced by cost savings through in-patient hospital stays, SHI reimbursed productivity loss and physician visits avoided.

PIN66

COST OF VIROLOGIC FAILURE WITH ETRAVIRINE AND RALTEGRAVIR IN THE BRAZILIAN NATIONAL AIDS PROGRAM

Morais AD[1], Pereira ML[2], Azevedo H[3]
[1]*Janssen Cilag Farmaceutica, Sao Paulo, Sao Paulo, Brazil,* [2]*Janssen Cilag Farmaceutica, São Paulo, Brazil,* [3]*Janssen Cilag Farmaceutica, São Paulo, São Paulo, Brazil*

OBJECTIVES: To estimate the cost of virologic failure with the treatment of etravirine and raltegravir in multi-experienced patients in the Brazilian National AIDS Program. **METHODS:** Treatment regimens of etravirine and raltegravir were defined by the guidelines of the Brazilian National AIDS Program. Upon virologic failure, subsequent treatments were defined according to the same guidelines considering new drug combinations not yet used by the patients. Treatment costs considered the cost of medication as purchased by the Brazilian government and published on their website. As maraviroc, a rescue treatment, is not yet reimbursed by the AIDS program, its price was defined by law. To estimate the total cost, patient numbers were calculated by the number of capsules of raltegravir dispensed in the past 96 weeks, and assumed the same for patients treated with etravirine. Virologic failure was gathered from the phase III clinical trials of raltegravir and etravirine at week 48 and week 96. **RESULTS:** The average cost of treatment for multi-failure patients with etravirine was on average R$ 26.692,26 at week 48 of treatment compared to R$ 26.634,15 per patient treated with raltegravir. At week 96, the average treatment cost per patient was R$ 56.810,59 for raltegravir and R$ 53.904,30 for etravirine. Given that 3.942 patients received treatment in the previous 98 weeks, around 1.301 patients will fail treatment with raltegravir and 630 with etravirine. The total cost of treating these patients is R$ 73 million for raltegravir and R$ 34 million for etravirine. **CONCLUSIONS:** Despite a similar average cost at week 48, etravirine treatment is a more economic option for the treatment of multi-failure patients compared to raltegravir, saving up to 50% of treatment costs with virologic failure patients in the Brazilian National AIDS program over 96 weeks. Virologic failure is therefore an important indicator to avoid subsequent treatment costs especially in the long-term.

PIN67

COST-EFFECTIVENESS ANALYSIS OF PEGINTERFERON ALFA-2A (40KD) IN HBEAG-NEGATIVE CHRONIC HEPATITIS B IN POLAND

Jakubczyk M[1], Pawèska J[2], Niewada M[2], Berak H[3], Szkultecka-dèbek M[4], Russel-szymczyk M[4]
[1]*Warsaw School of Economics, Warsaw, Other ->, Poland,* [2]*HealthQuest spółka z ograniczoń odpowiedzialnośći Sp. K., Warsaw, Poland,* [3]*Hospital for Infection Disease, Warsaw, Poland,* [4]*Roche Polska Sp. z o.o., Warsaw, Poland*

OBJECTIVES: The analysis aimed to evaluate the cost-effectiveness of 48-week therapy with peginterferon alpha-2a (PegIFNα-2a) in HBeAg-negative chronic hepatitis B (CHB) patients versus 48-week (short-term analysis) or 4-year (long-term analysis) therapy with adefovir, entecavir or lamivudine from the public payer perspective in Poland. **METHODS:** A life-time Markov model based on previously published analysis was used. States encompassed treatment response (ALT normalization), relapse, complications (compensated/decompensated cirrhosis, hepatocellular carcinoma, liver transplantation) and death. Quality-adjusted life years (QALYs) were the measure of effectiveness. Short-term efficacy assessment was based on the results of randomized clinical trials (RCTs) corrected for response duration. Long-term efficacy data for nucleos(t)ide analogues (NAs) were derived from other published models and RCTs extensions. Utilities and transition probabilities (spontaneous response, relapse, complications, death) were derived from published literature. Direct medical costs, i.e. costs of drugs and procedures used in the treatment of CHB and its complications were obtained using a survey conducted among Polish clinicians. In the base case analysis costs and benefits were discounted at a 5% and 3.5% annual rate, respectively. The robustness of the results was assessed using one-way, scenario and probabilistic sensitivity analyses. **RESULTS:** The short and long-term analysis demonstrated that the use of PegIFNα-2a increased QALYs and life years gained (LYGs) compared to all investigated NAs. In the short-term model PegIFNα-2a decreased the costs of complications treatment and increased the overall costs due to drug acquisition cost. ICERs for PegIFNα-2a vs. lamivudine, adefovir or entecavir amounted to 43,621, 6,600 and 25,166 PLN/QALY, respectively (1€≈4 PLN). In the long-term model PegIFNα-2a was cost-saving and dominated adefovir, while ICERs vs entecavir and lamivudine amounted to 5,385 and 73,857 PLN/QALY, respectively. Sensitivity analysis proved these results to be robust. **CONCLUSIONS:** Peginterferon alfa-2a is cost-effective when compared to adefovir, entecavir and lamivudine in Poland.

PIN68

COST- EFFECTIVENESS ANALYSIS OF HUMAN PAPILLOMAVIRUS VACCINATION PROGRAM IN RUSSIA

Omelyanovsky V, Avxentyeva M, Krysanov I, Ivakhnenko O, Goryaynov S, Tsfasman FM
Research Center for Clinical &Economic Evaluation and Pharmacoeconomics (RC CEE&Ph), Russian State Medical University, Moscow, Russia

OBJECTIVES: To estimate cost-effectiveness of the vaccination program with quadrivalent Human Papillomavirus (HPV 6, 11, 16, 18) recombinant vaccine for the prevention of cervical intraepithelial neoplasia (CIN) and cervical cancer (CC) in Russian health care. **METHODS:** Cost-effectiveness analysis of vaccination program vs no vaccination was performed. The previously published model (R. Insinga et al.) was adjusted for Russia. Rates of CIN and CC were simulated with and without vaccination in a cohort of girls 12-13 years old. Time-horizon was 24 years. 100% vaccination coverage was assumed. Direct medical costs were estimated. Outcomes measured were: the cost of averted CIN case and the cost per additional life-year saved. **RESULTS:** The cost of introducing HPV vaccination program with 100% coverage of the target audience of 12-13 years old girls is 408,16 mln € (16,282,34 bln rubles). In the absence of vaccination the costs of providing medical care to patients with CIN and CC are 160,027 mln € (6, 36 bln rubles). Therefore the overall costs in a vaccinated cohort were 481,14 mln € (16,285,25 bln rubles). HPV

vaccine prevents 408 469 cases of precancerous cervical lesions. Due to HPV vaccination the incidence of CC is reduced by1858 cases, which corresponds to 31 588 years of life saved in the vaccinated cohort. The cost of an additional life-year saved is 10,166 € (405,535 rubles), and the cost of averted CIN case is 786 € (31,360 rubles). **CONCLUSIONS:** Vaccination with Human Papillomavirus recombinant vaccine seems a cost-effective option in Russia.

PIN69

METHODOLOGICAL CHALLENGES FOR ECONOMIC EVALUATIONS OF VACCINATION PROGRAMS: THE CASE OF PERTUSSIS BOOSTER VACCINATION

Millier A[1], Aballea S[2], Annemans L[3], Quilici S[4]
[1]Creativ Ceutical, Paris, France, [2]Creativ Ceutical, Paris, Ile de France, France, [3]Ghent University, Ghent, Belgium, [4]Sanofi Pasteur MSD, Lyon, France

OBJECTIVES: Pertussis incidence has been increasing in adolescents and adults in the last two decades with transmission to vulnerable young infants. This epidemiological changing has raised interest in the cost-effectiveness of booster vaccination (extra administration of a vaccine after an earlier dose). A critical review of economic evaluations of pertussis booster vaccination was performed in order to develop recommendations for future studies. This review illustrates specific challenges encountered in economic evaluations of vaccination programmes. **METHODS:** The literature search covered cost-effectiveness studies of pertussis booster vaccination, published until November 2010, worldwide. We extracted information on model structures, input data and results. **RESULTS:** We identified 13 publications (9 distinct models) referring to cost-effectiveness of pertussis booster vaccination. The most frequently studied strategies were adolescent booster vaccination (9/13), cocooning strategy, i.e. vaccination of mothers and family member(s) of newborn infants (6/13), one-time adult pertussis booster vaccination (6/13), and decennial vaccination of adults with pertussis containing boosters (4/13). All studies found that booster vaccination was a cost-effective or cost-saving strategy compared to no booster vaccination. However, conclusions differed concerning the exact age groups to vaccinate and frequency of vaccination. Results were strongly affected by assumptions regarding unreported cases and uncertainty around incidence. Four models ignored herd immunity (HI) effects, 3 assumed incidence reduction attributable to HI, and 2 were transmission dynamic models predicting HI effects. Several studies considered incidence at steady state, although it was not reached before 80 years for some strategies. Methods used to compare multiple strategies were often inappropriate. **CONCLUSIONS:** Reviewed studies showed that pertussis booster vaccination is cost-effective or dominant vs. no booster vaccination, but did not identify any optimal vaccination schedule. Results are variable due to uncertainty surrounding disease incidence and extent of HI. Future economic evaluations should explore a wider range of strategies, according to local context.

PIN70

MODELLING THE EPIDEMIOLOGICAL IMPACT OF ROTAVIRUS VACCINATION TO ASSESS ITS COST-EFFECTIVENESS IN ENGLAND AND WALES

Atkins KE[1], Shim E[2], Carroll S[3], Quilici S[4], Galvani AP[1]
[1]Yale University, New Haven, CT, USA, [2]University of Pittsburgh, Pittsburgh, PA, USA, [3]Sanofi Pasteur MSD, Maidenhead, UK, [4]Sanofi Pasteur MSD, Lyon, France

OBJECTIVES: Rotavirus infection causes severe gastroenteritis in children worldwide. Its disease burden has been reduced in countries where mass rotavirus vaccination programmes have been introduced. England and Wales (E&W) have not yet implemented such a mass vaccination programme, but are currently re-evaluating its potential cost-effectiveness. Our study uses a dynamic model to predict the epidemiological and economical effect of such a mass vaccination programme in E&W beginning in the autumn of 2011. **METHODS:** A previously published age-structured dynamic model was upgraded and parameterised with country-specific data for the introduction of the oral rotavirus pentavalent vaccine. We report the impact of vaccination on disease incidence reduction, timing of seasonal epidemics and herd immunity levels. The model was then used to assess whether a mass vaccination of RotaTeq is cost-effective and affordable for E&W. **RESULTS:** Our results predict that vaccination can reduce the burden of severe disease by 70% and delay the epidemic peak by two and a half months with coverage of 95%. Our calculations further show that herd immunity accounts for about a quarter of the reduction in incidence. If the pentavalent vaccine-induced immunity does not wane over five years, severe disease in children under five years of age is eliminated within two years after the introduction of vaccination. The probability of a mass vaccination strategy being cost-effective is presented under likely vaccine waning scenarios, administration cost assumptions and possible dose prices. **CONCLUSIONS:** This work allows policymakers to determine both the epidemiological impact and cost implications of a mass vaccination programme against rotavirus with the pentavalent vaccine in England and Wales. Although long considered unlikely to be cost-effective in E&W using static models, the pentavalent vaccine demonstrates a significant impact in reducing rotavirus cases at acceptable levels of cost-effectiveness when using appropriate modelling techniques.

PIN71

PHARMACOECONOMIC ANALYSIS OF TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA (CAP)

Zaitsev A[1], Synopalnikov A[2], Tyrsin O[3]
[1]The Main Military Clinical Burdenko Hospital, Moscow, Russia, [2]Russian Medical Academy of post-graduate education, Moscow, Russia, [3]Bayer Healthcare Pharma, Moscow, Russia

OBJECTIVES: Evaluation of comparative cost-effectiveness of CAP treatment with moxifloxacin versus combined therapy with cefotaxime and macrolides in adult patients. **METHODS:** Patients were randomized in two groups. MOX group received moxifloxacin 400 mg i.v. once-daily with further switch to oral formulation 400 mg daily. COMB group received either cefotaxime 1000 mg i.m. 3 times per day as monotherapy or in combination with oral azithromycin or clarithromycin. Efficacy and safety criteria were evaluated according to clinical data, laboratory tests and X-ray examination. Cost-effectiveness analysis was performed. **RESULTS:** MOX group included 30 patients, mean age 33.6±16.5 years; COMB group included 50 patients, mean age 26.5±15.6 years. The efficacy of moxifloxacin treatment was 96.7%, in-hospital stay duration was 15.9±3.3 days. The efficacy of treatment in COMB group was 88.0%, patients were discharged after 18.2±3.7 days. Direct medical costs including antibacterial treatment and in-hospital days were 46712 RUB (€1173) in MOX group and 46970 RUB (€1180) in COMB group. CERMOX = 48307 RUB (€1213), CERCOMB = 53375 RUB (€1340). **CONCLUSIONS:** CAP treatment with moxifloxacin compared to combined therapy with cefotaxime and macrolides in adult patients is more effective and cost saving technology.

PIN72

COST-EFFECTIVENESS OF ROTAVIRUS IMMUNIZATION IN VIETNAM: RESULTS AND CHALLENGES

Tu HAT[1], Rozenbaum M[2], Coyte PC[3], Li SC[4], Postma MJ[5]
[1]University of Groningen, Groningen, The Netherlands, [2]Rijksuniversiteit Groningen, Groningen, The Netherlands, The Netherlands, [3]University of Toronto, Toronto, ON, Canada, [4]University of Newcastle, Callaghan , NSW, Australia, [5]University of Groningen, Groningen, The Netherlands, The Netherlands

OBJECTIVES: To assess the cost-effectiveness of universal rotavirus immunization, explicitly the use of Rotateq® and affordability of implementing rotavirus immunization based on the Global Alliance for Vaccines and Immunization (GAVI)-subsidized vaccine price in the context of Vietnamese health care system for the next 5 years. **METHODS:** An age-structured cohort model was developed for the 2009 Vietnamese birth cohort and applied a 5-year time horizon with time cycle of 1 month for < 1-year-old children and annually thereafter. Results from no vaccination and vaccination were compared. Outcomes included rotavirus episodes requiring home-treatment, outpatient visits, hospitalizations and deaths. Multiple outcomes per rotavirus infection are possible in the model. Acceptability and affordability analyses were done using Monte Carlo simulations. Costs were expressed in 2009 US$. **RESULTS:** Rotavirus immunization would not completely protect under-five-year-old children against rotavirus infection due to partial nature of vaccine immunity, however, would effectively reduce rotavirus severe cases by ~55%. Under the GAVI-subsidized price, the minimum vaccination budget would be US$1.6 million annually. In the base-case, the incremental cost per quality-adjusted-life-year (QALY) was US$665 from health care perspective, <Vietnamese per-capita-GDP in 2009. Affordability results showed that at the GAVI-subsidized vaccine price, rotavirus vaccination could be affordable in Vietnam. **CONCLUSIONS:** Rotavirus immunization in Vietnam would be a cost-effective health intervention. However, it only becomes affordable under the GAVI's financial support. Vaccine price is the most crucial factor to decision-makers regarding introducing this vaccine into the country's immunization. Given the high under-five mortality rate, results showed that rotavirus immunization is the "best hope" for prevention of rotavirus-related diarrhoeal disease in Vietnam. In the next five years, Vietnam is definitely in debt to external financial support in implementing rotavirus vaccination. It is recommended that new and cheaper rotavirus vaccine candidates be developed to speed up rotavirus vaccines introduction in the developing world.

PIN73

MODELING THE LONG TERM CLINICAL OUTCOMES AND HEALTH CARE COST IMPACT OF INITIATING TREATMENT WITH ATAZANAVIR/R COMPARED WITH DARUNAVIR/R, LOPINAVIR/R AND EFAVIRENZ FOR HIV-1 INFECTED TREATMENT-NAÏVE PATIENTS: COUNTRY RESULTS FOR ITALY, SPAIN, PORTUGAL AND UK

Thuresson PO[1], Verheggen B[1], Heeg B[1], Aldir I[2], Carrasco J[3], Didoni G[4], Mesa OA[5], Lescrauwaet B[6]
[1]Pharmerit International, Rotterdam, The Netherlands, [2]Hospital Egas Moniz, Lisboa, Portugal, [3]Bristol-Myers Squibb, Paço de Arcos, Portugal, [4]Bristol Meyer Squibb, Rome, Italy, [5]Bristol-Myers Squibb Pharmaceuticals Ltd, Uxbridge, Middlesex, UK, [6]Xintera Consulting BVBA, Leuven, Belgium

OBJECTIVES: To estimate the cost and effects of initiating treatment with atazanavir/r (ATV/r) compared to darunavir/r (DRV/r), lopinavir/r (LPV/r) and efavirenz (EFV) in treatment-naïve HIV-1 patients in Italy(I), Spain(S), Portugal(P) and UK. **METHODS:** HIV-disease progression is modeled using a micro-simulation model. Health states are a function of HIV-RNA, CD4+cells, AIDS defining events (ADEs), and comorbidities. At model entry patients receive either ATV/r, LPV/r, DRV/r, or EFV with a treatment backbone. Treatment-sequences are modelled following treatment discontinuation due to virological failure, adverse events, resistance, or treatment related co-morbidities. Country-specific patterns for HIV related drug use were applied to estimate specific treatment sequences; maximized at 8 treatment lines after which patient were assumed to be untreated. Efficacy and tolerability inputs of first line treatments were derived from a Mixed-Treatment-Comparison, supplemented by published literature and product-SPCs for remaining drug specific data for efficacy, tolerability and safety. Occurrence of (non)-AIDS defining malignancies was linked to current CD4+cell count and independent of therapy. Cost estimates were based on country specific sources. A 25-year time-horizon was chosen for the base-case analyses. A payer's perspective was chosen and country-specific discount rates were applied. **RESULTS:** Across countries, total costs per patient who started with ATV/r ranged between €126,947(I) and €154,285(P). Predicted incremental costs of ATV/r versus comparators ranged between -€27,004 (S) versus LPV/r and -€13,165 (P) versus EFV. Estimated incremental QALYs of ATV/r versus comparators varied from -0.68(UK) versus EFV to 0.78(UK)

versus DRV/r. **CONCLUSIONS:** The value of initiation with ATV/r in terms of durable viral suppression and favourable side-effect profile was most prominent in Spain. In general, starting with ATV/r is suggested to be a cost-effective treatment strategy for HIV-1 treatment-naïve patients in most of the country-specific comparisons made.

PIN74

A COST-EFFECTIVENESS ANALYSIS OF VACCINATING THE ELDERLY WITH 23-VALENT PNEUMOCOCCAL POLYSACCHARIDE VACCINE (PPV23) IN GERMANY

Jiang Y[1], Gauthier A[1], Annemans L[2], van der Linden M[3], Nicolas-Spony L[4], Bresse X[4]
[1]*Amaris Consulting UK, London, UK,* [2]*Ghent University, Ghent, Belgium,* [3]*National Reference Centre for Streptococci, Aachen, Germany,* [4]*Sanofi Pasteur MSD, Lyon, France*

OBJECTIVES: *Streptococcus pneumoniae* is a leading cause of life-threatening pneumococcal diseases (PDs). In Germany, PPV23 has been recommended in the elderly (aged 60 and over) since 1998. In 2006, the pneumococcal conjugate vaccine (PCV) was introduced in children. The US experience showed that PCV vaccination of children led, ten years after its introduction, to a decrease in IPD incidence caused by the PCV serotypes not only in vaccinated children but also in unvaccinated adults. This study aimed to re-assess the good cost-effectiveness profile of PPV23 vs. no vaccination (NoVac) in the elderly in Germany, accounting for epidemiological changes in adults due to PCV vaccination of children. **METHODS:** A population-based Markov model was developed, consisting of five health states: no PD, IPD (invasive PD), NBPP (non-bacteraemic pneumococcal pneumonia), post-meningitis sequelae (PMS) and death. A cohort of individuals was followed until death assuming vaccination or no vaccination. IPD and NBPP incidence were retrieved from German sources, while the changes in IPD incidence were estimated based on US data. IPD and NBPP case-fatality rates, probability of developing PMS, vaccine effectiveness, vaccine waning function and utilities were retrieved from the published literature. A discount rate of 3% was applied to costs and effects. **RESULTS:** PPV23 was associated with a discounted increment of 1,587 QALYs. From the third party payer's (TPP) perspective, incremental costs were estimated at €28 million and the ICER was €17,700/QALY gained. From the societal perspective, PPV23 was associated with an increment of €14 million, and the ICER was €8579/QALY gained. Results were sensitive to vaccine effectiveness and epidemiological trends assumptions. **CONCLUSIONS:** The model suggests that vaccinating the elderly with PPV23 is cost-effective in Germany. As PPV23 covers 80%-90% of all serotypes causing IPD, it is still cost-effective despite the reduction in IPD incidence in adults due to PCV vaccination of children.

PIN75

COST-EFFECTIVENESS OF POLYSACCHARIDE PNEUMOCOCCAL VACCINATION IN PEOPLE AGED 65 AND ABOVE IN POLAND

Grzesiowski P[1], Soluch S[2], Adamczyk K[2], Durand L[3], Aguiar-Ibáñez R[4], Martin M[4], Puig PE[3]
[1]*University Children's Hospital, Warsaw, Poland,* [2]*Sanofi Pasteur, Warszawa, Poland,* [3]*Sanofi Pasteur, Lyon, France,* [4]*i3 Innovus, Uxbridge, UK*

Vaccination of elderly (65 and older) population against Streptococcus pneumonia is recommended in Poland but not publicly funded. Therefore coverage rates for pneumococcal vaccine have remained very low (less than 1%) meaning that no benefit of the vaccine has been felt in Poland and individuals remain largely unprotected. **OBJECTIVES:** An analysis was designed to analyse the cost-effectiveness of implementing a public vaccination programme in the elderly considering a 50% reimbursement of a 23-valent polysaccharide vaccine (PPV23) by the public health care payer: Narodowy Fundusz Zdrowia (NFZ). **METHODS:** To do so, a semi-dynamic Markov model with a 1-year cycle length was developed, allowing up to 10 cohorts to enter the model over the lifetime horizon. The model was populated with demographic, epidemiological and cost data from Polish sources or when unavailable, from international literature. The analysis included routine vaccination of all elderly or high-risk (HR) elderly versus no vaccination. Deterministic and probabilistic sensitivity analyses (DSA and PSA, respectively) were conducted to assess the robustness of the cost-effectiveness results. **RESULTS:** The vaccination program targeting all elderly in Poland would avoid 8935 pneumococcal infections, 2542 hospitalisations, 671 deaths; for HR elderly the program would avoid 5886 infections, 1673 hospitalisations and 441 deaths. The incremental cost per QALY gained for vaccination in all elderly was PLN 3382 and was PLN 2148 for HR elderly. Ratios were even lower when actual in and outpatients' costs instead of reimbursed costs were considered. Finally, ratios estimated in the base case and the sensitivity analyses, were well below the gross domestic product (GDP) per capita (i.e. PLN 37,055). **CONCLUSIONS:** This analysis suggests that vaccinating all elderly regardless of risk status with a 23-valent pneumococcal vaccine is highly cost-effective and supports the continued recommendation of pneumococcal vaccines, as well as their public funding in Poland.

PIN76

COST EFFECTIVENESS ANALYSIS OF VACCINATION WITH 13-VALENT (PCV13) AND 23-VALENT (PPV23) PNEUMOCOCCAL VACCINES FOR SENIOR ADULTS IN BRAZIL

Fujii RK[1], Mould JF[2], Presa J[3], Jardim E[3], Sato R[4], Strutton DR[5]
[1]*Pfizer Pharmaceutics inc., São Paulo, São Paulo, Brazil,* [2]*Pfizer, Inc., New York, NY, USA,* [3]*Pfizer Parmaceutics Inc., São Paulo, São Paulo, Brazil,* [4]*Pfizer, New York, NY, USA,* [5]*Pfizer, Inc., Collegeville, PA, USA*

OBJECTIVES: According to World Health Organization, pneumococcal related diseases is a major public health concern in the world, especially for those under 2 years of age and older adults. The objective of this analysis is to evaluate the cost effectiveness of vaccinating the Brazilian population 65 years of age and older with the 13-valent pneumococcal conjugate vaccine (PCV 13) in comparison to the 23-valent pneumococcal polysaccharide vaccine (PPV 23), each as a single dose, from the public payer perspective. **METHODS:** In order to estimate the costs and the impact of the pneumococcal disease over a 35-year time horizon period, including invasive pneumococcal disease, hospitalized pneumonia and non complicated pneumonia, a patient level microsimulation model simulating vaccination and outcomes of one cohort of 12,653,613 individuals over 65 years of age was adapted to the Brazilian public health care system. The probabilities and direct medical costs were extracted from literature review and DATASUS for January 2011, with costs presented in US$ 2010. The effectiveness measures were expressed as cases of pneumococcal diseases avoided, overall deaths avoided, and life years (LYs) saved. Probabilistic sensitivity analyses were conducted considering key variables. A discount rate of 5% was applied. **RESULTS:** Vaccinating with PCV13 prevents 349 additional cases of acute meningitis, 1,589 cases of invasive pneumococcal disease, 100,158 hospitalized pneumonia, 12,954 non complicated pneumonia and 30,904 deaths, saving 139,189,74 LYs compared to PPV23 over 35 years. The total costs including vaccination costs and medical costs resulted in US$135,625,000 less for PCV13 compared to PCV23 (US$5,875,625,000 vs. US$5,740,000,000). The model showed robustness through sensitivity analyses. **CONCLUSIONS:** The analysis suggests that vaccinating adults with PCV13 in Brazil is cost-saving compared to PPV23. The results in economic and disease burden are substantial and they support the decision making in favor of PCV13 for its high impact in public health.

PIN77

COST EFFECTIVENESS OF DE-ESCALATION FROM MICAFUNGIN IN THE TREATMENT OF PATIENTS WITH SYSTEMIC CANDIDA INFECTIONS COMPARED TO TRADITIONAL ESCALATION FROM FLUCONAZOLE

Masterton R[1], Casamayor M[2], Musingarimi P[3], Van Engen A[2], Odufowora-Sita O[3]
[1]*University of the West of Scotland, Ayrshire, UK,* [2]*Quintiles, Hoofddorp, Noord-Holland, The Netherlands,* [3]*Astellas Pharma Europe Ltd, Staines, UK*

OBJECTIVES: Systemic Candida infections (SCI) occur predominantly in intensive care unit (ICU) patients and are a common cause of morbidity and mortality. The increasing prevalence of SCI caused by Candida non-albicans species and higher resistance to fluconazole and azoles in general have prompted changes in the management of SCI. Current guidelines tend to favour treatment initiation with a broad spectrum antifungal such as an echinocandin with subsequent switch to fluconazole if isolates are sensitive (de-escalation) over the traditional first-line treatment with fluconazole (escalation). Cost-effectiveness of de-escalation strategy versus escalation in patients with SCI was evaluated from the UK NHS perspective. **METHODS:** Cost-effectiveness was estimated using decision analysis based on clinical and microbiological data from pertinent studies. The model horizon was 42 days, and was extrapolated to cover a life time horizon. **RESULTS:** In patients with fluconazole-resistant isolates, de-escalation avoids 30% more deaths and successfully treats 23% more patients than escalation, with cost savings of £1621 per treated patient. In the overall population with SCI, initial treatment with micafungin results in 1.2% fewer deaths at a marginal cost of £740 per patient alive. Over a lifetime horizon, the incremental cost effectiveness of de-escalation compared with escalation is £15,522 per life-year and £25,673 per QALY. Univariate analyses indicate that the incremental costs per QALY of de-escalation are highly sensitive to the fluconazole-susceptibility profile, late mortality in fluconazole-resistant infections, fluconazole clinical success rate, excess hospitalization, life expectancy, underlying diseases and follow-up costs. **CONCLUSIONS:** The de-escalation strategy is associated with better clinical outcomes and improved survival, particularly among patients with fluconazole-resistant Candida strains. De-escalation from initial treatment with micafungin is a cost effective alternative to traditional escalation approach from a UK NHS perspective with a differential cost per QALY below the recognised willingness to pay threshold of £30,000.

PIN78

COST UTILITY OF INFANT VACCINATION AGAINST RESPIRATORY SYNCYTIAL VIRUS INFECTION IN THE NETHERLANDS

Meijboom M[1], Rozenbaum M[1], Benedictus A[1], Luytjes W[2], Kneyber M[3], Wilschut J[4], Hak E[1], Postma M[1]
[1]*University of Groningen, Groningen, Groningen, The Netherlands,* [2]*RIVM, former The Netherlands Vaccine Institute (NVI), Bilthoven, NL, The Netherlands,* [3]*University Medical Center Groningen, Groningen, Groningen, Groningen, The Netherlands,* [4]*University Medical Center Groningen, Groningen, Groningen, The Netherlands*

OBJECTIVES: Respiratory syncytial virus (RSV) infection is one of the major causes of respiratory symptoms in infants in many countries, infecting virtually every child by the age of two. Currently, several Phase 1 trials with RSV vaccines in infants are running or have been completed. Although no efficacy estimates are yet available, cost-effectiveness estimates might be informative enabling preliminary positioning. **METHODS:** A decision analysis model was developed following a Dutch birth cohort for 12 months. Vaccination strategies that were reviewed included vaccination at specific ages, different dosing schemes and seasonal versus year round vaccination. The impact of the assumptions was explored in sensitivity analyses. Outcome measures included number of GP visits, hospitalizations and deaths, costs, quality-adjusted life years and ICERs. **RESULTS:** Without vaccination, an annual number of 28,738 of RSV-related GP visits, 1,623 hospitalizations, and 4.5 deaths are estimated in the 0-1 year olds. The total cost to society in the non-vaccination scenario was €7.7 million and the annual disease burden was estimated at 597 QALYs. In case all infants would be offered a 3-dose RSV vaccination scheme at 0/1/3 months of age, the total annual net costs were estimated to increase to €21.2 million but a significant number of hospitalizations and deaths could be averted, 544 and 1.5 respectively. The ICER was estimated € 34,142 (95%CI: € 21,652 - € 87,766) per QALY. A reduced dose schedule, seasonal vaccination, out-of pocket payments all resulted in a more favorable ICERs while lowering the expected vaccine efficacy or delaying the time of vaccination in less favorable ICERs.

CONCLUSIONS: Recent updates on burden of disease estimates were used and utilities included but due to the absence of trial data still a number of assumptions were used. The outcomes of this modeling exercise show that a vaccine against RSV might be cost-effective, but trial data are warranted.

PIN79

COST-UTILITY ANALYSIS OF TENOFOVIR IN COMPARISON WITH OTHER NUCLEOSIDE ANALOGUES (AN) IN CHRONIC HEPATITIS B (CHB) TREATMENT

Gwiosda B[1], Krzystek J[1], Niesyczynski G[1], Osiewalski K[1], Mierzejewski P[2], Kazmierski M[2], Wladysiuk M[1], Plisko R[1]
[1]*HTA Consulting, Krakow, Poland,* [2]*Gilead Sciences Poland Sp. z o.o., Warszawa, Poland*

OBJECTIVES: To compare cost-effectiveness of tenofovir and other AN in treatment of adults with CHB in Poland. **METHODS:** Analysis was performed from the public payer perspective. A lifetime Marcov model (3-month cycle) was developed defining heath states based on HBV_DNA level. Following events were included: complications (liver cirrhosis, hepatocellular carcinoma), drug resistance and relapse after remission. Analysis was performed in total population (regardless of the HBeAg status) and in subpopulation of HBeAg(+) patients. Analysis for HBeAg(-) patients was impossible to conduct due to lack of effectiveness data. Effectiveness parameters were based on MTC conducted in systematic review of randomized clinical trials. In the analysis following costs were included: antiviral drugs, monitoring, hospitalization and CHB complications treatment. The reliability of the estimates was examined by sensitivity analyses of model parameters. **RESULTS:** In total population the estimated lifetime QALY per patient were: 12.33 for tenofovir, 11.32 for entecavir and 11.64 for adefovir. The estimated differences in QALYs between tenofovir and comparators were: 1.00 in comparison to entecavir and 0.69 in comparison to adefovir. The differences were not statistically significant. Average lifetime costs per patient were: 223,519 PLN for tenofovir, 358,565 PLN for entecavir and 349,535 PLN for adefovir. The resulting difference in costs between tenofovir and comparators were: -135,045 PLN in comparison to entecavir and -126,016 PLN in comparison to adefovir. The results for HBeAg(+) subpopulation were close to results for total population. **CONCLUSIONS:** Both in total population, as well as in HBeAg(+) subpopulation, tenofovir dominates adefovir and entecavir, which means that it allows for greater health effects (QALY, LYG) with lower costs of treatment. Results of probabilistic sensitivity analysis indicates that tenofovir therapy is cost-effective (for the assumed threshold of three GDP: 102,045 PLN) with a probability of ca 82% when compared with adefovir and ca 86% in comparison to entecavir.

PIN80

COST-EFFECTIVENESS OF VACCINATING CHILDREN AGED 2-17 YEARS WITH INTRANASAL LIVE ATTENUATED INFLUENZA VACCINE (LAIV) IN GERMANY

Damm O[1], Rose MA[2], Greiner W[3], Knuf M[4], Wahn U[5], Krüger H[6], Wutzler P[7], Schaberg T[8], Ruf B[9], Liese JG[10], Eichner M[11]
[1]*School of Public Health, University of Bielefeld, Bielefeld, Germany,* [2]*Children's and Adolescents' Hospital, Goethe University, Frankfurt, Germany,* [3]*Herescon GmbH, Hannover, Germany,* [4]*Children's Hospital, Dr. Horst Schmidt Klinik, Wiesbaden, Germany,* [5]*Children's Hospital, Charité, Berlin, Germany,* [6]*AstraZeneca GmbH, Wedel, Germany,* [7]*Jena University Hospital, Friedrich-Schiller University, Jena, Germany,* [8]*Deakoness-Hospital, Rotenburg, Germany,* [9]*Klinikum St. Georg, Leipzig, Germany,* [10]*University Children's Hospital, Würzburg, Germany,* [11]*Epimos geoInfoNet UG, Tübingen, Germany*

OBJECTIVES: In 2011, intranasal administrated live-attenuated influenza vaccine (LAIV) for prophylaxis of seasonal influenza was approved in the EU for children aged 2-17 years. Our objective was to estimate the potential epidemiological impact and cost-effectiveness of the current policy to vaccinate people over 60 years and people with underlying chronic conditions with trivalent inactivated vaccine (TIV) compared to the addition of routine childhood vaccination with LAIV in Germany. **METHODS:** A compartmental susceptible-exposed-infectious-recovered-susceptible (SEIRS) model populated with German specific data was developed to explore the impact of vaccination on the transmission dynamics of seasonal influenza. In addition, a decision tree was constructed to incorporate several consequences of influenza infections and to compare costs and outcomes of different vaccination strategies in the German health care setting. The time horizon was set to ten years after the introduction of LAIV, assuming childhood vaccination coverage of 70%. Input data were based on published literature or were derived by expert consulting using the Delphi technique. **RESULTS:** Under base-case assumptions, annual routine vaccination of children would prevent 8.8 million influenza illnesses, resulting in a reduction of 273,124 cases of acute otitis media and 68,102 cases of community-acquired pneumonia over ten years if left undiscounted. The discounted incremental cost-effectiveness ratio was €9601 per QALY gained from a third-party payer perspective, when compared to the current strategy of vaccinating only risk groups with TIV. Inclusion of patient co-payments and indirect costs resulted in a discounted 10-year cost-saving to society of €1.16 billion. **CONCLUSIONS:** Compared with the current vaccination policy, introducing childhood and adolescent vaccination with LAIV can substantially increase benefits and reduce overall costs when adopting a societal perspective. Using the commonly cited threshold of €50,000 per QALY gained, routine vaccination of children with LAIV can be considered cost-effective from a third-party payer perspective.

PIN81

COST-EFFECTIVENESS ANALYSIS OF PEG-INTERFERON ALPHA-2A PLUS RIBAVIRIN VERSUS CONVENTIONAL INTERFERON ALPHA-2A PLUS RIBAVIRIN FOR THE TREATMENT OF CHRONIC HEPATITIS C IN CHINA

Chen W[1], Wei L[2]
[1]*Fudan University, Shanghai, Shanghai, China,* [2]*Peking University People's Hospital, Beijing, China*

OBJECTIVES: This study aims to evaluate the cost-effectiveness of peg-interferon alpha-2a plus ribavirin compared with conventional interferon alpha-2a plus ribavirin for the treatment of chronic hepatitis C (CHC) in China. **METHODS:** A Markov health-state model was designed to estimate the direct medical costs and outcomes (life year gained and quality adjusted life year, QALY) of treating CHC. The model consists of 7 health states: cured (sustained virological response), CHC, compensated cirrhosis, decompensated cirrhosis, hepatocellular carcinoma, liver transplant, and death. Based on literature research, a two-round expert panel survey was conducted among experienced clinicians nationally in China to identify medical cost and clinical efficacy data. The evaluation was conducted from a perspective of China's health insurance system to compare combination therapy scenarios of peg-interferon alfa-2a (40KD) plus ribavirin with conventional interferon alfa-2a plus ribavirin. The evolution of a cohort of CHC patients was simulated along 40 years with yearly cycles. A discounting rate at 3% was used to discount utilities and medical costs happened at different years. A univariate sensitivity analysis was performed to understand the key drivers and general sensitivity of the model. **RESULTS:** The model showed that peg-interferon alpha-2a scenario could prolong 2.25 (30.02 years vs. 27.77 years) total life years compared with conventional interferon alpha-2a scenario. The discounted QALYs generated by peg-interferon were 2.19 longer than that of conventional interferon (18.58 QALYs vs. 16.39 QALYs). The discounted mean total cost per patient treated with peg-interferon alpha-2a scenario was 114,751 CNY (US$17,930), and 130,047 CNY (US$20,320) for patient treated with conventional interferon. **CONCLUSIONS:** The results of the model suggest that peg-interferon alfa-2a treatment is dominant in both health outcomes and long-term treatment costs compared with conventional interferon alpha-2a for the treatment of CHC, which means peg-interferon alfa-2a treatment can generate cost savings for the China's health insurance system.

PIN82

COST-EFFECTIVENESS OF ATAZANAVIR/R COMPARED TO DARUNAVIR/R IN GERMANY

Thuresson PO[1], Verheggen B[1], Heeg B[1], Kaspar I[2], Erhardt W[2], Lescrauwaet B[3]
[1]*Pharmerit International, Rotterdam, The Netherlands,* [2]*Bristol-Myers Squibb GmbH & Co. KGaA, München, Germany,* [3]*Xintera Consulting BVBA, Leuven, Belgium*

OBJECTIVES: Atazanavir/r (ATV/r) and darunavir/r (DRV/r) are commonly used to suppress HIV in Germany. Compared to lopinavir/r, both have demonstrated similar relative efficacy in randomized clinical trials (RCT) in previously untreated patients; whereas annual drug acquisition costs are 250 euro more for DRV/r. However, the objective was to estimate how these would translate into costs and effects, after 5 and 25 years. **METHODS:** The cost-effectiveness was forecasted using a microsimulation-model (monthly cycles) for previously untreated HIV-patients Response to medication was modeled as a reduction in HIV-RNA viral-load. In accordance with literature, increase in CD4+ could persist up to 5 years while having a response; whereas no response resulted in the opposite. The occurrences of AIDS defining events and non-AIDS defining malignancies were linked to the current CD4+ and independent of therapy. Adverse events (AE) on the other hand were treatment-specific and the following were considered: 1) diarrhea; 2) dizziness; 3) jaundice; 4) nausea; and 5) rash. Toxicities associated with the long-term use of agents considered in the model included: 1) cardiovascular events; 2) renal insufficiency; and 3) hepatic failure. Drug efficacy and AE incidences were based on published RCTs - compared via an indirect comparison - whereas, other data was based on published literature. **RESULTS:** After 5 years, initiation with ATV/r use was found to be associated with a lower total cost compared to DRV/r. In the long-term (i.e. 25 year time horizon) the use of ATV/r was found to be associated with an increase in survival of 16.0 (discounted) years; 0.31 life years and 0.55 QALYs compared to DRV/r. This resulted in an ICUR of € 11,241 per QALY gained. Results were most sensitive to changes in virological parameters, market shares for future lines and cost per CD4-level. **CONCLUSIONS:** The model forecasts ATV/r to be cost-effective compared to DRV/r in Germany.

PIN83

COST-EFFECTIVENESS AND COST-UTILITY ANALYSIS OF 200 DAYS PROPHYLAXIS OF CYTOMEGALOVIRUS (CMV) INFECTIONS IN HIGH RISK (D+/R-) KIDNEY TRANSPLANT RECIPIENTS IN POLAND

Kawalec P[1], Holko P[2], Boratynska M[3], Glyda M[4], Ignacak E[5], Russel-Szymczyk M[6], Szkultecka-Sebek M[6], Kaweczynska-Lason A[6]
[1]*Jagiellonian University, Kraków , Poland,* [2]*Centrum HTA, Cracow, Poland,* [3]*Wroclaw Medical University, Wroclaw, Poland,* [4]*District Hospital, Poznan, Poland,* [5]*University Hospital in Cracov, Cracow, Poland,* [6]*Roche Polska Sp. z o.o., Warsaw, Poland*

OBJECTIVES: To assess cost-effectiveness of CMV disease prophylaxis prolongation in kidney transplant recipients from 110 to 200 days from Polish public payer's perspective. **METHODS:** Clinical efficacy and safety of prolonged to 200 days prophylaxis of CMV disease in kidney transplant recipients (D+/R-) was assessed in systematic review. Following measurable differential direct medical costs were estimated and included: costs of drugs and diagnostic, hospital/ambulatory procedures, adverse events treatment, acute rejection, CMV disease treatment, opportunistic infections treatment, hemodialysis and subsequent kidney transplantation. Cost data were gathered in 4 medical centers. Markov model was used to calculate costs and efficacy in 23.5 years time horizon - the maximum expected survival of kidney transplant recipient. Costs and clinical effects were discounted (5% for costs and effects, 0% for costs and effects, 5% for costs and 0% for effects). Probabilistic, one-way, multiway sensitivity analyses were conducted. **RESULTS:** The prolongation to 200 days of CMV disease prophylaxis in kidney transplant recipients is lined to reduction in frequency of CMV infections, acute transplant rejections, loss of graft functions and need of subsequent kidney transplantation. In the 23.5 years gain of 0.3846 life years and 0.3178 quality adjusted life years can

be achieved. Total discounted costs in 23.5 years were 557 766.80 PLN (1EURO=3.96 PLN) for patients subjected to 200 days prophylaxis and 542 509.92 PLN for patients subjected to 110 days prophylaxis. The incremental cost-effectiveness ratio (ICER) was 39,669 PLN and cost-utility ratio (ICUR) 48,008 PLN. Sensitivity analysis confirmed the base case analysis results. The results were sensitive only to the time horizon assumed (when time horizon was shorter than 4 years ICER/ICUR were above the accepted 110,000 PLN cost-effectiveness threshold). **CONCLUSIONS:** The prolongation of CMV disease prophylaxis in kidney transplant recipients from 110 to 200 days is highly cost-effective from Polish payer perspective.

PIN84

LOST IN TRANSLATION: A MARKOV MODEL COST UTILITY ANALYSIS OF LOPINAVIR/RITONAVIR VS ATAZANAVIR + RITONAVIR

Foglia E[1], Restelli U[1], Bonfanti M[1], Porazzi E[1], Bonizzoni E[2], Bonfanti P[3], Rizzardini G[4], Ricci E[4], Casartelli L[1], Croce D[1]
[1]*University Carlo Cattaneo - LIUC, Castellanza, Varese, Italy,* [2]*University of Milan, Faculty of Medicine and Surgery, Milano, Milano, Italy,* [3]*A. Manzoni Hospital, Lecco, Lecco, Lecco, Italy,* [4]*"L. Sacco" Hospital Authority, Milano, Milano, Italy*

OBJECTIVES: This study will evaluate lifetime cost-utility of a therapy based on lopinavir/ritonavir vs atazanavir + ritonavir, using a tenofovir-emtricitabine backbone, in an Italian cohort of HIV infected anti-retroviral-naïve patients. An international literature review revealed, that there are limited useful data to inform Italian decision makers, taking into consideration Country specific costs and utility. **METHODS:** Starting from the Broder (2011) Markov microsimulation model and CASTLE study data, an Italian model was developed to specify direct costs and health outcomes from Italian HIV-infected patients and their treatment, adopting a national health service (NHS) payer perspective. The Health State (HS) transition probabilities were assessed within a sample of 319 patients on treatment within the Lombardy Region (the probability vector took into consideration the results of the 96-week CASTLE trial, the principal published literature and the evidence related to the Italian population in terms of cholesterol changes, coronary heart disease (CHD) events and adverse events (AEs). Costs related to AEs and to the care of HIV+ patients were correlated to clinical effectiveness data, as well as institutional indications, protocols and reimbursement tariff of hospitals located in Lombardy Region. **RESULTS:** The newly developed Italian Markov model consisting of 8 HS, informs about the distribution of the Italian population, and forecasting the evolution of the clinical pathway of anti-retroviral-naïve patients through different stages up to death. Clinical effectiveness and absorption of resources were investigated to truly represent the Italian HIV context. **CONCLUSIONS:** The innovative method of this Markov model construction based on national data, ensures the opportunity of a closer results alignment to specific Italian costs, and to its usability from an Italian decision making and payer's perspective.

PIN85

COSTS OF INFLUENZA AND INFLUENZA LIKE ILLNESS FROM THE EMPLOYER'S PERSPECTIVE IN POLAND

Kawecka K, Wrona W, Hermanowski T
Department of Pharmacoeconomic, Medical University of Warsaw, Warsaw, Poland

OBJECTIVES: Every year 5-25% of the world's population suffers from influenza. Influenza and ILI (influenza like illness) among working adults are responsible for the enhanced sickness absenteeism, limited work capacity and efficiency, as well as for the increased health service demand. The aim of this pilot study was to estimate the indirect cost of influenza and ILI (both absenteeism and presenteeism) from emloper's perspective. **METHODS:** Data was collected from Polish citizens in working age, who were employed at the time of collecting data. Human Capital Approach method was used in quantifying costs. Modified version of Work Productivity and Activity Impairment General Health questionnaire was used to estimate absenteeism and presenteeism in the population. Responders were questioned about the period from the first day of January 2011 to the day of the questionnaire completion, which represents the period when the highest ILI incidence rate. The results of the questionnaire were extrapolated for the whole year of 2011. The indirect costs were calculated on the basis of the average gross wage value in the corporate sector in 2011, which amounts to 911 EUR (1 EUR=3.95 PLN). **RESULTS:** The final population comprised 134 employees (average age 31 years, 56.7% men). Immunized against influenza were 23.1% of the people who participated in the study. 53.7% of all respondents reported that during the investigation period had influenza or influenza-like symptoms. The productivity loss at workplace due to illness was estimated at 4.0% (3,2 vs. 4,2, Immunized vs. non-immunized, respectivetly; p=0,44). Estimated absenteeism equaled 2.2% (1,7 vs 2,4, Immunized vs non-immunized, respectively; p=0,88). **CONCLUSIONS:** Indirect costs of productivity loss due to influenza and ILI are substantial to Polish economy. Due to the relatively small non-representative population results should be treated with caution.

Infection – Patient-Reported Outcomes & Preference-Based Studies

PIN86

INTERIM RESULTS ON ADHERENCE TO TREATMENT OF CHRONIC C HEPATITIS MONOINFECTED AND HCV/HIV CO-INFECTED PATIENTS ASSESSED BY THE ADHEPTA QUESTIONNAIRE

Solà R[1], Martín-Suárez JM[2], Castellano G[3], Tural C[4], Pérez-Álvarez R[5], De Cuenca B[6], Castro MA[7], Turnes-Vázquez J[8], Tomé S[9], Ripolles V[10], Alcántara R[11], Diago M[12], Hernández-Quero J[13], Perulero N[14], Planas R[15]
[1]*Hospital del Mar, IMIM, Barcelona, Spain,* [2]*Hospital de Gran Canaria Dr. Negrín, Las Palmas de Gran Canaria, Spain,* [3]*Hospital Universitario 12 de Octubre, Madrid, Spain,* [4]*Hospital Germans Trias i Pujol, Barcelona, Spain,* [5]*Hospital Universitario Central de Asturias, Oviedo, Spain,* [6]*Hospital Infanta Cristina, Madrid, Spain,* [7]*Hospital Universitario de A Coruña, A Coruña, Spain,* [8]*Complejo Hospitalario de Pontevedra, Pontevedra, Spain,* [9]*Hospital Clínico De Santiago, Santiago De Compostela, Spain,* [10]*Hospital General de Castellón, Castellón de la Plana, Spain,* [11]*Hospital Clínico Virgen de la Victoria, Málaga, Spain,* [12]*Hospital General Universitario, Valencia, Spain,* [13]*Hospital Universitario San Cecilio, Granada, Spain,* [14]*IMS Health, Barcelona, Spain,* [15]*Hospital Germans Trias i Pujol, CIBEREHD, Barcelona, Spain*

OBJECTIVES: To assess adherence to treatment for HCV monoinfected and HCV/HIV co-infected patients, interim analysis at 12 weeks after therapy initiation. **METHODS:** Observational, prospective study performed by 120 investigators in Spain. Patients were hepatitis C (HCV) monoinfected or HCV/HIV co-infected, ≥18 years and naïve to HCV treatment. Visits were at treatment initiation (baseline), 4, 12, and every 24 weeks during HCV therapy and 24 weeks after finalization; only interim results up to wk12 are presented. Each visit assessed adherence by Adhepta and Morinsky-Green questionnaires. Adhepta questionnaire includes two questions related to treatment adherence and 11 (monoinfected) or 13 (co-infected) questions about reasons for non-adherence; non-adherence to treatment was assessed following the 80/80/80 rule (not administered any HCV drug on ≥20% of the occasions). **RESULTS:** Evaluable patients were 1,120, 801 monoinfected (68.3% male) and 319 co-infected (74.9% male). Mean (SD) age was 45.3 (8.8) years. Non-adherent patients by Adhepta were 2.5% and 3.5% for monoinfected at wk4 and wk12, respectively; and 2.7% and 2.5% patients, among co-infected. No differences between study groups were observed. Non-adherent patients by Morisky-Green were 14.0% and 14.8% at wk4, and wk12, respectively for monoinfected; and 23.3% and 23.2% for co-infected. Monoinfected patients were more adherent to treatment than co-infected patients at wk4 and wk12 ($p<0.05$). Assessed by Adhepta questionnaire, non-adherence most common reason reported was 'forgetting to take the drug' (8.2% monoinfected and 10.8% co-infected). **CONCLUSIONS:** Adherence to treatment remains constant through 12 weeks after treatment initiation. Differences in treatment adherence observed between both questionnaires must be compared at the end of the HCV treatment and analysing their correlation with patient self-reported medication record.

PIN87

HEPATITIS C TREATMENT CONTINUATION RATES IN TREATMENT-NAÏVE GENOTYPE 1 PATIENTS IN THE BRAZILIAN PUBLIC HEALTH CARE SYSTEM

Mussolino F[1], Vaz P[1], Morais AD[2], Pereira ML[2]
[1]*NEW BD - Business Developers, São Paulo, SP, Brazil,* [2]*Janssen Cilag Farmaceutica, São Paulo, SP, Brazil*

OBJECTIVES: Determine real-life treatment continuation rates of chronic Hepatitis C (HCV) treatment from a database of medicine dispensation in the Brazilian public healthcare system. **METHODS:** Monthly data from a public database of medicine dispensation was analyzed for a period of 17 months. The patient cohort was defined as all new HCV (CID10 B18.2) patients initiating treatment between January and December 2009. To identify HCV genotype 1 (G1) patients, it was assumed G1 patients initiated treatment with the pegylated forms of the interferons (pegIFN), as defined by the Brazillian national guidelines for HCV. **RESULTS:** Between January and December 2009, 10,992 patients began treatment for HCV. Around 58% of these patients were male with a median age of 49.7 years. Of these, 82% of patients (9,019) were considered G1 as they began treatment with pegIFN and/or ribavirin. Almost all patients (97%) began treatment with the treatment combination pegIFN and ribavirin, with an equal split among both brands of pegIFN. For all HCV patients treatment mean/median was 38,3/40 weeks compared to 40.2/44.0 weeks for G1 patients. At week 48, 63% of all HCV patients had discontinued treatment compared to 58% of G1 patients. At week 24, around 19% of all HCV patients had discontinued treatment compared to 18% of G1 patients. The maximum observed treatment duration was 85 weeks in both all HCV and G1 patients. **CONCLUSIONS:** Discontinuation rates before week 24 were similar between all HCV and G1 patients. Although 48 weeks of treatment is the established duration for G1 patients, the majority of patients discontinue treatment earlier. These data, however, do not guarantee patients actually receive treatment, as it follows medicine dispensation.

PIN88

LATE IMMUNIZATION DOSES RECEIVED BY CHILDREN YOUNGER THAN TWO YEARS

Al-lela OQB[1], Bahari MB[1], Alabbassi MG[2], Saleh MR[3], Basher AY[1], Shafie AA[1]
[1]*Universiti Sains Malaysia (USM), Pinang, Malaysia,* [2]*Almustansaria Universiti, Baghdad, Iraq,* [3]*Universiti Sains Malaysia (USM), pinang, Malaysia*

OBJECTIVES: Immunization dose was considered as a late immunization dose if it was administered after the recommended age. The aims of this study are to determine the frequency and percent of this type of doses among child immunization schedule, and to determine the number of late immunization dose received by each child. **METHODS:** Data was collected retrospectively from 528 children immunization cards in Iraq to obtain the immunization history of each individual child. This study was restricted the analyses to the vaccines administered before age 2 years. Each children must received seven doses at seven times, every dose consist of many types of vaccines. **RESULTS:** More than 63% of late immunization doses were shown in the third dose (OPV+DTP) at fourth month of child life. Hundred and forty five children were immunized with four late immunization doses out of seven immunization doses, and 1.5% of children were immunized with 7 late immunization doses. **CONCLUSIONS:** This study found that compliance with WHO immunization recommendations is low and inappropriate immunization doses were occur frequently, and leading to incomplete or partial immunization compliance. With an increase in parent's knowledge of immunization guidelines against infectious agents, it is very important to implement strategies that will lead to improved and developed immunization practice and childhood immunization coverage in the future.

PIN89

DO PATIENTS AND PHYSICIANS HAVE SIMILAR PREFERENCES CHRONIC HEPATITIS B TREATMENT OUTCOMES IN TURKEY?

Mohamed A[1], Johnson FR[1], Hauber AB[1], Lescrauwaet B[2], Saylan M[3]
[1]RTI Health Solutions, Research Triangle Park, NC, USA, [2]Xintera Consulting BVBA, Brussels, Belgium, [3]Bristol-Myers Squibb, Istanbul, Turkey

OBJECTIVES: To quantify patient and physician preferences for therapeutic tradeoffs involving efficacy, side-effect risks, and evidence uncertainty in chronic hepatitis B (CHB) treatments. **METHODS:** Physicians who treat CHB patients and adult patients with a self-reported physician diagnosis of CHB completed a web-enabled, discrete-choice experiment survey in Turkey. Both patients and physicians answered 12 treatment-choice questions. Each question required evaluating a pair of hypothetical CHB medication profiles defined by years the medicine has been studied, probability that patient's viral load remains undetectable for five years with possible reversal of disease progression, five-year treatment-related risks of a fracture and renal insufficiency, and monthly medication cost. Nested-logit and random-parameters logit models were used to estimate preference weights for all attribute levels and the mean relative importance of each attribute. **RESULTS:** One hundred fifty-nine physicians and 117 patients completed the survey in Turkey. Turkish physicians and patients disagreed on the relative importance of all treatment attributes. Turkish patients ranked years of evidence as the most important attribute, while Turkish physicians ranked risk of renal insufficiency as most important. Turkish physicians were willing to accept a 3.2% smaller increase in fracture risk than patients for an additional year of evidence. **CONCLUSIONS:** This is the first study to quantify patient and physician preferences for CHB treatment attributes and the first study to elicit physician and patient preferences for years of evidence. We observe different discrepancies between physician and patient preferences in Turkey. Such discrepancies may interfere with optimal outcomes if not considered in patient-physician interactions.

PIN90

DISCRETE CHOICE EXPERIMENTS (DCES) IN HIV/AIDS TREATMENT: EXPERT JUDGEMENT IN COMPARISON TO PATIENT PREFERENCES

Mühlbacher AC[1], Stoll M[2], Ranneberg B[3], Nübling M[4]
[1]HS Neubrandenburg, Neubrandenburg, Germany, [2]Medical University of Hanover (MHH), Hannover, Germany, [3]Janssen Cilag, Neuss, Germany, [4]Gesellschaft für empirische Beratung mbH, Denzlingen, Germany

OBJECTIVES: In order to make HIV treatment as effective as possible expert judgement and patient preferences should be attuned. This study aims to elicit patients' preferences and to compare them to physicians' assumptions in HIV therapy. **METHODS:** In the first part qualitative and quantitative methods were applied to identify patient preferences. Literature review, focus groups, direct assessment and a discrete choice experiment were conducted to elicit relevant treatment objectives from the patients' perspective. In the second part an expert survey with German physicians (HIV specialists) was used to assess the experts' judgement for the same objectives. The discrete choice experiment was conducted using a fractional factorial design (two-fold, six attributes) and the statistical data analysis used random effect logit models. **RESULTS:** A total of 218 patients and 131 physicians participated in the study. "Emotional quality of life: HIV- infection not obvious" was ranked highest both by physicians and patients (coeff. phys.: 4.00, coeff. pat.: 2.98) followed by "social quality of life: possibility to take part in social life" (phys.: 1.95, pat.: 1.14) as well as "constitution: less diarrhoea, and nausea" (phys.: 1.93, pat.: 1.61), the latter on second rank for the patients. Less important and ranking of posts four to six were "life span: maximal increase" (phys.: 0.85, pat.: 0.74), "avoidance of long-term impairment" (phys.: 0.83, pat.: 0.41) and "flexibility and dosage: treatment-combination of max. 3 tablets per day" (phys.: 0.64, pat.: 0.45). All six attributes had significant effects in both models. **CONCLUSIONS:** This enables testing of the concordance between patient and physician valuation of multiple treatment goals for HIV/AIDS therapy. Experts' assumptions and patients' preferences were similar, showing that physicians in HIV treatment are aware of their patients' needs and wishes. DCE and direct assessment proved to be valid instruments to elicit treatment preferences in HIV treatment for experts as well as for patients.

PIN91

SENSITIVITY OF PRO'S IN EVALUATING ADVERSE EVENTS IN PEOPLE RECEIVING INFLUENZA VACCINATION

Wade A[1], Crawford G[1], Pumford N[1], Mcconnachie A[2]
[1]Patients Direct, Glasgow, UK, [2]Glasgow University, Glasgow, UK

OBJECTIVES: To investigate whether patient reported outcomes could detect differences between H1N1 and seasonal influenza vaccinations on adverse events over a 26 week follow up period. **METHODS:** In this evaluation, PROBE methodology consisting of a web-based system supplemented by telephone reporting was used to collect naturalistic data from people who had received an influenza vaccination during 2009-2010 season. People were recruited through media advertising and awareness campaigns in public places and work (West of Scotland). Data collection on day of immunisation, after 3 days, 8 days, 6 weeks, 12 weeks and 26 weeks. Data included age, sex, presence or absence of chronic illness, flu vaccination history, any side effects following vaccination including the duration and action taken. **RESULTS:** A total of 1103 vaccine recipients including 134 young children (< 5 years) participated; 694 (63%) received H1N1 vaccine only, 135 (12%) seasonal only, 224 (20%) both H1N1 and seasonal vaccines and 50 (5%) received H1N1 or seasonal vaccine with a non-influenza vaccine (e.g. travel or pneumococcal). Overall, 70% of respondents reported experiencing a side effect after vaccination – this includes pain/discomfort at the injection site and any other side effects. Of the 964 recipients of an H1N1 vaccine, significantly more (511, 74%) experienced a side effect compared with those who received only the seasonal flu vaccine (45%, χ2-test p <0.001). Multivariate regression analysis revealed that female sex and the H1N1 vaccination were more likely to report any side effect (OR 2.10, p<0.001 and OR 4.47, p<0.001 respectively) and age > 70 less likely to report (OR 0.29, p<0.001). **CONCLUSIONS:** People receiving the H1N1 vaccination were more likely to experience side effects than seasonal influenza vaccination alone. This evaluation shows that the PROBE methodology quickly and simply captured patient reported outcome information in a vaccinated population including children.

PIN92

PATIENT REPORTED OUTCOMES AMONG CHRONIC HEPATITIS C PATIENTS RE-TREATED WITH PEGINTERFERON ALFA-2A/RIBAVIRIN AFTER NON-RESPONSE TO PEGINTERFERON ALFA-2B/RIBAVIRIN IN SPAIN

Olveira A[1], Rincon D[2], Diago M[3], Crespo J[4], Calleja JL[5], Salmeron J[6], Andrade R[7], Romero M[8]
[1]Hospital Universitario La Paz, Madrid, Spain, [2]Hospital Universitario Gregorio Marañon, madrid, Spain, [3]Hospital General de Valencia, Valencia, Spain, [4]Hospital Universitario Marques de Valdecilla, Santander, Spain, [5]Hospital Puerta de Hierro, Madrid, Spain, [6]Hospital Universitario San Cecilio, Granada, Spain, [7]Hospital Clinico Virgen de la Victoria, Málaga, Spain, [8]Hospital de Valme, Sevilla, Spain

OBJECTIVES: Primary analysis of REPEAT study showed that 72 weeks treatment with PegIFN-alfa2a/ribavirin was more effective than 48 weeks in chronic hepatitis C patients non-responders to previous PegIFN-alfa2b/ribavirin. The aim of this prospectively planned secondary analysis was to assess patient reported outcomes (PRO) of re-treatment with PegIFN-alfa2a/ribavirin versus previous treatment with PegIFN-alfa2b/ribavirin in Spain. **METHODS:** In REPEAT, 950 non-responders to PegIFN-alfa2b were randomized to PegIFN-alfa2a 360μg/week for 12 weeks, then 180μg/week for a further 60 or 36 weeks (Arms A or B, respectively), or PegIFN-alfa2a 180μg/week for 72 or 48 weeks (Arms C or D, respectively); all patients received ribavirin 1000-1200mg/day. In this sub-analysis, 100 Spanish patients from 10 centres (Arms A: n=40; B: n=19; C: n=11; D: n=30) were administered a two-part questionnaire: part one was completed at baseline (questions on previous PegIFN-alfa2b/ribavirin therapy) and part two was completed at end of treatment (questions on recent PegIFN-alfa2a/ribavirin therapy). The questionnaire included 15 items concerning patient perception of viral load, tolerability of treatment, health status, management of devices as well as side effects and problems experienced specifically to one treatment. **RESULTS:** At baseline, 16% patients reported feeling good/excellent, 43% fair and 41% poor while receiving PegIFN-alfa2b/ribavirin versus 30%, 49% and 20%, respectively, at end of re-treatment. Significantly more patients perceived PegIFN-alfa2a/ribavirin to be associated with better/much better effects on viral load, tolerance, health status and handling of devices versus PegIFN-alfa2b/ribavirin. Problems exclusive to PegIFN-alfa2b/ribavirin were reported in 33% of patients while 17% reported new problems with PegIFN-alfa2a/ribavirin. With either treatment, >96% of patients reported side effects. Patient-reported tolerance to PegIFN-alfa2a/ribavirin was similar in all treatment arms, irrespective of dose (p=0.069). **CONCLUSIONS:** Re-treatment with PegIFN-alfa2a/ribavirin in Spanish patients improved assessed patient reported outcomes versus previous treatment with PegIFN-alfa2b/ribavirin. Patients reported good tolerance even in 72 weeks re-treatment.

PIN93

ASSESSMENT OF KNOWLEDGE AND AWARENESS OF HEPATITIS B AMONG GENERAL PUBLIC IN PAKISTAN

Haq N[1], Shafie AA[2], Hassali MA[3], Ibrahim MIM[4], Saleem F[1]
[1]Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia, [2]Universiti Sains Malaysia, Penang, P. Penang, Malaysia, [3]Universiti Sains Malaysia, Penang, Malaysia, [4]University Sains Malaysia, Penang, Malaysia

OBJECTIVES: To evaluate knowledge and awareness of hepatitis B in general population of Quetta, Pakistan. **METHODS:** A questionnaire-based cross sectional analysis was designed. A pre-tested and validated questionnaire containing 20 questions (6 questions for general information, 4 for symptoms, 6 for transmission and 4 for treatment) was used for data abstraction. Stratified groups from 2 towns of the city aging 18 years and above were approached. Descriptive statistics were used to describe demographic of the population. Percentages and frequencies were used to categorize categorical variables, while means and standard deviations were calculated for the continuous variables. Non parametric tests (Mann-Whitney and Kruskal Wallis Test) were used where appropriate. Knowledge scored was categorized into good, medium and poor knowledge. All analyses were performed using SPSS 16.0. **RESULTS:** Three hundred and ninety individuals were enrolled in the study with 210 (53.8%) of males. Majority (n=178, 45.6%) were categorized in age group of 18-30 years. The mean knowledge score was calculated as 8.67±2.730 (out of 20) and was categorized as poor. Education level, occupation, income level and locality had significant relation with knowledge scores of the general population regarding hepatitis B. **CONCLUSIONS:** This study shows that there is poor level of knowledge and awareness of hepatitis B in general population of the city. Disease specific educational and awareness interventional program is recommended.

PIN94

ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQOL) IN HEPATITIS- B PATIENTS

Haq N[1], Shafie AA[2], Hassali MA[3], Ibrahim MIM[4], Saleem F[1]
[1]Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia, [2]Universiti Sains Malaysia, Penang, P. Penang, Malaysia, [3]Universiti Sains Malaysia, Minden, Pulau Pinang, Malaysia, [4]University Sains Malaysia, Penang, Malaysia

OBJECTIVES: To evaluate HRQoL in hepatitis B patients attending public hospitals in Quetta, Pakistan. **METHODS:** A descriptive study was shaped as a questionnaire-

based cross sectional analysis. European Quality of Life scale (EQ-5D) was used for assessment of HRQoL. Registered Hepatitis B patients aging 18 years and above were approached. Descriptive statistics were used to describe demographic and disease related characteristics of the patients. Percentages and frequencies were used to categorize the categorical variables, while means and standard deviations were calculated for the continuous variables. Non paramatric tests (Mann-Whitney and Kruskal Wallis test) were used where appropriate. HRQoL was scored by using values from UK general population survey. All analyses were performed using SPSS 16.0. **RESULTS:** Three hundred ninety hepatitis B Patients were enrolled in the study with 232 (59.5%) of males. Majority (n=126, 32.3%) were categorized in age group of 18-30 years. HRQoL was measured poor in our study patients (0.3498± 0.31785) with Visual Analogue Scale score of 59.15±10.517. Among all variables, only gender had significant relation with HRQoL score. **CONCLUSIONS:** Hepatitis B has an adverse impact of on patients' well-being and HRQoL. Patient centric efforts are recommended to improve patients HRQoL with Hepatitis B.

PIN95

THE IMPACT OF INFLUENZA ON IN- AND OUTPATIENTS' HEALTH RELATED QUALITY OF LIFE DURING THE PANDEMIC SEASON 2009-2010 IN SPAIN

Garin O[1], Hollmann M[1], Galante M[1], Ferrer M[2], Garcia-Altés A[3], Sicuri E[1], Nebot M[1], Dominguez À[1], Alonso J[2]
[1]*CIBERESP, Barcelona, Spain,* [2]*IMIM-Research Institute Hospital del Mar, Barcelona, Spain,* [3]*Catalan Agency for Health Information, Assessment and Quality (CAHIAQ), Barcelona, Spain*

OBJECTIVES: The aim of this study was to estimate the impact on HRQL of in- and outpatients with confirmed Influenza A H1N1/2009, and estimate the associated burden during the pandemic season 2009-2010. **METHODS:** Longitudinal, observational, multi-centre study of in- and outpatients with confirmed diagnosis of influenza A H1N1/2009 in Spain. Baseline sociodemographic and clinical characteristics and HRQL were assessed at the hospitalization or primary care visit recruitment. HRQL in the previous 7 days was also assessed. A sub-sample of patients was followed-up after recovery. The EQ-5D was used to describe HRQL and calculate utilities. HRQL loss was evaluated among in- and outpatients by several characteristics. Loss of Quality Adjusted Life Years (QALYs) was calculated at individual level taking into account the length of the influenza syndrome. Global burden was estimated from the total number of cases in Spain. **RESULTS:** A total of 432 inpatients and 563 outpatients were included and 145 and 184, respectively, were followed-up. EQ-5D index previous to influenza was 0.81 (CI95% 0.78–0.84) for inpatients and 0.93 (CI95% 0.91–0.94) for outpatients. During influenza, HRQL loss was -0.58(0.02) for inpatients, and -0.43(0.02) for outpatients. For all patients, Pain/discomfort and Usual Activities were the most affected dimensions presenting a deterioration from 73% to 80%. The individual QALYs loss for inpatients was 0.0135 and for outpatients, 0.0098. In contrasts, the global burden was 41 (inpatients) and 7,283 QALYs (outpatients). **CONCLUSIONS:** Influenza H1N1/2009 supposed a significant, but transient, impact on patients HRQL. The pandemic produced a considerable QALYs loss, especially among less severe patients, comparable with the burden of some chronic diseases and higher than that of other infectious diseases.

PIN96

DOES CONNECTING TOBACCO CESSATION INTERVENTION IN TUBERCULOSIS CARE IMPROVE QUALITY OF LIFE OUTCOMES?

Awaisu A[1], Nik mohamed MH[2], Noordin NM[3], Abd. Aziz N[4], Syed Sulaiman SA[5], Ahmad Mahayiddin A[6], Muttalif AR[7]
[1]*Qatar University, Doha, Doha, Qatar,* [2]*International Islamic University of Malaysia, Kuantan, Pahang, Malaysia,* [3]*National Institute of Health, Kuala Lumpur, Malaysia,* [4]*Universiti Technology Mara, Puncak Alam, Malaysia,* [5]*University Sains Malaysia, Penang, Penang, Malaysia,* [6]*Institut Perubatan Respiratori, Kuala Lumpur, Malaysia,* [7]*Penang Hospital, Penang, Malaysia*

OBJECTIVES: There is growing evidence in the literature supporting the association between tobacco smoking and poor tuberculosis (TB) treatment outcomes. Connecting TB and tobacco cessation interventions has been strongly advocated as this may produce significant benefits. However, no study has documented the impact of such integration on health-related quality of life (HRQoL). The objective of the study was to document the impact of an integrated TB directly observed therapy short-course (DOTS) plus smoking cessation intervention (SCI) on HRQoL. **METHODS:** This was a non-randomized controlled study (quasi experimental design) involving 120 TB patients who were current smokers at the time of TB diagnosis. Patients were assigned to either of two groups: conventional TB-DOTS plus smoking cessation intervention (SCIDOTS group) or conventional TB-DOTS only (DOTS group). The effects of the novel intervention on HRQoL were measured using EQ-5D questionnaire. Two-way repeated measure ANOVA was used to examine the effects. **RESULTS:** When compared, participants who received the integrated intervention had a better HRQoL than those who received the conventional TB care. The SCIDOTS group had a significantly greater increase in EQ-5D utility score than the DOTS group during 6 months follow-up (mean ± SD = 0.98 ± 0.08 vs. 0.91 ± 0.14, p = 0.006). Similarly, the mean scores for EQ-VAS showed a consistently similar trend as the EQ-5D indices, with the scores increasing over the course of TB treatment. Furthermore, for the EQ-VAS, there were significant main effects for group [F (1, 84) = 4.91, p = 0.029, $\eta 2$ = 0.06], time [F (2, 168) = 139.50, p = <0.001, $\eta 2$ = 0.62] and group x time interaction [F (2, 168) = 13.89, p = <0.001, $\eta 2$ = 0.14]. **CONCLUSIONS:** This study provides evidence that an integrated TB-tobacco treatment strategy could potentially improve overall quality of life outcomes among TB patients who are smokers.

PIN97

HOW DOES HEALTH-RELATED QUALITY OF LIFE RELATE TO SYMPTOMS EXPERIENCE IN HIV PATIENTS TREATED WITH HIGHLY-ACTIVE ANTIRETROVIRAL THERAPY?

Lalanne C[1], Armstrong AR[1], Herrmann S[2], Chassany O[3], Duracinsky M[4]
[1]*St Louis Hospital, Paris, Ile de France, France,* [2]*Murdoch University, Perth, Western Australi, Australia,* [3]*Assistance Publique-Hopitaux de Paris, Paris, France,* [4]*Hospital Kremlin Bicetre, Paris, Ile de France, France*

OBJECTIVES: Health-related quality of life (HRQL) is modulated by the type and frequency of symptoms experienced in daily life. Such a relationship is likely determined in part by treatment regimen and health care system. We studied how symptoms reported by HIV patients under PI- vs. NNTI-based HAART relate to different HRQL dimensions on the PROQOL-HIV questionnaire. **METHODS:** N=424 HAART patients (41±10 yrs., 36% females, 8 countries), without comorbidity, completed a 31-symptom HIV checklist (presence/absence) and the PROQOL-HIV questionnaire (43 Likert items, 8 dimensions). Hierarchical cluster analysis uncovered the structure of symptoms experienced in patients under PI (N=242) or NNTI (N=182) regimen. Canonical correlation analysis (CCA) showed the relationships between symptoms and HRQL dimensions, and between-country variations. **RESULTS:** A common group of symptoms related to body fat (lipodystrophy) and weight changes was shared by patients across treatment regimens. However, frequency of some side-effects–sleep disturbance, headache, diarrhea, nausea, fatigue and pain–were more frequent with PI regimens. The CCA showed that a) body fat change, sleep disturbance, skin problems and abdominal pain symptoms were related to the 'body change' and 'physical health and symptoms' HRQL dimensions (canonical correlation, 0.78), and b) symptoms concerning physical appearance were related to the 'stigma' dimension, whereas other side-effects did not. It also replicated a common finding whereby patients from Western countries (France, Australia, USA) tend to report better HRQL compared to Chinese and Cambodian patients, the latter also experiencing more symptoms due to IP-based treatment. **CONCLUSIONS:** Treatment-related symptoms aligned with PROQOL-HIV dimensions and known differences between countries. The use of CCA as an exploratory multiple endpoints model helped to unravel complex relationships between symptoms and HRQL facets. The choice of treatment strategies should rely not only on symptoms experience, but also account for their relations to HRQL in light of varying access to care.

Infection – Health Care Use & Policy Studies

PIN98

EVALUATING OPTIMAL TREATMENT OUTCOMES OF ANTIVIRAL THERAPY IN HEPATITIS C FOR PRIOR NULL RESPONDERS IN THE ERA OF FIRST GENERATION PROTEASE INHIBITORS

Kim RW[1], Mcewan P[2], Yuan Y[3]
[1]*Mayo Clinic College of Medicine, Rochester, MN, USA,* [2]*HEOR Consulting, Monmouth, Monmouthshire, UK,* [3]*Bristol-Myers Squibb, Plainsboro, NJ, USA*

OBJECTIVES: New protease inhibitors (PIs) significantly improve sustained virological responses (SVRs) in patients with genotype 1 chronic hepatitis C. However, treatment (Tx) in prior null-responders with advanced fibrosis often results in failure to achieve SVR and development of resistant mutations. Emerging quadruple Tx adding two direct antiviral agents may achieve SVR in nearly all of these patients. This study aimed to compare two strategies: 1) treating prior null-responders with fibrosis stage 3 (F3) or stage 4 (F4) with telaprevir + peginterferon + ribavirin ("T+P+R strategy") versus 2) withholding Tx until more effective antiviral agents become available ("Wait strategy"). **METHODS:** The MONARCH Hepatitis C cost-effectiveness model was used to project outcomes in cohorts of 55-year-old prior null-responders using published dynamic transition rates for disease progression. "T+P+R strategy" achieves SVR in 42% of F3 and in 14% of F4 patients. In the Wait strategy, patients would wait for 5 years and then initiate quadruple Tx yielding 90% SVR. Quadruple Tx would be used as rescue in patients failing "T+P+R", 70% of whom would harbor virus resistant to PIs. Patient outcome in terms of SVR and quality-adjusted-life years (QALYs) were assessed 10 years thereafter. Benefits were discounted at 3.5%. **RESULTS:** Projected SVR rates were higher with the "Wait strategy" (76% and 65% for F3 and F4 respectively) than "T+P+R strategy" (50% and 30% for F3 and F4 respectively). Per-patient expected QALYs were higher for "Wait strategy" than "T+P+R strategy"; 8.59 versus 8.47 QALYs in F3 patients and 7.5 versus 6.7 QALYs in F4 patients. The "Wait strategy" was associated with one-third fewer re-treatments. **CONCLUSIONS:** Waiting for future quadruple antiviral therapy maximized the predicted health benefit both in terms of response (SVR) and QALYs; furthermore, the reduction in re-treatments associated with the "Wait strategy" is noteworthy given the likely high cost of triple therapy.

PIN99

MODELLING THE IMPACT OF EXTENDED VACCINATION STRATEGIES ON THE EPIDEMIOLOGY OF PERTUSSIS

Rozenbaum MH[1], De vries R[1], Postma MJ[2], Le HH[1]
[1]*University of Groningen, Groningen, The Netherlands,* [2]*University of Groningen, Groningen, The Netherlands, The Netherlands*

OBJECTIVES: To investigate the optimal pertussis booster vaccination strategy for the The Netherlands and to explore the impact of different assumptions for parameters surrounded by uncertainty. **METHODS:** The authors designed a realistic age-structured deterministic model. Assuming a steady state situation and correcting for underreporting, the model was calibrated using notification data from the period 1996-2000. Several sensitivity analyses were performed including varying the age of a booster dose (or multiple booster doses), expected vaccine uptake, duration of protection after natural infection, underreporting factors, contact function, and transmission probabilities. **RESULTS:** The results indicated that the optimal age of an additional booster dose is in the range of 10-15 years, and implementation of this booster dose will reduce both symptomatic and asymptomatic

infections, although the incidence of symptomatic infections in the older age classes does increase. The impact of the different assumptions used in the model was in general limited. **CONCLUSIONS:** We conclude that over a wide range of assumptions, an additional booster dose can reduce the incidence of pertussis in the population.

PIN100

WHY DON'T HEALTH PRACTITIONERS PRESCRIBE RATIONALLY IN MALARIA? A QUALITATIVE STUDY FROM PAKISTAN

Malik M[1], Hassali MA[2], Hussain A[1], Shafie AA[3]
[1]*Universiti Sains Malaysia (USM), Islamabad, Punjab, Pakistan,* [2]*Discipline of Social & Administrative Pharmacy, Universiti Sains Malaysia, Pinang, Palau Pinang, Malaysia,* [3]*Universiti Sains Malaysia (USM), Penang, Penang, Malaysia*

OBJECTIVES: To investigate doctors' perceptions towards factors underlying irrational prescribing practices in treatment of malaria in Pakistan. **METHODS:** A qualitative study with snowball sampling technique was used to identify nineteen doctors working at hospitals in Islamabad and Rawalpindi. Semi-structured interviews were conducted with the doctors until the point of saturation was obtained. The interviews, which were audio-taped and transcribed verbatim, were evaluated by thematic content analysis and by other authors' analysis. **RESULTS:** Thematic content analysis identified three major themes and several subthemes: 1) Factors responsible for irrational prescribing practices in treatment of malaria; 2) Lack of implementation of standard malaria treatment guidelines in the country; and 3) Strategies to improve irrational prescribing practices in treatment of malaria. All the doctors agreed on lack of implementation of standard guidelines in treatment of malaria while mixed responses were observed regarding factors influencing rational prescribing. Influence of pharmaceutical industry and unsupervised polytherapy were cited as major determinants for irrational prescribing practices in case of malaria. **CONCLUSIONS:** The findings suggest that the doctors in Pakistan are aware of irrational prescribing practices and its consequences in treatment of malaria but are facing significant barriers in terms of improving the current prescribing practices. There is an urgent need to design strategies such as implementation of standard malaria treatment guidelines, revision of health policies and up gradation of education and training of health players in order to improve the current prescribing practices for antimalarials.

PIN101

NEW INSIGHTS ON THE SPREAD OF INFLUENZA THROUGH AGENT BASED EPIDEMIC MODELING

Miksch F[1], Urach C[2], Popper N[1], Zauner G[3], Endel G[4], Schiller-Frühwirth I[4], Breitenecker F[2]
[1]*dwh Simulation Services, Vienna, Austria,* [2]*Vienna University of Technology, Vienna, Austria,* [3]*Dwh Simulation Services, Vienna, Austria,* [4]*Main Association of Austrian Social Security Institutions, Vienna, Austria*

OBJECTIVES: Every winter season an influenza epidemic occurs, although strength and duration may vary. In 2006-2007 in Austria presumably 5% of the whole population fell sick while 21% of age 15 and above were vaccinated. The goal was to build an agent based model to understand, model and simulate the progress of influenza epidemics. **METHODS:** The agent based model simulates single persons with an infection state (susceptible, infected with or without symptoms, resistant, vaccinated). Based on the results of a wide European study (POLYMOD, EC-Project SP22-CT-2004-502084) people have contacts in different places like housholds, schools or workplaces. Transmissions are possible upon contacts, then a person is infected for a while until he or she becomes resistant upon recovery. **RESULTS:** The outbreak of the epidemic starts when a few people are initially infected while the rest is susceptible or vaccinated. After some time the epidemic stops due to a larger number of resistant and a smaller number of susceptible people. Since only 5% of the population fall sick the situations at outbreak and at termination of the epidemic are similar and therefore it behaves very sensitive to parameter changes. **CONCLUSIONS:** Some parameter changes in the model can be interpreted as interventions in reality. But usually the influenza does not react sensitive to interventions. For example, an increase of the vaccination rate by 5% prevents an outbreak of the epidemic in the model which is obviously not true. This insight has two consequences: First, the influenza does not just spread and stop by transmission and recovery of people. There must be one or more other impacts modulating outbreaks like predestined people to fall sick or the climate. Second, without knowledge of these impacts it is almost impossible to predict the effect of vaccination strategies exactly.

PIN102

NATIONAL COST SAVINGS FROM THE BRAZILIAN HIV/AIDS ANTIRETROVIRAL UNIVERSAL ACCESS PROGRAM: ANALYSIS VERSUS CANADA AND AUSTRALIA

Becker RV[1], Teich V[2], Pepe C[2]
[1]*Russell Becker Consulting, Chicago, IL, USA,* [2]*MedInsight, Sao Paulo, Sao Paulo, Brazil*

OBJECTIVES: In 1996, the Brazilian government implemented a universal access program for anti-retroviral drugs to improve the treatment of HIV/AIDS. A recent study showed $1.78 billion USD savings from the program compared to pricing in the US. This study estimates the drug costs saved in 2010 by the program's implementation compared to pricing in Canada and Australia. **METHODS:** Nationwide drug distribution data and drug prices for the Brazilian government's antiretroviral access program were obtained for 2010 from the Ministry of Health data. Drug prices for each drug were converted to daily dosage costs in US dollars. Comparable government drug prices were obtained for Ontario, Canada and Australia. The Brazilian, Canadian, and Australian unit drug costs were multiplied by the distribution rates in Brazil to calculate and compare the cost of the Brazilian 2010 drug distribution using the Brazilian and Canadian/Australian pricing rates. Any cost savings to the Brazilian government were also calculated. The savings calculation assumes that the Brazilian government has paid for all of the drugs distributed regardless of patient utilization rates. Sensitivity analysis was conducted on the distribution rates, pricing, and utilization rates. **RESULTS:** The Brazilian government saved $448.1 million USD in and $403.1 million USD 2010 versus Canada and Australia, respectively through its pricing program. The total cost of the drugs distributed was $1.94 billion with the Brazilian pricing. This compares to $2.37billion and $2.41 billion dollars using Canadian and Australian pricing rates, respectively. Sensitivity analysis found the results to be stable. **CONCLUSIONS:** Significant costs savings have been realized by the Brazilian government through its drug pricing program. These costs savings should be included as part of any analysis of the overall impact of the program.

PIN103

A COMPARISON OF INVESTMENTS FOR DIFFERENT PREVENTION PROGRAMS: RESPIRATORY SYNCYTIAL VIRUS PROPHYLAXIS VERSUS HUMAN PAPILLOMA VACCINE

Roggeri D[1], Sambrook R[2], Lozano-Ortega G[3], Gooch K[4], Soro M[5]
[1]*ProCure Solutions Sas, Nembro, BG, Italy,* [2]*Oxford Outcomes Ltd., Vancouver, BC, Canada,* [3]*Oxford Outcomes, Vancouver, BC, Canada,* [4]*Abbott Laboratories, Abbott Park, IL, USA,* [5]*Abbott Italia Srl, ROMA, RM, Italy*

OBJECTIVES: Childhood prevention programs are important and imperative public health initiatives. However, prevention programs are often associated with considerable investments. This budget impact analysis was undertaken to position the Italian investment for a program to prevent respiratory syncytial virus (RSV) consequences in high-risk infants using palivizumab. This prevention program is compared to an existing immunization program in the Lombardy region of Italy: Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (HPV), considered standard of care. **METHODS:** Two budget impact models were developed to assess the impact of two different programs on Regional Health Service (RHS) expenditure: the budget impact of RSV prophylaxis program was compared with a non-prophylaxis program, while the budget impact of HPV active prophylaxis was compared with a non-prophylaxis approach. Only direct costs based on disease prevalence, and program efficacy were included. The model includes RSV prophylaxis administration costs, RSV-related resource consumption (visits, long term sequelae) and RSV hospitalization over one year; for HPV prevention program, one year prophylaxis was assessed against 5 years disease costs due to the low incidence of HPV related disease in 1 year. Eligible subjects were preterm and high-risk infants (as established by national guidelines) for RVS program and all 12-year-old girls cohort for HPV program. **RESULTS:** RSV prophylaxis expenditure was estimated at €11,577,776 in the prophylaxis program arm versus €5,206,534 in the 'without prophylaxis program' arm, while for HPV prevention program, vaccination program expenditure (including vaccine cost) would be 13,068,025€ vs. 356,385€ in no-vaccine arm. The net budgetary impact was calculated at €6.4 million for RSV vs. €12.7 million for HPV vaccination. **CONCLUSIONS:** Considering the RHS perspective, the budget impact of palivizumab had lower program costs and higher disease cost offsets vs. HPV vaccination program, positioning its economic value well within the parameters of cost-effective childhood prevention programs.

PIN104

PRO'S IN EVALUATING RESOURCE UTILISATION AND ABSENTEEISM IN PEOPLE RECEIVING INFLUENZA VACCINATION

Wade A[1], Crawford G[1], Pumford N[1], Mcconnachie A[2]
[1]*Patients Direct, Glasgow, UK,* [2]*Glasgow University, Glasgow, UK*

OBJECTIVES: To investigate whether patient reported outcomes could detect differences between H1N1 and seasonal influenza vaccinations on resource utilisation and time off work over a 26 week follow up period. **METHODS:** In this evaluation, PROBE methodology consisting of a web-based system supplemented by telephone reporting was used to collect naturalistic data from people who had received an influenza vaccination during 2009-2010 season. People were recruited through media advertising and awareness campaigns in public places and work (West of Scotland). Data collection on day of immunisation, after 3 days, 8 days, 6 weeks, 12 weeks and 26 weeks. Data included baseline demographics, any side effects following vaccination including the duration/ resource use and time off work. **RESULTS:** A total of 1103 vaccine recipients participated in the evaluation. Overall, 42% of respondents reported experiencing any side effect after vaccination (excluding pain/discomfort at site of injection) with more people reporting a side effect with H1N1 vaccination (45% versus 26% seasonal flu vaccination versus 42% receiving both vaccines $p=0.001$). However, there was no significant difference in health service utilisation between the groups – 5.2% H1N1, 2.3% Seasonal, 5.5% both vaccines $p=0.468$. 4 (0.6%) people in the H1N1 only group received hospital treatment, 1 (0.8%) in the seasonal only group and 2 (0.9%) receiving both vaccines. Time off work (absenteeism), in relation to flu like symptoms, also showed no significant difference between the groups – 1.7% H1N1, 1.9% Seasonal, 3.4% both vaccines $p=0.486$. **CONCLUSIONS:** This evaluation shows that the PROBE methodology quickly and simply captured patient reported outcome information on resource utilisation and absenteeism in a vaccinated population. People receiving the H1N1 vaccination alone were more likely to experience side effects than seasonal influenza vaccination alone but this did not lead to a significant increase in resource utilisation or time off work.

PIN105

FINANCIAL SUPPORT FOR HIV/AIDS PREVENTION, CARE AND TREATMENT IN THAILAND

Layton MR[1], Pachanee K[2], Prakongsai P[3]

[1]Khon Kaen University, Khon Kaen, Khon Kaen, Thailand, [2]International Health Policy Program (IHPP), Nonthaburi, Thailand, [3]International Health Policy Program, Nonthaburi, Thailand

OBJECTIVES: To describe the key financial resources allocation supporting the HIV/AIDS prevention, treatment, and social support programs in Thailand and to identify facilitators and barriers in financial management and monitoring system. **METHODS:** Based on a comprehensive review of financial reports from various sources such as UNGASS, NASA and NAMC reports, we explored the key financial resources that support the HIV/AIDS prevention, treatment, and social support programs in Thailand. In addition, we conducted in-depth interviews with different key informants responsible for the activities in response to the national policy on HIV/AIDS in provincial and district levels including domestic and international donors to assess the financial management, coordination and monitoring system. **RESULTS:** The total expenditure on HIV/AIDS in fiscal years 2007, 2008 and 2009 were 204, 210, and 218 million US$, respectively. The national HIV/AIDS spending was amount to 2.7% (2007) and 1.9% (2008 and 2009) of the total health expenditure. Domestic funding accounted for 83%, 85% and 93% of the HIV/AIDS programs in 2007, 2008 and 2009. Much of those spending emphasized on care and treatment while prevention budgeted for 14.1%, 21.7%, and 13.7%. The majority of treatment financing came from public health insurance schemes, but most preventive programs were from GFATM and other international sources. Effective system development in program management, monitoring and evaluation are still lacking among practitioners. **CONCLUSIONS:** Thailand has shown its potential to be self-reliant in combating HIV/AIDS. Nevertheless, care and treatment expenditures overshadow prevention, and most of the preventive programs are from international sources. Thus, the dominance of entitlement programs in funding for HIV/AIDS treatment challenges policy makers to monitor the extent and quality of HIV/AIDS care. For future savings in the cost of treatment and care, investing in prevention programs is essential, especially due to the declining support from international funds.

PIN106

HIV SCREENING PROGRAMME IN COMMUNITY PHARMACIES OF THE BASQUE COUNTRY

Gorostiza I[1], Elizondo I[2], Braceras L[2]
[1]Basurto Hospital - Osakidetza, Bilbao, Bizkaia, Spain, [2]Department of Health. Basque Government, Vitoria - Gasteiz, Araba, Spain

OBJECTIVES: One in four HIV infected patients is unaware of his condition, and implies a threefold increase in the risk of HIV transmission. To describe the outcomes, users' socio-demographic characteristics and test acceptance of a new rapid HIV antibody screening test programme offered at Basque community pharmacies. **METHODS:** Cross-sectional study based on the answers given by the users of the rapid HIV antibody screening test, to a questionnaire. The programme was performed in 20 community pharmacies. Data shown come from a random sample of the 3514 tests carried out in the first year of the programme. Data gathered include test outcomes, users' socio-demographic information, their HIV risk profile, the reasons for asking for the test, and why they chose community pharmacies to have the HIV test. Statistical analyses included exact tests. **RESULTS:** There were 806 valid questionnaires, the mean age of test users was 36.2 years (SD: 11.0; range: 16-82; 71% men). 7 HIV test outcome were positive (0.85%; 95%CI: 0.34 to 1.75), 5 out of them were men. Only 10% of test users came from another country. Users' risk behaviour was predominantly heterosexual and 1 in 5 users asked for the test in the following three months after the exposure to the risk factor, when the test is not still accurate. More than half of the users hadn't had a previous HIV test. The reasons for choosing this kind of HIV test were mainly its quickness (just 15 minutes), and the convenience and rapid access to a community pharmacy service. The cost of each test for the Basque Government in 2010 was 18.15€ (1887.57€ to detect a positive one). **CONCLUSIONS:** This new rapid HIV antibody screening test in community pharmacies can supplement other HIV screening programs running as the user profile partially differs from them.

PIN107

TOBRAMYCIN INHALED SOLUTION UTILIZATION BY CYSTIC FIBROSIS PATIENTS: AN ANALYSIS WITH THE RAMQ DATABASE

Lachaine J[1], Beauchemin C[1], Barbeau M[2]
[1]University of Montreal, Montreal, QC, Canada, [2]Novartis Pharmaceuticals Canada Inc, Dorval, QC, Canada

OBJECTIVES: Tobramycin inhaled solution (TIS) has been shown to preserve lung function in cystic fibrosis (CF) patients chronically infected with Pseudomonas aeruginosa. To minimize the emergence of aminoglycoside resistant P. aeruginosa strains, a chronic intermittent treatment of 28 days on and 28 days off TIS is recommended. The objective of this study was to assess TIS utilization modalities in CF patients. **METHODS:** Patients covered by the provincial public drug reimbursement program who had used TIS (Tobi™) on at least one occasion during the period from January 1, 2007 to December 31, 2008 were selected. To be included in the study they needed to be cover by the drug program for at least one year after the initiation of TIS. Patient's characteristics and drug utilization patterns were analyzed. For each patient, the number of 28 days periods for which they received TIS was estimated **RESULTS:** There were a total of 72 patients who have use TIS during the study period and were covered by the drug plan for at least one year after the initiation of TIS. The average age of TIS users was 25.6 years, with a similar proportion of males (51.4%) and females (48.6%). A large proportion of these patients (40,3%) had diabetes. In the first year following the initiation of TIS, different patterns of utilization were observed: For 15.3% of these patients, TIS was use as a continuous treatment (42 weeks or more of treatment), 41.7% received 4 cycles or more, 22.2% received 2 or 3 cycles and 20.8% received only 1 cycle of TIS during the year. **CONCLUSIONS:** In this sample, the utilization of TIS in CF patients was sub-optimal. TIS was used as recommended, as a chronic intermittent treatment by less than half of the study population.

Infection – Research On Methods

PIN108

SUSTAINED VIROLOGICAL RESPONSE AS PATIENT-RELEVANT ENDPOINT IN HEPATITIS C?

Kossmann B[1], Neuhäuser M[2], Schauer S[1], Slawik L[3], Fleischmann J[4], Wasem J[5], Aidelsburger P[1]
[1]CAREM GmbH, Sauerlach, Germany, [2]RheinAhrCampus, Remagen, D-Remagen, Germany, [3]Janssen-Cilag GmbH, Neuss, Germany, [4]Janssen-Cilag Germany, Neuss, Germany, [5]University Duisburg-Essen, Essen, Germany

OBJECTIVES: Chronic infection with Hepatitis C virus is causing advanced liver disease in a large proportion of patients. Standard treatment is antiviral therapy with the goal of a sustained virological response (SVR). The objective of the study is to validate SVR in the chronic infection Hepatitis C as patient relevant endpoint as defined by German code of social law. **METHODS:** Systematic literature searches were conducted in order to find relevant methods for the validation of surrogate endpoints in general and to find studies with appropriate data to perform the validation of SVR as a surrogate parameter in Hepatitis C. The validation will be realised with the best method according to the data available from the selected studies. **RESULTS:** Five studies were identified as basis for validation (out of 694 papers retrieved and 36 studies selected for further analysis). Due to the lack of long-term studies fulfilling the defined inclusion criteria, no differentiation between antiviral treatment schemes and different stages of the disease were possible. Methods of Prentice were identified as applicable for validation. With the four Prentice criteria, SVR could be validated as a surrogate endpoint for the endpoints liver cancer and mortality. However, this was not possible with data from all five studies and only partly with different analysis methods (combination) of data. For regression models or meta-analysis, data is not sufficient since individual patient data was not available. For one study further analysis (proportion of treatment effect) could be performed. **CONCLUSIONS:** When focussing on statistical methods current data allows for a very limited validation of SVR as a patient-relevant endpoint for treatment of Hepatitis C, only. There is a lack of long-term data (going beyond 5 years of follow up), especially for individual data of treated and untreated patients, likely due to the slow-evolving character of Hepatitis C.

PIN109

MODELLING THE POLICY OF MANAGING SEASONAL INFLUENZA IN THE UK

Van Bellinghen LA[1], Van Vlaenderen I[1], Meier GC[2]
[1]CHESS BVBA, Ternat, Belgium, [2]GlaxoSmithKline Biologicals, Wavre, Belgium

OBJECTIVES: Seasonal influenza policy in the UK is directed to the elderly and selected high-risk groups. The department of Health Policy suggests that these individuals should be vaccinated every year to avoid possible costly or life-threatening complicationsTo define a cost-effectiveness modelling approach and structure that reflects the season-to-season impact of influenza on the entire UK population, and the consequences of policy **METHODS:** A structured, iterative, literature review and analysis of seasonal influenza models **RESULTS:** Fifty-four references were reviewed, 32 were assessed. The vast majority of models are decision trees, considering one influenza season; however, if unit of outcome was life years or QALYs, impact of influenza mortality was incorporated as average life-expectancy foregone. Nine models considered healthy and at-risk paediatric populations, six were UK models of which three papers considered treatment only and the remaining considered treatment and prevention. Ten models reviewed healthy working adult populations only, two were UK models, one considering prevention, the other treatment. Sixteen other models reviewed adult populations (healthy and/or at-risk adults, excluding healthy working adults), nine were UK models. Eleven papers considered treatment only, two considered prevention only and the remaining considered treatment and prevention. Twenty-one models evaluated the elderly, including residential populations. Nine were UK papers; five considered treatment only and four considered treatment and prevention. **CONCLUSIONS:** No study assessed the cost-effectiveness in the entire population, only sub-group analyses have been performed. None of the studies considered the impact of policy options over multiple consecutive flu seasons during a lifelong time horizon, and – as a consequence – were not able to incorporate accumulated (Quality Adjusted) Life Years gained for various age groups. Our suggested approach is a one-year cycle length, life-time, multi-cohort, Markov model from the perspective of the NHS, with cohorts starting in different age groups and accounting for at-risk populations.

PIN110

DEVELOPMENT OF A LARGE SAFETY DATABASE USING STUDIES CONDUCTED DURING THE CLINICAL DEVELOPMENT AND POST-MARKETING OF A VIROSOMAL ALUMINIUM-FREE HEPATITIS A VACCINE

Faure C[1], Koller A[2], Hartmann K[2], Chrétin S[1], Doux S[1], Visèle N[1], Bugnard F[1], Maier W[3]
[1]REGISTRAT-MAPI, LYON, France, [2]CRUCELL, Berne, Switzerland, [3]REGISTRAT-MAPI, London, UK

OBJECTIVES: Development of a unique database using data from studies conducted during the vaccine development and its post-marketing to evaluate the safety profile of a virosomal aluminium-free hepatitis A vaccine in a large population. **METHODS:** Available data from various studies, retrieved either from paper or electronic files, were evaluated and harmonized in order to be combined in a single database and all adverse events, concomitant diseases and concomitant vaccinations underwent a new coding. **RESULTS:** Initial data were available from 3 distinct sources, totalizing 35 studies: individual and summary data from clinical

study reports (18 studies), 1 SAS® database pooling data from 16 studies and 1 SAS® database composed of 1 study. While pooling data from these different sources, several issues had to be faced: 1) the need to harmonize data between studies; 2) the fact that some variables were not collected in some studies, and 3) the fact that for 6 studies, part of the data were available only as summarized data. After taking into account all these issues, an exploitable database was obtained whose strengths are its large sample size (35 studies comprising 7923 patients), its range of study settings and designs (phase I to IV across numerous countries) and the time period encompassed (1990 to 2007). **CONCLUSIONS:** Pooling data from various sources raised several problems, not all of them resolvable. However, this work allowed to obtain an exploitable database with undisputable strengths i.e. sample size, large range of study settings and design and time period encompassed. Once constituted, this database became a valuable tool in evaluating the safety profile of the virosomal aluminium-free hepatitis A vaccine, and will constitute a valuable database to answer further safety questions in the future.

PIN111

DYNAMIC MODELING OF COST-EFFECTIVENESS OF 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINATION AGAINST STREPTOCOCCUS PNEUMONIAE IN TAIWAN

Chang CJ[1], Wu DBS[2], Fann CSJ[3], Wen YW[4], Huang YC[5], Wu CL[1]
[1]*Chang Gung University, Taoyuan, Taiwan,* [2]*National Yang Ming University, Taipei, Taiwan,* [3]*Academia Sinica, Taipei, Taiwan,* [4]*Chang Guang University, Taoyuan, Taiwan,* [5]*Chang Gung Memorial Hospital, Taoyuan, Taiwan*

OBJECTIVES: Many pharmacoeconomic studies have applied the decision analytic model or Markov model (collectively termed as static models) to evaluate the cost-effectiveness of pneumococcal conjugate vaccines without taking herd effect into account. The objective of the study is to carry out a cost-effectiveness analysis of 13-valent pneumococcal conjugate vaccine PCV13 in Taiwan using a transmission dynamic model (TDM) to circumvent static models. **METHODS:** We develop an age-structured TDM populated with parameters from the Taiwanese National Health Insurance Research Database (NHIRD), Centers for Disease Control, government websites and public available sources to evaluate the clinical and economic impact of PCV13. Pneumococcal diseases included in the TDM are invasive pneumococcal diseases (IPD), hospitalized pneumonia and acute otitis media (AOM). One-way deterministic and multivariate probabilistic sensitivity analyses based on 5000 Monte Carlo simulations are performed to explore model uncertainties. Confidence intervals for ICER and cost-effectiveness acceptability curves (CEAC) are calculated for further inferences. **RESULTS:** In the base-case analysis, 4-dose scheduled universal infant PCV13 vaccination is expected to prevent 5,112 cases of IPD, 535,607 cases of all-cause hospitalized pneumonia, 726,986 cases of AOM, and 420 deaths over a 10-year time horizon. The vaccination program is estimated to yield an incremental cost-effectiveness ratio (ICER) of US$38,045 and US$18,299 from payer and societal perspectives. One-way sensitivity analyses indicated that ICER is most sensitive to vaccine price and recovery rate of pneumonia. Ninety-five percent confidence interval of ICER is US$10,186 to US$34,563 by multivariate probabilistic sensitivity analyses in societal perspective. **CONCLUSIONS:** With a WHO-recommended cost-effectiveness threshold of 3 times the gross domestic product per capita, PCV13 vaccination program would be cost-effective in Taiwan. With the lack of long-term real data, TDM can be informative to decision makers on evaluating the long term cost-effectiveness of national immunization program.

PIN112

USE OF DYNAMIC MODELS TO MEASURE HEALTH OUTCOMES OF PNEUMOCOCCAL VACCINATION IN SPANISH ADULT POPULATION

Pradas R[1], Guijarro P[2], de Salas-Cansado M[2], Lorente R[1], Antoñanzas F[1]
[1]*Universidad de la Rioja, Logroño, La Rioja , Spain,* [2]*Pfizer Spain, Alcobendas, Madrid, Spain*

OBJECTIVES: Pneumococcal vaccination programmes change the natural course of infection as the number of susceptible subjects decrease along time. Markovian and Discrete Event Simulation models enable to capture the whole vaccination effect as infection rate remains constant. A differential equation dynamic model based on Anderson and May work was developed to describe how pneumococcal vaccination modifies the extension of the disease in the susceptible population. **METHODS:** Measure of epidemiological effectiveness was the number of contagions avoided by the preventive intervention. No assumptions on mortality and life-years-gained were considered. The nonlinear ordinary differential equations system proposed was $dS(t)/dt = -\beta^*I(t)^*S(t)+\gamma^*I(t)-V(t)$ $dI(t)/dt = +\beta^*I(t)^*S(t)-\gamma^*I(t)$ where: t = moment in time (months); I(t) and S(t) = number of infective and susceptible subjects at each time t; β = transmission coefficient; γ = natural withdrawal coefficient. The first order derivatives with respect to t, $dI(t)/dt$ and $dS(t)/dt$, indicate the instantaneous variation rates in time of infective and susceptible, while V(t) indicates the number of vaccinated individuals at each time. Study time horizon was five years. Spanish 65-years-old cohort annually vaccinated was 318,000 subjects. The parameters to populate the model came from Spanish Ministry of Health database (CMBD) and published data. **RESULTS:** Over a 5-year period, the number of avoided contagions derived from the implementation of the vaccination strategy would be 83,844 with a clear cumulative profile (1,922 on the 1st year; 7,874 on the 2nd; 15,748 on the 3rd; 24,683 on the 4th and 33,617 on the 5th). **CONCLUSIONS:** Dynamic models should be used to assess the impact of vaccination programs for infectious diseases where the infection strength varies along time. The goodness of fit of this pneumococcal dynamic model was high and captured health outcomes more easily than alternative modelling methodologies.

PIN113

A NEW FRAMEWORK FOR UNDERSTANDING THE IMPACT OF HEPATITIS C AND ITS TREATMENT ON QUALITY OF LIFE

Armstrong AR[1], Duracinsky M[2], Lalanne C[1], Da Silva M[3], Jamal L[3], Herrmann S[4], Carrieri PM[5], Davril J[6], Chassany O[1]
[1]*St Louis Hospital, Paris, Ile de France, France,* [2]*Hospital Kremlin Bicetre, Paris, Ile de France, France,* [3]*Health Secretariat of the State of São Paulo, Disease Control Centre, São Paulo, São Paulo, Brazil,* [4]*Murdoch University, Perth, Western Australi, Australia,* [5]*INSERM, Marseille, Provence-Alpes-C, France,* [6]*Collectif Hépatites Virales, Paris, France*

OBJECTIVES: To develop a conceptual framework demonstrating the impact of Hepatitis C (HCV) and treatment on health-related quality of life (HRQL). **METHODS:** 1) PUBMED literature were reviewed. HRQL issues raised by HCV patients in qualitative studies were compared with those emphasized in quantitative studies. Numerous issues important to patients were not adequately covered by commonly used HRQL instruments; 2) An in-depth interview guide was developed to investigate the issues raised in both study types. HCV patients from France (n=20), Brazil (n=20) and Australia (n=20) were sampled; and 3) interview data were examined for recurring issues, which were grouped by concept and theme. Commonalities and variation within emerging concepts and themes were explored, iteratively re-examined and refined. **RESULTS:** The process of analysis facilitated construction of an HCV-specific HRQL conceptual framework, within which new and previously identified issues, concepts and themes were organised into Physical, Mental and Social domains. This framework was compared against HRQL measures commonly used in HCV research, including the SF-36 and Hepatitis Quality of Life Questionnaire (HQLQ). HCV-related issues absent or not adequately represented by these instruments include: (Physical) HIV/HCV co-infection issues, impact of treatment side effects, mobility change, bodily changes, sexual dysfunction, and fatigue variability; (Mental) illness uncertainty and unpredictability, treatment fears, treatment management and adherence, addiction, identity change, emotional volatility, minor cognitive impairment, concerns for the future, positive disease impact, and coping; (Social) contagiousness and transmission-related issues, multidimensional nature of stigma, social isolation and withdrawal, loss of independence, and reduced participation modes. **CONCLUSIONS:** Numerous important issues raised by HCV patients are absent or inadequately represented by commonly used HRQL instruments. The proposed HCV HRQL conceptual framework encompasses these issues. This forms the foundations for the development of a new HCV-specific HRQL instrument. It can also assist health care providers to educate patients, plan individual interventions, and assess treatment impact.

Mental Health – Clinical Outcomes Studies

PMH1

ADJUNCTIVE PHARMACOTHERAPY AMONG INITIATORS OF SSRI TREATMENT FOR MAJOR DEPRESSIVE DISORDER: A COHORT STUDY USING A UK PRIMARY CARE DATABASE

Ball S[1], Classi P[1], Dave S[2], Maguire A[3], Kim le T[1]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*United BioSource Corporation, London, UK,* [3]*United Biosource Corporation, London, UK*

OBJECTIVES: For patients with major depressive disorder (MDD), adjunctive therapy is often a second treatment step following a partial response to an antidepressant. Although the role of adjunctive treatment is supported in practice guidelines, there is little information regarding the actual practice of adjunctive therapy, particularly for patients seen in primary care. The objectives of the study were to examine the incidence and predictors of adjunctive pharmacotherapy among patients with MDD treated with selective serotonin reuptake inhibitors (SSRIs) by primary care physicians (PCPs) in the UK (UK). **METHODS:** The General Practice Research Database was used to identify 15,274 patients with MDD who were prescribed first-line treatment with SSRIs from 2006-2008. Treatment trajectories were identified and classified as adjunctive therapy, drug switches, dose increases, discontinuation, and restart of therapy. Incidence and predictors of adjunctive therapy were assessed. Comparisons in healthcare resource utilization were made between patients receiving adjunctive therapy and patients receiving other treatment strategies. **RESULTS:** Overall incidence of adjunctive therapy was 3.07/100 person years (95% CI 2.90-3.25). Patients prescribed adjunctive therapy were more likely to be female (IRR 1.17, p=0.02), of higher age (IRRs 1.53-2.41, p<0.001), and had greater depression severity (IRR 1.02, p=0.004). Presence of postherpetic neuropathy (IRR 3.06, p=0.01), irritable bowel syndrome (IRR 1.33, p=0.01), and an increasing Charlson Comorbidity Index (IRR 1.08, p=0.03) were associated with a higher incidence of adjunctive therapy. MDD-related general practitioner consultations were lower among those prescribed adjunctive therapy compared with patients receiving other treatment interventions (IRRs 0.79-0.87, p<0.001). **CONCLUSIONS:** Incidence of adjunctive treatment was relatively low and was associated with several patient demographics, a higher burden of illness, and less PCP visits. The incidence of adjunctive therapy suggests that it is infrequently used in the management of MDD among patients who are partial responders to SSRI treatment in UK primary care.

PMH2

THE EFFICACY OF THE NEW ANTIDEPRESSANT AGOMELATINE AS COMPARED AGAINST PLACEBO AND SSRIS: A META-ANALYSIS COMBINING PUBLISHED AND UNPUBLISHED DATA

Ballesteros J[1], Tarapues M[2], Santos B[3], Rueda JR[2]
[1]*University of the Basque Country, UPV/EHU and CIBERSAM, Leioa, Spain,* [2]*University of the Basque Country, UPV/EHU, Leioa, Spain,* [3]*University of the Basque Country, UPV/EHU, and CIBERSAM, Leioa, Spain*

OBJECTIVES: To asses the efficacy of agomelatine, a melatonin MT1/MT2 agonist and $5\text{-}HT_{2B}/5\text{-}HT_{2C}$ antagonist, when compared with placebo and SSRIs. **METHODS:** An extensive trials search was conducted on electronic databases, clin-

ical trials registries, and EMA reports. We extracted data for depression severity (mean differences or related statistics) on the primary comparisons of 1) agomelatine 25 mg/day *versus* placebo, and 2) agomelatine 25 mg/day *versus* any SSRI. We calculated Hedges' g effect size for each trial and combined them by the inverse variance method assuming a random effects model. Two meta-analyses were conducted: one with the results of published and unpublished trials and the other only with results of published trials. **RESULTS:** Ten trials (5 unpublished) gave data on the efficacy of agomelatine versus placebo. Overall, the results were homogeneous (I^2 = 9.2%), and showed agomelatine was better than placebo for reducing the severity of depression at 8 weeks (g = -0.18; 95% CI = -0.25 to -0.10; p <0.0001). However when the analysis was restricted to published trials the effect size was 45% overestimated (g = -0.26; 95% CI = -0.36 to-0.15; p < 0.0001; I^2 = 3.4%). 7 trials (4 unpublished) gave data on the comparison of agomelatine versus any SSRI. There was no difference in efficacy with all trials combined (g = 0.01; 95% CI = -0.16 to 0.18; p = 0.87), but agomelatine significantly outperformed SSRIs in the subset of published trials (g = -0.17; 95% CI = -0.29 to -0.05; p = 0.0052). **CONCLUSIONS:** When combining all available data agomelatine presents a small to moderate efficacy as antidepressant with similar effect sizes to those reported for SSRIs. Previous reports pointing to better results of agomelatine as compared with SSRIs are the result of selective publication bias.

PMH3

OLANZAPINE LONG-ACTING INJECTION FOR SCHIZOPHRENIA: AN EVALUATION OF PATIENT FUNCTIONING DURING 24 WEEKS OF MAINTENANCE THERAPY

Novick D[1], Anand H[1], Ascher-Svanum H[2], Haro J[3], Bertsch J[3], Cui Z[2], Detke H[2], Mcdonnell D[4], Montgomery W[5]
[1]*Eli Lilly and Company, Windlesham, Surrey, UK,* [2]*Eli Lilly and Company, Indianapolis, IN, USA,* [3]*Parc Sanitari Sant Joan de Deu, CIBERSAM, Sant Boi de Llobregat, Spain,* [4]*Eli Lilly S.A.-European SSC Irish Branch, Co. Cork,, Ireland,* [5]*Eli Lilly Australia Pty Ltd, West Ryde, Australia*

OBJECTIVES: This study aimed to describe the functional level of patients treated with olanzapine long-acting injection (OLZ-LAI) during maintenance treatment of schizophrenia for up to 24 weeks. A secondary objective was to compare OLZ-LAI with oral olanzapine on these functional measures. **METHODS:** We present a secondary analysis of a multicenter, randomized, double-blind, study comparing the safety and efficacy of OLZ-LAI (405mg/4weeks, 300mg/2weeks, 150 mgs/2weeks, active depot groups) with oral olanzapine and OLZ-LAI 45mg/4weeks (very low dose/pseudo-placebo group) for maintenance treatment of clinically stable patients with schizophrenia (n=1064). Heinrichs and Carpenter's Quality of Life Scale (QLS) mean total scores were calculated for each of the three active OLZ-LAI treatment groups and for their pooled group. Patients' functional status was also classified - at baseline and endpoint, per QLS - as "good," "moderate" or "poor" using a recent data-driven approach to defining levels of functioning in schizophrenia. **RESULTS:** Over the 24-week treatment period, the OLZ-LAI-treated patients improved their level of functioning - per QLS total score - from a mean (±SD) of 66.4 (±18.9) to 72.0(±19.1) (p<0.001). At baseline, 16.8% of the OLZ-LAI-treated patients were identified as having a "good" level of functioning, which increased to 27.5% following up to 24 weeks of therapy (p<0.001). There was a decrease both in the proportion of patients with a "moderate" level of functioning (from 66.8 to 61.8%; p=0.002) and patients with a "poor" level of functioning (from 16.3% to 10.7%; p=0.06). Results were not significantly different between oral olanzapine and the three OLZ-LAI active dosing groups or the pooled OLZ-LAI treatment group. **CONCLUSIONS:** In this 24-week study, clinically stable patients treated with OLZ-LAI maintained their favorable baseline level of functioning or further improved it over time. Results did not significantly differ between OLZ-LAI and oral olanzapine.

PMH4

EXTENT OF ATTAINING AND MAINTAINING SYMPTOM REMISSION BY ANTIPSYCHOTIC MEDICATION IN THE TREATMENT OF CHRONIC SCHIZOPHRENIA: EVIDENCE FROM THE CATIE STUDY

Levine SZ[1], Rabinowitz J[1], Ascher-Svanum H[2], Faries D[2], Lawson T[2]
[1]*Bar Ilan University, Ramat Gan, Israel,* [2]*Eli Lilly & Company, Indianapolis, IL, USA*

OBJECTIVES: Data on attaining and maintaining symptom remission associated with specific antipsychotic medications are rare and variant. The aim of this study is to examine remission rates and their variation by antipsychotic medication in chronic schizophrenia in the National Institute of Mental Health Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) give it has an 18-month duration and representative antipsychotic medications. **METHODS:** Symptom remission was examined using the Remission in Schizophrenia Working Group remission criteria of attaining and maintaining for 6 months with mild ratings on 8 specific Positive and Negative Syndrome Scale (PANSS) items. Remission rates were assessed (a) up to 18 months across CATIE's switching phases (n=1332); and (b) in phase 1 (that involved double-blind randomization to one of five antipsychotic medications) to compare antipsychotic medication differences in attaining and maintaining remission among patients not in remission at baseline (n=941). **RESULTS:** A total of 15.7% of patients were in symptomatic remission at baseline. Across the switching phases of CATIE only 11% attained and then maintained at least 6 months of symptomatic remission, and 55.5% (n=623) experienced no symptom remission at any visit. In phase 1, attaining and maintaining remission for 6 months was highest for the olanzapine (13.3%) medication group followed by quetiapine (8.9%), ziprasidone (6.6%), perphenazine (6.2%), and risperidone (6.2%) groups. **CONCLUSIONS:** As currently defined, remission appears to be a very difficult therapeutic target to attain and maintain in chronic schizophrenia and may differ by antipsychotic medication. Pragmatically, remission gradients may be effectively studied by applying modified duration and symptom criteria.

PMH5

EMPIRICALLY-DRIVEN DEFINITIONS OF "GOOD" "MODERATE" AND "POOR" LEVELS OF FUNCTIONING IN THE TREATMENT OF SCHIZOPHRENIA

Ascher-Svanum H[1], Novick D[1], Haro J[2], Aguado J[2], Cui Z[1], Anand H[3]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*Parc Sanitari Sant Joan de Deu, CIBERSAM, Sant Boi de Llobregat, Spain,* [3]*Eli Lilly and Company, Surrey, UK*

OBJECTIVES: Despite marked heterogeneity among patients with schizophrenia in their level of functioning, little is known what "good" "moderate" or "poor" levels of functioning look like on various functional measures. This study used an empirical approach to identify and then validate these functional definitions. **METHODS:** We used baseline data of a multicenter, effectiveness study comparing antipsychotics in the treatment of outpatients with schizophrenia (n=524; NCT00320489), as this study included several functional measures. A cluster analysis used the Heinrich's Carpenter Quality of Life Scale (QLS), the 12-item Short Form Health Survey (SF-12) mental composite score, and a previously studied productivity measure, to classify patients into functional groups. A three cluster solution was chosen to maximize simplicity, explanatory power and separation among the groups. Clusters were validated using two other functional measures and two previously published definitions of functional levels: an empirical definition that incorporated functioning and symptom severity, and another, using theoretically-driven definitions. Classification and regression tree (CART) analysis was used to establish the criteria for classifying functioning as "good" "moderate" or "poor" with the QLS. **RESULTS:** The three clusters consistently differentiated patients on the QLS, SF-12 and productivity measures, reflecting "good" "moderate" and "poor" functional levels. The clusters similarly differed on other functional measures (the Schizophrenia Outcomes Functioning Interview [SOFI] and the Euro-QOL-5D scale), and were concordant with two previously published functional classifications. The CART analysis identified "good" functioning as QLS total score >84.5, whereas "moderate" and "poor" functioning were separated by a cut-off score of 15.5 on the QLS intrapsychic foundation domain. Sensitivity ranged from 86% to 93% and specificity from 89% to 99%. **CONCLUSIONS:** The substantial heterogeneity among schizophrenia patients in their level of functioning can be reliably classified in an empirical manner, using specific cut-off scores on commonly used functional measures. Findings have utility for schizophrenia research.

PMH6

EFFECTIVENESS OF LONG-ACTING INJECTABLE RISPERIDONE AND ORAL ATYPICAL ANTIPSYCHOTICS IN A 24-MONTHS OBSERVATIONAL STUDY IN ADULT PATIENTS WITH SCHIZOPHRENIA IN GERMANY

Hargarter L[1], Fleischmann J[2], Diels J[3], Rabinowitz J[4], Hemels M[5], Gaudig M[2], Van sanden S[3], Schreiner A[6]
[1]*Medical Affairs, Janssen Germany, Neuss, Germany,* [2]*Health Economics, Janssen Germany, Neuss, Germany,* [3]*EMEA HEMAR Analytics, Janssen EMEA, Beerse, Belgium,* [4]*Bar Ilan University, Ramat Gan, Israel,* [5]*EMEA Hemar Analytics, Janssen EMEA, Birkerod, Denmark,* [6]*Medical Affairs, Janssen EMEA, Neuss, Germany*

OBJECTIVES: Treatment continuity plays a major role in achieving favorable outcomes in patients suffering from schizophrenia. Long-acting injectable risperidone (RLAI) has shown its beneficial effects compared to oral antipsychotics (oAP) in randomized controlled trials, but observational data reflecting routine clinical practice are sparse. Objective is to evaluate the clinical effectiveness of RLAI compared to oAP in clinical practice. **METHODS:** A total of 746 patients with schizophrenia newly initiated from oral antipsychotic treatment to either an atypical oAP (n=268) or RLAI (n=478) were enrolled in this prospective, longitudinal 24-month open-label observational study. Primary efficacy measure was time to discontinuation of medication using Kaplan-Meier and multivariate Cox proportional hazards regression, adjusting for patient demographics, disease severity and treatment history. **RESULTS:** At baseline, patients treated with RLAI were more likely to be male, non-compliant, substance abuser, and had significantly higher levels of psychotic symptoms and disease severity, poorer psychosocial functioning (GAF, days unable to work), and poorer cognitive function, compared to patients treated with oral antipsychotics. 107 patients were identified as having a history of poor adherence (RLAI: n=84; oral: n=23) with previous antipsychotic treatment. Time to treatment discontinuation was numerically but not significantly longer for patients treated with RLAI compared to patients treated with atypical oAP. Among the subset of patients with history of poor adherence this difference was significant (unadjusted hazard ratio=0.42, p=.014; adjusted hazard ratio=0,35; p=0,0098). Symptom improvement was significantly better for patients on RLAI as compared to oAP on the Positive and Negative Syndrome Scale (PANSS) total score (p=.029), positive (p=.004) and negative (p=.023) subscores, respectively. **CONCLUSIONS:** In routine clinical practice, RLAI appears to be used more frequently in patients with more severe schizophrenia, substance abuse and poor adherence. The benefits of RLAI treatment compared to oAP seem to be most pronounced in a subset of patients with poor adherence.

PMH7

ASENAPINE VERSUS OTHER ANTIPSYCHOTICS IN BIPOLAR I DISORDER: INDIRECT COMPARISONS AT TWELVE WEEKS

Sapin C, Corson H, Beillat M, Hansen K
Lundbeck SAS, Issy les Moulineaux, France

OBJECTIVES: Asenapine is a novel antipsychotic indicated for the treatment of moderate to severe manic episodes associated with bipolar I disorder. The clinical programme included one 12-week trial versus olanzapine in monotherapy and one 12-week adjunct therapy trial versus placebo. While no head-to-head data were available to compare asenapine with all atypical antipsychotics, the objective of this project was to provide comparative efficacy data of asenapine versus olanzapine, quetiapine and aripiprazole in both monotherapy and adjunct therapy using

indirect comparison techniques. **METHODS:** All twelve-week randomised controlled trials of olanzapine, quetiapine and aripiprazole conducted in monotherapy or in adjunct therapy were identified through a literature review. Five monotherapy studies were found, allowing the comparison of asenapine versus quetiapine and aripiprazole, with olanzapine and haloperidol as common references, using Bucher's method (Bucher et al., J Clin Epidemiol 1997). One twelve-week and four six-week placebo-controlled adjunctive therapy trials were identified, enabling the comparison of asenapine to olanzapine, quetiapine and aripiprazole through pairwise comparisons using placebo as a common reference. The outcomes used for comparison were the Young Mania Rating Scale (YMRS) change from baseline, YMRS response and remission rates. **RESULTS:** In monotherapy, the differences of mean YMRS change from baseline to week 12 between asenapine versus quetiapine and aripiprazole were 0.10 (p=0.959) and 1.76 (p=0.342), respectively. Relative risks for response and remission were close to one. In adjunct therapy, the differences of mean YMRS change from baseline to week 6 between asenapine versus olanzapine, quetiapine and aripiprazole were 0.63 (p=0.656), 0.10 (p=0.967) and -0.10 (p=0.946), respectively. Relative risks for response and remission were numerically in favour of asenapine but not statistically significant. **CONCLUSIONS:** The results of these indirect comparisons consistently showed comparable efficacy of asenapine versus the investigated atypical antipsychotics.

PMH8

US GOVERNMENT INITIATIVES FOR SUPPORTING COMPARATIVE EFFECTIVENESS RESEARCH, AN EXAMPLE FROM PROJECT LIBRA

Marder WD[1], Chang S[2], Pepitone T[3], Hatzmann M[2], Mark T[2], Goodrich K[4]
[1]*Thomson Reuters (Healthcare), Cambridge, MA, USA,* [2]*Thomson Reuters, Washington, DC, USA,* [3]*Thomson Reuters, Santa Barbara, CA, USA,* [4]*Assistant Secretary for Planning and Evaluation, Washington, DC, USA*

OBJECTIVES: Reducing hospital readmission rates has emerged as an important strategy for increasing the quality of health care, while reducing the cost of care. An analysis was conducted using an US government-funded tool to investigate the impact of post-hospitalization follow-up on readmissions for depression. **METHODS:** Public (Medicare) and proprietary (MarketScan Commercial, Medicare Supplemental and Medicaid) administrative databases were standardized and linked via a common data model. A web-based tool was developed that captured the logic typically required by CER methods, e.g. searches on drugs, diagnoses, and procedures, application of time constraints, and development of variables for intervention, outcomes and covariates. Patients with a hospitalization for depression and was discharged to home were selected. Additional inclusion criteria were a minimum of one year of enrollment prior to and 60 days of enrollment following discharge. Patient claims histories were searched to determine outpatient visits with 7 and 30 days post-discharge and rehospitalization within 30 days post-discharge. SAS procedures embedded in the tool were utilized for bivariate and multivariate analyses. **RESULTS:** The study included 39,985 patients. Patients with a follow-up visit were slightly older and were more likely to be female. Prior to index hospitalization, patients with follow-up were more likely to have filled an antidepressant or antianxiety medication and had a diagnosis of depression or anxiety pre-index hospitalization. Little difference was found in the rate of pre-period hospitalization. A logistic regression model found that having a follow-up visit within 7 days of discharge was negatively and statistically significantly associated with having a readmission within 30 days (odds ratio = 0.88, CI=0.80 – 0.97, once other factors (demographics, diagnosis, and drug treatment) were controlled. **CONCLUSIONS:** The data model and tool may be leveraged in a similar manner to compare drug and medical treatment options more rapidly and efficiently.

PMH9

PRESCRIBING PATTERNS AND COST OF DRUGS FOR ALZHEIMER'S DISEASE

Truter I
Nelson Mandela Metropolitan University (NMMU), Port Elizabeth, Eastern Cape, South Africa

OBJECTIVES: Few studies of mental illness in Africa have centered on Alzheimer's disease. The primary aim of the study was to determine the prescribing patterns and cost of drugs for Alzheimer's disease in a South African private health care sector patient population. **METHODS:** A retrospective drug utilization study was conducted. Data were obtained from a South African private medical aid administrator for 2010. The database consisted of 2,126,264 records for medication and procedures. **RESULTS:** A total of only 25 patients (13 females and 12 males) received 114 medicine items for Alzheimer's disease at a cost of R70 794.11 (average cost per item R621.00 (SD=R208.73)). This medicine is relatively expensive, yet not all medical aid schemes pay for medication for Alzheimer's disease. The average age of patients was 72.52 (SD=10.03) years, with ages ranging from 46 to 88 years. Memantine was the most frequently prescribed active ingredient (42.98% of prescribing frequency and 46.35% of cost), followed by donepezil (40.35% of frequency and 41.59% of cost). The average cost per memantine prescription was R669.61, followed by R640.12 for donepezil and R449.35 for galantamine. The different medical aids only paid, on average, 78.86% of the total amount claimed by patients for these medicines. Most products were claimed between February and June 2010. Average Prescribed Daily Doses (PDDs) of active ingredients were generally lower than their respective Defined Daily Doses (DDDs). The average PDD for memantine was 18.27 mg (DDD=20 mg), for donepezil was 7.07 mg (DDD=7.5 mg) and for galantamine was only 6.95 mg (DDD=16 mg). Most prescriptions for memantine (75.51%) were prescribed in its PDD of 20 mg. **CONCLUSIONS:** The results were generally similar to those of previous South African studies. Studies on larger patient populations are necessary to investigate the cost-effectiveness of the different treatment options.

PMH10

EXPOSURE TO ANTIPSYCHOTIC MEDICATIONS DURING FOUR YEAR PERIODS FOLLOWING TREATMENT INITIATION AMONG CHILDREN UNDER SIX YEARS OLD

Constantine RJ, Jentz S, McPherson M
University of South Florida, Tampa, FL, USA

OBJECTIVES: In short term clinical trials antipsychotic medications are well tolerated by children under six years old. While concerns have been raised about the impact of long term exposure on metabolic and cardiovascular health and on the developing brain, little is known about the extent of long term antipsychotic exposure in this age group. This study quantifies antipsychotic exposure over a 4 year period of children who began antipsychotic treatment before their sixth birthday and identifies the variables associated with the risk of long term exposure. **METHODS:** Children were identified who initiated an index episode of antipsychotic treatment before their sixth birthday in Florida's fee for service Medicaid program. Using claims data the medication utilization of these children was tracked during the year before and the four years following the start of their index episodes (pre-index and four post-index periods). Generalized estimating equations were used to identify variables associated with the risk of additional days of antipsychotic exposure. **RESULTS:** Five hundred twenty-eight children were included in the cohort. The mean total days of exposure was 821.9 (±431.9) representing 56.3 % of all days during the four post-index periods. The mean days of exposure to combinations of antipsychotics and other classes of psychotherapeutic medications were 623.8 ±447.6 days. Children with primary diagnoses of pervasive developmental disorders and affective disorders were at greater risk of additional days of exposure than children with ADHD. Exposure tended to be greater among children with indicators of clinical complexity including the presence of secondary diagnoses and the use of other classes of psychotherapeutic medications in addition to antipsychotics. **CONCLUSIONS:** Exposure to antipsychotic mediations was extensive. Although these children may have had complex and severe problems, additional research is urgently needed on the benefits and risks of long term antipsychotic exposure among very young children.

PMH11

PSYCHOTROPIC-RELATED HIP FRACTURES AROUND THE WORLD: A META-ANALYSIS

Young J[1], Pepper GA[2], Oderda L[1], Asche CV[3]
[1]*University of Utah College of Pharmacy, Salt Lake City, UT, USA,* [2]*University of Utah College of Nursing, Salt Lake City, UT, USA,* [3]*Center for Health Outcomes Research, University of Illinois College of Medicine, Peoria, IL, USA*

OBJECTIVES: Up to one-third of older adults fall each year with medications representing a well-known risk factor for falling. Ultimately, falls that result in injury are the true target of fall prevention and are of interest to healthcare practitioners. Therefore, this meta-analysis focused on evaluating the association of antipsychotic and antidepressant drugs with hip fracture, a common and debilitating fall-related injury. **METHODS:** A search of Pubmed/Medline was conducted from 1966-2010 with key words including "antipsychotic agents", "psychotropic drugs", "antidepressive agents", "aged", and "hip fracture". Inclusion criteria included mean age ≥ 65 years and statistical adjustment or stratification by age and gender. Excluded were studies where hip fractures were not distinguished from other fracture types or authors failed to answer queries for required information. A random effects model was used to calculate summary odds ratios for the specific classes of psychotropic medications. **RESULTS:** Of 166 studies identified, 10 antipsychotic-related studies and 14 antidepressant-related studies met the inclusion criteria. Combined, these studies represent over 70,000 hip fracture cases and approximately 272,000 total subjects from eight different nations and four continents. Summary odds ratios include (95% confidence interval): conventional antipsychotics 1.68 (1.43, 1.99), atypical antipsychotics 1.30 (1.14, 1.49), tricyclic anti-depressants 1.71 (1.43, 2.04), and selective serotonin re-uptake inhibitors 1.94 (1.37, 2.76). Although some studies reported drug-specific risk measures, the availability of drug-specific data was limited. **CONCLUSIONS:** All classes considered in this analysis are associated with an increased risk of hip fracture in older adults. There is a trend towards reduced risk associated with atypical antipsychotics compared to conventional antipsychotics, although this does not reach statistical significance. To minimize the risk of hip fracture in older adults requiring psychotropic medications, further research examining the association of hip fractures to specific drugs within these classes is essential.

PMH12

RISK OF RELAPSE AND HOSPITALIZATION IN THE 2-YEAR OPEN-LABEL TREATMENT OF OUTPATIENTS WITH SCHIZOPHRENIA RANDOMIZED TO OLANZAPINE LONG-ACTING INJECTION OR ORAL OLANZAPINE

Novick D[1], Ascher-Svanum H[2], Bertsch J[3], Detke H[2], Mcdonnell D[4], Witte M[2], Haro J[3]
[1]*Eli Lilly and Co, Windlesham, Surrey, UK,* [2]*Eli Lilly and Company, Indianapolis, IN, USA,* [3]*Parc Sanitari Sant Joan de Deu, CIBERSAM, Sant Boi de Llobregat, Spain,* [4]*Eli Lilly and Company, Cork, UK*

OBJECTIVES: This post-hoc analysis assessed the risk and the factors associated with relapse and hospitalizations during the 2-year treatment of outpatients treated with oral olanzapine or olanzapine long-acting injection (LAI). **METHODS:** We used data of a 104-week multicenter, effectiveness study comparing oral and LAI olanzapine in the treatment of outpatients with schizophrenia (n=524; NCT00320489). Relapse was defined as hospitalization for schizophrenia; a 25% increase from baseline on the PANSS total score (if baseline score >40), a 10 point increase (if baseline score ≤40); a ≥1-point increase from baseline on the CGI-S scale, provided that final CGI-S score was ≥4; deliberate self-injury or injury to others that is associated with worsening of psychosis; or discontinuation from the

study because of worsening of psychosis. Functional activity was measured using the resource utilization inventory. Non-adherent patients are those with non-adherence as reason for discontinuation of the antipsychotic medication used at baseline, per physician rating. **RESULTS:** Over the 2-year study, 30% of patients have relapsed and 8% were hospitalized, without significant differences between the two medication formulations. Patients non-adherent before baseline were more likely to be hospitalized (14%) compared to adherent patients (7% hospitalized, $p<0.05$). Relapse in non-adherent patients was 36% compared to 29% in adherent patients. A logistic regression model on baseline factors associated with relapse found that a greater extent of functional activity was associated with a lower risk of relapse. The risk of subsequent hospitalization was significantly associated only with previous hospitalization. **CONCLUSIONS:** In this 2-year open label study, the rate of relapse and hospitalization was similarly low among patients treated with oral olanzapine or olanzapine-LAI. While prior non-adherence with oral antipsychotics and previous hospitalization were associated with hospitalization, only the latter predicted subsequent hospitalization in the logistic model. Lower risk of relapse was associated with a greater level of productivity.

PMH13

DIFFERENCES BETWEEN PATIENTS UNDERGOING AUGMENTATION OR SWITCHING OF ANTIPSYCHOTIC MEDICATIONS DURING TREATMENT OF SCHIZOPHRENIA

Ascher-Svanum H[1], Brnabic AJ[2], Lawson T[1], Kinon BJ[1], Stauffer VL[1], Feldman PD[1], Kelin K[2]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*Eli Lilly Australia Pty Ltd, Sydney, NSW, Australia*

OBJECTIVES: Treatment optimization for patients with schizophrenia remains a challenge, and it is often difficult to determine whether augmenting the current medication or switching to another will better benefit a patient. This post hoc analysis compares outcome measures between patients whose antipsychotic medication was either augmented or switched. **METHODS:** Adult outpatients receiving oral antipsychotic treatment for schizophrenia were assessed during a 12-month, multi-country, observational study (F1D-AY-B033). Clinical and functional outcomes were assessed at the time of first treatment switch/augmentation (0–14 days preceding change) and compared between patients undergoing medication augmentation or switching. Due to low numbers of patients with such data, interpretation of findings is based on effect size (ES). **RESULTS:** Data at the time of medication change were available for 87 patients (34 augmented, 53 switched). The primary reason for treatment change in both groups was inadequate response, but lack of adherence was more prevalent in the switched group (26.4% versus 8.8%). Although changes in clinical severity from study initiation to medication change were similar (per the Clinical Global Impressions—Severity scale), patients' physical well being, as measured by physical component scores of the 12-item Short Form Health Survey (SF-12), improved in the augmented group but worsened in the switched group (augmented: $+7.71\pm11.98$, switched: -1.87 ± 10.98, ES=0.85). Similarly, mental health state improved in the augmented group but declined in the switched group, as indicated by SF-12 mental health component scores (augmented: $+2.41\pm13.64$, switched: -1.08 ± 9.98, ES=0.314). **CONCLUSIONS:** Patient's worsening or lack of meaningful improvement may prompt clinicians to switch antipsychotic medications, whereas, when a patient shows improvement, clinicians appear more likely to try to bolster the improvement through augmentation with another antipsychotic medication. Current findings are consistent with physicians' stated reasons for augmenting versus switching antipsychotics in the treatment of schizophrenia. Confirmation of these findings requires further research.

PMH14

SPEED OF DETECTION OF ADVERSE EVENTS IN SPONTANEOUS ADVERSE EVENT DATABASES COMPARED WITH EPIDEMIOLOGICAL STUDIES: TWO RELATED CASES

Qizilbash N[1], Méndez I[2], Sánchez-de la Rosa R[3]
[1]*Oxon Epidemiology Limited, London, London, UK,* [2]*Oxon Epidemiology Limited, Madrid, Madrid, Spain,* [3]*TEVA Pharma SLU, Madrid, Spain*

OBJECTIVES: The risk of bradycardia and its consequences from use of cholinesterase inhibitors (ChI) in dementia was reported in epidemiological studies in 2009 and from a case series for memantine in 2008. We compared the detection and timing of these associations between disproportionality analysis and published epidemiological studies. **METHODS:** We conducted 1) a systematic review of the literature to identify epidemiological studies reporting AEs in patients taking currently prescribed ChI and memantine, and 2) an analysis in the FDA spontaneous Adverse Event Reporting System database (AERS) using the Empirical Bayesian Geometric Mean (EBGM) statistic and 90% credibility intervals (90%CI), to allow for low frequencies of drug-event pairs. A composite event consisted of any of the following: bradycardia, bradyarrythmia, pacemaker insertion, complete atrio-ventricular block and hip and femoral fracture. AEs from all drugs in AERS was the comparator. **RESULTS:** A total of 246 cases suspected of being associated with ChI and the composite event were identified. A statistically strong signal of disproportionate reporting, adjusted for age, sex and year was observed (EBGM of 6.58, 90%CI: 5.79 – 7.47). Cumulative yearly analyses revealed that the signal became statistically strong in 1997, one year after approval of the first currently used ChI. The first signal was reported in an epidemiological study in 2009. For memantine, 69 suspected cases were identified with the composite event. A statistically strong signal of disproportionate reporting, adjusted for age, sex and year, was observed (EBGM of 1.87; 90%CI: 1.47 – 2-38). Cumulative yearly analyses revealed that the signal became statistically strong and stable two years after the first reported composite event. No epidemiological studies have yet been published. **CONCLUSIONS:** Analysis of suspected events can be followed over time and may detect, confirm or refute drug-event signals much earlier than epidemiological studies and inform health technology assessments.

PMH15

MORTALITY IN RELATION TO DISEASE SEVERITY IN SUBJECTS WITH DEMENTIA

Jonsson L[1], Fratiglioni L[2], Wimo A[2]
[1]*i3 Innovus, Stockholm, Sweden,* [2]*Karolinska Institutet, Stockholm, Sweden*

OBJECTIVES: The impact on mortality is a major driver in determining the cost-effectiveness of diagnostics and treatment of dementia disorders. We examined the relationship between the degree of dementia severity and mortality in a longitudinal, population-based study in Sweden. **METHODS:** From a total sample of 1810 subjects aged 75 years or older, 211 were identified as having a clinical diagnosis of dementia at baseline and were included in the study. Disease severity was assessed with the Mini-Mental State Examination (MMSE) as well as the Clinical Dementia Rating (CDR), administered at baseline and again at two follow-up visits after approximately 40 and 80 months respectively. Mortality data was obtained from the national death statistics, 10 years post baseline. Survival analysis was conducted using Weibull regression with baseline as well as time-varying covariates. Age and gender were also included as covariates in addition to dementia severity. **RESULTS:** A total of 198 deaths were observed during the observation period, and the time to death was 935 days on median. Annual mortality rates in females were estimated to 12% for mild dementia (MMSE 21-26), 15% for moderate dementia (MMSE 10-20) and 19% for severe dementia (MMSE 0-9) at baseline. The corresponding estimates for males were 19%, 24% and 31% respectively. Each point lower result on the MMSE scale was associated with a decrease in survival by 2.5%. There was no statistically significant relationship between baseline CDR scores and mortality, though a trend was seen towards increasing mortality in more severe CDR states. Similar results were observed in an analysis incorporating changes in disease severity over time. **CONCLUSIONS:** Mortality in subjects with dementia increase with the severity of dementia, as measured by the MMSE. Incorporating differential survival by disease severity has important implications for the long-term cost-effectiveness of diagnosis and therapies for dementia disorders.

Mental Health – Cost Studies

PMH16

BUDGETARY IMPACT ANALYSIS OF BUPRENORPHINE/NALOXONE (SUBOXONE®) IN OPIOID MAINTENANCE TREATMENT IN SPAIN

Martinez-Raga J[1], Casado MA[2], González Saiz F[3], Oñate J[4]
[1]*Agencia Valenciana de Salut & Universidad CEU Cardenal Herrera, Valencia, Valencia, Spain,* [2]*Pharmacoeconomics & Outcomes Research Iberia (PORIB), Pozuelo de Alarcón, Madrid, Spain,* [3]*UGC Salud Mental Hospital de Jerez, Jerez, Cádiz, Spain,* [4]*Drogodependencias y Salud Mental, Murcia, Murcia, Spain*

OBJECTIVES: Prior to the approval of buprenorphine/naloxone (B/N) (Suboxone®) we evaluated its economic impact in the treatment of heroin dependence. Three years since its approval we aimed to reassess the economic impact of B/N considering the availability of data on its actual use in clinical practice and the changing costs of medicines in the current economic crisis. A pharmacoeconomic modeling was applied to evaluate the economic impact of B/N as a maintenance therapy for opioid dependent individuals in the Spanish National Health Care System (NHS) during a three-year period. **METHODS:** We used an interactive budgetary impact analysis model that was developed to calculate the annual costs (drugs and associated costs) to the Spanish NHS of methadone versus B/N depending on the number of patients receiving either medication. Data for the model were obtained from scientific databases and expert panel opinion. **RESULTS:** It was estimated that 81.706 patients would be in agonist opioid maintenance treatment program each of the three-years of the study. More importantly, the introduction of B/N combination has not resulted in an increase in the number of patients receiving treatment for their opioid dependence. The budgetary impact (drugs and associated costs) for opioid maintenance treatment in the first year of the study is expected to be 90,92 million €. In the first year of the pharmacoeconomic modeling the budgetary impact of B/N would rise to 4.85 million € (4.9% of the total impact) to the NHS, with an incremental cost of 0.86 million € (1.0% of the total impact). The mean cost per patient in the first year with and without B/N has been calculated at € 1102 and 1113, respectively. **CONCLUSIONS:** With an additional cost of only € 11 per patient, B/N is an efficient addition to the available pharmacotherapies for opioid dependent patients, particularly when considering the favorable clinical aspects of this novel medication.

PMH17

THE ECONOMIC AND SOCIAL CONSEQUENCES OF SCHIZOPHRENIA TREATMENT WITH SEROQUEL XR® (QUETIAPINE PROLONGED RELEASE TABLETS) IN POLAND: ANALYSIS OF THE IMPACT ON THE HEALTH CARE SYSTEM

Faluta T[1], Rdzanek M[1], Pierzgalska K[2], Wróbel B[1]
[1]*AstraZeneca, Warsaw, Poland,* [2]*Institute of Psychiatry and Neurology, Warsaw, Poland*

OBJECTIVES: To estimate the economic consequences of replacing the normal tablets of quetiapine with Seroquel XR® in the treatment of schizophrenia in Poland. **METHODS:** Based on the established model of the economic consequences of schizophrenia treatment, we calculated the cost of treating schizophrenia with quetiapine in Poland. Expenditures for the purchase of medicines, hospital costs and the costs of lost productivity were highlighted. The analysis was performed from a societal perspective, taking into account the Payer's perspective, in one-year time horizon. **RESULTS:** The use of Seroquel XR® will increase the population of patients who comply with the recommended treatment, which will reduce the

likelihood of suicide, absenteeism, and the hospitalisation rate. The reimbursement of Seroquel XR® could generate annual budget savings of PLN 8.6 million (2150 thousands Euro), if Seroquel XR® were used in 31% of quetiapine-treated patients with schizophrenia. The maximum savings resulting from the reimbursement of quetiapine prolonged release tablets (Seroquel XR®) could amount to PLN 27.6 million (6900 thousands Euro) per year. **CONCLUSIONS:** The reimbursement of Seroquel XR® with the reimbursement limit at the level of the reimbursement limit for normal tablets of quetiapine is profitable for the state budget – it will not only bring budgetary savings, but also allow patients to return to active life, which is crucial in the case of schizophrenia.

PMH18

THE ECONOMIC AND SOCIAL CONSEQUENCES OF SEROQUEL XR® (QUETIAPINE PROLONGED RELEASE TABLETS) REIMBURSEMENT IN BIPOLAR DISORDER TREATMENT FOR PATIENTS CURRENTLY TREATED WITH SEROQUEL (QUETIAPINE IMMEDIATE RELEASE TABLETS) IN POLAND: ANALYSIS OF THE IMPACT ON THE HEALTH CARE SYSTEM

Faluta T[1], Rdzanek M[1], Pierzgalska K[2]
[1]*AstraZeneca, Warsaw, Poland,* [2]*Institute of Psychiatry and Neurology, Warsaw, Poland*

OBJECTIVES: To estimate the economic consequences of replacing Seroquel (the normal tablets of quetiapine) with Seroquel XR® in the treatment of bipolar disorder in Poland. **METHODS:** Based on the established model of the economic consequences of bipolar disorder treatment, we calculated the cost of treating bipolar disorder with quetiapine in Poland. Expenditures for the purchase of medicines, hospital costs and the costs of lost productivity were highlighted. The analysis was performed from a societal perspective, taking into account the Payer's perspective, in three–year time horizon. **RESULTS:** The use of Seroquel XR® will decrease hospitalisation rate and length of hospitalisation, what will reduce direct costs of bipolar disorder treatment by PLN 645 thousands (161 thousands Åuro). The use of Seroquel XR® will increase the population of patients who comply with the recommended treatment, which will reduce the likelihood of suicide, absenteeism, and the disability pension. The budget savings related to indirect costs reduction are estimated at PLN 15,3 million (3825 thousands Euro). Moreover, the reimursement of Seroquel XR® would decrease the social transfers by PLN 157,6 thousands (39,4 thousands Euro) in comparison to current scenario. **CONCLUSIONS:** The reimbursement of Seroquel XR® with the reimbursement limit at the level of the reimbursement limit for normal tablets of quetiapine is profitable for the state budget – it will not only bring budgetary savings, but also allow patients to return to active life, which is crucial in the case of bipolar disorder.

PMH19

COST OF RELAPSE IN SCHIZOPHRENIA IN EUROPE: THE CONSTATRE STUDY

Hemels M[1], Diels J[2], González B[3], Jensen R[4]
[1]*Janssen EMEA, Birkerod, Denmark,* [2]*Janssen Pharmaceutica, Beerse, Belgium,* [3]*Janssen, Madrid, Spain,* [4]*Janssen EMEA, Birkerød, Denmark*

OBJECTIVES: Schizophrenia is a debilitating chronic psychiatric illness with a considerable impact on the patient and the patient's environment, in terms of morbidity, mortality, human suffering and societal costs. Currently, little is known of the exact cost of relapse in schizophrenia. Our objective is to estimate cost of relapse based on resource utilization data collected alongside a clinical trial. **METHODS:** "Constatre" is a multicenter, open-label, randomized, active-control, long-term study comparing risperidone long acting injectable treatment with oral quetiapine, conducted from October 2004 to November 2007 at 124 sites in 25 countries (ClinicalTrials.gov identifier: NCT00216476). Information regarding Medical Resource Utilization (MRU) during the three months following relapse was collected for a subset of patients. To estimate the associated relapse related costs, average purchase power parity adjusted country resource unit costs (2010 Euro) were applied. **RESULTS:** Detailed MRU data were available for 63 patients spread across Europe. The overall mean MRU cost per patient in the three months following the relapse was €7592, of which 79% was related to psychiatric hospitalisation. 68% of the relapsed patients were hospitalized, for on average 38.8 days, representing a total cost of €9117 (range €277 - €20,868) per hospitalised patient. 5% of the patients were in day-clinic, on average for 41.3 days, representing a cost of €5829 per patient. The majority (60%) of the relapsed patients had outpatient visits, representing a mean cost per patient of €1834, mainly to psychiatrists (57% of patients, average = 14.5 visits) and nurses (10% of patients, average = 105.9 visits). **CONCLUSIONS:** Costs related to relapse of schizophrenic patients are considerable, and mainly driven by psychiatric hospitalisation. Antipsychotic treatment that prevents or reduces relapse and psychiatric hospitalisation can have a major impact on the total schizophrenia related treatment cost.

PMH20

HEALTH CARE COST COMPARISONS BETWEEN ALCOHOL OR OPIOID-DEPENDENT PATIENTS WHO WERE TREATED WITH MEDICATION AND THOSE WHO WERE NOT

Baser O[1], Wang L[2], Xie L[3]
[1]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA,* [2]*STATinMED Research, Dallas, TX, USA,* [3]*STATinMED Research, Ann Arbor, MI, USA*

OBJECTIVES: To compare the differences in health care costs between alcohol or opioid-dependent patients who were treated with pharmacological ('Any Medication') and non-pharmacological substances ('No Medication'). **METHODS:** A retrospective analysis was conducted using a large U.S. health plan claims database from 2005 to 2009. Continuously eligible patients with at least one claim of alcohol/opioid dependence during the identification period, and an alcohol/opioid use disorder diagnosis during the baseline period were included. Propensity score matching (PSM) was applied to compare the risk-adjusted outcomes between the 'Any Medication' and 'No Medication' cohorts. Baseline differences in age, gender, region, comorbidity scores, socioeconomic status, baseline health care utilization and costs were controlled. **RESULTS:** During the pre-index period, for both alcohol and opioid dependent patients, those in the 'Any Medication' cohort had more distinct psychiatric diagnoses, and were more likely to have Elixhauser Index Scores of higher than 3, when compared to patients from the 'No Medication' cohort. After adjusting baseline patient and clinical characteristics, 10,376 alcohol-dependent patients were matched from each cohort. Patients who were treated without pharmacological medication had more rehabilitation time, a higher detoxification cost burden ($1,350,000 per 1000 patients), and higher total health care costs, compared to patients who were treated with pharmacological medication. Similarly, there were 6,658 patients from each cohort matched for opioid-dependent patients. Patients in the 'No Medication' cohort incurred higher total health care costs than patients in the 'Any Mediation' cohort ($14,353,000 vs. $ 10,192,000 per 1000 patients) during the post-index period. **CONCLUSIONS:** After controlling for confounders such as demographic factors, comorbid conditions and baseline health care utilization, we showed that pharmacological medication treatments were associated with lower health care costs than non-pharmacological substance treatment for both alcohol and opioid-dependent patients.

PMH21

ECONOMIC COST OF ALCOHOL AND DRUG ABUSE IN WASHINGTON STATE, USA

Wickizer TM
The Ohio State University, Columbus, OH, USA

OBJECTIVES: Substance abuse (SA) represents a significant public health problem that impacts tens of millions of persons in the US and imposes over $400 billion in annual economic costs on a national basis in the form of lost productivity, premature death, criminal activity and use of medical care. The objective of this study was to estimate the economic costs associated with drug and alcohol abuse for Washington State in 2005. **METHODS:** We used standard cost of illness (COI) methods, relying on the prevalence approach, to estimate the costs of SA in six areas, including mortality, morbidity, treatment costs, crime, and health care. We obtained data for the analysis from various sources, including the Washington State Health Department, the National Survey on Drug Use and Health, the State Department of Corrections, and the Washington Association of County Sheriffs, and the Washington State Department of Transportation. **RESULTS:** We estimated costs of SA for 2005 for Washington State at $5.21 billion, $832 per non-institutionalized person in the state. Alcohol abuse accounted for 56% of total costs. The per-capita, inflation-adjusted costs increased by 47% from 1996. Categories accounting for the greatest costs were mortality ($2.03 billion), crime ($1.09 billion), morbidity ($1.03 billion) and health care ($791 million). There were 3,224 deaths (7% of all deaths), 89,000 years of productive life lost, and 29,000 hospital discharges in 2005 in Washington associated with SA. **CONCLUSIONS:** SA imposes significant costs on society. Its economic costs far outweigh the resources expanded to treat persons with SA. For every $1 dollar the state collected in tax revenue for treatment from alcohol sales in 2005, $20 in economic loss was incurred from alcohol abuse. Renewed attention needs to be directed at finding more effective ways to reduce the economic and human loss arising from SA.

PMH22

ECONOMIC BURDEN OF ATTENTION DEFICIT HYPERACTIVITY DISORDER IN CHILDREN AND ADOLESCENTS IN EUROPE

Taneja A, Ahuja A, Kataria A, Kaushik P, Kumar P
Heron Health Private Ltd, Chandigarh, Chandigarh, India

OBJECTIVES: This comprehensive review was conducted to report existing evidence from published studies evaluating the economic burden of attention deficit hyperactivity disorder (ADHD) in children and adolescents in Europe. **METHODS:** A systematic search of electronic literature databases (EMBASE and MEDLINE), was conducted from January 2001 to June 2011 to identify economic studies on ADHD in children and adolescents in Europe. All economic studies in English language, regardless of design and intervention were included. Eligibility of trials was assessed by two reviewers with any discrepancy reconciled by a third, independent reviewer. **RESULTS:** A total of 591 citations were retrieved out of which eight met pre-defined inclusion criteria. Five studies were cost-analyses while three were cost-effectiveness analyses. In Germany, the total direct costs for ADHD were €158 million in 2002 which increased to €287 million in 2006 with inpatient treatment costs comprising approximately 40% of the total direct costs in 2006 (Wehmeier 2009). Other contributors to total direct costs included hospitalisations, special health-care services, comorbidities, and physician visits (Ridder 2006). The total projected costs of ADHD in Germany during 2012 are estimated to be €311 million (Schlander 2007). The mean annual direct medical costs of ADHD patients with psychiatric comorbidities were €5908 compared to €974 for ADHD alone in the The Netherlands (Roijen 2007). The cost-effectiveness studies retrieved primarily focused on atomoxetine (ATX) and methylphenidate (MPH). ATX was found to be more cost-effective than MPH in the UK (ICER of £15 224 per QALY gained) (Cottrell 2008) as well as in Spain (ICER of €34 308 per QALY gained) (Hong 2009). **CONCLUSIONS:** ADHD is associated with substantial fiscal burden in Europe. Since 2002, a trend of increase in direct costs has been observed which may be due to increasing demand for healthcare services, and presence of comorbidities.

PMH23

THE ECONOMIC BURDEN OF MENTAL ILL HEALTH IN THE WORKPLACE: A COSTING APPROACH FOR BRAZILIAN EMPLOYERS

Reis TC, Takemoto MMS, Takemoto MLS, Fernandes RA, Tolentino ACM, Cukier FN, Santos PML, Cruz RB, Ribeiro ACP, Fernandes RRA, Moretti AIP

ANOVA - Knowledge Translation, Rio de Janeiro, Brazil

OBJECTIVES: There has been a growing concern about the economic burden of work incapacity due to mental health problems; meanwhile studies examining the employer's perspective are still scarce. This study aims to propose a rationale to estimate the burden of mental health problems in Brazilian corporations. **METHODS:** Data from an observational study investigating absenteeism due to sick leaves in a Brazilian bank were used to build a costing estimation model (total number of employees, average number of sick days per employee, and proportion of sick days due to mental ill health). These data were combined with average wage and turnover rate national statistics and published data on presenteeism due to mental health problems. **RESULTS:** Based on n=7499 workers, 3.36 annual sick days per employee, a proportion of sick days attributable to mental health disorders of 15.58%, and a mean daily wage of 51.33BRL, the costing model projected annual costs due to absenteeism of 201,534BRL. If presenteeism is included in the costing estimation, using a previously published presenteeism/absenteeism ratio of 4.0 (for depressed workers), costs due to presenteeism would represent 806,138BRL per year. There is a lack of Brazilian observational studies assessing turnover rates and associated costs. National rates according to economic sector were employed to estimate the impact of turnover of mental ill workers (Service Industry=4.15% in 2010) and a turnover cost of 3 times the average monthly cost per employee were used as a proxy. Turnover costs would incur in additional 115,500BRL per year. The annual economic burden of mental health disorders under the employers perspective was estimated in 1,123,173BRL. **CONCLUSIONS:** The cost of mental ill health to employers, particularly the cost of productivity losses due to lower performance of employees at work (presenteeism), can represent a significant burden for companies and society.

PMH24

ECONOMIC BURDEN OF MENTAL ILLNESSES IN PAKISTAN

Malik AM[1], Khan MM[1], Khan ZM[2]
[1]*Aga Khan University, Karachi, Sindh, Pakistan,* [2]*Aga Khan University, Karachi, Sindh, PR*

OBJECTIVES: Mental illnesses in Pakistan are at rise. Decade long terrorism, suicide bombing, recent floods, political uncertainty and transition to market economy are some of the key factors that are contributing to increasing mental illnesses in the country. This study emphasizes the importance of economic consequences of mental illness in Pakistan and provides estimates of cost on mental illness in the country. **METHODS:** Aga Khan University Hospital patient records of psychiatry clinics inpatient (N=727) and outpatient (N=1458) data for the year 2005-06 were classified into ten ICD-10 classification. For each category of mental illness the direct cost included consultation fee, diagnostics, bed charges, laboratory charges medication and procedure. The indirect costs on travel and productivity losses are being estimated drawing a stratified random sample for both inpatient and day care dataset. **RESULTS:** Mental illnesses categories 2(Schizophrenia (N=227) and 3(mood/depressive disorder (N=415) accounted for 82% of burden of mental illnesses in inpatient care. While in day care 2(Schizophrenia 3(mood/depressive disorder and 4(Panic/OCD) accounted for 75 % of the burden of mental illnesses in Pakistan. Mean cost for all categories in inpatient care is Pak Rs. 21701 per treatment episode. Illnesses category 8 (anorexia) was the most costly (Mean=Rs.71687) and category 1(dementia and other organic disorders were relatively less expensive to treat (Mean=Pak Rs.1183). **CONCLUSIONS:** Initial findings suggest the economic burden of mental illnesses is alarmingly high and its treatment is unaffordable by many families in the country. This might result in denied or delayed care. Using country level available data on burden of mental illness the economic impact of mental illnesses in Pakistan will be estimated. We will also explain socio-economic determinates of mental illnesses.

PMH25

COST OF DELIVERING PSYCHIATRIC INPATIENT CARE TO MENTAL HEALTH PATIENTS WITH PSYCHOSIS AND CO-OCCURING SUBSTANCE USE: A UK-BASED STUDY

Shabaruddin FH[1], Davies LM[2]
[1]*University of Malaya, Kuala Lumpur, Malaysia,* [2]*University of Manchester, Manchester, UK*

OBJECTIVES: There is little data describing current practice in the clinical management of patients with psychosis and co-occurring substance use and the associated costs. In the UK, standard psychiatric care is based on the care programme approach and includes community and hospital-based treatment. Inpatient psychiatric treatment is the key cost driver of psychiatric care. This study aimed to describe practice-based patient-level costs of inpatient psychiatric treatment for NHS patients with psychosis and co-occurring substance use. **METHODS:** Resource use data of inpatient psychiatric treatment were collected from the medical records of 327 patients recruited in the MIDAS trial, a randomised controlled trial of an experimental intervention programme (integrated motivational interviewing and cognitive-behaviour therapy, MiCBT) plus standard care or standard care alone. Using the hospital perspective, data were collected from trial entry until end of 2-year trial follow-up (between 2004 to 2009). Unit costs were assigned, based on NHS Reference Costs 2008/09 and PSSRU 2009. Data were analysed using descriptive statistics and variations around the costs were obtained. **RESULTS:** Of the 327 patients, 95 patients (29%) experienced at least one episode of hospitalisation, with a mean of 85 inpatient days (95% CI: 65 – 105, median 42, range 2 - 568) per hospitalised patient. Total cost for these 95 patients was £2.43million (UK £2008/09) over 8,108 inpatient days. Mean cost per hospitalised patient was £25,547 (95% CI: £18,453 – £32,640, median £12,180, range £580 – £273,208). Cost components comprised: acute psychiatric admission (total 6,428 days, £1.86million), psychiatric rehabilitation admission (total 621 days, £165,186), psychiatric long-stay admission (total 434 days, £91,574), psychiatric ICU admission (total 57 days, £32,832) and psychiatric forensic medium secure unit admission (568 days, £273,208). **CONCLUSIONS:** This study provided practice-based data describing patient-level costs associated with standard NHS care of inpatient psychiatric treatment for patients with psychosis and co-occurring substance use.

PMH26

DIRECT COST OF SCHIZOPHRENIA IN QUEBEC, CANADA: AN INCIDENCE-BASED MICROSIMULATION MONTE-CARLO MARKOV MODEL

Dragomir A[1], Tarride JE[2], Angers JF[3], Joober R[4], Rouleau G[3], Perreault S[5]
[1]*University of Montreal, Montreal, QC, Canada,* [2]*McMaster University, Hamilton, ON, Canada,* [3]*Université de Montréal, Montreal, QC, Canada,* [4]*Institut Douglas, Montreal, QC, Canada,* [5]*Université de Montréal, Montréal, QC, Canada*

OBJECTIVES: Pharmacological strategies for schizophrenia have received increasing attention due to the development of new and costly drug therapies. To estimate the direct healthcare and non-healthcare cost of schizophrenia and to simulate cost reductions potentially obtained with a new pharmacogenomics treatment, in a cohort of patients newly diagnosed with schizophrenia, over the first 5 years following their diagnosis. **METHODS:** A microsimulation Monte-Carlo Markov model was used. Six discrete disorder states defined the Markov model: 1): first episode (FE); 2) low dependency state (LDS); 3) high dependency state (HDS); 4) Stable state (Stable); 5) Well state (Well); and 6) Death state (Death). Costs and individual probabilities of transition were estimated from the Régie de l'assurance maladie du Québec and Med-Echo databases. **RESULTS:** A total of 14,320 individuals were identified in the study cohort as newly diagnosed patients with schizophrenia. Over the first 5 years following diagnosis the mean cost per person was estimated at $36,701 (95%CI: 36,264 to 37,138). The direct health care cost accounted for 56.2% of the total cost, welfare assistance for 34.6% and long term care facilities for 9.2%. On the direct health care cost, hospitalisation cost accounted for 64.6%, medical cost for 11.4% and drug-related cost for 24%. In the case where a new pharmacogenomic treatment with 20% increase of effectiveness will be available, the direct healthcare and non-health care costs can be reduced up to 14.2%. **CONCLUSIONS:** This model is the first Canadian model incorporating transition probabilities adjusted for individual risk-factor profiles and costs using real-life data. Our results indicate that a new pharmacogenomics treatment could possibly reduce hospitalization and long-term care facility costs while potentially enabling patients to return to active employment that would in turn contribute to the reduction of the welfare assistance cost.

PMH27

AN ECONOMIC ANALYSIS OF THE IMPACT OF CRIME AND HOSPITALISATION ASSOCIATED WITH DIFFERENT INTERVENTIONS FOR OPIOID ABUSE IN THE UNITED KINGDOM

Taylor M[1], Lewis L[1], Mckeganey N[2]
[1]*University of York, York, UK,* [2]*University of Glasgow, Glasgow, UK*

OBJECTIVES: People addicted to opioids contribute a significant burden to society, both in terms of quality of life (QoL) and economic consequences. Untreated users are more likely to be out of work, commit crimes and require healthcare resources. Treating patients has been demonstrated to reduce these factors. However, some users receiving formal care continue to misuse that treatment, leading to other significant consequences for society. This study evaluated the potential impact of a novel formulation (buprenorphine/naloxone; suboxone), aimed at mitigating misuse and diversion. Increasing the currently limited number of treatments available will likely increase the number of people in treatment. The objective was to assess cost-effectiveness of two approaches to managing opioid users, buprenorphine/naloxone and methadone, and, further, to compare the use of any treatment against no treatment. **METHODS:** A cost-effectiveness model was built, incorporating the costs and benefits associated with each treatment. Healthcare unit cost data were taken from published data and databases, including NHS Reference Costs 2009-2010 and PSSRU Unit Costs of Health and Social Care 2010. Crime costs were taken from Home Office publications. Crime and hospitalisation rates, by treatment, were taken from an observational study of 109 patients in Scotland. Health related QoL figures, by treatment, were taken from an SF-36 questionnaire study. **RESULTS:** Over 6 months, it was estimated that savings associated with reduced crime (buprenorphine/naloxone versus methadone) were £2129, and savings from reduced health care visits were £1409. Based on a combination of mortality and QoL improvements, patients on buprenorphine/naloxone were shown to gain 0.087 QALYs compared to those receiving methadone. **CONCLUSIONS:** The model showed that the cost implications of crime, hospitalisation and misuse and diversion were key drivers of the results. Use of buprenorphine/naloxone resulted in a saving of £3538 due to reduced crime and hospitalisations, whilst providing a benefit to QoL.

PMH29

COST EFFECTIVENESS OF EXTENDED RELEASE QUETIAPINE FUMARATE (QUETIAPINE XR) MONOTHERAPY IN TURKEY IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER (MDD) WHO HAVE FAILED PREVIOUS ANTIDEPRESSANT THERAPY

Aydemir O[1], Dilbaz N[2], Malhan S[3]
[1]*Adnan Menderes University, Manisa, Turkey,* [2]*Ankara Numune Research & Training Hospital, Ankara, Turkey,* [3]*Baskent University, Ankara, Turkey*

OBJECTIVES: The objective of this exploratory analysis was to assess the cost-effectiveness of quetiapineXR as monotherapy compared to other key drug treatments in MDD patients, who have failed on previous therapy. **METHODS:** A Markov Model with one week cycles was used to assess the cost effectiveness of quetiapineXR treatment over 52 weeks. Key outcomes were: response rates, costs and Incremental Cost-Effectiveness Ratios (ICERs) for second line monotherapy. The

obtained clinical trials data for all drugs represented first line therapy for MDD. For this reason, response rates were down-adjusted to reflect their use as a second-line therapy, with each response rate being multiplied by a factor obtained from the STAR*D- trial. Since response rates were reported at a constant rate in clinical trials, they were converted into "weekly probabilities" of response. Patients entering second-line monotherapy were not differentiated by switch or add-on. QuetiapineXR(150mg) was compared with venlafaxineXR(150mg), escitalopram(10mg) and bupropionXL(300mg), which are considered to be the most relevant monotherapy comparators in Turkey. One-way sensitivity analyses were conducted on key model parameters to evaluate the robustness of the model. **RESULTS:** The response rates at any time over 52 weeks were 22.5% for quetiapineXR, venlafaxineXR 17.8%, escitalopram 12.6% and bupropionXL 10.7%. In terms of incremental cost per additional second-line responder, quetiapineXR was found to be dominant (more effective and less costly) versus venlafaxineXR (-353.55€) and quetiapineXR was cost-effective (more effective and more costly) versus escitalopram (1785.43€) and bupropionXL (652.90€). The cost per responder of quetiapineXR(48.85€) was less than venlafaxineXR(62.68€), escitalopram(73.20€) and bupropionXL(95.52€). **CONCLUSIONS:** This exploratory analysis demonstrated that in patients with MDD who have failed on previous antidepressant therapy, quetiapineXR 150mg as monotherapy was found to be cost-effective compared to escitalopram and bupropionXL, in terms of cost per responder, and was dominant when compared to venlafaxineXR, demonstrating higher efficacy at lower costs.

PMH31

COST-EFFECTIVENESS OF LONG-ACTING OLANZAPINE VERSUS LONG-ACTING RISPERIDONE IN PATIENTS WITH SCHIZOPHRENIA IN SPAIN

Dilla T[1], O'Donohoe P[2], Möller J[2], Álvarez M[3], Sacristán J[3], San L[4], Happich M[5], Tockhorn A[6]
[1]*Eli Lilly, Spain, Alcobendas, Madrid, Spain,* [2]*United BioSource Corporation, London, London, UK,* [3]*Eli Lilly, Spain, Alcobendas, Madrid, Spain,* [4]*Hospital Sant Joan de Déu, Barcelona, Barcelona, Spain,* [5]*Eli Lilly, HTA ACE-J Group, Germany, Bad Homburg, Hessen, Germany,* [6]*Eli Lilly, HTA ACE-J Group, UK, Windlesham, Surrey, UK*

OBJECTIVES: In schizophrenia, medication adherence is critical to achieve better patient outcomes and to avoid relapses, which are responsible for a significant proportion of total healthcare costs for this chronic illness. The aim of this study was to assess the cost-effectiveness of olanzapine long-acting injection (OLAI) compared with risperidone long-acting injection (RLAI) in patients with schizophrenia in Spain. **METHODS:** A discrete event simulation (DES) model was developed from a Spanish healthcare system perspective to estimate clinical and economic outcomes for patients with schizophrenia over a five year period. Patients who had earlier responded to oral medication and have a history of relapse due to adherence problems were considered. These patients faced the option to be treated with either OLAI or RLAI. In the absence of a head-to-head clinical trial, discontinuation and relapse rates were obtained from an indirect comparison of open-label studies. The model accounted for age, gender, risks of relapse and discontinuation, relapse management, hospitalization, treatment switching and adverse events. Direct medical costs (year 2011) and outcomes including relapse avoided, life years (LYs), and quality-adjusted life years (QALYs) were discounted at a rate of 3%. **RESULTS:** When comparing RLAI and OLAI, the model predicts that OLAI would decrease 5-year costs by €2940, and results in a QALY and LY gain of 0.07 and 0.04, respectively. Patients on OLAI had fewer relapses compared to RLAI (1.39 vs. 1.82) and fewer discontinuations (1.22 vs. 1.71). Sensitivity analysis indicated that the study was robust and conclusions were largely unaffected by changes in a wide range of parameters. **CONCLUSIONS:** The present evaluation results in OLAI being dominant over RLAI, meaning that OLAI represents a more effective and less costly alternative compared to RLAI in the treatment of patients with schizophrenia in the Spanish setting.

PMH32

COST-EFFECTIVENESS OF AGOMELATINE IN THE TREATMENT OF MAJOR DEPRESSIVE EPISODES IN THAILAND

Prukkanone B[1], Kongsuk T[2]
[1]*Galaya Rajanagarindra Institute, Bangkok, Thailand,* [2]*Prasrimahabhodi Hospital, Ubonratchathani, Thailand*

OBJECTIVES: To determine the cost-effectiveness of agomelatine for major depression in adults. **METHODS:** A hypothetical cohort was simulated from a discrete event simulation (DES) model developed to describe the course of disease in individuals. Model inputs included Thai data on disease parameters and costs while impact measures are derived from systematic reviews and meta-analyses of the international literature. The costs for treatment of adverse events of these drugs, insomnia and sexual dysfunction, were taken into account in the model. Antidepressant drugs were analyzed for treatment of episodes (12-24 weeks) plus a continuation phase (6-9 months) and for maintenance treatment over 2 years of follow up. Results are presented as Thai Baht cost (THB) per quality adjusted life year (QALY) gained, compared to a matrix comparators (50 % venlafaxine and 50% escitalopram). **RESULTS:** Preliminary results show that daily costs for average dose of agomelatine (25 mg), escitalopram (10 mg) and venlafaxine (150 mg) are 52, 60, 98 THB, respectively. Total cost of agomelatine is 52,000 THB and total cost of matrix comparator is 76,000 THB. Health benefit measures of agomelatine and the matrix comparator are almost the same at 2,500 QALY gained. Agomelatine is considered a cost-effective intervention with an ICER of 400,000 (95% uncertainty range: 410,000- 390,000) THB per QALY gained. The ICER is less than three times Gross Domestic Product (GDP) per capita in Thailand of 420,000 THB. **CONCLUSIONS:** Agomelatine is the most cost-effective treatment option for episodic continuation and maintenance treatment of major depression when compared with venlaflaxine and escitalopram. As recommended by the World Health Organization (WHO) for cost-effectiveness health intervention, agomelatine is an affordable option for treatment of major depressive episodes in Thailand.

PMH33

THE COST-EFFECTIVENESS OF PALIPERIDONE ER IN SPAIN

Treur M[1], Baca E[2], Bobes J[3], Cañas F[4], Salvador L[5], González B[6]
[1]*Pharmerit, Rotterdam, The Netherlands,* [2]*Universidad Autónoma de Madrid, Madrid, Spain,* [3]*Universidad de Oviedo - CIBERSAM, Oviedo, Spain,* [4]*Hospital Dr. Rodríguez Lafora, Madrid, Spain,* [5]*UNIVIDD, Fundación Villablanca, Reus, Spain,* [6]*Janssen, Madrid, Spain*

OBJECTIVES: Paliperidone ER Extended Release OROS (ER) is a relatively new atypical antipsychotic for the treatment of schizophrenia. The objective is, based on a previously published model, to analyze the clinical and economic effects of Paliperidone ER in Spain compared to olanzapine oral and aripiprazole. **METHODS:** An existing discrete event simulation model was adapted to reflect the treatment of schizophrenia in Spain in terms of costs, resource use and treatment patterns. Inputs for the model were derived from clinical trial data, literature search, database analysis, and interviews with local clinical experts. The time horizon is five years and Spanish discount rates were applied. Outputs included direct medical costs and Quality Adjusted Life-Years (QALYs). Sensitivity analyses were conducted to assess the uncertainty surrounding incremental outcomes and to identify model drivers, by performing probabilistic sensitivity analysis (PSA) and ordinary least squares analysis (OLSA). **RESULTS:** The mean (95% CI) incremental QALYs compared to olanzapine is 0.033 [-0.14, 0.30] and compared to aripiprazole 0.029 [-0.11,0.30]. The corresponding mean incremental costs (95% CI) are -€ 1,425 [-€ 10,247, €3,084] and -€ 759 [-€ 10,479, € 3,404] respectively. Based on the PSA, the probability that paliperidone ER is cost-saving and improves QALYs compared to olanzapine and aripiprazole is 76% and 72% respectively. Paliperidone ER was estimated to have 80% and 81% probability of being cost effective compared to olanzapine at a willingness to pay of €20,000 and €30,000 and 73% and 74% compared to aripiprazole respectively. OLSA identified drug acquisition costs, side effects and risk of relapse to be major model drivers. **CONCLUSIONS:** Based on differences in drug acquisition costs, side effects and risk of relapse, the model predicts that in Spain paliperidone ER provides QALY gains and cost savings compared with oral olanzapine and aripiprazole with a probability of 76% and 72% respectively.

PMH34

COST-UTILITY OF AMISULPRIDE COMPARED WITH FIRST GENERATION ANTIPSYCHOTICS IN TREATMENT OF SCHIZOPHRENIA IN POLAND

Kostrzewska K[1], Lis J[2], Glasek M[2], Rys P[1], Wladysiuk M[1], Plisko R[1]
[1]*HTA Consulting, Krakow, Poland,* [2]*Sanofi Poland, Warszawa, Poland*

OBJECTIVES: To evaluate cost-utility of amisulpride compared with first generation antipsychotics (FGA) in treatment of schizophrenia in adult patients in Poland. **METHODS:** A decision-tree model was used to estimate utilities and costs of treatment of amisulpride therapy in comparison to FGA (antipsychotics, management of main antipsychotics' adverse events - extrapyramidal symptoms' (EPS) and health care costs). The FGA group included the following drugs: haloperidol, perazine and flupenthixol. Analysis was performed from the National Health Fund (NHF) perspective with a time horizon of 1 year. The range of possible events in the model included: therapy discontinuation (regardless of reason), EPS occurrence, schizophrenia relapse and suicide. Range of events was assumed to be the same for amisulpride and FGA but probabilities of those events varied between antipsychotics. Based on systematic review of RCTs amisulpride is more effective than FGA in terms of compliance rate and in reduction of both the risk of relapse and occurrence of EPS. A probabilistic sensitivity analysis was performed to estimate the probability that amisulpride is cost effective in Polish conditions (threshold about 100,000 PLN/QALY). **RESULTS:** From the NHF perspective amisulpride compared with FGA was more effective (ΔQALY = 0.004) and it was cheaper (comparing to flupenthixol) or cost-effective (ICUR=1 079/QALY PLN and ICUR=31 810/QALY PLN in comparison to haloperidol and perazine, respectively). The calculated probability that amisulpride is more effective than any of FGA was 100%, while the probability that it is also cost-effective varied between 68% for perazine to 83% for flupenthixol. **CONCLUSIONS:** Treatment of schizophrenia with amisulpride is a cost-effective option in comparison to FGA in Poland. The obtained difference in QALY is very small, but reduced risk of relapse and necessity of hospitalization due to better effectiveness of amisulpride and reduced occurrence of EPS results in a better cost benefit outcome for amisulpride compared to FGA.

PMH35

A COST-EFFECTIVENESS ANALYSIS OF PALIPERIDONE PALMITATE VERSUS OLANZAPINE PAMOATE IN THE TREATMENT OF SCHIZOPHRENIA IN NORWAY

Einarson TR[1], Vicente C[2], Zilbershtein R[3], Piwko C[4]
[1]*University of Toronto, Toronto, ON, Canada,* [2]*Pivina Consulting Inc., Mississauga, ON, Canada,* [3]*PIVINA Consulting Inc., Thornhill, ON, Canada,* [4]*Pivina Consulting Inc., Thornhill, ON, Canada*

OBJECTIVES: Paliperidone palmitate long-acting injection (PP-LAI) has recently been approved in Europe for treatment of schizophrenia as an alternative to olanzapine pamoate (OLZ-LAI). Their relative cost-effectiveness has not yet been adequately assessed. The purpose was to compare costs and outcomes of these two LAIs in treating schizophrenia in Norway. **METHODS:** A previously validated and published decision analytic model estimating costs and outcomes of treatment schizophrenia over a 1-year time horizon was adapted to simulate clinical practice patterns in Norway. Drugs of interest were PP-LAI and OLZ-LAI. Clinical inputs were derived from the literature and experts, and costs from standard lists. Clinical outcomes included days in remission, hospitalizations, hospitalized days, and quality-adjusted life-years (QALYs). Costs were derived from the public health care provider perspective and reported in 2010 Norwegian kroner (NOK; €1=7.8 kroner, USD$1=5.4 kroner). The pharmacoeconomic outcome was the incremental cost

per QALY gained. Multiple sensitivity analyses were undertaken to test the robustness of the model including both one-way sensitivity analyses and multivariate probabilistic sensitivity analyses using Monte Carlo simulations. **RESULTS:** PP-LAI treated patients were in remission 249 days and accumulated a total of 0.633 QALYs at a cost of 89,360 NOK. OLZ-LAI treated patients were in remission 243 days and accumulated a total of 0.621 QALYs at a cost of 100,888 NOK. The result was that PP-LAI was the dominant treatment strategy (more effective and less costly). Results were robust over a wide range of sensitivity analyses tested. The main drivers of the model included compliance rates and the price of each pharmacotherapy, with PP-LAI being less costly than OLZ-LAI. **CONCLUSIONS:** PP-LAI was cost-effective compared with OLZ-LAI in the treatment of schizophrenia in Norway.

PMH36

COST-EFFECTIVENESS OF DEPOT FLUPENTIXOL VERSUS LONG-ACTING RISPERIDONE – A MARKOV MODEL PARAMETERIZED USING ADMINISTRATIVE DATA

Frey S[1], Stargardt T[1], Linder R[2], Juckel G[3]
[1]*University of Hamburg, Hamburg, Germany,* [2]*Scientific Institute of TK for Benefit and Efficiency in Health Care, Hamburg, Germany,* [3]*LWL-Universitätsklinik Bochum, Bochum, Germany*

OBJECTIVES: To use administrative data in a Markov simulation that compares the cost-effectiveness of depot flupentixol and long-acting risperidone in the treatment of schizophrenia. **METHODS:** We employed a Markov model to simulate treatment for schizophrenic patients during 24 cycles with a cycle length of 30 days. The model comprised three non-absorbing states, i.e. inpatient treatment, outpatient treatment with the patient either being compliant or not, and three absorbing states, i.e. switching from index medication, death and dropout. Compliance was defined using a refill persistence measure. Treatment costs from the payer's perspective, i.e. cost of outpatient, inpatient and pharmaceutical care, and hospitalization were used as outcomes. Transition probabilities between Markov states and outcomes for each state were estimated from an administrative dataset comprising 935 patients who were hospitalized with schizophrenia (ICD-10:F20) between 2005 and 2008 and who subsequently received depot flupentixol or risperidone. It was adjusted for age, sex, prior hospitalization, prior sick leave, early retirement, and comorbid conditions according to the Elixhauser score using multinomial logistic and gamma regression models, respectively. **RESULTS:** Cohort simulation based on 1000 patients on average aged 40.8 years, 55.0% male with 38.0 days of prior annual hospitalization, showed that 102 (266) patients treated with flupentixol (risperidone) remained in a non-absorbing state after 24 cycles. Thus switching to other antipsychotics occurred more often with flupentixol. Average cost of treatment with flupentixol (risperidone) was 544.52 € (1,109.67 €) per patient and cycle. While patients treated with flupentixol were hospitalized more often compared to risperidone (5.2% vs. 4.8% per cycle), length of hospitalization was lower with flupentixol as compared to risperidone (16.11 vs. 16.53 days). **CONCLUSIONS:** The effectiveness of depot flupentixol in preventing relapse appears to be similar to long-acting risperidone. While treatment costs were lower with flupentixol, switching rates seem to be higher.

PMH37

COST-MINIMISATION ANALYSIS OF ASENAPINE MONOTHERAPY VERSUS OTHER ANTIPSYCHOTICS IN BIPOLAR I DISORDER IN TWO NORDIC COUNTRIES

Despiégel N[1], Davie AM[2], Corson H[3], Beillat M[3], Sapin C[3]
[1]*OptumInsight, Nanterre, France,* [2]*OptumInsight, Uxbridge, Middlesex, UK,* [3]*Lundbeck SAS, Issy les Moulineaux cedex, France*

OBJECTIVES: To evaluate the treatment management cost, over 12 weeks, of asenapine relative to quetiapine, olanzapine, and aripiprazole which are currently used in Finland and Sweden to treat moderate to severe manic in bipolar I disorder. **METHODS:** A cost-minimisation analysis was conducted from a Finnish and Swedish societal perspective. Costs were the only consideration due to similar clinical efficacy of asenapine demonstrated in active controlled non-inferiority clinical trial vs olanzapine and through indirect comparisons with quetiapine and aripiprazole. Due to significant differences in adverse events and healthcare system costs, we included management of weight gain, akathesia and insomnia. Patients were assumed to start treatment as an inpatient for the first month of therapy, and then followed for two months in an outpatient setting. All direct and indirect resource use and unit cost estimates were derived from the latest available sources and literature. No evidence exists suggesting any differences with respect to healthcare management (e.g. hospitalisation) between treatment strategies. Thus, estimated resource use and costs applied were assumed the same across treatment strategies. Deterministic sensitivity analyses were conducted to explore uncertainty around input parameters. **RESULTS:** The estimated direct cost of treatment and of the management of adverse events related to treating adults with bipolar I disorder suffering a manic or mixed episode for 12 weeks with asenapine monotherapy for Finland and Sweden were respectively: €421 and €670 (SEK 6,044) compared to €502 and €1139 (SEK 10,257; aripiprazole), €141 and €827 (SEK 7,453; quetiapine), and €344 and €957 (SEK 8,616; olanzapine). **CONCLUSIONS:** Asenapine has been shown to be cost saving relative to aripiprazole in Finland and to quetiapine, olanzapine, and aripiprazole in Sweden at the short-term endpoint of 12 weeks. The estimated treatment cost represented less than 6% of the overall burden of bipolar disorder from societal perspective.

PMH38

BUPRENORPHINE/NALOXONE VERSUS BUPRENORPHINE AND METHADONE IN HEROIN ADDICTION DETOXIFICATION: AN ITALIAN COST-UTILITY ANALYSIS

Marino V[1], Lazzaro C[2]
[1]*ASL Varese, Varese, Italy,* [2]*Studio di Economia Sanitaria, Milan, Italy*

OBJECTIVES: prevalence of heroin addiction among Italian population aged 15-64 is 0.8%. Three different drugs are currently available for treating heroin addiction: methadone, buprenorphine and buprenorphine/naloxone. A monocenter, retrospective, one-year follow-up cost-utility analysis (CUA) was performed to compare buprenorphine/naloxone (211 patients) vs buprenorphine (214 patients) and methadone (512 patients) for heroin addiction detoxification at Department of Addictions, Local Health Authority of Varese, Italy. **METHODS:** CUA adopted the Department of Addictions viewpoint. Clinical, economic and utility data were obtained from the database of the Department of Addictions and literature. Drugs, bottles for methadone take-home doses, health care and social services were identified, quantified and valued in Euro (€) 2009. One-way and probabilistic sensitivity analyses (SAs) were performed. **RESULTS:** 87.8% of patients are male. Mean (±standard deviation) patients' age is 37.9±7.2 years, whereas patients' first contact with heroin dates back to 16.7±8.5 years. Neither heterogeneity nor sample selection bias have been detected among treatment groups. Buprenorphine and methadone are the most and the least costly options (€3257.24 and €2219.47 per patient, respectively). Buprenorphine/naloxone costs €2541.05 per patient. During one-year follow-up patients accrue 0.573 (methadone), 0.599 (buprenorphine) and 0.602 (buprenorphine/naloxone) Quality-Adjusted Life Years (QALYs). Buprenorphine is strongly dominated by buprenorphine/naloxone and hence ruled out from the base case CUA. The incremental cost-utility ratio for buprenorphine/naloxone vs methadone is €11,195.12. SAs confirm the robustness of the base case findings. Cost-Effectiveness Acceptability Curve shows that the probability for buprenorphine/naloxone to be cost-effective equals 0.58, 0.61 and 0.62 against €25,000, €40,000 and €50,000 threshold-values, respectively. Cost-Effectiveness Acceptability Frontier highlights that buprenorphine/naloxone is the optimal alternative from a threshold-value of €11,391.14. **CONCLUSIONS:** Buprenorphine/naloxone seems advisable even from an economic point of view, since its incremental cost-utility ratio falls well within the usual acceptability standards for incremental QALY saved (€25,000-40,000; €50,000).

PMH39

COST EFFECTIVENESS OF A COLLABORATIEVE CARE STEPPED INTERVENTION FOR ANXIETY DISORDERS IN THE PRIMAIRY CARE SETTING

Goorden M[1], Muntingh A[2], Balkom AJ[3], Van marwijk HW[4], Spinhoven P[5], De waal MW[6], Assendelft PJ[6], van der Feltz-Cornelis CM[7], Hakkaart - van Roijen L[8]
[1]*institute for Medical Technology Assessment, Rotterdam, Zuid Holland, The Netherlands,* [2]*Trimbos Institute, Utrecht, Utrecht, The Netherlands,* [3]*VU University medical centre (VUmc), Amsterdam, Noord Holland, The Netherlands,* [4]*Institute for Health and Care Research of VU University medical centre (VUmc), Amsterdam, Noord Holland, The Netherlands,* [5]*Leiden University, Leiden, Zuid Holland, The Netherlands,* [6]*Leiden University Medical Center, Leiden, The Netherlands,* [7]*University of Tilburg, Tiburg, The Netherlands,* [8]*Erasmus Universiteit Rotterdam, Rotterdam, Zuid Holland, The Netherlands*

OBJECTIVES: To evaluate the cost-effectiveness of a collaborative stepped care intervention (CSC) for panic disorder and generalised anxiety disorder in primary care compared to care as usual (CAU). **METHODS:** A two armed cluster randomised controlled trial, 43 primary care practices participated in the study. Patients selected by their general practitioner and patients selected from files screening positive on an anxiety screener, had a MINI International Neuropsychiatric Interview to classify DSM-IV disorders. Eventually, 180 patients with a diagnosis of panic disorder or generalised anxiety disorder were included in the study (114 collaborative stepped care, 66 care as usual). Baseline measurements and follow up measures (3, 6, 9 and 12 months) were assessed using questionnaires. We applied the TiC-P and the EQ-5D respectively assessing the health care utilization, production losses and general health related quality of life. The incremental analysis indicated costs per QALY. **RESULTS:** The average annual direct medical costs in the collaborative stepped care group were 1987 Euro (sd 2027), compared to 1645 Euro (sd 1844) in the care as usual group. The average quality of life years (QALY's) gained was higher in the collaborative stepped care group compared to the care as usual group, 0.08 QALY. The incremental cost utility was about 4100 euro per QALY. Including both the direct medical costs and productivity costs the collaborative stepped care group dominated CAU. **CONCLUSIONS:** The study showed that CSC is a cost effective intervention for anxiety disorder in the primary care setting and even dominant including productivity costs.

PMH40

ECONOMIC EVALUATION OF AGOMELATINE FOR MAJOR DEPRESSIVE DISORDER IN AUSTRALIA

O'Leary BA[1], Hamann GB[2], Adena MA[3]
[1]*Covance Pty Ltd, North Ryde, NSW, Australia,* [2]*Servier Laboratories (Aust) Pty Ltd, Hawthorn, VIC, Australia,* [3]*Datalytics Pty Ltd, Bruce, ACT, Australia*

OBJECTIVES: Despite the availability of numerous antidepressants, persistence with treatment is poor and adverse events are a key factor. Agomelatine is a new chemical entity for the treatment of major depressive disorders (MDD) with a placebo-like side effect profile resulting in a statistically significantly higher proportion of patients continuing treatment compared with venlafaxine. The objective of this study was to conduct a cost-utility analysis of agomelatine compared with venlafaxine from an Australian healthcare perspective to inform reimbursement decision making by the Pharmaceutical Benefits Advisory Committee (PBAC). **METHODS:** An Excel-based Markov model was developed with four states 'depressed', 'remission', 'well' and 'death' with a three year time-horizon. Agomelatine and venlafaxine were assumed to be equally effective in the treatment of depressive symptoms but to differ in discontinuation rates, requirement for down titration and costs. Patients enter the model in the 'depressed' state and can progress to 'remission' where they may relapse and re-enter 'depressed' or move to the 'well' state (after spending six months in 'remission'). Patients in the 'depressed' or

'remission' states may discontinue treatment. The relative risk of discontinuation on venlafaxine (2.37 at Week 6) compared with agomelatine is applied to the discontinuation rate of venlafaxine in the Australian population. When a patient is off treatment, they have a reduced likelihood of moving to the 'remission' and 'well' states compared with patients remaining on treatment. Costs are in 2010 dollars and costs and outcomes discounted at 5%. **RESULTS:** Compared with venlafaxine, treatment with agomelatine yields 0.011 additional quality-adjusted life-years (QALY) at an incremental cost of AU$196 giving an incremental cost-effectiveness ratio (ICER) of AU$18,098/QALY. The presentation will discuss the issues raised by the PBAC and how these were addressed. **CONCLUSIONS:** When the impact of a lower discontinuation rate is modelled, agomelatine is a cost-effective treatment for MDD versus venlafaxine.

PMH42

COST-UTILITY ANALYSIS OF PALIPERIDONE PALMITATE LONG ACTING INJECTION(PLAI) VERSUS ORAL ATYPICAL ANTIPSYCHOTICS IN NON-ADHERENT SCHIZOPHRENIA PATIENTS

Kim BRM[1], Lee TJ[2], Woo JM[3], Park JI[4], Kwon JS[5]
[1]Seoul National University, Seoul, Seoul, South Korea, [2]Seoul National University, Seoul, South Korea, [3]Seoul Paik Hospital, Seoul, Seoul, South Korea, [4]Kangwon university hospital, Chuncheon, Kangwon-do, South Korea, [5]Seoul National University hospital, Seoul, Seoul, South Korea

OBJECTIVES: Schizophrenia patients who suffer from frequent relapses have their cognition damaged and need heavy medical resource utilization such as long-term hospitalization. Schizophrenia incurs a burden not only to patients and caregivers, but also to society. This study aims to carry out cost-utility analysis of 'paliperidone palmitate long acting injection (PLAI)' that improves drug adherent compared with atypical oral antipsychotics (risperidone, olanzapine, aripiprazole and paliperidone) from a payer's perspective. **METHODS:** The study subjects are non-adherent schizophrenia patients with exacerbation of symptoms. A decision-tree model was constructed to compare the clinical and economic outcomes of PLAI and oral comparator over 1 year. Clinical data such as relapse rate, EPS rate, suicide rate and non-adherent rate as well as utility weight were obtained from published literature. Direct medical cost data were also obtained from a domestic literature. Sensitivity analyses were performed on PLAI drug cost and major variables. **RESULTS:** : Based on model estimates, PLAI showed some advantages of reducing hospitalization and increasing utility over its comparators. Total direct medical costs were KRW 5.62million for PLAI, and KRW 4.71million for comparators. Incremental cost-effectiveness ratio of PLAI versus oral atypical antipsychotics was KRW 2.22million per quality-adjusted life year (QALY). Sensitivity analyses showed that hospitalization cost per day and frequency of hospitalization per year had greatest influence on the result. **CONCLUSIONS:** The use of PLAI may result in improved health effect and QALY compared with atypical antipsychotics. Despite its higher cost, PLAI can be considered as one of the options for non-adherent patients in schizophrenia, as it reduces hospitalization and increases quality of life.

Mental Health – Patient-Reported Outcomes & Preference-Based Studies

PMH43

ASSOCIATION BETWEEN ANTIDEPRESSANT-RELATED WEIGHT GAIN AND MEDICATION ADHERENCE IN EMPLOYED INDIVIDUALS BY GENDER

Schneider G[1], Roy A[2], Dabbous OH[3]
[1]United BioSource Corporation, Lexington, MA, USA, [2]Takeda Pharmaceuticals International, Inc, Deerfield, IL, USA, [3]Takeda Pharmaceuticals International, Inc., Deerfield, IL, USA

OBJECTIVES: To better understand antidepressant-related weight gain and its association with medication adherence in employees experiencing depression. **METHODS:** Employed individuals (≥18 years of age) with diagnosed depression (excluding bipolar disorder) completed a web-based computer-generated 25-minute survey (population identified by Harris InteractiveTM). Antidepressant adherence was quantified via 8-item Morisky Medication Adherence Scale (MMAS-8) where scores of 0, 1-2, and 3-8 were categorized as high, medium, and low adherence, respectively. Weight gain was measured using the Toronto Side Effects Scale which measures medication-related side effects in the 2-weeks preceding the survey, and analyzed as a 4-level ordinal variable (none, <=2lbs, <=4lbs, and <=7lbs), where "none" was the referent category. Gender stratified cumulative logit models were used to estimate effect of weight gain on medication adherence. Binary logit models were used to estimate effect of weight gain on each of the 8 MMAS-8 questions. **RESULTS:** Of 1521 survey respondents, 872 (57%) reported current antidepressant use (60.6% female, mean age 49.9 ± 13.5 years). A higher proportion of female patients (39%) belonged to the "low adherence" category compared to male patients (31%) (p=0.02). Compared to males with no weight gain, odds of being in a poorer overall adherence category were greater in the <=7lbs weight gain category (odds ratio [OR]=2.33; p= 0.09); likewise, odds of reporting not taking medication for "reasons other than forgetting" were greater for <=4lbs (OR=2.35; p=0.05) and <=7lbs (OR=2.92; p=0.04). Among female patients, odds of reporting "reductions or stoppage of medication use" increased with increasing weight gain of <=2lbs (OR=1.72; p=0.05), <=4lbs (OR=2.00; p=0.06), and <=7lbs (OR=2.50; p=.07). **CONCLUSIONS:** These data suggest that antidepressant-related weight gain may result in diminished adherence to prescribed medication. Additional research should focus on further quantification of this association as medication non-adherence may be closely associated with depressive relapse.

PMH44

IMPROVING HEALTH-RELATED QUALITY OF LIFE FOR PATIENTS WITH REFRACTORY POST-TRAUMATIC STRESS DISORDER: USE OF LOCAL ANESTHETICS SHOW PROMISE IN A CLINICAL CASE SERIES

Lipov EG[1], Navaie M[2], Stedje-Larsen ET[3], Burkhardt K[1], Smith JC[2], Hickey AH[3]
[1]Advanced Pain Centers, S.C., Hoffman Estates, IL, USA, [2]Advance Health Solutions, La Jolla, CA, USA, [3]Naval Medical Center San Diego, San Diego, CA, USA

OBJECTIVES: Existing evidence-based treatments for the anxiety condition Post-Traumatic Stress Disorder (PTSD) have an overall success rate of only 20% to 30% with pharmacologic therapies. Thus, an urgent need exists for alternative PTSD treatment options. This investigation examined the impact of local anesthetics delivered via stellate ganglion block (SGB) injection on mitigating PTSD severity, thereby improving health-related quality of life (HRQoL). **METHODS:** A retrospective case series (n=8) who received one (n=6) or more (n=2) SGB treatments consisting of 0.5% bupivacaine was identified at one private practice setting. A wide range of demographic and clinical data was extracted from medical records. PTSD severity and dimensions of HRQoL were examined using standardized valid instruments. T-tests were used to compare mean changes in PTSD severity scores, with p<0.05 denoting significance. **RESULTS:** The majority of cases were male (88%) and veterans (63%). The average age was 43.4 years (range, 29 to 66 years). Mean follow-up time after SGB treatment was 17.5 days (range, 1 to 59 days). Among cases who received one SGB injection, significant improvements in overall PTSD severity were observed (p=0.02) including symptoms related to the psychological dimensions of avoidance (p=0.03), and hyperarousal (p=0.01). On average, these patients experienced a 41% decrease in PTSD severity (range, 6% to 70%). Relative to cases who received one SGB injection, the two cases with multiple SGB injections reported greater levels of PTSD symptom relief (58.6% and 73.4%), with substantial improvements in all three PTSD-related psychological clusters, namely re-experiencing, avoidance, and hyperarousal symptoms. All patients reported substantial improvements in HRQoL and none experienced adverse events. **CONCLUSIONS:** Local anesthetics delivered via SGB show promise as an alternative treatment for refractory PTSD. Double-blind randomized placebo-controlled trials are needed to generate further confirmatory evidence for sound clinical decision-making and health advocacy to expand SGB's indication for PTSD.

PMH45

COMPARISON OF THE SF-6D AND THE EQ-5D IN PATIENTS WITH SCHIZOPHRENIA

Millier A[1], Perthame E[2], Aballea S[3], Toumi M[4]
[1]Creativ Ceutical, Paris, France, [2]Creativ-Ceutical, Paris, France, [3]Creativ Ceutical, Paris, Ile de France, France, [4]University of Lyon, Lyon, France

OBJECTIVES: The SF-6D and the EQ-5D are two ways to generate utility values. Many studies compared these methods, but there is limited information in schizophrenia. The objective of this study is to compare the SF-36 and EQ-5D utility values and to compare their evolution over time in European schizophrenic patients. **METHODS:** We used data from EuroSC, a multicenter 2-year cohort study conducted in France, England and Germany. In several subpopulations, we used paired-samples t-test to identify significant differences at baseline, and calculated the Pearson correlation. Changes from baseline were also calculated at 6 and 24 months. **RESULTS:** The overall sample was composed of 1088 patients. Mean utility scores were significantly different at baseline (EQ-5D: 0.73 (0.28); SF-6D: 0.65 (0.09); p<0.0001), and values modestly correlated (r = 0.314, p<0.001). The SF-6D scores distribution was found to be normal, contrary to EQ-5D, highly negatively skewed. Range of values was much larger for EQ-5D (EQ-5D: [-0.35; 1.00]; SF-6D: [0.32; 0.87]). The difference was also significant at baseline when considering subpopulations, with higher values for EQ-5D. When considering patients whose illness was stable or had improved at 6 months, change from baseline was significantly different from 0 for EQ-5D (mean 0.067 (0.29) p<0.0001), but not for SF-6D (0.007 (0.11) p=0.28). The result was not significant for patients whose illness worsened (EQ-5D: -0.040 (0.29) p=0.19; SF-6D: -0.007 (0.12) p=0.56). The same trends were observed after 24 months, using depression scores to evaluate improvement or worsening, and when adjusted on the baseline value. **CONCLUSIONS:** In our study, EQ-5D tends to generate wider and higher scores in schizophrenic patients. EQ-5D seems to be more sensitive to change than SF-6D. The method by which QALYs have been computed is of importance in an economic evaluation.

PMH46

THE QUALITY OF LIFE OF CHILDREN WITH ADHD AND THEIR PARENTS: RESULTS OF EQ-5D AND KIDSCREEN-10

Van Der Kolk A[1], Bouwmans C[2], Schawo S[2], Buitelaar JB[3], van der Gaag RJ[4], Van agthoven M[1], Hakkaart-van Roijen L[2]
[1]Janssen-Cilag B.V., Tilburg, The Netherlands, [2]Erasmus University, Rotterdam, The Netherlands, [3]Donders Institute for Brain, Cognition and Behaviour, Nijmegen, The Netherlands, [4]Karakter Universitair Centrum, Nijmegen, The Netherlands

OBJECTIVES: The aim of this study is to describe the Quality of Life (QoL) of children with Attention Deficit Hyperactivity Disorder (ADHD) and their parents. The objective was to compare QoL in different states of compliance to medication (methylphenidate and atomoxetine), in remission status after medication use or being naïve to medication using EQ-5D (proxy version for the children) and KIDSCREEN-10 (KS) questionnaires. **METHODS:** A cross-sectional, retrospective, survey was performed using online questionnaires (September 1, 2010 to October 3, 2010) that was completed by the parent/caregiver. Inclusion criterion was being a parent/caregiver of a child (age 6-18 years) diagnosed with ADHD. Parents/caregivers were contacted via the Dutch patient organization. Subgroups of medication use were defined by parents as 'optimal', 'suboptimal', 'remission' and 'medication use stopped' according to current medication intake. The fifth group were children who never used ADHD-medication. Qol data of the child and the parent were compared in these different groups of medication intake, using Students' t-tests for continuous variables and Kruskal-Wallis tests for categorical data. **RESULTS:** Analyses were performed on 873 returned questionnaires. The QoL in the classified

groups are described here for children (proxy EQ-5D and KS) and parents (EQ-5D). Optimal compliance: proxy EQ-5D 0.8257, KS 47.5152, EQ-5D 0.8331. Suboptimal compliance: proxy EQ-5D 0.7321, KS 42.7671, EQ-5D 0.8050. Medication use stopped: proxy EQ-5D 0.7635, KS 42.5969, EQ-5D 0.8169. Remission after medication use: proxy EQ-5D 0.8518, KS 45.8929, EQ-5D 0.8220. Naïve to medication: proxy EQ-5D 0.7719, KS 43.3744, EQ-5D 0.7899. **CONCLUSIONS:** Children with a good compliance to medication and naïve children have a better QoL compared to non-compliant children and children who stopped treatment (non-remission). The QoL of children in remission is better than the QoL of children using medication. QoL of parents follows a similar pattern.

PMH47

VALIDITY OF THE Q10 QUESTIONNAIRE FOR DIAGNOSIS OF WEARING-OFF PHENOMENA IN PARKINSON'S DISEASE: A Q10 STUDY

Ruyra J[1], Lahoz R[1], Martínez-Martín P[2], Ricart J[1], Hernández B[1]
[1]*Novartis Farmacéutica, S.A., Barcelona, Spain,* [2]*Carlos III institute of Health, Alzheimer Center Reina Sofia Foundation, Madrid, Spain*

OBJECTIVES: To test the characteristics of a QUICK Questionnaire-Short version (Q10) as diagnostic instrument for wearing-off phenomenon (WO) in Parkinson's disease (PD) patients. **METHODS:** Observational, cross-sectional, multicenter, and national study developed in clinical practice. The study was developed in two consecutive phases: I, to determine the sensitivity and specificity of Q10; and II: to assess the usefulness (investigators) and the ability and ease of use (patients) of Q10 questionnaire. Furthermore, the prevalence of WO among PD patients consecutively attending the specialist was also assessed (phase II). Patients ≥30 years old at the onset of the disease with ≤5 years from diagnosis and under treatment were selected. **RESULTS:** In phase I, 162 patients were included, 67.4±9.7 years old, 53.8% males, and 3.1±1.4 years from diagnosis. Most of them (85%) were in Hoehn-Yahr stage 2-3. WO was presented in 64.8% (33.3% mild; 31.5% moderate/severe). Q10 was completed in 6.6±4.9 minutes. With two positive responses the Q10 showed good sensitivity (90%) and moderate specificity (70%) and with 3 positive responses both values reached an arbitrarily hypothesized 75% threshold (sensitivity: 81%; specificity: 75%). The mean usefulness Q10 score was good [7.3 (1.6), scale 1-10]. In phase II, most patients considered Q10: easy to understand (80.6%), reflect their present situations (78.8%), and useful to communicate discomfort to the doctor (80.6%). The prevalence of WO among the total PD patients attending to the neurologist was of 59.0%, higher in males (64.9%), Hoehn-Yahr staging (80%, 3-4 stage) and in patients with more time of PD evolution (71.9%). **CONCLUSIONS:** The Q10 is a useful instrument for screening and diagnosis of WO, showing good sensitivity and specificity, as well as, good usefulness, ability and ease to use. Almost two out of three PD patients attending to the neurologist presented WO.

PMH48

THE SPANISH VERSION OF THE CLINICALLY USEFUL DEPRESSION OUTCOME SCALE: A VALID INSTRUMENT TO EVALUATE DEPRESSIVE SYMPTOMS IN PRIMARY CARE

Agüera L[1], Monton C[2], Medina E[3], Cuervo J[4], Rodríguez Aguilella A[4], Maurino J[3]
[1]*Hospital Doce de Octubre, Madrid, Spain,* [2]*Centro de Salud Casablanca, Zaragoza, Spain,* [3]*AstraZeneca, Madrid, Spain,* [4]*BAP Health Outcomes Research, Oviedo, Spain*

OBJECTIVES: Develop a cross-cultural adaptation, English to Spanish, of the Clinically Useful Depression Outcome Scale (CUDOS): a validated instrument to assess depressive symptoms in patients with major depressive disorder (MDD). **METHODS:** CUDOS is a brief self-administered scale with 18 items assessing all of the DSM-IV inclusion criteria for MDD, psychosocial impairment and patients' quality of life. Three independent translators (2 Spanish and 1 English) performed forward-backward translations of the original scale. Draft version was reviewed by an expert panel (4 general practitioners, 1 psychiatrist, and 2 psychologists) and tested in 19 adult patients with MDD. Regarding experts' and patients' responses, comprehension and importance (C/I) of each item were evaluated using a Likert scale ranging from 0 (lowest level of C/I) to 4 (highest level of C/I). Furthermore, feasibility, ceiling and floor effects and reliability were preliminary analyzed. **RESULTS:** According to experts' criteria, mean C/I values of items were over 2 points (comprehension mean range: 3.25-4 & importance mean range: 2.5-4). Regarding patients' responses, acceptable mean values in comprehension (range: 2.26-3.37) were obtained. However, 4 items were modified to improve comprehension: loss of interest in usual activities, psychomotor retardation, indecisiveness and hopelessness Patients reported low importance scores in items related to thoughts of death (mean= 1.42), suicidal ideation (mean= 1.26), guilt (mean= 1.79), hypersomnia (mean= 1.37) and insomnia (mean= 1.78). Missing data was only found in 2 patients. Internal consistency was high (Cronbach $\alpha = .886$), Neither item ceiling nor floor effects were observed and patients perceiving a moderate to severe psychosocial impairment obtained higher CUDOS scores –indicating a higher impact- than those with mild or null impairment (Mann-Whitney U=9.500; p=.019). Finally, the Spanish version of the CUDOS was reached by consensus. **CONCLUSIONS:** The original CUDOS instrument was culturally adapted into Spanish. Psychometric analyses are needed to validate this measure in Spain.

PMH49

DEVELOPMENT AND CONTENT VALIDITY OF A PATIENT REPORTED OUTCOMES MEASURE TO ASSESS SYMPTOMS OF MAJOR DEPRESSIVE DISORDER (MDD)

Hassan M[1], Lasch KE[2], Piault-Louis E[3], Jernigan K[3], Hwang S[2], Fitz-randolph M[3], Pathak S[4], Locklear J[1], Endicott J[5]
[1]*AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA,* [2]*MAPI Values, Boston, MA, USA,* [3]*Mapi Values, Boston, MA, USA,* [4]*Astrazeneca LP, Wilmington, DE, USA,* [5]*Columbia University, New York City, NY, USA*

OBJECTIVES: FDA guidance on the use of Patient Reported Outcomes (PRO) for product labeling claims emphasizes the importance of documented evidence of patient input in PRO instrument development. A review of existing PROs used in Major Depressive Disorder (MDD) suggested the need to conduct qualitative research with patients with MDD to better understand their experience of MDD and develop an evaluative instrument with content validity. The aim of this study was to develop such a measure. **METHODS:** Ten MDD severity-specific focus groups (n=3-4 patients per group; total n=38) with adult patients between the ages of 18 and 65 having a clinician-confirmed diagnosis of MDD and varying in severity levels as defined by the DSM-IV TR criteria were conducted in January 2009. Grounded theory data collection and analysis methods were used including an open-ended discussion guide, an iteratively developed coding scheme, and the comparison of coded segments of patients' quotes to identify the patient experienced signs and symptoms of MDD. Saturation of concepts, where no new relevant information emerges in later interviews, was assessed. A new PRO instrument for MDD was developed; cognitive interviews (n=20) were conducted to test its content validity in terms of item relevance and comprehension, comprehensiveness, instructions, recall period and response categories. **RESULTS:** Thirty-five unique concepts falling into the following 6 domains: emotional symptoms; ideation symptoms; neuro-vegetative or somatic symptoms; physical impact; social impact; and cognitive impact were elicited. Concept saturation was achieved for each of the symptom concepts across severity levels. The MDD PRO instrument includes 15 daily and 21 weekly items. Cognitive interviews supported its content validity. Items were revised, deleted, or moved from daily to weekly assessment based on cognitive interview results **CONCLUSIONS:** Rigorous qualitative research resulted in the development of a PRO measure for MDD with supported content validity; its psychometric properties and responsiveness requires assessment.

PMH50

DIFFERENCES BETWEEN OPIOID DEPENDENT PATIENTS IN ITALY AND GERMANY RECEIVING SUBSTITUTION THERAPY

Severt J, Tkacz J, Ruetsch C
Health Analytics, LLC, Columbia, MD, USA

OBJECTIVES: Substitution therapy is commonly used across the world for the treatment of opioid dependence (OD), yet little evidence exists examining country-specific differences between acceptance and effectiveness of this treatment. The purpose of this study was to examine differences between patient demographics, treatment accessibility, and attitudes toward substitution therapy among OD patients in Germany and Italy. **METHODS:** A telephonic survey, initiated by the Italian Federation of Operators of Dependences Departments and Services, examining substitution therapy was administered to OD patients across two countries: Germany (n=200) and Italy (n=378). The survey assessed experiences prior to and during substitution therapy. **RESULTS:** Italian patients reported being in better physical and mental health than German patients (p's < 0.001); were more likely to get information about substitution therapy from family members than German patients (8.9% vs. 3.2%, $\chi 2 = 5.22$; $p < 0.05$); and were more likely to report that it was either very easy or fairly easy to find a doctor from whom they could receive substitution treatment than German patients (89.9% vs. 68.7%, $\chi 2 = 40.35$; $p < 0.001$). In contrast, German patients were more likely to get information from other drug users (63.9% vs. 47.7%, $\chi 2 = 10.72$; $p < 0.01$) or their family physicians (14.6% vs. 4.3%, $\chi 2 = 14.59$; $p < 0.0001$), and were also more likely than Italian patients to misuse their substitution drug by either snorting (11.5% vs. 3.2%, $\chi 2 = 15.94$; $p < 0.0001$) or injecting it (18.5% vs. 11.1%, $\chi 2 = 6.05$; $p < 0.05$). **CONCLUSIONS:** The present results highlight key differences in patient attitudes and experiences regarding substitution therapy. Differences in social and institutional attitudes, in addition to cultural norms and health care policies, may explain the present findings, which demonstrate the complexity of the OD population.

PMH51

MEASURING RELAPSE AFTER SUBSTANCE ABUSE TREATMENT: A PROPORTIONAL HAZARD APPROACH

Ciesla J[1], Mazurek K[2]
[1]*Northern Illinois University, DeKalb, IL, USA,* [2]*University of Illinois, Champaign-Urbana, Champaign, IL, USA*

OBJECTIVES: This research uses Cox regression to analyze relapse patterns of adults treated for substance use disorder (SUD). The objective is to evaluate the role psychosocial, treatment and environmental characteristics play in the relapse process. While relapse is a much-studied phenomenon, there is no research describing in detail how the risk of relapse changes over time (especially in the months immediately following primary treatment) given known protective factors. Since SUD is a chronic relapsing disorder, it is important to understand ways treatment gains can be maintained. **METHODS:** Subjects are 408 adults discharged between 2000-2009 from an ASAM-defined Level 1.A primary inpatient treatment program. Data were collected via a 215-item questionnaire as part of the treatment program's annual outcomes evaluation. The sampling frame was people who successfully completed treatment and who gave consent. The response rate was 56 percent. The researchers obtained the treatment records of each person completing the questionnaire and matched the treatment outcomes from the questionnaire to treatment and sociodemographic variables present in the treatment records. A comprehensive data set was created from these two sources. Data were analyzed using Cox proportional hazard regression. **RESULTS:** Statistically significant covariates include: home environment variables (those with supportive people at home are 3.17 times less likely to relapse; those with supportive spouses are 4.91 times less likely to relapse) and support group variables (those attending self-help meetings

are 1.61 times less likely to relapse; those with sponsors are 1.64 times less likely to relapse), cetertis paribus. Adjustor covariates include: Global Assessment of Functioning, addiction severity, DSM diagnosis and length of stay. **CONCLUSIONS:** Since this survival model relates the time that passes before relapse occurs to known risk factors for relapse, this research will help treatment providers identify not only the best types of interventions but also the correct timing of interventions.

PMH52

RELATIONSHIP BETWEEN PSYCHOPATHOLOGY AND SELF-RATED EQ-5D HEALTH STATES AMONG PATIENTS WITH SCHIZOPHRENIA

Taha NA[1], Mohamed Ibrahim MI[2], Ab Rahman AF[3], Shafie AA[4]
[1]*Universiti Sains Malaysia, Penang, Malaysia,* [2]*Qassim University, Buraidah, Saudi Arabia,* [3]*Universiti Sains Malaysia, Kubang Kerian, Malaysia,* [4]*University Sains Malaysia, Penang, Penang, Malaysia*

OBJECTIVES: In previous studies, psychopathology particularly negative, depressive and cognitive syndromes adversely influenced health-related quality of life (HRQoL). The objective of the study was to examine the relationship between schizophrenia symptoms and the HRQoL dimensions of the EQ-5D descriptive system. **METHODS:** This was a cross-sectional study conducted at the Psychiatric Clinic, Universiti Kebangsaan Malaysia Medical Centre. Patients were assessed for symptom severity using the Clinical Global Impressions-Schizophrenia (CGI-SCH) severity scale (scores range from (1) no illness to (7) most severe possible) by the attending clinicians. Patients' perceived health states in 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with 3 levels of response; (1) no problems, 2 (moderate problems) and 3 (extreme problems) were evaluated using the EQ-5D descriptive system. The association between the 2 scales were examined by Spearman rank correlations. **RESULTS:** A total of 222 out-patients (Mean age= 37.7, SD= 10.1; Mean duration of illness = 11.42, SD=8.0) with a DSM-IV chart diagnosis of schizophrenia participated in the study. There was a moderate positive correlation between the EQ-5D 'usual activities' dimension and each of the CGI-SCH overall, depressive and cognitive symptom dimension scores (rs = 0.35, 0.37 and 0.31, respectively & for all $p < 0.01$). A significant moderate correlation was also found between the EQ-5D 'anxiety/depression' and the CGI-SCH depressive symptom dimension scores (rs = 0.35, $p < 0.01$). Weak correlations were found between the CGI-SCH symptoms and other EQ-5D dimensions scores (rs ranges from 0.16 to 0.26, $p < 0.01$). **CONCLUSIONS:** In chronic schizophrenics living in the community, worsening of overall, depressive and cognitive symptoms were moderately associated with deterioration in patients' usual life activities and worsening of depressed mood was moderately associated with worsening of anxiety or depression states. Schizophrenia syndromes were only weakly associated with patients' mobility, self-care and sense of pain or discomfort.

PMH53

FOLLOW-UP OF HEALTH-RELATED QUALITY OF LIFE IN YOUNG HEROIN USERS

Català L[1], Ferrer M[1], Sanchez-Niubò A[1], Brugal MT[2], Domingo-Salvany A[3], Itinere I[4]
[1]*IMIM-Hospital del Mar, Barcelona, -, Spain,* [2]*Agència de Salut Publica de Barcelona, Barcelona, -, Spain,* [3]*IMIM-Hospital del Mar & CIBERESP, Barcelona, -, Spain,* [4]*Instituto de Salud Carlos III, Madrid, -, Spain*

OBJECTIVES: To ascertain changes in Health related Quality of Life (HRQL) among young heroin users after one year follow-up. **METHODS:** Heroin users (18-30y) were recruited in outdoor settings in three Spanish cities (Barcelona, Madrid, Seville) from 2001 to 2003 and followed up, on average, 1.4(SD:0.6) years later. Standardised laptop interviews included socio-demographic data, drug use patterns, health related issues, the Severity of Dependence Scale (SDS) and the Nottingham Health Profile (NHP). For bivariate analyses, non parametric Mann-Whitney U and Kruskal-Wallis tests were used. Factors associated to NHP score changes over time were analysed through a multiple linear regression taking into account socio-demographic factors, consumption patterns and health related variables. **RESULTS:** A total of 628 subjects (72.5% males), mean age 27.9 (SD:3.4) years were followed (63.4%). Mean total NHP score improved, from 36.4 (SD:24.2) at baseline to 27.0 (SD:22.4) at follow-up. Variables associated with total NHP score worsening were HIV infection during follow-up, having experienced an overdose during the last 12 months and psychiatric treatment ever; conversely, total NHP score improved among those who got a job by the end of the study. Each additional substance with a weekly regular use and higher SDS scores for both cocaine and heroin, measured as a difference from baseline values, were also related to worsening total NHP score. We observed an interaction between severity of heroin dependence (as measured with SDS) and methadone maintenance treatment. The NHP total score only improved, with decreasing heroin SDS, among drug users in methadone maintenance treatment. **CONCLUSIONS:** HRQL improved over 12 months for young heroin users. The main variables independently related with HRQL were changes in heroin and cocaine SDS. Further holistic models taking into account social variables are needed.

PMH54

QUALITY OF LIFE AS A PREDICTOR OF CLINICAL OUTCOME: EXAMPLE IN SCHIZOPHRENIA

Millier A[1], Boyer L[2], Perthame E[1], Aballea S[3], Auquier P[2], Toumi M[4]
[1]*Creativ Ceutical, Paris, France,* [2]*Timone University Hospital, Marseille, France,* [3]*Creativ Ceutical, Paris, Ile de France, France,* [4]*University Claude Bernard Lyon1, Lyon, France*

OBJECTIVES: Developing practical strategies to incorporate quality of life (QoL) data in clinical management is an unmet need, and using quality of life (QoL) as a predictor of clinical event is a new trend in outcomes research. The objective of this study was to investigate relapse rate as a function of QoL in schizophrenic patients. **METHODS:** We used data from EuroSC, a multicenter 2-year cohort study conducted in France, England and Germany. We first examined the association between occurrence of relapse and baseline QoL, as measured by SF36 mental composite score (MCS) and physical composite score (PCS), by EQ-5D and QOLI subjective score. Then bivariate analyses were performed to identify confounding factors (CF). Finally CF and QoL were incorporated in several multivariate Cox models. **RESULTS:** Our sample consisted in 922 patients with schizophrenia. QoL was found to be lower for those who relapsed (418 patients with MCS = 40.1, PCS = 47.1, EQ-5D utility = 0.70 and QOLI = 4.65 vs. 504 patients with MCS = 43.9 ($p<0.0001$), PCS = 49.2 ($p<0.001$), EQ-5D utility = 0.77 ($p<0.0001$), and QOLI = 4.8 ($p<0.01$)). Bivariate analyses identified several outcomes: age, gender, severity of disease, depression, antipsychotic medication, compliance, subjective side effects and functioning. Multivariate Cox models confirmed that a higher level of QoL predicts a significantly lower rate of relapse at 2 years (HR = 0.94, p=0.03 for MCS; HR 0.89; $p<0.01$ for PCS; HR=0.97; $p<0.001$ for EQ-5D utility; HR=0.83; p=0.004 for QOLI). **CONCLUSIONS:** This study shows that QoL can be considered as a mediator of relapse in schizophrenia, independently of clinical severity scales. These results are consistent with new research trends. Our findings can contribute to develop credible strategies on how to integrate QoL data in clinical practice.

PMH55

AN EXAMINATION OF ANTIDEPRESSANT-RELATED SEXUAL DYSFUNCTION AND DEGREE OF ENJOYMENT AND SATISFACTION WITH DAILY ACTIVITIES, AND CURRENT MEDICATION IN EMPLOYED PATIENTS

Schneider G[1], Roy A[2], Dabbous OH[3]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Takeda Pharmaceuticals International, Inc, Deerfield, IL, USA,* [3]*Takeda Pharmaceuticals International, Inc., Deerfield, IL, USA*

OBJECTIVES: To understand the association of antidepressant-related sexual dysfunction with degree of enjoyment and satisfaction from daily activities, and current medication. **METHODS:** Employed individuals (≥18 years of age) with depression (excluding bipolar disorder) completed a web-based computer-generated 25-minute survey (population identified by Harris Interactive). Sexual dysfunction (SD) was assessed using the Arizona Sexual Experience (ASEX) Scale on 5 components of sexual functioning (Drive, Arousal, Penile Erection/Vaginal Lubrication, Orgasm, Satisfaction); each rated on a 6-level ordinal scale (higher scores indicate increased SD). Using distribution among current antidepressant users, overall SD score was categorized into quartiles (lowest quartile represented better sexual functioning). Degree of enjoyment and satisfaction related to general activity and current medication was measured using a 5-point ordinal scale (1=very poor and 5=very good) using the Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (QLESQ-SF). A summary "percent-of-max" score for general activity items, transformed to 5-level ordinal variable employing cut-points of 20, 40, 60 and 80%, was used (<20% represented the poorest experience). Gender stratified cumulative logit models were used to estimate effect of SD on QLESQ measures. **RESULTS:** Of 1,521 respondents, 872 (57%) reported current antidepressant use (60.6% female, mean age 49.9 ± 13.5 years). Among antidepressant users, compared to the first SD quartile, odds of being in a poorer overall "percent-of-max" score (i.e., lower enjoyment/satisfaction) were greater in the highest (4th) SD quartile for both males (odds ratio [OR] =3.03; p=0.0007) and females (OR=1.96; p=0.0021). Sexual dysfunction was associated with lack of satisfaction with medication for both genders: (males - 3rd SD quartile (OR=2.17; p=0.001); highest SD quartile (OR=3.33; p=0.0003); females - highest SD quartile (OR=1.49; p=0.06)). **CONCLUSIONS:** These data suggest that antidepressant-related SD may be associated with diminished enjoyment and satisfaction with daily activities and current medication. Such perceptions may impact eventual treatment outcomes.

PMH56

NEGATIVE SYMPTOMS HAVE GREATER IMPACT ON FUNCTIONING THAN POSITIVE SYMPTOMS IN SCHIZOPHRENIA: ANALYSIS OF CATIE DATA

Rabinowitz J[1], Garibaldi G[2], Levine S[1], Bugarski-Kirola D[3], Berardo C[3], Kapur S[4]
[1]*Bar Ilan University, Ramat Gan, Israel,* [2]*F. Hoffmann-La Roche Ltd, Basel, Switzerland,* [3]*Roche, Basel, Switzerland,* [4]*Kings College London, London, UK*

OBJECTIVES: There has been increased attention to the antipsychotic treatment of negative symptoms in schizophrenia and the potential impact that this could have on various functional outcomes. We compared the relative effects of negative symptoms on functioning as compared to other symptoms. **METHODS:** Data are from 18 months of the National Institute of Mental Health (NIMH) CATIE trial of chronic schizophrenia (n=1447). Measures were the Positive and Negative Syndrome Scale (PANSS), functioning from the Heinrich's (Instrumental role, Common place objects and activities) and items from the Lehman Quality of Life Scales (Leisure activities, Instrumental activities of daily living). Quality of life items measuring negative symptoms were excluded. Correlations between the five PANSS factors and the functional measures were examined at baseline and change. Functioning items were summed to create a standardized total score. Multiple regression was used to predict the functioning total score at baseline using the five PANSS factors and change in functioning using change on the PANSS factors. **RESULTS:** The negative symptom factor correlated more strongly than other symptom factors with functioning at baseline and change scores. Multiple regression predicting functioning at baseline including all five PANSS factors showed that the negative symptom factor was the strongest predictor, almost three times that of positive symptoms (r=-0.25 vs. r=-0.07). A similar multiple regression predicting change in total functioning with change on PANSS also found that the negative factor was the best predictor and was double that of the positive factor (r=-0.08 vs. r=-0.045). **CONCLUSIONS:** Baseline and change in functioning were more strongly related to the PANSS negative factor than the other four PANSS factors. Since we focused on negative symptoms we chose domains of functioning that did not overlap with

negative symptoms. The results suggest that functioning and improvement in functioning are more strongly correlated with negative than with positive and other symptom factors.

PMH57

ASSOCIATION OF ANTIDEPRESSANT-RELATED WEIGHT GAIN WITH DEGREE OF ENJOYMENT AND SATISFACTION REGARDING GENERAL DAILY ACTIVITIES, MEDICATION AND OVERALL QUALITY OF LIFE

Schneider G[1], Roy A[2], Dabbous OH[3]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Takeda Pharmaceuticals International, Inc, Deerfield, IL, USA,* [3]*Takeda Pharmaceuticals International, Inc., Deerfield, IL, USA*

OBJECTIVES: To examine the association of antidepressant-related weight gain with degree of enjoyment and satisfaction from general daily activities, medication and overall quality of life. **METHODS:** Employed individuals (≥18 years of age) with depression (excluding bipolar disorder) completed a web-based computer-generated 25-minute survey (population identified by Harris Interactive). Weight gain was measured using the Toronto Side Effects Scale which measures medication-related side effects in the two weeks preceding the survey, and analyzed as a 4-level ordinal variable (none, <=2lbs, <=4lbs, <=7lbs). Degree of enjoyment and satisfaction related to general activities, satisfaction with current medication, and overall quality of life were measured using a 5-point ordinal scale (1=very poor; 5=very good) employing the Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (QLESQ-SF). A summary "percent-of-max" score was calculated for general activity items, and transformed to a 5-level ordinal variable using cut-points of 20, 40, 60 and 80% (<20% represented least overall enjoyment/satisfaction) . Gender stratified cumulative logit models were used to estimate the effect of weight gain on QLESQ-SF measures. **RESULTS:** Of the 1,521 survey respondents, 872 (57%) reported current antidepressant use (60.6% female, mean age 49.9 ± 13.5 years). Compared to females with no weight gain, the odds of having lower enjoyment/satisfaction were greater for females who experienced any weight gain: <=2lbs (odds ratio [OR] =2.22; p=<0.0001), <=4lbs (OR=2.27; p=0.004) and <=7lbs (OR=12.50; p=<0.0001). Among males lower QLESQ score was associated only with the <=7lbs category (OR=5.26; p=0.0004). Satisfaction with medication was inversely associated with weight gain for females; <=2lbs (OR=1.49; p=0.051), <=4lbs (OR=2.33; p=0.002) and <=7lbs (OR=8.33; p=<0.0001) and males; <=7lbs (OR=2.78; p=0.031). **CONCLUSIONS:** These data suggest that antidepressant-related weight gain may have strong associations with patient perceptions of diminished enjoyment and satisfaction in general daily activities and with current medication, which may affect medication adherence.

PMH58

DONEPEZIL ORAL DISINTEGRATING VERSUS DONEPEZIL STANDARD TABLETS ON OBJECTIVE BURDEN OF CAREGIVERS OF NAÏVE PATIENTS WITH ALZHEIMER'S DISEASE

Gonzalez JL[1], Peset V[2], Casado-naranjo I[3], González-Adalid M[4], Rejas J[5]
[1]*Hospital Clínico Universitario San Carlos, Madrid, Spain,* [2]*Hospital General Universitario de Valencia, Valencia, Spain,* [3]*Complejo Hospitalario de Cáceres, Caceres, Spain,* [4]*Pfizer Spain, Alcobendas, Madrid, Spain,* [5]*Pfizer España, Alcobendas/Madrid, Spain*

OBJECTIVES: The goal of this research was to compare the effect of donepezil oral standard tablets (OST) versus donepezil oral disintegrating tablets (ODT) on stress and objective burden in caregivers of de novo patients with dementia of AD in routine medical practice. **METHODS:** A 6-month, prospective, observational study enrolled naïve patients with possible/probable AD according to DSM-IV/NINCDS-ADRDA criteria. Comparison on caregiver stress and objective burden was carried-out between donepezil formulations of OST and ODT for a 6 month period. The self-administered ZARIT scale and daily hours devoted to the care of patients on basic and instrumental activities of daily-living (BADL, IADL), behaviour supervision and nursing home institutionalization were computed. **RESULTS:** 547 naïve and de novo AD patients were analyzed: 123 (22.5%) received OST and 424 (77.5%) ODT, at 7.1 (2.5) and 7.1 (2.6) mg/day, respectively. No significant differences were observed in age, sex distribution, schooling, educational training, or relationship with main caregiver between groups. Baseline clinical characteristics (comorbidities, symptoms of dementia duration, MMSE scoring) were homogeneous between groups and remained unchanged during the study; Adjusted ZARIT scoring was reduced significantly in ODT group by -1.1 point (p=0.001) but this was not statistically higher than the reduction observed in OST cohort; -0.5 (p=0.527 between groups comparison). Daily hours of care on BADL and IADL were not statistically different between cohorts and remained unchanged during the study. Also, average number of hours/day on behaviour supervision or general supervision and the percentage of caregivers having to quit their jobs were similar. **CONCLUSIONS:** Findings of this study show that both subjective and objective burden of caregivers of de novo patients with AD treated with donepezil remain stables during the 6-month period of the study, and it is unrelated with type of formulation given to patients.

PMH59

EMPLOYMENT STATUS AND SELF REPORTED QUALITY OF LIFE IN CHINESE PATIENTS RECEIVING TREATMENT FOR MAJOR DEPRESSIVE DISORDER

Xue HB[1], Wu SH[1], Brnabic AJ[2], Novick D[3], Kadziola Z[2], Granger RE[2], Montgomery W[4]
[1]*Development Centre of Excellence Asia-Pacific, Lilly Suzhou Pharmaceutical Co Ltd, Shanghai Branch, Shanghai, China,* [2]*Development Centre of Excellence Asia-Pacific, Eli Lilly Australia Pty Ltd, Macquarie Park, Australia,* [3]*Eli Lilly and Co, Windlesham, Surrey, UK,* [4]*Eli Lilly Australia Pty Ltd, West Ryde, Australia*

OBJECTIVES: Patients with major depressive disorder (MDD) frequently report lower quality of life (QoL) and increased disability compared with the general population. This post hoc analysis describes the association between QoL, painful physical symptoms (PPS), depressive symptoms and employment status in a Chinese MDD patient cohort. **METHODS:** Chinese MDD patients (299) from a prospective observational study of six East Asian countries/regions were compared at baseline and after 3 months of naturalistic treatment on QoL (EuroQoL Questionnaire-5 Dimensions [EQ-5D] utility score), PPS (Somatic Symptom Inventory [SSI]), depression (17-item Hamilton Depression Rating Scale [HAMD17]) and employment status measures. Patients were classified as PPS positive or negative (PPS+, PPS-; SSI mean score ≥2 or< 2 respectively). Effect sizes (ES) were calculated using Cohen's d. **RESULTS:** Patients who were employed at baseline reported higher QoL (EQ-5D: 0.60 vs. 0.42; ES 0.7) and were less severely ill (HAMD17 total score: 22.7 vs. 26.0; ES -0.7) than those who were unemployed. Few transitions in employment status were observed during the study. Self-reported QoL was low (EQ-5D: mean 0.52) at baseline and improved substantially after 3 months (EQ-5D: 0.89). PPS+ patients were more severely ill (HAMD17: 25.4 vs. 23.3; ES 0.4) and had a lower QoL (EQ-5D: 0.41 vs. 0.58; ES -0.6) at baseline than PPS- patients. The higher illness severity (HAMD17: 7.0 vs. 4.6; ES 0.4) and lower QoL (EQ-5D: 0.83 vs. 0.92; ES -0.6) of PPS+ patients persisted after 3 months. **CONCLUSIONS:** Employed patients reported a higher QoL and a lower symptomatic burden than unemployed patients. Patients with a low QoL were more likely to be unemployed. The QoL of Chinese MDD patients improved over 3 months of naturalistic treatment. The presence of PPS was associated with higher illness severity and lower QoL at baseline and after 3 months.

PMH60

FACTORS ASSOCIATED WITH HEALTH-RELATED QUALITY OF LIFE IN ALCOHOL DEPENDENT PATIENTS

Guennec M[1], Sanglier T[2], Milea D[3]
[1]*Université Victor Segalen Bordeaux2, Bordeaux, France,* [2]*Lundbeck SAS, Issy-les-Moulineaux, France,* [3]*Lundbeck SAS, Issy-les-Moulineaux, France*

OBJECTIVES: Health-related Quality of Life (HRQoL) has become both a target of intervention and a crucial outcome in evaluating treatment of alcohol dependence. Little has been studied on the factors associated with HRQoL before alcohol dependence treatment. We explored the association between HRQoL and several risk factors including level of alcohol consumption. **METHODS:** We used data from CONTROL, an observational cohort study on 143 alcohol dependent patients from Lausanne hospital, Switzerland, followed for 12 months. Average daily alcohol consumption was collected every month and categorised according to the World Health Organisation's risk levels (WRL) classification: high, medium, low or abstinent. Other measures were collected every three months: HRQoL (SF-36), Beck inventory depression score (BDI) and sociodemographic characteristics. The mean score for each dimension and for the Physical and Mental Component Summary Score (PCS and MCS) were calculated at baseline and at 12-months. Correlates of MCS and PCS were identified using Pearson correlation coefficients and factors associated with change from baseline to 12-months were identified using linear mixed models. **RESULTS:** At baseline, except for physical functioning, all average SF-36 scores were below those in the general population. The most impaired scores were those with the heavier contribution to MCS. MCS was significantly correlated with BDI, WRL and age. Compared to abstinent patients, difference in MCS scores was significantly lower in patients with medium (difference=-12.9; p<0.005) or high risk (difference=-14.8; p<0.0001) levels whereas no significant difference was observed between abstinent and low risk patients (difference=-7.3; N.S.). Change in MCS from baseline to 12-months was associated with BDI and WRL. No significant association was found with PCS. **CONCLUSIONS:** HRQol is significantly in alcohol-dependent patients. The level of alcohol consumption and depression appeared as important drivers of HRQoL related to mental health.

PMH61

A DESCRIPTIVE ANALYSIS OF ATOMOXETINE UTILIZATION IN ATTENTION DEFICIT/HYPERACTIVITY DISORDER (ADHD) THE UNITED KINGDOM AND ITALY

Sikirica V[1], Mitra D[2], Fridman M[3], Davis KL[2], Hodgkins P[1]
[1]*Shire Pharmaceuticals, Wayne, PA, USA,* [2]*RTI Health Solutions, Research Triangle Park, NC, USA,* [3]*AMF Consulting, Inc., Los Angeles, CA, USA*

OBJECTIVES: To describe treatment characteristics among children with Attention Deficit/Hyperactivity Disorder (ADHD) using atomoxetine in two European countries. **METHODS:** Medical charts of patients aged 6-17 with ≥1 diagnosis of ADHD between 1/2004-6/2007 were reviewed by physicians from 6 European countries. All patients had ≥2 years of follow-up data and received pharmacological or behavioral therapy post-diagnosis, and were not enrolled in a clinical trial. This analysis focused on two countries with the largest samples of Strattera® (atomoxetine HCL) users: UK (UK) and Italy (IT). Outcomes presented include descriptive statistics (means, rates, percentages) describing treatment: patterns, response and satisfaction. **RESULTS:** 94 patients met inclusion criteria (UK [n=51], IT [n=43]). Patients were predominantly male 80.4% (UK) and 76.7% (IT), Caucasian, 88.2% and 95.3% and mean (SD) age at diagnosis was 9.5(2.6) and 9.0(2.9). Most patients were diagnosed via the Connors (76.5%) (UK) or DSM-IV (51.1%; IT) criteria. A majority of patients presented as combined type ADHD (hyperactive/impulsive and inattentive symptoms) (UK >74% and IT >62%). Between 63% to 76% of all patients indicated ≥8 impairment for impulsivity and hyperactivity (scale from 0 "no impairment" to 10 "high level impairment"). 76.5% (UK) and 55.8% (IT) of patients received two or more ADHD treatments and 42.1% and 20.5% received a methylphenidate product; 37.3% and 32.6% of physicians in the UK and IT, respectively, indicated that these patients had a "poor" or "very poor" response to methylphenidate. 64.9% of patients were currently prescribed atomoxetine vs. 35.1% previously prescribed. 23.0% of physicians of current patients indicated that they were "neither satisfied nor dissatisfied," "moderately dissatisfied," or "very dissatisfied" with current ato-

moxetine treatment. **CONCLUSIONS:** At baseline, country-level variations in some patient characteristics were evident in children with ADHD treated with atomoxetine in the UK and IT. Further, this study suggests an opportunity for improved ADHD treatment response and satisfaction outcomes.

PMH62

AN EXAMINATION OF THE ASSOCIATION BETWEEN ANTIDEPRESSANT-RELATED WEIGHT GAIN AND VARIOUS ASPECTS OF WORKER PRODUCTIVITY

Schneider G[1], Roy A[2], Dabbous OH[3]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Takeda Pharmaceuticals International, Inc, Deerfield, IL, USA,* [3]*Takeda Pharmaceuticals International, Inc., Deerfield, IL, USA*

OBJECTIVES: To understand the association of antidepressant-related weight gain with various aspects of worker productivity. **METHODS:** Employed individuals (≥18 years of age) with diagnosed depression (excluding bipolar disorder) completed a web-based computer-generated 25-minute survey (study population identified by Harris Interactive). Weight gain was measured using the Toronto Side Effects Scale which measures medication-related side effects in the 2-weeks preceding the survey, and was analyzed as a 4-level ordinal variable (none, <=2lbs, <=4lbs, and <=7lbs), where "none" was the referent category. The Work Productivity and Activity Impairment (WPAI) questionnaire was used to assess percent of impaired productivity (overall, absenteeism, presenteeism, activity impairment) during the 2-weeks preceding the survey, with higher numbers indicating greater impairment and less productivity (i.e., worse outcomes). Using distribution among current antidepressant users, each WPAI measure was categorized into quintiles, with the lowest and highest representing least and greatest impairment, respectively. Cumulative logit models were used to estimate the overall effect of weight gain on WPAI measures as well as across gender. **RESULTS:** Of the 1521 survey respondents, 872 (57%) reported current antidepressant use (60.6% female, mean age 49.9 ± 13.5 years). Weight gain was associated with loss of productivity: <=2lbs (odds ratio [OR]= 1.54; p=0.005), <=4lbs (OR= 2.14 ; p=0.0007) and <=7lbs (OR= 2.96; p= 0.0009). In females, using "no weight gain" as a reference group, the odds of being in a worse overall productivity category increased with the increase of weight gain: <=2lbs (odds ratio [OR]=1.59; p=0.02), <=4lbs (OR=2.17; p=0.005) and <=7lbs (OR=3.13; p=0.01). Similar trends were observed in males: <=2lbs (OR=1.43; p=0.15), <=4lbs (OR=2.00; p=0.06) and <=7lbs (OR=2.86; p=0.02). **CONCLUSIONS:** In employees with depression, antidepressant-related weight gain was associated with loss in overall productivity. Additional research to quantify the indirect costs of antidepressant-related weight gain in terms of productivity losses may be useful.

Mental Health – Health Care Use & Policy Studies

PMH63

STAY HEALTHY THROUGH GAME-CARE THERAPEUTICS: IT'S TIME TO PLAY THE GAME!

Aggarwal A
Independent Research Consultant, Delhi, India

OBJECTIVES: Health care research in present scenario is a platform wherein a range of interventions play their role to alleviate suffering and mitigate the course of diseases. Gaming console have so far demonstrated promising and considerable potential as rehabilitation and lifestyle treatments. The objective of this review was to study the advent and role of new generation gaming consoles (e.g. Nintendo Wii, Xbox, and PS3) in healthcare research in a systematic manner. **METHODS:** A consolidated search strategy was developed and run in EMBASE, MEDLINE, Cochrane, POPLINE, SCOPUS, and Clinicaltrials.gov databases to identify the trials utilising gaming consoles as principal intervention or supportive treatment in various disease areas. Grey literature was also identified though Google Scholar. Data extraction was performed and results were summarized. **RESULTS:** The data revealed that motion sensor and interactive gaming consoles have found their role in multiple health care fields ranging from rehabilitation, weight loss, stroke recovery, improvement in locomotor activity, Parkinson's disease, Alzheimer's disease, and back pain, etc. Also, their active presence in promoting exercise, health care coaching and monitoring, and health awareness programs has seen a marked increase due to new and innovative applications being identified every day. **CONCLUSIONS:** Newer health care technologies and platforms like gaming consoles help in numerous disease area to improve patient outcomes. Their transformation, propagation, and implementation as tools of healthcare services is a valuable strategy that the health care organizations should consider taking into consideration the emerging field of gaming technology in parallel with health technology. Detailed analysis, data tables, and graphs describing the study results will be presented.

PMH64

DIABETIC CARE AND RISK OF ACUTE COMPLICATIONS OF TYPE II DIABETICS WITH SCHIZOPHRENIA: A THREE-YEAR FOLLOW-UP OF HYPOGLYCEMIC THERAPY

Cheng JS[1], Shih YT[2]
[1]*Ghang Gung University, Kwei-Shan, Tao-Yuan, Taiwan,* [2]*National Health Research Institutes, Jhunan, Miaoli county, Taiwan*

OBJECTIVES: Individuals with schizophrenia are found to receive poorer medical care, and have a higher prevalence of diabetes than general population. Once a hypoglycemic therapy is needed, proper compliance to the therapy and diabetic care are important for achieving good glycemic control as well as preventing acute complications. Therefore, this study aimed to compare diabetic care and risk of acute complications after the initiation of the therapy for three years, between type II diabetics with schizophrenia versus those without schizophrenia. **METHODS:** This study used the claims database of the National Health Insurance program. Enrollees who began oral hypoglycemic therapy in 2001, and had been diagnosed with schizophrenia and refilled at least one prescription of antipsychotic(s) in the year prior to the index date were included in the study (the case group). Enrollees without schizophrenia who began oral hypoglycemic therapy in 2001 were selected from a randomly selected sample of the enrollees to match the age and gender of the case group (1:1) (the comparison group). Indicators of diabetic care included good medication compliance (a medication possession ratio≥0.8), blood glucose test, and HbA1c test. Indicators were measured annually. Acute complications were defined as emergency room visits or hospital admissions due to coma, hypoglycemia, hyperglycemia, or diabetic ketoacidosis. Cox proportional hazards model was adopted to assess risk of acute complications. **RESULTS:** There were 544 subjects in the case group and comparison group, respectively. The percentage of subjects compliant to the therapy in the case group was decreasing. In addition, the case group had poorer blood glucose-related monitoring in the long run, and had a higher risk of acute complications than the comparison group. **CONCLUSIONS:** Diabetics with schizophrenia, compared with those without such a condition, had worse diabetic care. Better disease management will be necessary for this patient group.

PMH65

THE CHALLENGE OF ADHERENCE AND INDIVIDUALIZED TREATMENT IN SEVERE MENTAL DISORDERS – A NORDIC PERSPECTIVE

Granström O[1], Dencker Vansvik E[2]
[1]*AstraZeneca Nordic MC, Södertälje, Sweden,* [2]*AstraZeneca Nordic MC, Södertälje, Södertälje, Sweden*

OBJECTIVES: Drug choice and adherence are important aspects in schizophrenia and bipolar disorder (BD) and depend on patient and drug characteristics. Our aim was to examine Nordic psychiatrists' views on treatment choice, adherence, once daily dosing (ODD), and the use of extended release (XR) and instant release (IR) quetiapine. **METHODS:** We conducted a quantitative, telephone-based survey with 201 respondents randomly selected from a list of all 1906 Swedish and 677 Danish psychiatrists (excluding child and geriatric psychiatrists). Structured, one-hour qualitative interviews with 10 psychiatrists per country allowed us to further interpret the results. Data was collected by an independent research company. For binary variables, we performed a binomial test of the null hypothesis that the alternative responses were equally likely. **RESULTS:** One hundred one Danish and 100 Swedish psychiatrists were included; 65% were male and the mean (SD) psychiatric experience was 15.4 (8.2) years. No relevant country differences were found. 198 psychiatrists (99%) agreed on the importance of individualized treatment (p≤0.0001). Respondents reported that 42% of schizophrenia and 33% of BD patients tried ≥3 antipsychotics before being stabilized. All respondents reported non-adherence to be common and all associated non-adherence with side-effects. 199 (99%) psychiatrists thought that ODD would improve adherence (p≤0.0001), and 196 (98%) that it could mitigate partial adherence problems (p≤0.0001). 179 respondents (89%) said that ODD reduces relapse rates (p≤0.0001). A total of 147 psychiatrists (73%) associated quetiapine XR with less day sedation than IR (p≤0.0001), and 132 (66%) associated XR with a reduced need for injection treatment (p≤0.0001). In the qualitative interviews, XR was to a higher extent associated with antipsychotic monotherapy and IR more often with short-term use for e.g., sedation. **CONCLUSIONS:** Nordic psychiatrists considered individualized drug therapies in schizophrenia and BD to be important and perceived ODD to improve adherence. Respondents associated quetiapine XR with differential use compared to IR.

PMH66

12-YEAR TREND ANALYSIS ON THE CHARACTERISTICS, PRIMARY PAYER, AND PRESCRIBED MEDICATIONS OF PHYSICIAN-OFFICE VISITS FOR PATIENTS WITH DEMENTIA IN THE UNITED STATES

Chen YJ[1], Sankaranarayanan J[2], Murman DL[2]
[1]*Covance Market Access Services, Gaithersburg, MD, USA,* [2]*University of Nebraska Medical Center, Omaha, NE, USA*

OBJECTIVES: This study was to estimate the national trend of physician-office visits for patients with Alzheimer's disease and senile dementia (AD+SD), related characteristics, primary payment source, and prescribed medications over a period of 12 years (1998 – 2009) in the United States. **METHODS:** Physician-office visits with AD+SD diagnosis were identified in the National Ambulatory Medical Care Survey, stratified by time frame, to perform a trend analysis for patients aged 40+ with relevant ICD-9-CM codes (290.xx, 294.xx, 331.xx). Main outcomes of interest are the changes in AD+SD physician-office visits, primary payer source, and prescribed medications. A series of multivariate regressions (generalized linear model [GLM] with Poisson distribution) for number of medications prescribed per visit were employed by year to estimate the increased medication numbers associated with AD+SD, controlling for patient demographics, comorbidities, and visit/payment characteristics. The impact of explanatory variables at both physician-office and visit level was also assessed through hierarchical modeling. **RESULTS:** Over the 12-year period, the annual AD+SD visits and average all-purpose medications prescribed per AD+SD visit have yearly growth rates of 18.2% and 10.7%, respectively. Medicare has consistently been the largest primary payer for AD+SD physician-office visits (from 67% of visits in 1998 to 77% in 2009). Private payer and Medicaid also have increased shares (from 6% to 13% and from 4% to 5%, respectively) as primary payer, while fewer visit portions are primarily covered by Self-pay and Other sources. Numbers of drug mentions per visit attributable to AD+SD, estimated through GLM regressions, are 0.64 in 1998, 1.92 in 2004, and 2.20 in 2009. **CONCLUSIONS:** AD+SD patients' use of physician-office services has increased

steadily over time in overall visits, all-purpose prescribed drugs, and prescribed drugs attributable to AD+SD. Future studies are needed to assess trend patterns in specific classes of anti-dementia drugs (e.g., memantine, cholinesterase inhibitor, or donepezil/rivastigmine/gallantamine).

PMH67

DRUG UTILISATION ADAPTATIONS IN SWEDEN AFTER THE EFFEXOR PATENT EXPIRY

Bruce S[1], Hjelmgren J[2], Löfroth E[1], Myrén KJ[3]
[1]*IMS Health, Stockholm, Sweden,* [2]*IMS Health Sweden AB, Stockholm, Sweden,* [3]*IMS Health, Stockholm, Stockholm, Sweden*

OBJECTIVES: Here, we evaluated the effect of the Effexor (N06AX16) patent expiry in Sweden. The aim was to see if adaptations, such as generic penetration, increased new prescriptions, or switches from other SNRIs, could be seen when evaluating all dispatches in the year before (2008) and after (2009) the patent expiry. **METHODS:** We used the CEBRxA database, which combines data from the national Swedish drug registry, with a public claims database for the South-West region of Sweden, comprising around 1.5 million individuals. For the generic penetration analysis, all prevalent patients were selected. For the longitudinal analysis, all patients who had made at least 2 dispatches of any antidepressant (N06A*) were selected and a 6 months washout-period was applied. Subsequently, all dispatches were annotated, at the ATC level, as either new (no other antidepressants within 105 days), add-on (specific antidepressant dispatched both before and after), switch (specific antidepressant dispatched before, but not after), or continuation (dispatched same ATC-code within 105 days). **RESULTS:** Of all N06AX16 dispatches in 2009, 81% corresponded to generic Venlafaxin, and the remaining 19% corresponded to branded Effexor. However, the prevalent patient counts decreased from 12,467 in 2008, to 12,248 in 2009. This trend was opposite to that of other SNRIs; generic Mirtazapine (N06AX11) and branded Cymbalta (N06AX21) both increased by three and 10 percent, respectively. Amongst the incident population, only minor differences were observed when comparing the proportion of dispatches with evidence of a new treatment, switch or add-on, between 2008 and 2009 for N06AX16. **CONCLUSIONS:** Al though generic penetration was quite efficient, we did not observe an increased proportion of patients switching to, or new prescriptions for, generic Venlafaxin during 2009. This can to some extent be explained by the expiry date on prescriptions, extending into 2009, while the decreasing prevalent patient population suggests additional dimensionality.

PMH68

DIFFERENTIAL USE OF EXTENDED AND INSTANT RELEASE QUETIAPINE: A NATURALISTIC STUDY OF FINNISH INPATIENTS WITH SCHIZOPHRENIA SPECTRUM OR BIPOLAR DISORDERS

Hallinen T[1], Soini EJ[1], Granström O[2], Ovaskainen Y[3], Leinonen E[4], Koponen HJ[5], Hänninen K[6]
[1]*ESiOR Ltd, Kuopio, Finland,* [2]*AstraZeneca Nordic MC, Södertälje, Sweden,* [3]*AstraZeneca Finland, Espoo, Finland,* [4]*University of Tampere, Tampereen yliopisto, Finland,* [5]*Kuopio University Hospital, Kuopio, Finland,* [6]*South Karelia Central Hospital, Lappeenranta, Finland*

OBJECTIVES: Extended release (XR) and instant release (IR) quetiapine differ with respect to e.g. dosing, titration, and plasma concentration profiles. This could result in differential XR and IR use in schizophrenia and bipolar disorder (BD). We compared the use of XR and IR in a naturalistic, inpatient setting. **METHODS:** We retrospectively collected registry data among patients discharged between June 2008-June 2010 from a Finnish psychiatric hospital. Patients with a schizophrenia spectrum (SCZ; ICD-10 codes F20-F29) or a BD (F30-F31) diagnosis who used quetiapine in hospital were included in the study. Descriptive statistics and significance tests of differences between groups were performed. To assess the profile of XR- vs. IR-patients, logistic regressions were performed. **RESULTS:** Amongst 156 patients included (58% male), 43 used XR, 58 used IR, and 55 used both quetiapine formulations; 102 patients (65%) were diagnosed with SCZ and 54 (35%) with BD; no significant differences in diagnosis between quetiapine formulations. The mean XR dose was significantly higher than that of IR (542mg versus 328mg; $p<0.001$). This was true also for the SCZ (XR: 593mg vs. IR: 338mg; $p<0.001$) and BD (XR: 466mg versus IR: 308mg; $p=0.009$) subgroups. 48% of all IR-patients used a mean dose ≤200mg, compared to 2% of XR-patients. IR was combined with injectable antipsychotic treatment whereas XR was not (12% vs. 0%; $p=0.019$). XR was associated with antipsychotic monotherapy to a higher extent than IR (44% vs. 28%; $p=0.08$). In the logistic regressions, XR use was significantly associated with decreasing age and prior XR use; IR use was associated with e.g. substance abuse. **CONCLUSIONS:** Among schizophrenia spectrum or bipolar disorder inpatients, quetiapine XR was used in significantly higher doses than IR. Compared to XR, IR was more often combined with other antipsychotics. Differential use of quetiapine formulations seemed partly dependent on patient characteristics.

PMH69

DEPRIVATION AND USE OF ATIPYCAL ANTIPSYCHOTICS IN SCHIZOPHRENIA

Moisan J[1], Lauzier S[1], Vanasse A[2], Lesage A[3], Courteau J[2], Fleury MJ[4], Gregoire JP[1]
[1]*Faculté de pharmacie, Université Laval, Québec, QC, Canada,* [2]*Université de Sherbrooke, Sherbrooke, QC, Canada,* [3]*Université de Montréal, Montréal, QC, Canada,* [4]*McGill University, Montréal, QC, Canada*

OBJECTIVES: To describe the use of atypical antipsychotics (AA) among individuals suffering from schizophrenia in a public managed healthcare system according to material and social deprivation. **METHODS:** We conducted a population-based cohort study using a spatiotemporal information system built with Quebec administrative health data. For four consecutive 2-year periods from 1998-2005, a cohort of inhabitants aged ≥18 years was built. Individuals were included in a cohort if they had a diagnosis of schizophrenia recorded in the hospital registry or in the physician consultations database during the 2-year period and if they were covered by the public drug plan during the year following the date of the 1st schizophrenia diagnosis in the period. Material and social deprivation were measured using indices built at a geographical level. Individuals in the 1st and 5th quintiles were the least and most deprived, respectively. Individuals were considered exposed to an AA if they obtained such a drug in the year following the date of 1st schizophrenia diagnosis. **RESULTS:** The proportion of individuals exposed to an AA in the year following the diagnosis of schizophrenia increased from a low 44% (15,386/34,765) in 1998-99 to a high 71% (25,555/35,771) in 2004-05. In terms of social deprivation, the proportion of those exposed to an AA among the least deprived and the most deprived were respectively 42% and 47% in 1998-99 and 67% and 73% in 2004-05. In terms of material deprivation, these proportions ranged from 44% and 45% in 1998-99 to 69% and 72% in 2004-05. **CONCLUSIONS:** The proportion of individuals exposed to AA has increased over the years 1998-2005, both among the least and the most socially and materially deprived suggesting that the most deprived may have a better access to AA. This may be due to free access to medication in Quebec's publicly managed healthcare system.

PMH70

ECONOMIC IMPACT OF FOCAL EPILEPSY IN SPAIN: RESULTS OF THE ESPERA STUDY

Villanueva V[1], Brosa M[2], Doz M[3], Aguade AS[4], Levy-bachelot L[5], Lahuerta J[6], Hernández-Pastor LJ[7]
[1]*University Hospital La Fe de Valencia, Valencia, Spain,* [2]*Oblikue Consulting, Barcelona, Spain,* [3]*Cemka, Bourg la Reine, France,* [4]*Cemka Eval, Bourg la Reine, France,* [5]*Laboratoire Glaxosmithkline, Marly Le Roi, France,* [6]*GlaxoSmithKline Spain, Madrid, Spain,* [7]*Glaxosmithkline, Tres Cantos, Madrid, Spain*

OBJECTIVES: Epilepsy produces a significant burden on health care systems worldwide. Focal epilepsy represents approximately 70% of all types of epilepsy. The International League Against Epilepsy (ILAE) defined drug-resistant epilepsy in 2009 as a failure to achieve sustained seizure freedom, despite adequate trials of two tolerated and appropriately chosen and used antiepileptic drug (AED) schedules whether as monotherapies or in combination.The objective of this study was to estimate the economic impact of AED resistance in Spanish patients with focal epilepsy. **METHODS:** A multicentre, observational, cross-sectional, retrospective study was conducted in Spain among a representative sample of adults with focal epilepsy receiving at least two AEDs in combination, regardless of the seizure-free status. Investigators were hospital-based general neurologists and epileptologists; patients were consecutively included. Health resources utilisation data were collected over a retrospective 12-month period. Estimation of direct costs was calculated by multiplying unitary costs (at National Health System- NHS- values for the year 2010) by resource use from a NHS perspective. **RESULTS:** A total of 263 evaluable patients were analysed (out of 304 recruited patients, 86.5%). Responsiveness to AED treatment was assessed: 71% of the patients were AED resistant, 24% achieved seizure freedom and 5% were undefined. On average, resistant patients received more AEDs compared to seizure-free patients: 2.7 versus 2.4, respectively ($p=0.0037$). Annual costs for AED resistant and seizure-free patients were 4419€ and 3228€ respectively (37% increase per patient/year; $p=0.0273$). Drug costs (57%) and hospitalisation costs (33%) accounted for 90% of the incremental costs of AED resistant patients. **CONCLUSIONS:** Results suggest that drug resistant epilepsy is associated with higher health care use and consequently with higher costs, thus representing a considerable burden to the National Health System.

PMH71

THE IMPACT OF ONCE-DAILY EXTENDED-RELEASE QUETIAPINE FUMARATE (QUETIAPINE XR) ON LENGTH AND COSTS OF HOSPITALISATION OF PATIENTS WITH SCHIZOPHRENIA OR BIPOLAR DISORDER

Locklear JC[1], Wahlqvist P[2], Gustafsson U[3], Udd M[3], Fajutrao L[3], Eriksson H[3]
[1]*AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA,* [2]*AstraZeneca, Mölndal, Sweden,* [3]*AstraZeneca, Södertälje, Sweden*

OBJECTIVES: Rapid titration of extended-release quetiapine fumarate (quetiapine XR) allows an effective dose to be reached by Day 2 in schizophrenia and bipolar mania, and Day 4 in bipolar depression (versus Day 4 or later with quetiapine immediate release [IR]). This study evaluates the impact of quetiapine XR on length and cost of hospitalisation in patients with schizophrenia or bipolar disorder, compared with quetiapine IR, using Premier Perspective™ Inpatient Hospital database data. **METHODS:** Inpatient discharges classified within diagnosis-related group 430 (psychoses), prescribed either quetiapine XR or IR, were identified. Evaluable patients had an ICD-9 diagnosis of schizophrenia or bipolar disorder (295.0x, 296.0x, 296.1x, 296.4x, 296.5x, 296.6x, 296.7x or 296.8x). Impact of the XR formulation on length and cost of hospitalisation was assessed using multiple logistic regression (GENMOD procedure), adjusting for patient and hospital characteristics. The data were not normally distributed, therefore log-transformed data were used. **RESULTS:** In total, 30,429 discharges between January 1, 2008 and June 30, 2009 were analysed. GENMOD analyses showed that patients who received quetiapine XR had significantly reduced hospitalisation length (10.7% estimated reduction, $p=0.001$) and cost (9.5% estimated reduction, $p<0.001$), compared with patients who received quetiapine IR. These rates correspond to -1.0 days (10.7% of 9.2 days) and -US$531 (9.5% of US$5588) per patient, based on least squares mean estimations of length and cost of hospitalisation in patients treated with quetiapine IR. Evaluation of patient sub-populations indicated that the significant reduction in length of hospitalisation for quetiapine XR versus IR was driven mainly by patients with bipolar disorder, whereas the significant reduction in costs was driven mainly by patients with schizophrenia. **CONCLUSIONS:** Inpatient use of quetiapine XR in patients with schizophrenia or bipolar disorder is associated with significantly reduced length and cost of hospitalisation, possibly due to the faster titration schedule for quetiapine XR versus IR.

PMH72

THE IMPACT OF ONCE-DAILY EXTENDED-RELEASE QUETIAPINE FUMARATE (QUETIAPINE XR) ON LENGTH OF HOSPITALISATION OF PATIENTS WITH ACUTE BIPOLAR MANIA

Bonafede M[1], Locklear JC[2], Wahlqvist P[3], Fajutrao L[4], Szamosi J[4], Pan K[5], Eriksson H[4]
[1]Thomson Reuters, Andover, MA, USA, [2]AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA, [3]AstraZeneca, Mölndal, Sweden, [4]AstraZeneca, Södertälje, Sweden, [5]Thomson Reuters, Cambridge, MA, USA

OBJECTIVES: Rapid titration schedule of extended-release quetiapine fumarate (quetiapine XR) for acute bipolar mania means an effective dose can be reached by Day 2 (versus Day 5 with quetiapine immediate release [IR]). This study evaluates the impact of quetiapine XR on length of hospitalisation in patients with acute bipolar mania, compared with quetiapine IR, using Thomson Reuters MarketScan® Hospital Drug Database data. **METHODS:** Inpatient discharges with an ICD-9 diagnosis of acute bipolar mania (296.0x, 296.1x, 296.4x or 296.6x), receiving quetiapine XR or IR, were identified. The impact of the XR formulation on length of hospitalisation was assessed using a generalised linear model, adjusting for patient and hospital characteristics. Length of hospitalisation data were not normally distributed, therefore log-transformed data were included. A post hoc sensitivity analysis evaluated length of hospitalisation (excluding an outlier quetiapine XR patient, with a length of stay 3x higher than the second longest). **RESULTS:** In total, 3088 discharges between July 1, 2007 and August 31, 2010 were analysed. Modelled results showed that treatment with quetiapine XR reduced the length of hospitalisation by 6.7% compared with IR (p=0.11), which corresponds to 0.6 fewer days in hospital (6.7% of 9.6 days), based on least squares mean estimations of length of hospitalisation in patients treated with quetiapine IR. With the outlier excluded, quetiapine XR significantly reduced the length of hospitalisation by 9.6% compared with IR (p=0.02), corresponding to 0.9 days (9.6% of 9.6 days). **CONCLUSIONS:** Inpatient use of quetiapine XR in patients with acute bipolar mania may be associated with reduced length of hospitalisation, possibly due to the faster titration schedule for quetiapine XR versus IR. Given the high costs associated with hospitalisation, a reduction in length of stay of approximately 7 to 10% could represent a non-trivial cost reduction and potential savings.

PMH73

INCREASING USE OF MEDICATION FOR TREATMENT OF ATTENTION-DEFICCIT/HYPERACTIVITY DISORDER (ADHD) IN GERMANY BETWEEN 2003 AND 2009

Schlander M[1], Schwarz O[1], Trott GE[2], Banaschewski T[3], Scheller W[4], Viapiano M[5], Bonauer N[6]
[1]Institute for Innovation & Valuation in Health Care, Wiesbaden, Germany, [2]University of Wuerzburg, Aschaffenburg, Germany, [3]University of Heidelberg, Mannheim, Germany, [4]Verband der Ersatzkassen (vdek), Stuttgart, Germany, [5]KV BaWue, Karlsruhe, Germany, [6]KV Baden-Wuerttemberg, Karlsruhe, Germany

OBJECTIVES: Between 2003 and 2009, psychostimulant prescriptions in Germany increased 2.75-fold. During the same period, administrative prevalence of ADHD in Nordbaden/Germany grew from 0.53% (overall; age group 6-12 years, 4.74%; age 13-17 years, 1.73%, in 2003) to 0.95% (overall; 8.02% and 4.21%, respectively, in 2009). In our earlier analyses for year 2003, we did not identify overprescribing. The present analysis revisits the use of medication in children and adolescents with ADHD in light of its recent increase. **METHODS:** The complete claims database of the organization of physicians registered with statutory health insurance [SHI] (Kassenaerztliche Vereinigung, KV) in Nordbaden/Germany was available for analysis, covering the total regional population enrolled in SHI (>2.2 million). Data were available for calendar years 2003 to 2009 and were combined with prescription data from the SHI in order to create a patient-centered database enabling health care utilization research. **RESULTS:** During the observation period, the use of medication among patients diagnosed with ADHD (in Germany, methylphenidate and atomoxetine) increased continuously in children age 6 to 12 years, from 32.5% (2003) over 35.3% (2006) and 40.9% (2009), whereas the increase flattened in adolescents (45.7% in 2003; 53.9% in 2006, and 54.3% in 2009). Male patients and patients with externalizing comorbidities, in particular conduct disorder, were more likely to receive medication (peak among male adolescents with hyperkinetic conduct disorder: 56.9% in 2003; 60.0% in 2006; 59.5% in 2009). The nonstimulant, atomoxetine, was prescribed rarely (overall, 3.1%versus 38.2% of patients with ADHD), but used more often in adolescents with externalizing comorbidity (up to 9.7% in male adolescents, 2009). Compared to these numbers, only few control patients without a diagnosis of ADHD (total number, 29) received psychostimulants in 2009. **CONCLUSIONS:** Although medication use grew faster than the number of cases diagnosed with ADHD, our data provide no evidence of overprescribing.

PMH74

IMPACT OF AGE AND GENDER IN THE PHARMACEUTICAL EXPENDITURE OF ANXIOLYTICS IN PRIMARY HEALTH CARE

Guadalajara-Olmeda N, De la Poza-Plaza E, Barrachina-Martínez I, Vivas-Consuelo D
Universitat Politècnica de València, Valencia, Valencia, Spain

OBJECTIVES: Study the prescription of anxiolytics in Primary Health Care measured by the number of daily doses prescribed (DDD) to each patient (adjusting for age and gender) in order to quantify the pharmaceutical expenditure of anxiolytics. **METHODS:** Descriptive analysis of the anxiolytics prescribed during 2010 at four districts of Primary Health Care, with an assigned population of 747,566. Population was classified in four groups attending to the DDD prescribed: non-consumers (0 DDD), incidental consumers (1-30DDD); regular consumers (31-180DDD); long term users (>180DDD). Then, these groups were arranged by age and gender. Finally regression analysis was applied, where the pharmaceutical expenditure in Primary Health Care was explained through the gender. **RESULTS:** The 14% of the total population were users of anxiolytics. It was observed a higher expenditure of women's than men. Also the expenditure increases significantly with the age and also by groups of DDD prescribed. The group of incidental consumers shows the greater difference at age 15-55 years. In particular, women consumed 1.64 times more than men. In the group of regular consumers, the greater difference is shown at the age 30-66 years (women consumed 1.86 times than men). The long term consumer group shows a greater difference at the age 45-77. (Women consumed 2.5 times more than men). Two models of regression were obtained (male/female). The models confirmed the previous results, and let us quantified the expenditure by age and gender. **CONCLUSIONS:** The study shows the difference of pharmaceutical expenditure of anxiolytics by gender and age in Primary Health Care. It is important to analyze the causes (physical conditions and also psychological and labor conditions or a combination of them) in order to provide public health recommendations to the National Health System.

PMH75

PHYSICIAN DIFFERENCES BETWEEN ITALY AND GERMANY: THE TREATMENT OF OPIOID DEPENDENCE WITH SUBSTITUTION THERAPY

Severt J, Tkacz J, Ruetsch C
Health Analytics, LLC, Columbia, MD, USA

OBJECTIVES: Substitution therapy is commonly used across the world for the treatment of opioid dependence (OD), yet little evidence exists examining country-specific differences between acceptance and effectiveness of this treatment. The purpose of this study was to examine differences between physician experiences and attitudes regarding substitution therapy among a sample of OD treatment providers in Germany and Italy. **METHODS:** A telephonic survey, initiated by the Italian Federation of Operators of Dependences Departments and Services, examining opioid substitution therapy among treating physicians was administered across two countries: Germany (n=152) and Italy (n=100). **RESULTS:** German physicians treated more than 3 times as many patients than Italian physicians (808.09 vs. 237.16; t = 9.79, p < 0.05), but Italian physicians treated twice as many with substitution therapy (10.91 vs. 5.00; t = -7.53, p < 0.0001). Italian physicians placed more importance on a number of key factors when deciding to treat patients with substitution therapy, including substitution treatment history, patient medication requests, OD severity, and drug-drug interaction profile of the treatment medication (p's < 0.05). Italian physicians are more satisfied with treatment options (7.81 vs. 5.88; t = -6.70, p < 0.0001) and believe their patients feel more satisfied with these options (7.86 vs. 5.73; t = -8.01, p < 0.0001) than their German counterparts. Finally, Italian physicians feel that municipal drug policies facilitate patient entry into substitution therapy (2.48 vs. 2.99; t = 3.83, p < 0.001) and that these policies make physicians more willing to treat patients with substitution therapy (2.67 vs. 3.51; t = 5.91, p < 0.0001). **CONCLUSIONS:** There are key differences in physician attitudes and experiences regarding substitution therapy across EU countries, suggesting that the diversity in health care policies across countries may explain the greater satisfaction of Italian physicians to use substitution therapy.

PMH76

PATTERNS AND DETERMINANTS OF SICKNESS ABSENCE AMONG USERS OF ANTIDEPRESSANTS IN A DANISH WORKING POPULATION

Gasse C[1], Chollet J[2], Petersen L[1], Saragoussi D[2]
[1]Aarhus University, Aarhus C, Denmark, [2]Lundbeck SAS, Issy Les Moulineaux Cedex, France

OBJECTIVES: To describe the patterns and determinants of sickness absence (SA) among users of antidepressants in the Danish working population. **METHODS:** Persons starting antidepressant use in 2004 or 2005, aged 18-64 years and in the workforce during the week prior to the first antidepressant prescription (index prescription, IP) were identified from a representative 25% sample of the Danish population by linking Danish national registries. Only SA >2 weeks are centrally registered in Denmark and could be assessed. Time-to-event and Cox regression analyses were performed to identify predictors of SA during the year following the IP, based on previous history of SA and clinical and socio-demographic baseline characteristics. **RESULTS:** The cohort comprised 26,741 persons (59.6% women). The prevalence of SA increased from 36.0% during the year prior to 46.6% in the year after the IP. The mean duration of first SA episodes after the IP was 19.7 weeks (SD=17.6); 68.5% of individuals on SA received cumulative SA payments for >8 weeks and 34.7% for >26 weeks. The incidence of SA increased from approximately 6 months prior to the IP, and peaked during the week after, affecting 30% of the individuals during this period. Almost 70% of persons with a SA in the year before the IP were on SA during the first week afterwards compared to <10% of those without previous SA. SA at any time during the year prior to the IP increased the risk of SA by up to 3-fold. Clinical and socio-demographic baseline characteristics were only modest predictors of SA after the IP. **CONCLUSIONS:** SA was prevalent in persons starting a new episode of antidepressant use, with SA often lasting longer than 8 weeks. Previous SA was the strongest predictor of subsequent SA in this study.

PMH77

PRESCRIPTION PATTERN EVALUATION FOR BIPOLAR DISORDER IN A TREATMENT FACILITY IN INDIA

Nagappa AN[1], Kumar M[1], Noorunnisa S[1], Bhandary PV[2], Veerupaksh D[2], Balakrishnan R[3]
[1]Manipal College of Pharmaceutical Sciences, Manipal, Karnataka, India, [2]DR. A. V. Baliga Memorial Hospital, Udupi, Karnataka, India, [3]University of Michigan, Michigan, MI, USA

OBJECTIVES: There is a paucity of literature examining pharmaceutical care in bipolar patients in India. This study examined prescribing patterns and associated pharmaceutical care among bipolar disorder patients in a South Indian Psychiatric Hospital. **METHODS:** A prospective observational study was carried out in patients with bipolar disorder in a mental health specialty hospital in Udupi, india. The patients were identified by medical case record reviews during study period. From

the medical records of the enrolled patients, prescriptions were analyzed. Relevant patient information such as gender, age, and data concerning psychotropic prescribing patterns such as type of medication, route of administration, dose and frequency were collected and evaluated for prescription patterns and associated pharmaceutical care. **RESULTS:** Among the 60 bipolar patients enrolled during the study period from January 2011 to April 2011, majority of the patients (78.3%) were prescribed with antipsychotics, with olanzapine (25%) and resperidone (23.3%) being the two most common drugs followed by sedatives (73.3%), with clonazepam (38.3%) being the most common drug. A total of 68.3% of patients were prescribed with Lithium as the most common mood stabilizer. Among the patients (43.3%) prescribed with antidepressants, the combination of fluoxetin and amitriptyline was most common (23.3%) followed by fluoxetin alone (11.6%).Only 9 patients (15%) were prescribed with divalproex sodium, an anticonvulsant. **CONCLUSIONS:** This study showed that antipsychotics and sedatives were the two most commonly prescribed drugs in bipolar patients with lithium being the most widely prescribed mood stabilizer. The quality of pharmaceutical care is highly variable among patients with bipolar disorders, even in a specialty treatment setting.

PMH78

RETROSPECTIVE PRESCRIPTION ANALYSIS OF DEMENTIA IN A SOUTH INDIAN PSYCHIATRIC HOPITAL

Nagappa AN[1], Gayathri P[2], Kachappally S[3], Devaramane V[4], Bhandary V[4], Balkrishnan R[5]
[1]*Manipal College of Pharmaceutical Sciences, Manipal, Karnataka, India,* [2]*Manipal Univeristy, Manipal, India,* [3]*Manipal Univeristy, Manipal, Karnataka, India,* [4]*Dr A V Baliga Memorial Hospital, Udupi, Karnataka, India,* [5]*University of Michigan, Michigan, MI, USA*

OBJECTIVES: The aim of the study is to investigate the use of medications prescribed to dementia patients in a secondary care hospital **METHODS:** A retrospective chart review method was performed in patients with diagnosis of dementia for the duration of six months. The relevant information related to the study objectives such as demographic details, type of medication, dose and frequency etc has been collected. The patient who has come for follow up during the study period has also been included to find out any outcomes **RESULTS:** Out of 30 patients included in the study, 63.3% were females and 36.7% were males. Most of the patients belong to the age group of 60-80 years. On prescription pattern analysis, it was found that 86.7% of the patients were on donepezil, cholinesterase inhibitors. Among antipsychotics Quetiapine was the most commonly used atypical antipsychotic. Five (16.7%) patients were on memantine where as 4 (13.3%) patients were on combination of donepezil and memantine. On follow up it was found that in three patients who was on donepezil has been changed to a combination of donepezil and memantine. Whereas in other two patients the dose of the donepezil has been increased. As a result of improvement seen in two patients donepezil was stopped and memantine was continued and in the other patient who has been on the combination of donepezil and memantine has been tapered gradually and stopped as there was a marked improvement seen. In this study, we could also find prescription error in 13.33% (4) of the prescription related to the overdose of donepezil **CONCLUSIONS:** In a developing country like India, dementia still remains as an underrecognized public health burden. Our study depicts a picture of usage of antidementia drugs, it shows that further research to be done in dementia patients related to cost effectiveness

Mental Health – Research On Methods

PMH79

THE IMPACT OF COMPARATIVE EFFECTIVENESS RESEARCH ON HEALTH AND HEALTH CARE SPENDING

Basu A[1], Jena AB[2], Philipson TJ[3]
[1]*University of Washington, Seattle, WA, USA,* [2]*Massachusetts General Hospital, Boston, MA, USA,* [3]*University of Chicago, Chicago, IL, USA*

OBJECTIVES: Driven by rising costs of health care and concern that much of this spending could be reduced without detriment to health, comparative effectiveness research (CER) has been offered as a means to identify what works and does not work in health care. Little conceptual and empirical efforts have been made, however, to quantitatively assess the impact of CER on health and health care spending. We interpret CER as infusing publicly subsidized evidence on product quality into health care markets, shifting the relative demand for products in CER studies. We analyze how these shifts in demand affect health and health care spending, allowing for the possibility that "winners" of CER may be both more demanded by patients and doctors as well as more favorably covered by payers. We also analyze how CER may either raise or lower overall health when treatments have heterogeneous effects across patients, but payers respond with product-specific coverage policies. **METHODS:** We calibrate the effects of product-specific coverage policies for a major CER study for antipsychotics, the CATIE trial. **RESULTS:** We find that such policies would have led to a decrease in overall health and value by inducing some patients to switch away from treatments that were effective for them towards winners of the CER. **CONCLUSIONS:** Our overall conclusion is that CER may not always have the intended effects when the market responds to the CER and patient specific effects of treatments are present.

PMH81

COST-EFFECTIVENESS ANALYSIS OF ANTIDEPRESSANTS BY THE IQWIG IN GERMANY

Akmaz B, Kessel-Steffen M, Friede M, Weidenauer H, Flürenbrock W
Lundbeck GmbH, Hamburg, Germany

OBJECTIVES: German HTA-Agency (IQWIG) has published its preliminary report plan for Order G09-01 "Cost-benefit analysis of venlafaxine, duloxetine, bupropion and mirtazapine in comparison to other prescription drug treatments" (version 1.0, updated 05-09-2011). This report plan provides important indicators, on how and to what extent innovative drugs are to be reimbursed by German statutory health insurances (SHI). **METHODS:** IQWIG conducts a cost-benefit analysis that can be divided into five steps with main focus on Mixed Treatment Comparison (MTC). The individual steps in the cost-benefit analysis are largely dependent upon one another, since the results of one step serve as the foundation for the next step of the analysis. It is critical to note that IQWIG compares the four individual antidepressants to active agent categories such as serotonin reuptake inhibitors (SSRIs), without having previously conducted a benefit analysis for these active agent groups. **RESULTS:** Preliminary report with the provisional assessments is expected in the 3rd quarter of 2011. At present, essential information and specifications of the methodical approach are still missing. Each of these steps yields considerable methodological challenges and can significantly influence the results of the cost-benefit analysis. The MTC method, in particular, must be transparently described. Only in this manner, will it be possible to prevent uncertainties after every step from adding up to an invalid overall result. **CONCLUSIONS:** When MTC do not present relevant differences, or present them inadequately, this has significant effects on the assessment of therapeutic superiority, as well as on the appropriateness of the costs within the scope of the cost-benefit analysis. The result of such a cost-benefit analysis would be that the benefits and additional benefits of new drugs are levelled and the price level for modern antidepressants is decreased for Germany in future.

PMH82

EXAMINING VARIABILITY IN DEPRESSION AMONG PRE-RETIREES: INNOVATIVE ANALYTIC METHODS APPLIED TO OBSERVATIONAL DATA

Stull DE, Houghton K
RTI Health Solutions, Manchester, UK

OBJECTIVES: To apply innovative methods to observational data to explore variability in depression scores over 12 years and examine whether there are subsets of individuals with different trajectories of change. **METHODS:** Latent Growth Modeling (LGM) and Growth Mixture Modeling (GMM) analyses were applied to observational data collected over a 12-year period. Data was obtained from the RAND version of the Health and Retirement Survey (HRS), consisting of N = 5090 individuals aged 51 - 61 years at the time of recruitment. Scores on an 8-item version of the Center for Epidemiological Studies–Depression Scale (CES-D) were examined. LGMs were conducted to determine the level of variability in depression scores over the 12-year period. When considerable variability was identified, GMMs were conducted to assess whether there were subsets of individuals with differential changes. **RESULTS:** LGMs showed an intercept (first assessment point) score of 0.75 ("no depression") on the CES-D, which increased to 1.3 ("sub-threshold depression") at year 12. Substantial variability was found around the mean intercept and slope of change. GMMs identified three subsets of individuals with differential slopes of change. The largest subset (83% of the sample) had a mean intercept of 0.22 and a 12-year score of 1.0 ("no depression"). A smaller subset (13.7%) had a mean intercept of 2.5 and showed no change over the 12-year period ("stable, sub-threshold depressed"). The smallest subset (3.3%) had a high mean intercept (6.0) and showed a decrease in depression scores (4.0 at year 12; "improved, actively depressed"). Post hoc analyses showed that these three classes were significantly different in terms of gender, self-reported health, whether health limits their work or activities, and activities of daily living **CONCLUSIONS:** Examining highly variable data can yield insights about subsets of respondents who show different levels of initial depression and different trajectories of change.

PMH83

ESTIMATING UTILITIES IN SCHIZOPHRENIC AND BIPOLAR PATIENTS FROM DISEASE-SPECIFIC OR GENERIC INSTRUMENTS ASSESSING PATIENTS' HEALTH STATES: WHERE ARE THE DIFFERENCES?

Cuervo J[1], Rebollo P[1], Maurino J[2], Cordero L[2], Castejón N[1]
[1]*BAP Health Outcomes Research, Oviedo, Spain,* [2]*AstraZeneca, Madrid, Spain*

OBJECTIVES: To compare the utility values estimated from a disease-specific instrument with those obtained from the EQ5D and SF6D in a sample of patients suffering from a psychotic disorder. **METHODS:** Data on patients diagnosed with schizophrenia or bipolar disorders was gathered in a multicentre, cross-sectional study. Patients completed both generic and specific measures: the TooL questionnaire, EQ-5D -VAS and TTO-, SF6D and the Clinical Global Impression -CGI-SI-. As it has been recently published, a multi-attribute utility function (MAUF) for the Spanish version of the TooL questionnaire was estimated. Differences in utility scores regarding CGI-SI- were tested with ANOVA and Kruskal-Wallis test. The Spearman correlation coefficient (rho), intraclass correlation coefficient and Wilcoxon rank test were calculated. Finally, the Bland-Altman method was followed for concordance assessment. **RESULTS:** In total, 37 patients with schizophrenia and 33 with bipolar disorder were assessed. Mean age (SD) was 41.88 (11.08), 62.9% were male and CGI-SI- was: borderline-mildly (50%), moderately (35.7%) and markedly-extremely ill (13.3%). Significant differences according to CGI-SI were found in all utility measures ($p<0.05$). Although all associations were high (rho range: 0.657-0.996), differences between the TooL scores and generic scales (SF6D and EQ5D; $p<0.001$) were found. Also between EQ5D and SF6D remarkable differences were found ($p<0.001$). Generic measures tended to overestimate at least 80% of health states in comparison to the TooL values. Finally, a low concordance was detected, even between generic measures. **CONCLUSIONS:** Although all measures of health values are highly associated, a low concordance has been evidenced. Utility values obtained from the TooL questionnaire could be used to complement the information from the EQ5D or SF6D. Finally, the specific measure could be even considered

to test the robustness of the incremental effectiveness in economical analysis carried out in patients with schizophrenia or bipolar disorders.

PMH84

THE CORNELL-BROWN SCALE FOR QUALITY OF LIFE IN DEMENTIA: SPANISH ADAPTATION AND VALIDATION

Lucas-Carrasco R[1], Gomez-Benito J[1], Rejas J[2], Ott BR[3]
[1]University of Barcelona, Barcelona, Spain, [2]Pfizer España, Alcobendas/Madrid, Spain, [3]Warren Alpert Medical School of Brown University, Providence, RI, USA

OBJECTIVES: The objective of this study was to culturally adapt and validate the Cornell-Brown Scale (CBS) for Quality of Life (QoL) in Dementia into Spanish. **METHODS:** The original CBS was translated into Spanish by mean of a conceptual equivalence approach, including forward and backward translations in duplicate. Subjects with mild-to-moderate dementia were recruited and interviewed by a psychologist who was trained in administering questionnaires to obtain sociodemographic information, health perceptions, depressive symptoms (GDS-15), functional ability (Barthel Index), dementia severity (MMSE), specific QoL (CBS) and generic QoL (WHOQOL-BREF). Participants were included if they had a diagnosis of dementia according to DSM-IV criteria, a MMSE scoring $\geq$ 9, were living at home, and had a known and stable caregiver with whom were living or had daily contact. Acceptability, reliability, and validity were assessed using standard psychometric methods. Exploratory factor analysis (EFA) was applied to analyze the dimensional structure of the scale for the first time. **RESULTS:** A total of 100 persons with dementia (66% female; 79.18 years) were recruited: 61% Alzheimer's disease; 17% vascular dementia; 14% mixed dementia; and 8% other dementia. Internal consistency reliability was good (Cronbach's α= 0.87). A priori hypotheses about the relationship between CBS and the WHOQOL-BREF psychological domain and GDS-15 were confirmed, indicating good criteria validity; Pearson's r= 0.570 and -0.537, respectively. Discriminant validity was confirmed by the ability of the scale to significantly differentiate between healthy and unhealthy and depressed and non-depressed participants; but not between mild and moderate dementia. The EFA showed a five-factor solution which accounted for 63.9% of the total variance of CBS. **CONCLUSIONS:** The Spanish version of CBS showed good psychometric properties of validity and reliability to explore QoL in patients with mild-to-moderate dementia in Spain. The factor structure of the CBS is reported for the first time.

Muscular-Skeletal Disorders – Clinical Outcomes Studies

PMS1

TUMOR NECROSIS FACTOR ALPHA INHIBITORS FOR THE TREATMENT OF ACTIVE ANKYLOSING SPONDYLITIS

Ubago R[1], Castillo MA[1], Marín R[2], Flores S[3], Rodríguez R[1]
[1]Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, Seville, Andalucia, Spain, [2]Hospital Universitario Virgen del Rocío, Seville, Andalucia, Spain, [3]Andalusian Agency for Health and Technology Assessment, Seville, Andalucia, Spain

OBJECTIVES: To compare the efficacy and safety of tumour necrosis factor alpha (TNF) inhibitors in the treatment of active ankylosing spondylitis (AS), in adult patients naïve to biologic therapy. **METHODS:** A literature search was performed, first focused on identifying health technology assessment reports (HTAR), meta-analysis and systematic reviews. The databases searched were MEDLINE, EMBASE, CRD, and the Cochrane Library. An exhaustive search of randomized controlled trials (RCTs) that compared directly the TNF-inhibitors was also carried out in MEDLINE and EMBASE. Both searches covered until November 2010. Two authors independently selected the studies, assessed the quality, and performed the data extraction, with disagreements resolved by a third reviewer until consensus was obtained. In addition, an analysis of adjusted indirect comparisons (AIC) against a common comparator was done using the method of Bucher et al. and the software from the Canadian Agency for Drugs and Technologies in Health version 1.0. **RESULTS:** A HTAR was included, it compared the clinical efficacy of infliximab, etanercept and adalimumab associated with conventional treatment versus conventional treatment and it also compared TNF-inhibitors between them. Five RCTs were included to update the report. One study directly compared infliximab and etanercept and the other four RCTs evaluated each of the TNF-inhibitors (infliximab, etanercept, adalimumab and golimumab) versus placebo. In the AIC analysis performed considering all the evidence available, no statistically significant differences in the ASAS20 response between infliximab, etanercept, adalimumab and golimumab were found. Also, there were no statistically significant differences between the TNF-inhibitors in the rate of serious infections or withdrawals due to adverse events. **CONCLUSIONS:** Only one RCT directly compares two TNF inhibitors. Therefore, in the absence of such trials, AIC are considered. No clinically relevant differences are observed in the efficacy and safety between infliximab, etanercept, adalimumab and golimumab in the treatment of adult patients with AS.

PMS2

RISK AND COST OF INFECTIONS IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH ANTI-TNF THERAPY IN ALBERTA, CANADA

Ohinmaa A[1], Thanh NX[1], Homik J[2], Barnabe C[3], Martin L[3], Barr S[3], Maksymowych W[2]
[1]Institute of Health Economics, Edmonton, AB, Canada, [2]University of Alberta, Edmonton, AB, Canada, [3]University of Calgary, Calgary, AB, Canada

OBJECTIVES: To evaluate the risk of infection and associated healthcare costs in Rheumatoid Arthritis (RA) patients treated with anti-Tumor Necrosis Factor (anti-TNF) therapy in Alberta, Canada. **METHODS:** RA patients initiating anti-TNF therapy between January 2004 and March 2009 in Edmonton and Calgary were followed prospectively to identify treatment efficacy and adverse events. Clinical and self-reported data was linked with provincial healthcare administrative databases. Infections (any and severe) were identified by using ICD 9 and 10 diagnosis codes. We used Cox-regression to assess the risk of infection and linear regression to assess the associated costs. **RESULTS:** The cohort consists of 1,086 patients (70% female, mean age of 54 years) with a mean follow-up of 2.3 years. Seventy percent of patients (n=764) reported an infection during follow-up, while 4% (n=42) suffered a severe infection. Compared to patients on their first anti-TNF (n=731), patients who switched to another anti-TNF (n=212), patients on DMARD (n=75), and patients switched from DMARD to anti-TNF (n=68) had similar Hazard Ratios (HR) ($p>0.05$) for both any and severe infection. Pre-existing lung disease (HR=1.98, $p<0.001$) and heart disease (HR=1.42, $p=0.037$) increased, while male sex (HR 0.79, $p=0.005$) decreased the risk of any infection. The risk of a severe infection was increased by underlying anemia (HR=3.20, $p=0.018$) and in those with longer disease duration (HR=1.03, $p=0.032$), but was reduced in patients with university-level education (HR=0.34, $p=0.018$), and osteoarthritis (HR=0.37, $p=0.035$). In linear regression, Log(cost) was significantly associated with higher baseline HAQ score and longer disease duration and in patients who required a switch between anti-TNF agents for inefficacy or adverse events. **CONCLUSIONS:** The risk of any or severe infection did not differ significantly between treatment groups. Some pre-existing diseases increased while being male and having university education decreased the infection risk. Healthcare cost variations between the treatment groups were small.

PMS3

DIFFERENTIATION OF OSTEOPOROSIS TREATMENTS ACTION ON BONE REMODELING: PRINCIPAL COMPONENTS ANALYSIS OF BONE HISTOMORPHOMETRY PARAMETERS

Wan X, Zhao Y, Liu E, Burge RT
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: Osteoporosis is a disease with accelerated bone loss associated with an increased risk of fractures. Histomorphometry of bone biopsy specimens from postmenopausal women with osteoporosis measures bone remodeling activities which include both bone formation and resorption. This study compared the effects of two osteoporosis treatments (20 μg/day teriparatide vs. 10 mg/day alendronate) on bone remodeling using the principal components analysis (PCA) of bone histomorphometry parameters. **METHODS:** Postmenopausal women with osteoporosis treated with either teriparatide or alendronate and completed iliac crest bone biopsy at either the sixth or eighteenth month in the randomized, double-blind Forteo Alendronate Comparator Trial were included in the analysis (teriparatide: N=12; alendronate: N=9). Eighteen histomorphometric parameters were grouped into either the formation (13) or resorption (5) category. Within each category, the first principal component was estimated through the PCA and defined as the principal formation component (PFC) and principal resorption component (PRC). The summation of PFC and PRC was calculated to represent the overall level of bone turnover. The difference between PFC and PRC was computed to determine the imbalance between formation and resorption. **RESULTS:** The PFC accounted for 61.8% of total variance in the 13 formation parameters, and the PRC accounted for 70.4% of total variance in the 5 resorption parameters. The PFC was significantly higher in the teriparatide group than in the alendronate group (0.68 vs. -0.95, $p<0.0001$), while the PRC was significantly lower in the alendronate group (-0.47 vs. 0.32, $p<0.05$). The difference between the PFC and PRC was positive in the teriparatide group and negative in the alendronate group. **CONCLUSIONS:** In postmenopausal women with osteoporosis, teriparatide treatment stimulates both bone formation and resorption, and formation dominates resorption. Treatment with alendronate suppresses both bone formation and resorption, and resorption dominates formation.

PMS4

EFFICACY AND EFFECTIVENESS OF COLLAGENASE CLOSTRIDIUM HISTOLYTICUM FOR DUPUYTREN'S CONTRACTURE

Skodny P[1], Mackowiak JI[2], Peimer C[3]
[1]Auxilium Pharmaceuticals, Inc., Malvern, PA, USA, [2]Center for Outcomes Research, Nashville, TN, USA, [3]College of Human Medicine - Michigan State University, Marquette, MI, USA

OBJECTIVES: The objective was to determine if the effectiveness of collagenase clostridium histolyticum (XIAFLEX, CCH) in real-world settings is comparable to the efficacy demonstrated in the clinical trials. **METHODS:** A retrospective chart review was conducted at selected sites. Charts of each patient treated with CCH in 2010 were abstracted. Effectiveness results were compared to efficacy findings from the clinical registration trial (CORD-I)1 on 1) final contracture angle, 2) change in contracture, 3) final range of motion, and 4)change in range of motion, with means of 12°, 38°, 81°, and 37° respectively. The equivalence range was set at +/− 10°. **RESULTS:** 501 patient charts were abstracted from 10 sites. The average patient age was 65 years; 76% were male. The 95% confidence interval (C.I.) fell within the corresponding predefined equivalence range of +/− 10° for each of the 4 effectiveness measures (with means of 12°, 37°, 81°, and 37° respectively.) The effectiveness injections/joint rate was 1.08±0.32(n=629 joints) with a 95% C.I. of 1.05 to 1.11, This CI does not fall within the reported C.I. of 1.6 to 1.8 in published trials ($p<0.05$). The average number of (injection, manipulation, and follow-up) office visits/injection was 2.92±1.05 (n=620). **CONCLUSIONS:** CCH effectiveness findings were equivalent to those published for the CORD-I clinical trial, yet the effectiveness injections/joint rate was 36% lower than in the trial. Visits per injection cycle were also lower than in the published CORD-I trial. The number of CCH injections used in real-world settings may be lower because a) both patient/physician knew that active drug was administered; b) anesthesia was used at manipulation; c) patient focused treatment outcomes were used without the strict requirements of a clinical trial protocol.

PMS5

THE EFFECT OF ONE-TIME PHYSICAL THERAPY ON BIOCHEMICAL MARKERS OF BONE METABOLISM

Gombos G[1], Fekete J[1], Domján P[1], Schmidt B[1], Molics B[2], Boncz I[2]
[1]*University of Pécs, Zalaegerszeg, Hungary,* [2]*University of Pécs, Pécs, Hungary*

OBJECTIVES: A number of studies suggest that weight-bearing exercises have beneficial effects on bone and increases in BMD of the skeleton. In Hungary 900,000 people suffer from OP, there are 30,000 vertebral fractures, 51,000 other fractures in a year. The aim of this study was to measure if there is any direct, detected effect of one specific physiotherapy programme on biomechanical markers of bone metabolism. **METHODS:** Total of 50 young, healthy adults (age 25±2) were included without any disease or condition of the calcium and bone metabolism (using laboratory tests and Quantitative Ultrasound). Fifteen men and 15 women carried out specific exercises during 60 min, directed by physiotherapist; and 20 women performed 60 min steady walking in the same time. At the beginning and in the end of training programs laboratory tests were carried out to measure the level of bone-specific alkaline phosphate (BALP) and β-cross-laps value. Data were analysed by Wilcoxon tests applying SPSS statistic programme. **RESULTS:** In both groups a slight, statistically not significant decrease was detected in the value of BALP ($p=0.322$ vs. $p= 0.219$; rate of decrease in the target group 3.67%, in control group: 7.16%). Significant decrease was detected in the β-cross laps-values in all groups. In the target group the value of β-cross laps decreased with 23.13% ($p=0.0066$), in the control group with 53.2% ($p=0.0008$). No relationship was found between smoking, rheumatic diseases run in the family and BMD, but a medium relationship between regular exercise and BMD could be detected ($r=0.4392$). **CONCLUSIONS:** This study proved that the 60-minute, middle intensity, appropriate physiotherapy (even one-time) has an immediate effect on BALP level, in contrary β-cross-laps scores decrease significantly measured immediately after the training. So bone loss and at the same time bone formation started due to mechanical overload.

PMS6

A NETWORK META-ANALYSIS OF BIOLOGIC TREATMENTS IN TNF-IR RHEUMATOID ARTHRITIS PATIENTS

LeReun C[1], Neophytou I[2], De Vries R[3], Diamantopoulos A[2], Pompen M[4]
[1]*Independent Biostatistician, Carrigaline county, Cork, Ireland,* [2]*Symmetron Limited, Elstree, Herts, UK,* [3]*Roche, Woerden, Woerden, The Netherlands,* [4]*Roche, Woerden, Woerden, The Netherlands*

OBJECTIVES: Following the introduction of biologic DMARDs, clinicians have now a multitude of options for the treatment of RA patients with inadequate response to anti-TNFα. This study considers evidence on ACR response from randomised controlled trials of biologic treatments and employs a network meta-analysis to identify differences amongst them. **METHODS:** The study considers evidence for the following treatments: abatacept, anti-TNFα, rituximab, and tocilizumab. Pivotal studies were reviewed and ACR response was extracted for each of the above treatments. A network meta-analysis using a Bayesian approach was implemented in WinBUGS®. Fixed-effects and random effects models were explored. Initially, the development of the study considered all anti-TNFα treatments separately. However, there was limited evidence on ACR response for all of them in the specified patient subgroup (TNF-IR). This was considered an important factor for treatment efficacy since studies performed on DMARD-IR or MTX-IR population would include a subgroup of patients with less severe disease. A class effect was assumed for all anti-TNFα and ACR response from Smolen et. al (2009) was assumed to represent treatment efficacy of all anti-TNFs. **RESULTS:** For the base-case analysis, the result shows tocilizumab to have a significant benefit on ACR 20 response of patients. In ACR 50 all biologics have a similar profile. Rituximab becomes the most efficacious treatment in ACR 70. **CONCLUSIONS:** The study demonstrates that assuming an indirect comparison of biologics based on a network analysis, tocilizumab has better profile than the other biologics in ACR 20 and ACR 50 while rituximab is better in ACR 70. Further research is needed to produce evidence on ACR response for all treatments in TNF-IR population.

PMS7

THE OSTEOPOROTIC FRACTURE INCIDENCE IN ELDERLY WOMEN OF TAIWAN

Chang WL[1], Tang CH[2], Huang KC[2], Ling YL[3]
[1]*National Yang Ming University, Taipei, Taiwan,* [2]*Taipei Medical University, Taipei, Taiwan,* [3]*The University of Texas at Austin, Austin, TX, USA*

OBJECTIVES: This study aims to investigate the major osteoporotic fractures incidence in Taiwan from 2006 to 2009. **METHODS:** Using the inpatient and outpatient database of the National Health Insurance. Elderly Women (50-100 years) who had primary and secondary diagnosis of hip fracture (ICD9 code 820, 733.14), vertebral fracture (ICD9 code 805, 806, 733.13), wrist fracture (ICD9 code 813, 733.12), and other fracture (ICD9 code 807, 808, 810, 811, 812, 821, 823, 733.10, 733.11, 733.15, 733.16, 733.19) were identified and included in the study. Frequencies and incidences of each fracture by age were estimated, and the 4-year incidence trend was further evaluated. **RESULTS:** A total of 65,118 hip fractures, the most serious osteoporosis outcome, occurred during the study period and the incidence is increasing by 3-6% per year. We found a high annual incidence rate of clinical vertebral fracture in 4 consecutive years in Taiwan. The average rate was 1.43%, 1.51%, 1.59%, and 1.63% respectively. In addition, Wrist fracture and other fracture all increased slightly. Each type of fractures showed a steady increase in the age-adjusted incidence. **CONCLUSIONS:** The age-specific incidence rates of hip fractures and vertebral fractures were higher with increasing age, especially after 60 years of age. Compared with other countries, Elderly Taiwanese women also have a high incidence rate of hip and vertebral fracture. Our results clearly demonstrated that the effect of osteoporosis and osteoporotic fracture in Taiwan. We should take more active public health strategies in the rapidly aging society.

PMS8

PREVALENCE OF CLINICAL RISK FACTORS FOR FRACTURES IN THE CANADIAN MULTICENTRE OSTEOPOROSIS STUDY

Burge R[1], Ionnadis G[2], Adachi J[2], Papadimitropoulos M[3]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*McMaster University, Hamilton, ON, Canada,* [3]*Eli Lilly & Company, Unionville, ON, Canada*

OBJECTIVES: Low bone mineral density (BMD) is one of several important clinical risk factors (CRFs) for fractures. However, frequency distributions of individual and multiple CRFs have not been extensively reported. The study aim was to quantify the CRF profile in a Canadian population. **METHODS:** Data on CRFs were obtained from the Canadian Multicentre Osteoporosis Study (CaMos) database, a prospective and longitudinal cohort study following subjects for over10 years. Subjects with femoral neck BMD T-scores < -1.0 were selected and grouped as osteopenia ($-1.0 <$ T-score< -2.5), osteoporosis [OP] (T-score < -2.5), very-low BMD [VLBMD] ($-3.5 <$ T-score < -2.5), and extremely-low BMD [ELBMD] (T-score < -3.5). Frequencies of other CRFs (prevalent fracture, rheumatoid arthritis, glucocorticoid use, parental hip fracture, smoking status, alcohol consumption, recent falls) were estimated for BMD T-scores, by age and sex. **RESULTS:** Among low-BMD women, 2716 (85%) had osteopenia, 491 (15%) had OP; 460 and 31 had VLBMD and ELBMD, respectively. There were 635 low-BMD men (602, 33, 30, and 3 with osteopenia, OP, VLBMD, and ELBMD, respectively). OP prevalence increased by age in women (men): <4% (9%) in age 50-59 to 43% (44%) in age 70-79. In OP women, 21% had 1 previous fracture; 10% had 2+. Corresponding values for ELBMD women were 32% and 52%, respectively. The distribution of multiple CRFs among OP women was: 35%, 43%, 17%, 4%, and 1% for 0-4 additional CRFs. None had over four. In OP women with prevalent fracture, the distribution was 65%, 29%, 6%, and 1% for 1-4 additional CRFs. **CONCLUSIONS:** Among the low-BMD population in CaMos, 15% of women and 5% of men had OP, and over 30% also had prevalent fracture. Over 50% with OP and prevalent fracture also had at least one additional CRF. These data may inform estimates on potential fracture incidence and burden in the population.

PMS9

PREVALENCE OF SHOULDER OSTEOARTHISTIS AND TREATMENT IN A LARGE US MANAGED CARE POPULATION

Kozma CM[1], Bhattacharyya SK[2], Palazola P[2]
[1]*Research Consultant/Adjunct Professor, University of South Carolina, St. Helena Island, SC, USA,* [2]*DePuy Mitek, Inc, Raynham, MA, USA*

OBJECTIVES: To estimate the prevalence of shoulder osteoarthritis (OA) and its treatments. **METHODS:** Data from Thomson MarketScan (2005-2008), a large national managed care population database representing more than 500 million employer-based medical and pharmacy claims were analyzed. Annual prevalence was calculated as the number of continuously eligible patients who had at least one shoulder OA diagnosis divided by the total number of continuously eligible patients. Treatment prevalence was assessed for inpatient shoulder surgery, steroid injections, physical therapy and pain medication and was calculated as the number of patients receiving these treatment divided by the number of patients with a shoulder OA diagnosis. Prevalence percentages were presented descriptively by age group and overall. **RESULTS:** There were approximately 20 to 26 million continuously eligible patients in the data annually between 2005 and 2008. The overall prevalence of patients with at least one shoulder OA diagnosis was relatively stable over the years and ranged from 1.1 to 1.2%. In 2008, the shoulder OA prevalence by age group was: 0 to <18 – 0.01%; 18 to <40 – 0.21%; 40 to <65 – 1.55%; and 65 and greater – 4.16%. Shoulder surgery was most prevalent in the 40 to <65 age group (~1%), with around 2% prevalence in the 65 and greater age group. Physical therapy was most common in the <65 year old groups (16.2% to 14.8%), while 65 and older age group had around 8% prevalence. Steroid injections occurred in ~10% of the patients who were 18 or greater. Use of pain medications increased with age and ranged by age group from ~ 5% to 36%. **CONCLUSIONS:** The prevalence of a shoulder OA diagnosis was approximately 1.1%, with patients >65 age having the highest prevalence (>4%). Shoulder OA treatment related resource utilization showed significant use of drug therapy, physical therapy, and steroid use.

PMS10

EVALUATION THE RISK FACTORS OF SECOND HIP FRACTURES IN THE ELDERLY

Sebestyén A[1], Sándor J[2], Patzai B[3], Gõcze K[3], Kriszbacher I[3], Mintál T[3], Boncz I[3]
[1]*South-Trasdanubian Regional Health Insurance Fund Administration, Pécs, Hungary,* [2]*University of Debrecen, Debrecen, Hungary,* [3]*University of Pécs, Pécs, Hungary*

OBJECTIVES: The aim of the study is to evaluate the risk factors of second hip and femur fractures in patients aged over 60 years after initial hip fractures. **METHODS:** In this retrospective study the data derive from the financial database of the Hungarian National Health Insurance Fund Administration. The study includes patients over 60 years following primary treatment of femoral neck fracture (S7200) discharged from inpatient care institutions in 2000. Fractures that happened in hospitals were excluded from the analysis. The follow up period was 8 years. We evaluated data according to sex, age group, type of living place, type of hospital treated the primary fracture, type of primary femoral neck fracture, absence or presence of comorbidities, type of surgical intervention for primary fracture, and antiosteoporotic pharmacologic treatment after primary fracture. The effects of prognostic factors were evaluated by Cox proportional hazard regression analysis (HR, 95 % CI, p). **RESULTS:** Altogether 3638 patients were included into the study. During the observation period 323 second hip fracture (8,87 %) were identified. The following predictors (hazard ratios and p values) are listed: Sex (female/male): 1.516(0.010); Age group (70-79/60-69y): 1.350(0.058); (80-89/60-69y): 1.496(0.020); (90y-/60-69y): 1.666(0.067); Residency (capital/village): 1.445(0.072); (city/village): 1.022(0.888); (big city/village): 1.238(0.219); Hospital (capital/county): 0.970(0.878); (city/county): 1.228(0.156); (clinic/county): 1.105(0.598); Fracture type (lateral/dis-

placed): 0.929(0.712); (undisplaced/displaced): 0.847(0.249); Comorbidities (no/yes): 0.963(0.836); Surgical types (arthroplasty/osteosynthesis): 1.405(0.026); Antiosteoporotic treatment (<2years/none): 0.512(0.006); (2years/none): 0.529 (0.004). **CONCLUSIONS:** The risk of second hip fracture in elderly 8 year follow up period was the highest in female, in older age-group, in patient after arthroplasty and in patient without pharmacologic treatment for osteoporosis. The effect of single risk factors on the risk of subsequent hip fractures should be investigated in the future.

PMS11

ESTABLISHING THE SAFETY OF TUMOUR NECROSIS FACTOR INHIBITION (TNF-I) IN RHEUMATOID ARTHRITIS (RA) FROM AN ANALYSIS OF REAL WORLD DATA

Heatley R[1], Walsh C[1], Johnson KI[1], Reynolds AV[2]
[1]*Complete Medical Group, Macclesfield, Cheshire, UK,* [2]*Reynolds Clinical Sciences Ltd, Eastleigh, Hampshire, UK*

OBJECTIVES: To perform a systematic review of prospective observational studies in patients with RA to examine the safety of TNF-I in daily practice, with particular focus on malignancy, and serious and opportunistic infections. **METHODS:** Comprehensive searches of Medline, Embase, the Cochrane Database of Systematic Reviews, and ACR, EULAR and BSR conference abstracts were performed according to a pre-specified protocol that excluded randomised controlled trials. Type and site of malignancies, as well as serious and opportunistic infections, such as tuberculosis, were extracted. Publications that reported incidence rates, standardised incidence ratios or measures of relative risk, such as incidence rate ratios, odds ratios or hazard ratios, were selected for random effects meta-analyses. **RESULTS:** A total of 2039 papers and 1979 abstracts were identified, of which 48 and 21 respectively met the pre-specified inclusion criteria. The pooled estimate for the relative risk (RR) of overall malignancy from seven studies was 0.94 (95% CI 0.84, 1.05; I2 = 0.0%). In contrast, the meta-analysis of serious infections had much higher heterogeneity, I2 = 40.9%, RR = 1.34 (95% CI 1.06, 1.62). **CONCLUSIONS:** This review included data from European, US and Japanese studies with >130,000 patient years of exposure. Data from such a large number of patients, often with extended follow-up, overcomes the weaknesses of clinical trial data, specifically fewer patient numbers and usually shorter exposure times. Observational data has known weaknesses related to non-randomisation such that statistical techniques have to be used to overcome differences between the exposed and reference cohorts. Despite such confounding factors, consideration of the available evidence leads to the conclusion that there is an increased risk of serious and opportunistic infections with TNF-I, although no evidence of increased the risk of malignancy. Meta-analyses of randomised controlled trials have come to different conclusions regarding both the risk of infections and of malignancy.

Muscular-Skeletal Disorders – Cost Studies

PMS12

A BUDGET IMPACT MODEL FOR THE USE OF ABATACEPT AS A FIRST BIOLOGIC TREATMENT FOR RHEUMATOID ARTHRITIS IN ITALY

Iannazzo S[1], Didoni G[2], Crocchiolo D[2]
[1]*AdRes HE&OR, Turin, Italy,* [2]*Bristol Myers Squibb S.r.l., Rome, Italy*

OBJECTIVES: Objective of the study was the budget impact analysis (BIA) of the use of abatacept as first biologic line for rheumatoid arthritis (RA) patients in Italy. **METHODS:** The BIA was based on a Markov model with 6-months cycles and 3-years time horizon. The target population, formed by RA patients starting a first biologic treatment, was estimated based on RA prevalence and market share data for biologic drugs. The sequence including abatacept (ABA) as first line was compared with two more traditional sequences of anti-TNFα (IFX=infliximab; ETN=etanercept; ADA=adalimumab) and rituximab (RTX). The compared sequences were: ABA-IFX-RTX; ETN-IFX-RTX; ADA-IFX-RTX. The switch between treatments for intolerance, adverse events or lack of efficacy was simulated on the basis of data from RCTs. The disease progression was classified with the ACR (American College of Rheumatology) I, II, III and IV functional states. Treatments efficacy was obtained from published RCTs as average reduction of the Health Assessment Questionnaire (HAQ) score. The HAQ score was then correlated with the ACR states. Direct costs were valued in the perspective of the Italian health care system and classified in purchasing, administration and patients routine management (visits, exams, hospital stay and other drugs). **RESULTS:** Italian target population was estimated in about 7000 RA patients. At the end of the third year patients still on first biologic drug were 5670, 4610, and 4680 in the sequence with ABA, ETN and ADA. Patients in ACR I or II were 6240, 6160 and 6000 respectively. The annual cost at the third year was €47.0 million, €48.5 million and €47.8 million for the sequence with ABA, ETN and ADA respectively. **CONCLUSIONS:** The use of ABA as first biologic line treatment for RA showed to provide better control of the disease along with a positive impact in total costs, when compared with traditional sequences based on anti-TNFα in Italy.

PMS13

THE BURDEN OF JUVENILE IDIOPATIC ARTHRITIS (JIA) IN RUSSIA: A RETROSPECTIVE REVIEW OF DIRECT AND INDIRECT COSTS

Vorobyev PA[1], Alekseeva EI[2], Bezmelnitsyna L[1], Borisenko O[1], Kirdakov FI[3], Hájek P[4]
[1]*Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia,* [2]*National Center for Child Health of Russian Academy of Medical Sciences, Moscow, Russia,* [3]*University Child Hospital of First Moscow Medical University named I.M.Sechenov, Moscow, Russia,* [4]*Pfizer, Praha, Czech Republic*

OBJECTIVES: Data about the burden of JIA are necessary to allocate health care resources. **METHODS:** Records were examined for 6 months retrospectively. Burden of JIA in Russia was gotten by summarizing direct and indirect medical costs of all patients with JIA. The total number of JIA patients and annualized costs were calculated based on extrapolation method. **RESULTS:** Data on 405 patients were obtained. Group with biologics included 124 patients(30.6%), without biologics – 269(66.4%), data about 9(3%) persons were absent. Among 6 biologics used in Russia for JIA treatment (Abatacept, Adalimumab, Etanercept, Infliximab, Rituximab and Tocilizumab), costs of biologics and total costs per patient were the smallest in case of Etanercept – 5,131 USD and 6,967 USD and the biggest with Rituximab - 19,530 USD and 21,944 USD. One-year direct costs per patient with biologics were 36,065 USD. One-year direct costs per patient without biologics was 3149 USD. Average one-year indirect costs were the same for patients with and without biologics - 1442 USD. Total number of patients with JIA in 2010 was 18,626 people, only 930(5%) (data of National Center for Child Health of Russian Academy of Medical Sciences, Moscow, Russia) received biologics. One-year direct costs of all patients with JIA - 89,491,976 USD; indirect costs - 27,491,976 USD; the burden of JIA -116,754,031 USD. **CONCLUSIONS:** In 2010 total number of patients with JIA in Russia was estimates as 18,626 people; burden of JIA was 116,754,031 USD.

PMS14

COST OF ETANERCEPT, ADALIMUMAB, AND INFLIXIMAB PER TREATED PATIENT ACROSS ADULT INDICATIONS USING REAL-WORLD DATA

Bonafede M[1], Gandra SR[2], Watson C[2], Princic N[3], Fox KM[4]
[1]*Thomson Reuters, Andover, MA, USA,* [2]*Amgen, Inc., Thousand Oaks, CA, USA,* [3]*Thomson Reuters, Cambridge, MA, USA,* [4]*Strategic Healthcare Solutions, LLC, Monkton, MD, USA*

OBJECTIVES: To estimate the annual cost of etanercept, adalimumab and infliximab per treated patient across adult indications using drug utilization from a US managed care population. **METHODS:** MarketScan Commercial Database was used to identify all adult patients (18-64 years) with ≥1 claim for etanercept, adalimumab, or infliximab between November 1, 2005-June 6, 2009 who were biologic-naïve or continuing TNF-blocker treatment (i.e., received a TNF-blocker before the first (index) claim in the study period) and had a diagnosis for rheumatoid arthritis, psoriasis, psoriatic arthritis, or ankylosing spondylitis. Patients were required to be continuously enrolled for 6-months pre-index and 1-year following the index claim. Patients with Crohn's disease, or ulcerative colitis in the pre-index period were excluded. Mean monthly dose was calculated for the 3 TNF-blockers for a 12-month period while patients were on therapy. Wholesale acquisition costs and the Medicare Physician Fee Schedule were applied to the mean monthly dose and related drug administration to estimate TNF-blocker cost per treated patient. **RESULTS:** Overall, 12,065 etanercept, 5,685 adalimumab, and 3,902 infliximab patients were included. Biologic-naïve patients consisted of 43% of patients. Patient characteristics were similar across treatment groups with a mean age (SD) of 49 (10) years and 66% female. The mean annual TNF-blocker cost per treated patient for all patients was $14,446 for etanercept, $18,000 for adalimumab, and $23,348 for infliximab. In biologic-naïve patients, the TNF-blocker cost per treated patient was $13,703 for etanercept, $16,932 for adalimumab, and $20,500 for infliximab; in patients continuing treatment it was $14,901 for etanercept, $19,410 for adalimumab, and $25,028 for infliximab. **CONCLUSIONS:** Patients receiving etanercept had the lowest TNF-blocker cost per treated patient for adult indications when using actual drug utilization from a US managed care population. TNF-blocker costs per treated patient on adalimumab and infliximab, respectively are approximately 25% and 62% higher than etanercept.

PMS15

COSTS OF TUMOR NECROSIS FACTOR BLOCKERS PER TREATED PATIENT ACROSS ADULT INDICATIONS USING REAL-WORLD DATA IN US COMMERCIALLY-INSURED POPULATION

Schabert V[1], Gandra SR[2], Watson C[2], Fox KM[3], Yeaw J[4], Goodman S[4], Milev S[5], Harrison DJ[2]
[1]*IMS Health, Falls Church, VA, USA,* [2]*Amgen, Inc., Thousand Oaks, CA, USA,* [3]*Strategic Healthcare Solutions, LLC, Monkton, MD, USA,* [4]*IMS Health, Watertown, MA, USA,* [5]*IMS Brogan, A unit of IMS, Ottawa, ON, Canada*

OBJECTIVES: To describe annual costs of etanercept, adalimumab and infliximab per treated patient across adult indications using real-world US drug data. **METHODS:** IMS LifeLink™ Health Plan Claims database was used to identify adult patients (≥18y) with ≥1 claim for etanercept, adalimumab or infliximab between January 1, 2005-March 31, 2009 (first TNF-blocker claim in study period is index claim); patients who were biologic-naïve or continuing TNF-blocker treatment were included. Patients had to have 360 days continuous enrollment following index claim and 180 days prior to index claim (pre-index period). In the pre-index period, patients were included if they had a diagnosis of rheumatoid arthritis, psoriasis, psoriatic arthritis, or ankylosing spondylitis, but were excluded if they had a diagnosis of Crohn's disease or ulcerative colitis. Patients were followed for 1-year. Mean monthly dose was computed for patients on therapy; wholesale acquisition costs were applied to mean monthly dose and Medicare Physician Fee Schedule was applied to related drug administrations. Costs from restarting index TNF-blocker therapy after discontinuation and costs from switching to a different TNF-blocker were attributed to patients' index therapy. **RESULTS:** Overall, 27,704 patients (14,777 etanercept, 6,862 adalimumab, 6,065 infliximab), were identified. The indication mix was 65% rheumatoid arthritis, 11% psoriasis, 13% psoriatic arthritis, 5% ankylosing spondylitis, and 6% with multiple indications. The 1-year mean cost per treated patient for all patients was lowest for etanercept, $14,013, followed by adalimumab, $17,716, then infliximab, $20,665. For biologic-naïve patients, mean cost per treated patient was $13,342 for etanercept, $16,718 adalimumab, and $18,589 infliximab. For patients continuing biologic therapy, cost per treated patient was $14,438 for etanercept, $18,816 adalimumab, and $21,846 infliximab. **CONCLUSIONS:** When comparing TNF-blocker cost per treated patient across adult indications, etanercept has the lowest cost per treated patient com-

pared to adalimumab and infliximab when using actual drug utilization data from US commercially-insured population.

PMS16

POTENTIAL COST SAVING OF EPOETIN ALFA COMPARED TO AUTOLOGOUS BLOOD DONATION OR TO NO-BLOOD-CONSERVATION-STRATEGY BEFORE ELECTIVE HIP OR KNEE SURGERY DUE TO REDUCTION IN ALLOGENEIC BLOOD TRANSFUSIONS AND ITS SIDE EFFECTS

Tomeczkowski J[1], Frietsch T[2], Müller A[3], Schleppers A[4], von Heymann C[5]
[1]*Janssen-Cilag GmbH, Neuss, Germany,* [2]*Ostseeklinik Damp GmbH, Damp, Germany,* [3]*Alfred Müller, München, Germany,* [4]*Berufsverband Deutscher Anästhesisten, Nürnberg, Germany,* [5]*Virchow-Klinikum/Campus Charité Mitte, Berlin, Germany*

OBJECTIVES: Transfusion of allogeneic blood still is common in orthopedic surgery albeit associated with higher morbidity and mortality. This analysis evaluates from the perspective of a German hospital the potential cost savings of Epoetin alfa compared to predonated autologous blood transfusions or to no-blood-conservation-strategy during elective hip and knee replacement surgery by reducing allogeneic blood transfusions and their associated infectious adverse events. **METHODS:** Individual patients (n = 10,000) were created based on data from controlled trials, the German DRG institute (InEK) and various publications and entered into a stochastic model (Monte-Carlo) one of three treatment arms: Epoetin alfa, preoperative autologous donation and no-blood-conservation-strategy. The model is focused on the costs and events of the procedure and follow-up. The model was validated by an independent external consultant. Clinical and economical variables were obtained from clinical trial databases, the German DRG System, patient records and medical publications- in particular cost per transfusion (allogeneic red blood cells: € 320/unit and autologous red blood cells: € 280/unit), pneumonia treatment (€ 5,000), and length of stay (€ 300/day). Probabilistic sensitivity analyses were performed to determine which, if any, factors had an influence on the model's clinical and cost outcomes. **RESULTS:** At acquisition costs of € 375/40,000 IE Epoetin alfa is cost saving compared to autologous blood donation, and at € 185/40,000 IE compared to no-blood-conservation-strategy. The results were most sensitive to the cost of Epoetin alfa, blood units and hospital days. **CONCLUSIONS:** Upcoming shortages and increasing prices of red blood cells will make Epoetin alfa an attractive blood conservation strategy for anemic patients at reasonable costs, due the reduction in allogeneic blood transfusions and their associated infectious adverse events.

PMS17

THE EFFECT OF BIOLOGICAL TREATMENT ON WORK PRODUCTIVITY AND PRODUCTIVITY COSTS OF RHEUMATOID ARTHRITIS PATIENTS

Klimes J[1], Dolezal T[2], Vocelka M[3], Petrikova A[4], Kruntoradova K[5]
[1]*Charles University, Faculty of Pharmacy, Hradec Kralove, Czech Republic,* [2]*Institute for Health Economics and Technology Assessment, Prague, Czech Republic,* [3]*Third Faculty of Medicine, Charles Universitiy in Prague, Praha 10, Czech Republic,* [4]*VFU Brno, Brno, Czech Republic,* [5]*Czech Technical University in Prague, Faculty of Biomedical Engineering, Kladno, Czech Republic*

OBJECTIVES: Biologics represent significant costs of rheumatic diseases treatment. Our study has focused on productivity comparison of rheumatoid arthritis (RA) patients treated with biologics and patients on DMARDs who are indicated to biologic treatment however therapy is unavailable due to economic limitations. **METHODS:** Work Productivity and Activity Impairment Questionnaire (WPAI:RA) was administered to two groups of patients - patients treated with biologics (n=76) with low disease activity and patients just on DMARDs (n=23) with high disease activity (DAS28 score ≥ 5,1). All patients were in productive age. Patients' demographics, clinical and PRO parameters (DAS28, HAQ, time from diagnosis) and working statuses we collected by rheumatologist. Productivity costs were calculated by friction cost approach using friction period of 130 work-days and average monthly gross income as denominator. **RESULTS:** Mean patients' age on biologics and on DMARDs were 41.0 years (21-61) and 45.7 (22 – 61), respectively. Mean time from diagnosis of biologics and DMARDs groups were 13.5 and 11.6 years, respectively. Average HAQ and DAS28 were 0.77 and 2.64, respectively for patients on biologics and 1.14, 5.62, respectively for patients on DMARDs. Patients on biologics were slightly more work-disable (26.3%) compare to 25.0% DMARDs patients. Overall work-impairment (for patients that reported any work-impairment) for patients on biologics and for patients on DMARDs was 28.1% and 49.6%, respectively. Patients on biologics reported less reduction of daily activities (39.8%) in compare to patients on DMARDs (50.5%). Average annual productivity costs per one patient on biologics and for DMARDs patient were € 1802 and € 2769, respectively. **CONCLUSIONS:** Despite of the fact, patients on biologics had longer time from diagnoses, they reported significantly lower work-impairment and reduction of daily activities in compare to DMARDs patients, which reflected about 53.6% higher productivity costs for patients on DMARDs. Biologic treatment preserves productivity and save productivity costs.

PMS18

BURDEN OF RHEUMATOID ARTHRITIS IN THE CZECH REPUBLIC – DIRECT AND PRODUCTIVITY COSTS

Klimes J[1], Vocelka M[2], Dolezal T[3], Petrikova A[4]
[1]*Charles University, Faculty of Pharmacy, Hradec Kralove, Czech Republic,* [2]*Third Faculty of Medicine, Charles Universitiy in Prague, Praha 10, Czech Republic,* [3]*Institute for Health Economics and Technology Assessment, Prague, Czech Republic,* [4]*VFU Brno, Brno, Czech Republic*

OBJECTIVES: International pharmacoeconomic studies suggest Health Assessment Questionnaire (HAQ) as an important predictor of evaluation both direct and productivity costs. Costs are supposed to increase with increasing HAQ score. Therefore, we calculated direct and productivity costs for five groups of patients according to their HAQ (<0.6, 0.6-1.1, 1.1-1.6, 1.6-2.1, ≥2.1) to confirm this assumption also in the Czech Republic. **METHODS:** This calculation was based on a retrospective cross-sectional study. We included 126 patients with rheumatoid arthritis, aged 18-84 years either at working status, part-time disabled or full-time disabled. For estimation of direct medical costs, we used microcosting method retrospectively reviewing individual patients' medical records. For calculation of productivity costs we excluded patients older than 63 years of age (retirement pensioners). We used friction costs approach (FCA) with defined friction period of 130 workdays, based on patients' absenteeism. Productivity of part-time-disabled and full-time disabled patients were assumed to be deteriorated by 52% and 70%, respectively, based on the Czech law on pension insurance. The height of average monthly income in year 2010, €960.3 was used as denominator. Costs were expressed as mean value per one patient with RA in each of the HAQ-group. **RESULTS:** Average patients' age was 57.3 years; average time from diagnosis was 17.5 years with mean HAQ score 1.4 and mean DAS28 3.62. Mean annual medical direct costs, for each HAQ-group, were €4076.7, €5950.2, €4691.3, €6932.1, and €6727.1, respectively. Mean annual indirect costs associated with productivity loss were €481.5, €1178.6, €1267.7, €1585.6, and €2122.5, respectively. **CONCLUSIONS:** Direct and productivity costs for patients with rheumatoid arthritis are closely related to the height of HAQ score. Total (direct and productivity) annual mean costs were €7135.6. 31.0% of all patients were treated with biological treatment which represented up to 79.4% of the overall direct medical costs.

PMS19

THE ECONOMIC BURDEN OF POST-MENOPAUSAL OSTEOPOROSIS AND RELATED FRACTURES IN GREECE

Athanasakis K[1], Karampli E[1], Hollandezos M[1], Papagiannopoulou V[2], Badamgarav E[3], Intorcia M[4], Kyriopoulos J[1]
[1]*National School of Public Health, Athens, Greece,* [2]*AMGEN Hellas, Marousi, Greece,* [3]*Amgen, Thousand Oaks, CA, USA,* [4]*Amgen S.A., Barcelona, Spain*

OBJECTIVES: To determine the healthcare resource use (HRU) and costs attributable to osteoporosis and osteoporosis-related fractures in post-menopausal women in Greece **METHODS:** A multi-point data collection procedure, based on strictly-structured interviews with 137 geographically distributed physicians, was used to construct and populate the disease management model for women with post-menopausal osteoporosis (PMO) aged >50years. The model was further validated by a group of 12 experts. Secondly, all HRU items in the model were costed in order to provide per-patient costs of treatment. Cost variables included costs of consultations, laboratory tests, osteoporotic medication, dietary supplements, hospitalization due to fractures and rehabilitation, allcalculated from a third-party payer perspective (Euros, 2011) for a 1year timeframe (retrospective). **RESULTS:** The mean annual cost per PMO patient was €1,384.67 (95%CI: 423.27 – 7281.16). When distinguishing between women with established (PMO with a previous fracture) (27.6% of total) and non-established PMO, the mean annual cost per patient was €2027.46 (95%CI: 508.09-7241.90) and €1139.63 (95%CI: 461.86 - 1324.44) respectively. For PMO women with an established osteoporosis for <1year the mean annual cost was significantly higher compared to those with an established osteoporosis for > 1year €2714.98 (95%CI: 820.17 – 7284.42) versus €1805.54 (95%CI: 508.09 – 7241.77). The mean annual cost per patient with a fracture was €4,334.27 (95%CI: 1,452.86 – 10,730.17) for a hip, €2,723.27 (95%CI: 1,470.39 – 7,839.55) for a vertebral and €1,731.35 (95%CI: 1,131.17 - 1,942.48) for a Colles fracture respectively. The sensitivity analysis (±10% change of baseline values) showed that the factors with the greatest impact on total cost were the probability of established osteoporosis, the probability of a fracture in the previous 12 months, cost of parathormone treatment and the cost of patient monitoring. **CONCLUSIONS:** Treatment of osteoporosis is costly. Efforts to control the main osteoporosis cost drivers and hence its economic impact on the health care budgets, are necessary.

PMS20

TREATMENT OF PATIENTS WITH MODERATE AND SEVERE PSORIASIS – COST-OF-ILLNESS IN THE CZECH REPUBLIC

Petrikova A[1], Klimes J[2], Dolezal T[3], Marinov L[4], Petrova G[5]
[1]*VFU Brno, Brno, Czech Republic,* [2]*Charles University, Faculty of Pharmacy, Hradec Kralove, Czech Republic,* [3]*Institute for Health Economics and Technology Assessment, Prague, Czech Republic,* [4]*Medical University, Sofia, Bulgaria,* [5]*Medical University, Faculty of Pharmacy, Sofia, Bulgaria*

OBJECTIVES: Psoriasis (prevalence 2-3%) is not directly life-threatening disease. However, patients suffering from psoriasis and psoriatic arthritis (PsA) are experiencing lower quality of life. Treatment of these diseases represents a significant financial burden for the healthcare system. **METHODS:** Study was based on 12-months retrospective electronic questionnaire reported by dermatologist. We used societal perspective using friction cost approach method for productivity costs calculation. Patients' demographics, clinical data (PASI and BSA index), direct costs (inpatient/outpatient care, local/systemic treatment etc.), productivity costs (invalidity, sick leave) and on QoL (EQ-5D, DLQI) were collected. **RESULTS:** A total of 256 patients participated in the study, average patients' age was 46.79 years (9-75 years), average time from diagnosis was 25.52 years with average PASI 13,76, BSA 28,09%, DLQI 11,74 and EQ-5D 0,7633. Occurrence of PsA was 34.4%. Major direct costs driver was phototherapy (47% of direct costs), systematic treatment (17%) and inpatient care (15%). Within the productive-age patients (18-63 years), 8.6% of patients were fully disabled, 7.4% partially disabled, 73% patients were work-active, and 11% were unemployed, retired or students. 17.2% of work-active patients reported incapacity to work with average duration of 33 days in previous 6 months. Mean indirect costs associated with productivity loss were €848.3 per work-active patient per year €1343.0 per work-active patient with PsA. Mean annual costs per patient with moderate to severe psoriasis and/or PsA were calculated to €3736.5 (direct costs 77%, €2888.2). Mean annual costs per patient with PsA were €4328.3 including €2985.3 for direct costs (69%). **CONCLUSIONS:** Direct costs remain major

drivers of cost consumption in the treatment of patients with psoriasis and PsA in the Czech Republic. Cohort in our study was not treated with biological treatment which would certainly increase the costs therefore further study is required to access the cost-effectiveness of such treatment in the Czech Republic.

PMS21

DIFFERENCES IN COST-OF-ILLNESS AND QUALITY OF LIFE BETWEEN RHEUMATOID ARTHRITIS AND ANKYLOSING SPONDYLITIS IN SOUTH KOREA

Lee TJ[1], Park BH[1], Son HK[1], Kim JW[2], Shin K[3], Lee EB[2], Song YW[2]
[1]*Seoul National University, Seoul, South Korea,* [2]*Seoul National University Hospital, Seoul, South Korea,* [3]*Seoul National University Hospital, Seoul, South Korea*

OBJECTIVES: To estimate and compare cost-of-illness (COI) and health-related quality of life (HRQOL) of rheumatoid arthritis (RA) and ankylosing spondylitis (AS) in South Korea. **METHODS:** Patients with RA (n=196) and AS (n=191) were surveyed by face-to-face interviews at the Rheumatology Clinic of Seoul National University Hospital. Direct costs [medical costs (treatment, drug, private physiotherapy, traditional Chinese medicine, other alternative medicine), non-medical costs (travel, dietary supplements, auxiliary device, home assistance)], indirect costs (productivity loss due to job loss and sick leave) and deterioration in HRQOL of RA and AS patients were measured. HRQOL was assessed using KEQ-5D. Factors associated with COI and HRQOL were analyzed using multiple regression and multivariate logistic regression. **RESULTS:** COI of AS patients was more than double compared to that of RA patients (RA: 6,446,376 Korean Won, AS: 12,433,629 Korean Won) but HRQOL of RA patients was lower than that of AS patients (RA: 0.49, AS: 0.62). As functional severity worsened in both diseases, the total costs increased accordingly (RA: functional class (FC) I: 4,230,204 Korean Won, FC II: 7,250,674 Korean Won, FC III: 8,046,434 Korean Won, FC IV: 8,206,215 Korean Won, AS: FC I: 8,125,096 Korean Won, FC II: 13,995,292 Korean Won, FC III, IV: 30,118,247 Korean Won) and the HRQOL scores decreased (RA: FC I: 0.67, FC II: 0.50, FC III: 0.29, FC IV: 0.23, AS: FC I: 0.72, FC II: 0.61, FC III, IV: 0.24). Functional severity was the major determinant of COI and HRQOL in RA and AS. **CONCLUSIONS:** Although the HRQOL of AS patients was not as low as that of RA patients, the COI of AS patients was higher than that of RA patients. Considering the relatively low HRQOL and relatively low medical costs of RA patients, re-examination of reimbursement plan of Korean National Health Insurance is needed to figure out this problem.

PMS22

THE BURDEN OF ILLNESS OF OSTEOPOROSIS IN CANADA

Tarride JE[1], Hopkins R[1], Leslie WD[2], Morin S[3], Adachi J[1], Papaioannou A[1], Bessette L[4], Brown JP[5], Goeree R[1]
[1]*McMaster University, Hamilton, ON, Canada,* [2]*University of Manitoba, Winnipeg, MB, Canada,* [3]*McGill University, Montreal, QC, Canada,* [4]*CHUL, Quebec, QC, Canada,* [5]*Laval University, Quebec, QC, Canada*

OBJECTIVES: Since the 1993 estimate of the burden of osteoporosis in Canada, the population has aged and new treatment options have been introduced. The study purpose was to estimate the current burden of illness due to osteoporosis in Canadians aged 50 and over. **METHODS:** Analyses were conducted using five national administrative databases from the Canadian Institute for Health Information for the fiscal-year ending March 31 2008 (FY 2007/08). Gaps in national data were supplemented by provincial data extrapolated to national levels. Osteoporosis-related fractures of the hip, humerus, vertebra, wrist, other sites and multiple sites were identified using a combination of most responsible diagnosis and intervention codes. Fractures associated with severe trauma codes were excluded from the analysis. Costs, expressed in 2010 dollars, were calculated for osteoporosis-related hospitalizations, emergency care, same day surgeries, rehabilitation, continuing care, home care, long-term care, prescription drugs, physician visits and productivity losses. Sensitivity analyses were conducted to measure the impact on the results of key assumptions. **RESULTS:** Osteoporosis-related fractures were responsible for 57,413 acute care admissions and 832,594 hospitalized days in FY 2007/08. Acute care costs were estimated at $1.2 billion. When outpatient care, prescription drugs and indirect costs were added, the overall yearly cost of osteoporosis was over $2.3 billion for the base case analysis and as much as $3.9 billion if a proportion of Canadians were assumed to be living in long-term care facilities due to osteoporosis. **CONCLUSIONS:** Osteoporosis is a chronic disease that results in a substantial economic burden to the Canadian society.

PMS23

ANALYSIS OF INDIRECT COSTS FOR CARE OF RHEUMATOID ARTHRITIS PATIENTS USING LARGE COHORT DATABASE, IORRA, IN JAPAN

Igarashi A[1], Hoshi D[2], Tanaka E[2], Inoue E[2], Nakajima A[2], Momohara S[2], Taniguchi A[2], Yamanaka H[2], Tsutani K[1]
[1]*Tokyo Univ. Faculty of Pharmacy, Tokyo, Japan,* [2]*Tokyo Women's Medical University, Tokyo, Japan*

OBJECTIVES: To examine annual indirect cost in large-scale rheumatoid arthritis (RA) patient cohort (IORRA) in Japan. **METHODS:** From patients' perspective, we calculated indirect costs of RA patients, participants of the 15-17th IORRA studies in Oct. 2007- Oct. 2008. Productivity losses due to occasional absence from working and those due to permanent retirement were separately estimated, by multiplying average time with average wage, stratified by age & sex distribution of the cohort. We also assessed correlations between these costs and RA disease activity, disability level and QOL. **RESULTS:** Data from 5284 RA patients were extracted. A total of 34.8% of those were staying working in spite of RA. However, 9.9% reduced there working time and 8.4% quitted their job due to RA. In average, RA patient missed 435.1 working hours per 1year. By multiplying average wage, JPY1,753, annual indirect costs per RA patient was estimated to JPY762,000. For whole RA patients in Japan (n=700,000), it would be JPY53.3billion per year. These costs increased progressively with worsening RA disease activity, disability level, or QOL. For example, patients with lower EQ-5D score (less than 0.5) missed more working time than those with higher one did (more than 0.8). Average missed time for working and annual indirect cost among them were 1,087hours versus 275.8 hours and JPY1,906,000 versus JPY484,000, respectively. With same cohort data, we had already proved that direct costs also had same trend. Total costs for RA patient were JPY4,800,000 (JPY2.9mil. for direct cost and JPY1.9mil. for indirect cost) for patients with lower EQ-5D score and JPY1,800,000 (JPY1.3mil. for direct cost and JPY0.5mil. for indirect cost) for patients with higher one from societal perspective. **CONCLUSIONS:** Heavy economic burden lies in RA patients and grows heavier as the disease state is exacerbated using IORRA database. The increase indirect cost may be suppressed by proactively controlling RA.

PMS24

THE COST OF CARE OF RHEUMATOID ARTHRITIS AND ANKYLOSING SPONDYLITIS PATIENTS IN TERTIARY CARE RHEUMATOLOGY UNITS IN TURKEY

Malhan S[1], Pay S[2], Ataman S[3], Dalkilic E[4], Dinc A[2], Erken E[5], Ertenli I[6], Ertugrul E[7], Gogus F[8], Hamuryudan V[9], Inanc M[10], Karaaslan Y[11], Karadag O[12], Karakoc Y[13], Keskin G[14], Kisacik B[15], Kiraz S[6], Oksel F[16], Oksuz E[17], Parildar T[18], Sari I[19], Soy M[20], Senturk T[21], Taylan A[22]
[1]*Baskent University Faculty of Health Sciences, Ankara, Turkey,* [2]*Gulhane Military Medical Academy, Ankara, Turkey,* [3]*Ankara University Faculty of Medicine, Ankara, Turkey,* [4]*Uludag University Faculty of Medicine, Bursa, Turkey,* [5]*Cukurova University Faculty of Medicine, Adana, Turkey,* [6]*Hacettepe University Faculty of Medicine, Ankara, Turkey,* [7]*Kayseri Erciyes University Faculty of Medicine, Kayseri, Turkey,* [8]*Gazi University Faculty of Medicine, Ankara, Turkey,* [9]*Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey,* [10]*Istanbul University Istanbul Faculty of Medicine, Istanbul, Turkey,* [11]*Ankara Numune Training and Research Hospital, Ankara, Turkey,* [12]*Diyarbakir Training and Research Hospital, Diyarbakir, Turkey,* [13]*Bursa Sevket Yilmaz Training and Research Hospital, Bursa, Turkey,* [14]*Ankara Diskapi Yildirim Beyazit Training and Research Hospital, Ankara, Turkey,* [15]*Gaziantep University Faculty of Medicine, Gaziantep, Turkey,* [16]*Ege University Faculty of Medicine, Izmir, Turkey,* [17]*Baskent University Faculty of Medicine, Ankara, Turkey,* [18]*Celal Bayar University Faculty of Medicine, Manisa, Turkey,* [19]*Izmir Bozyaka Training and Research Hospital, Izmir, Turkey,* [20]*Bolu Izzet Baysal University Faculty of Medicine, Bolu, Turkey,* [21]*Adnan Menderes University Faculty of Medicine, Aydin, Turkey,* [22]*Izmir Tepecik Training and Research Hospital, Izmir, Turkey*

OBJECTIVES: To determine direct and indirect cost due to rheumatoid arthritis (RA) and ankylosing spondylitis (AS) in Turkey. **METHODS:** An expert panel composed of 21 experts chosen from all national tertiary care rheumatology units (n=53) was convened to estimate the direct and indirect costs of care of patients with RA and AS in Turkey, using "cost-of-illness" methodology. To measure indirect costs, the number of days of sick leave, the extent of disability, and the levels of early retirement and early death were also evaluated. Lost productivity costs were calculated using the "human capital approach", based on the minimum wage. **RESULTS:** The total annual direct costs were 2.917,03 Euro per RA patient and 3.565,9 Euro for each AS patient. The direct costs were thus substantial, but the indirect costs were much higher because of extensive morbidity and mortality rates. The total annual indirect costs were 7.058,99 Euro per RA patient and 6.989,81 for each AS patient. Thus, the total cost for each RA patient was 9.976,01 Euro and that for an AS patient 10.555,72 Euro, in Turkey. **CONCLUSIONS:** From the perspective of those who pay for health care, both RA and AS has become a burden in Turkey. The cost of lost productivity is higher than the medical cost. Another important conclusion is that indirect costs constitute 70% and 66% of total costs in patients with RA and AS, respectively. The annual cost of RA for whole Turkish population is 2.130.424.680 Euro. This amount contributes to 0.37% of the GDP in Turkey. Whereas for AS, the annual cost of disease in Turkey is 2.209.201.904 Euro and this corresponds to 0.38% of the GDP. To conclude, RA and AS diseases have total burden of 4.339.626.584 Euro that is 0.75% of the Turkish GDP.

PMS25

EVALUATION OF DIRECT COSTS FOR THE TREATMENT OF ACTIVE JUVENILE RHEUMATOID ARTHRITIS USING BIOLOGICS

Yagudina R, Kulikov A, Zinchuk I
First MGMU named after I.M. Sechenov, Moscow, Russia

OBJECTIVES: Evaluate direct costs for the treatment of patient with active juvenile rheumatoid arthritis (JRA) in the inefficiency of conventional therapy. **METHODS:** Direct costs applied to patient, health care and society in process of medical care provision were evaluated. In the study direct costs included cost of biologics for the treatment of active JRA, therapy cost of the most common side effects caused by biologics use, cost of inpatient care and cost of out-patient diagnostic and treatment of JRA patients. **RESULTS:** Therapy cost with Etanercept and Abatacept was evaluated on the first stage including spending on one patient treatment with active JRA with body weight 15 till 65 kg. during one year after three months of inefficient conventional therapy. Biologics doses and dosing regimen were defined on the basis of application sheet. Calculated annual therapy cost for Etanercept varied from 11,752 EUR to 23,503 EUR depending on body weight and for Abatacept from 8,879 EUR to 26,638 EUR respectively. During cost analysis authors considered only very often (>1/10) and often (>1/100, < 1/10) occurred side effects. Thus, cost of side effects treatment caused by Etanercept use resulted in 44 EUR and for Abatacept – 69 EUR. Next stage of cost analysis was evaluation of therapy cost for patients with JRA according standard of inpatient treatment è standard of out-patient treatment. Cost of 30 days of inpatient care and 14 months of out-patient care was considered during cost analysis for the treatment of patients with JRA. Cost of inpatient and out-patient care for patient with JRA excluding biologics cost amounted to 33585 EUR. **CONCLUSIONS:** Finally total direct costs for the treatment of patient with JRA during one year with body weight from 15 till 65 kilogram varied from 45,380 EUR to 57,132 EUR for Etanercept and from 42,534 EUR to 60,292 EUR for Abatacept respectively.

PMS26

COST OF DUPUYTREN CONTRACTURE IN THE CZECH REPUBLIC

Skoupá J[1], Hájek P[2]
[1]Pharma Projects s.r.o., Prague 5, Czech Republic, [2]Pfizer, Praha, Czech Republic

OBJECTIVES: To determine the cost of Dupuytren's contracture in the Czech Republic. **METHODS:** Survey among general surgery specialists and orthopedic surgeons (panel of total 9 surgeons) conducted. The assessment itself was done using a classical Delphi panel method, combined with data from medical charts and/or hospital information systems. Besides the surgeons, also rehabilitation specialists (to cover costs for rehabilitation) and internal medicine specialists (to cover complications) were included into the panel. **RESULTS:** If indirect costs (productivity loss) are included, they represent the major part of all costs (76 %). In case of direct cost inclusion, rehabilitation stands for more than 50% of costs, followed by surgery costs (almost 30 %). Mean direct costs (1 operation field) are estimated at about 12,000 CZK with a variation of 9 200 to 14,400 CZK. If indirect costs (productivity loss) are included, total costs increase dramatically, arriving at mean costs of almost 50 thousand CZK (21,800 to 90,200 CZK). **CONCLUSIONS:** Cost of Dupuytren's contracture range from 21,800 to 90 200 CZK if indirect cost included. Indirect cost represent 76% of all costs.

PMS27

RETROSPECTIVE CHART REVIEW TO ASSESS UTILIZATION OF RESOURCES AND COSTS RELATED TO POSTMENOPAUSAL OSTEOPOROSIS TREATMENT OF PATIENTS WITHOUT FRACTURES IN SLOVENIA, SERBIA, SLOVAKIA AND BULGARIA

Rutkowski J[1], Haldas M[1], Bolisega D[1], Jedynasty K[2], Komadina R[3], Bumbasirevic M[4], Popivanov P[5], Bielik J[6]
[1]HTA Consulting, Krakow, Poland, [2]Amgen GmbH, Headquarters Office for CEE, Vienna, Austria, [3]Public Institution General Hospital Celje, Celje, Slovenia, [4]Institute of Orthopedic Surgery and Traumatology at Clinical Center Serbia, Beograd, Serbia and Montenegro, [5]University Hospital, Sofia, Bulgaria, [6]Public Health Faculty in Trencin, Trencin, Slovak Republic

OBJECTIVES: To evaluate utilization of resources and direct medical costs of postmenopausal osteoporosis treatment in patients without fractures. **METHODS:** A medical chart review was performed to examine the medical resources used to treat osteoporosis during the year preceding the start of the study. Data were collected between July 2010 and April 2011 by local investigators from 5 centers in Slovenia (99 patients), 5 in Serbia (105), 10 in Slovakia (100) and 3 in Bulgaria (106). Data of patients above 50 years of age, diagnosed with osteoporosis without fractures and treated for osteoporosis was included in the study. Based on these data, costs of osteoporosis treatment from the public payer and patient's perspective in all countries except Bulgaria were estimated. Costs of ambulatory and outpatient visits, examinations and drugs were calculated. **RESULTS:** Patients with osteoporosis were monitored more frequently in Slovenia and Slovakia (on average 2.00 and 1.87 ambulatory visits per year, respectively). In Serbia and Bulgaria, ambulatory visits were less frequent (0.79 and 0.67 visits per year, respectively). Percentages of patients treated with bisphosphonates were 99%, 98%, 78% and 61% in Slovakia, Bulgaria, Slovenia and Serbia, respectively, while 83%, 85%, 81% and 57% was treated with calcium and vitamin D supplements, respectively. Average 1-year cost of osteoporosis treatment was highest in Slovakia and Slovenia, accounting for 491 € (CI95%: 444; 634) and 384 € (CI95%: 345; 435), respectively, while in Serbia these costs were 190 € (CI95%: 164; 231). **CONCLUSIONS:** The highest standard of treatment and monitoring osteoporosis was observed in Slovenia. On the other side treatment of osteoporotic patients generated the highest costs in Slovakia, however some of these costs could be related to comorbidities.

PMS28

RETROSPECTIVE CHART REVIEW TO ASSESS UTILIZATION OF RESOURCES AND COSTS RELATED TO POSTMENOPAUSAL OSTEOPOROTIC FRACTURES IN SLOVENIA, SERBIA AND BULGARIA

Rutkowski J[1], Haldas M[1], Bolisega D[1], Jedynasty K[2], Kozlevcar Zivec M[3], Komadina R[4], Bumbasirevic M[5], Popivanov P[6]
[1]HTA Consulting, Krakow, Poland, [2]Amgen GmbH, Headquarters Office for CEE, Vienna, Austria, [3]Ambulanta za osteoporozo Medicus, Ljubljana, Slovenia, [4]Public Institution General Hospital Celje, Celje, Slovenia, [5]Institute of Orthopedic Surgery and Traumatology at Clinical Center Serbia, Beograd, Serbia and Montenegro, [6]University Hospital, Sofia, Bulgaria

OBJECTIVES: To evaluate utilization of resources and direct medical costs of postmenopausal osteoporotic fractures (proximal femur and vertebral) in the first and subsequent years after the event. **METHODS:** A medical chart review was performed to examine the medical resources used to treat the two most costly osteoporotic fractures in the first and second or subsequent year after the event. Data were collected between December 2009 and April 2011 by local investigators from 5 centers in Slovenia (159 patients), 5 in Serbia (199) and 3 in Bulgaria (186). Documentation of patients above 50 years of age with a low-energy fracture sustained no later than 5 years before the start of the study was included. Patients with multiple fractures were excluded. Cost of treatment from a public payer and patient perspective in all countries except Bulgaria was estimated. These costs were compared to GDP per capita in each country (International Monetary Fund data – year 2010: 15,953 € in Slovenia, 3,522 € in Serbia) to evaluate economic burden of fractures. **RESULTS:** All Slovenian patients were hospitalized after proximal femur and 53% after vertebral fracture, compared with 84% and 30% in Serbia and 69% and 5% in Bulgaria. However, in the following years after the fracture, hospitalization was most common in Serbia (49% of patients after proximal femur and 18% after vertebral fracture yearly).The 2-year treatment cost of proximal femur fracture was 4463 € (SD 1750) in Slovenia and 3277 € (SD 2409) in Serbia, while the 2-year cost of vertebral fracture during was estimated at 3902 € (SD 2714) in Slovenia and 491 € (SD 295) in Serbia. **CONCLUSIONS:** Osteoporotic fractures are responsible for high economic burden. Mean cost of treatment of low-energy proximal femur fracture is equal 28% of GDP per capita in Slovenia and 93% in Serbia.

PMS29

ABATACEPT OR INFLIXIMAB FOR PATIENTS WITH RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE TO METHOTREXATE: A TRIAL-BASED AND REAL-LIFE COST-CONSEQUENCE ANALYSIS

Benucci M[1], Stam W[2], Gilloteau I[3], Crocchiolo D[4], Sennfält K[3], Leclerc A[3], Bengtsson N[5], Maetzel A[6], Lucioni C[7]
[1]Ospedale S. Giovanni di Dio ASL 10, Firenze, Italy, [2]Stam Consulting, Houten, The Netherlands, [3]Bristol-Myers Squibb, Rueil Malmaison, France, [4]Bristol Myers Squibb S.r.l., Roma, Italy, [5]Bristol-Myers Squibb, Rueil Malmaison, Other ->, France, [6]Stratas Partners, Basel, Switzerland, [7]Wolters Kluwer Health Italy Ltd, Milan, Italy

OBJECTIVES: In the 1-year, double-blind, placebo-controlled ATTEST trial, efficacy of abatacept or infliximab vs. placebo was reported in patients with rheumatoid arthritis (RA) and inadequate response to methotrexate. We estimated trial-based and real life costs of abatacept and infliximab for achieving pre-defined remission or low disease activity state (LDAS) as recommended by the European League Against Rheumatism (EULAR). **METHODS:** Quantity of drug, serious adverse event (SAE) rates and time (months) in remission or LDAS were taken from ATTEST for the trial-based calculation to derive a cost per remitting/LDAS patient and cost per patient-month in remission/LDAS. We used list prices for drugs and public tariffs for infusion and hospitalization due to SAEs. Trial-based analyses were made for the full year, and the first and subsequent 6 months (initiation & maintenance). Maintenance costs were extrapolated to real life, taking into account dose escalation and shortening of infusion intervals with infliximab. SAE rates from a Cochrane network meta-analysis were considered in the real-life analyses. All analyses were conducted from a health care system perspective for Italy. **RESULTS:** In Italy, the annual trial-based costs per remitting/LDAS patient were €70,259/€37,219 for abatacept vs. €85,547/€46,592 for infliximab. In the initiation phase, costs per patient-month in remission/LDAS were €11,028/€6,020 for abatacept vs. €8,347/€4,173 for infliximab. Abatacept showed lower costs per patient-month in remission/LDAS in the maintenance phase €5,046/€2,673 vs. €5,500/€2,996 for infliximab. Real-life maintenance costs per month in remission/LDAS were: €5,347/€2,832 for abatacept vs. €7,210/€3,927 for infliximab. Higher initiation cost for abatacept to achieve remission/LDAS would be offset at 14.6/16.1 months during real life. **CONCLUSIONS:** Our findings suggest a lower cost-consequence for abatacept during the maintenance phase and its real-life extrapolation. Abatacept is a sustainable, safe, and economically attractive biologic for the long-term treatment of RA when compared to infliximab.

PMS30

COST-EFFECTIVENESS OF TOCILIZUMAB COMPARED TO STANDARD THERAPEUTIC SEQUENCES FOR THE TREATMENT OF MODERATE/SEVERE RHEUMATOID ARTHRITIS (RA) PATIENTS IN PORTUGAL

Diamantopoulos A[1], Andrade S[2], Bernardo A[3], Branco J[4], Inês L[5], Pereira da Silva JA[6], Santos MJ[7], Monteiro I[8]
[1]Symmetron Limited, London, UK, [2]KeyPoint Group, Lisbon, Portugal, [3]Hospital de São João, E.P.E, Oporto, Portugal, [4]Centro Hospitalar Lisboa Ocidental – Hospital Egas Moniz, Lisbon, Portugal, [5]Hospitais da Universidade de Coimbra, EPE, Coimbra, Portugal, [6]Centro Hospitalar de Lisboa Norte – Hospital de Santa Maria, Lisbon, Portugal, [7]Hospital Garcia de Orta, E.P.E., Almada, Portugal, [8]Roche Farmacêutica Química, Lda., Amadora, Portugal

OBJECTIVES: To evaluate the cost-effectiveness of treatment sequences initialized with tocilizumab 8mg/kg compared to similar treatment sequences initialized with a TNF-inhibitor for the treatment of moderate to severe RA patients with inadequate response to previous DMARD therapy (DMARD-IR) in Portugal. **METHODS:** A cost-utility analysis was conducted from a societal perspective. The analysis compares DMARD-IR patient outcomes, in three different scenarios, in a treatment sequence initialized with tocilizumab followed by a TNF inhibitor (adalimumab, etanercept, or infliximab, for scenarios 1, 2 and 3, respectively), rituximab, abatacept and palliation versus the same sequence initialized with a TNF inhibitor (etanercept, adalimumab and etanercept, respectively, for scenarios 1, 2 and 3). Patients characteristics (age, starting HAQ-DI score, sex and weight) were based on tocilizumab clinical trial data. ACR response for biologic treatments was obtained by a mixed treatment comparison. Clinical trial data was used to model the relationship between HAQ-DI scores and utility as described by EQ-5D. Resource utilization was obtained from an expert panel of Portuguese rheumatologists. Unit costs were obtained from Portuguese official sources. Analysis of clinical trial data or secondary sources provided evidence for appropriate distributions to perform probabilistic sensitivity analysis (PSA). Costs and QALYs were discounted annually at 5%. **RESULTS:** The model estimated that the treatment sequence initialized with tocilizumab resulted in higher QALYs and lower costs versus comparator sequences in all three scenarios (0.22 QALYs and −1.881€, 0.27 QALYs and −4.449€, 0.22 QALYs and −1.851€ for scenarios 1, 2 and 3 respectively). Several sensitivity and scenarios analyses showed that the model is robust to changes in parameter values. In PSA (2000 samples) the tocilizumab sequence produces always additional QALYs at lower costs. **CONCLUSIONS:** In DMARD-IR patients, the model consistently predicts that starting treatment with tocilizumab is a dominant alternative compared to similar treatment sequences initialized with a TNF-inhibitor in Portugal.

PMS31

COST-EFFECTIVENESS OF ABATACEPT FOR THE TREATMENT OF RHEUMATOID ARTHRITIS (RA) AFTER THE FAILURE OF A FIRST TNF INHIBITOR IN THE UNITED KINGDOM

Pericleous L[1], Lebmeier M[2]
[1]Bristol Myers Squibb Pharmaceuticals, Uxbridge, UK, [2]Bristol-Myers Squibb, Uxbridge, Middlesex, UK

OBJECTIVES: Anti-tumour necrosis factor inhibitor (anti-TNF) therapy has been widely and successfully used in patients with rheumatoid arthritis (RA). However, about 30% of these patients have an inadequate response to these medicines. Abatacept has shown significant clinical and functional benefits in patients who have inadequate response to anti-TNF therapy. The aim of this analysis is to examine the cost-effectiveness of abatacept after the failure of a first anti-TNF. **METHODS:** A patient simulation model was constructed using clinical data from the (abatacept) ATTAIN trial and the British Society for Rheumatology Biologics Register (BSRBR). The time horizon of this model was lifetime. Clinical effectiveness was evaluated by changes in Health Assessment Questionnaire (HAQ) score from baseline up to 12 months. Patients discontinued treatment due to a lack of efficacy or adverse events. After treatment discontinuation, patients received supportive care, regardless of treatment group. Utilities were obtained by mapping HAQ to EQ-5D. Cost inputs included drug and administration, monitoring, medical costs associated with HAQ level, and joint replacement costs obtained from published literature and inflated to 2009 British pounds. **RESULTS:** Abatacept was estimated to yield 1.06 additional quality-adjusted life years (QALYs) per patient (3.28 vs. 2.22) over a lifetime, compared to conventional DMARDs. The total lifetime costs associated with abatacept were £46,522 and total costs for conventional DMARDs were £17,025, resulting in an incremental cost-effectiveness ratio (ICER) of £27,936 per QALY gained. Probabilistic and univariate sensitivity analyses confirmed the robustness of our findings. **CONCLUSIONS:** Abatacept is a cost-effective treatment option for patients with RA after the failure of a first anti-TNF in the UK.

PMS32

ECONOMIC ANALYSIS OF ETANERCEPT IN RHEUMATOID ARTHRITIS FROM A PUBLIC PERSPECTIVE IN VENEZUELA

Fernandes RA[1], Boada V[2], Mould JF[3]
[1]*ANOVA - Knowledge Translation, Rio de Janeiro, Brazil,* [2]*Pfizer, Inc., Caracas, Venezuela,* [3]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: Rheumatoid Arthrtis (RA) leads to significant impact on management costs and patient's quality of life. In Venezuela, annual per capita cost for RA management increased from 698USD in 1997 to 3494USD in 2002. Biologic treatment after disease-modifying antirheumatic drugs fail is an alternative, but their high cost represents a challenge for decision makers. This study aims to perform cost-effectiveness and cost-utility analysis of biologic alternatives for moderate to severe RA in Venezuela. **METHODS:** An economic analysis was developed through a decision-tree model to simulate RA evolution after treatment with etanercept (basecase treatment), adalimumab, infliximab, tocilizumab or rituximab as first-line therapies and their associated costs over a 12-month time horizon. Therapy continuation or switch was evaluated at week 24. Effectiveness measures were ACR70 response and quality adjusted life years (QALYs) gained. Direct medical costs included biologics, concomitant drugs, medical follow-up and adverse events management. Clinical response was extracted from published literature, while costs were collected from Venezuelan public official databases. Probabilistic sensitivity analyses were performed through Monte Carlo Simulation second-order approach. **RESULTS:** In base case analysis estimated effectiveness resulted in [ACR70,QALY]: etanercept [31.3%,0.79]; adalimumab [18.1%,0.77]; infliximab [12.8%,0.73]; tocilizumab [21.1%,0.77] and rituximab [11.9%, 0.75]. Expected mean costs per patient were 13,588USD, 15,451USD; 15,950USD; 18,705USD and 14,350USD, respectively. In cost-effectiveness and cost-utility analysis, etanercept was the least costly and the most effective alternative being cost-saving in all comparisons: 5117USD less than tocilizumab (most costly alternative); 19.4% more patients met ACR70 response regarding rituximab (the least effective alternatives); incremental utility reached +0.0576 QALYs versus infliximab. Acceptability curves showed that etanercept regardless willingness to pay would be the most cost-effective biologic. **CONCLUSIONS:** Due to its lower costs and favorable effectiveness profile, etanercept is dominant regarding ACR70 response and QALYs gained over other biologic treatments in the management of RA at Venezuelan public health care system.

PMS33

ECONOMIC EVALUATION OF INTRAVENOUSLY IBANDRONATE FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS IN MEXICO

Carlos F[1], Clark P[2], Lechuga D[3]
[1]*R A C Salud Consultores S.A. de C.V., Mexico City, Mexico,* [2]*Hospital Infantil Federico Gómez, Secretaría de Salud, Mexico, Mexico, Mexico,* [3]*Roche Mexico, Mexico, Mexico, Mexico*

OBJECTIVES: Osteoporosis (OP) and fragility fractures (FF) significantly affect both mortality and health-related-quality-of-life, causing high costs. We aimed to determine the cost and the effectiveness of three different bisphosphonates (BP) in Mexico. **METHODS:** A six health-state life-time Markov microsimulation model was adapted to compare intravenously (IV) ibandronate 3mg injection every 3 months (IBD), oral weekly (OW) alendronate 70mg (ALD) and OW risedronate 35mg (RSD), under the perspective of the public health care system in Mexico. Target population consists of postmenopausal (PW) women over 50 years with or without prior fracture. Only direct costs were accounted for and these included drug acquisition and acute medical attention of FF. All costs are expressed in 2009 United States dollars (USD). Unit cost and antifracture efficacy was derived from published literature. Outcomes measures were the type and frequency of FF avoided with each agent compared with no treatment and quality-adjusted life years (QALY). Cost and efficacy were calculated taking into account persistence and compliance data. **RESULTS:** The avoided fractures rate was higher with IV IBD (644 per 10,000 patients Vs. 205 and 203 with ALD and RSD, respectively). When compared with OW BP, IV IBD reduced the total FF frequency in about 10%. Hence, the use of IV IBD resulted in a gain of 37 QALY per every 1,000 patients. The incremental cost per QALY gained with IV IBD ranged from 9898 USD (vs. ALD) to 15,047 USD (vs. RSD). The gross domestic product per capita in Mexico during 2009 was estimated at 8337 USD. Results were robust to variation in all parameters. **CONCLUSIONS:** By reducing significantly the number of doses needed per year, IV IBD improves adherence and decrease the expected frequency of FF in comparison with OW BF. These results suggest that IV IBD is a cost-effective intervention for PM OP in Mexico.

PMS34

COST-EFFECTIVENESS ANALYSIS OF BIO- HYALURONIC ACID (HA) IN PATIENTS WITH KNEE OSTEOARTHRITIS IN MEXICO

Aguirre A[1], Bierschwale H[1], Espinosa F[1], Michel M[2], Aguilera J[3], Esquivel R[4], Oliva C[4], Sierra M[5], Martínez M[6]
[1]*UCB de Mexico, S.A. de C.V., Mexico, D.F., Mexico,* [2]*ISSSTE, 20 de Noviembre, Mexico, D.F., Mexico,* [3]*Instituto Nacional de Rehabilitación, Mexico, D.F., Mexico,* [4]*IMSS, Lomas Verdes, Estado de México, Naucalpan, Mexico,* [5]*PEMEX Norte, Mexico, D.F., Mexico,* [6]*Hospital General Balbuena, Mexico, D.F., Mexico*

BACKGROUND: Osteoarthritis (OA) is the most common rheumatic disease in the world and one of the main causes of joint pain and disability of the adult population; it therefore represents an important use of medical resources for the institutions and compromises the quality of life of patients. **OBJECTIVES:** To analyze the cost-effectiveness of Bio-HA vs. Hilano G-F20 in patients with knee osteoarthritis. **METHODS:** We conducted an economic evaluation. The alternatives to compare were Bio-HA vs Hilano, administered three weekly injections, with follow-up evaluations at week 12. The perspective is the Mexican Social Security Institute (IMSS). The economic model included the cost of drug acquisition and management of adverse events (AE). The use of resources associated with each AE was defined according to a Delphi Panel. The efficacy measure was the proportion of patients with OMERACT-OARSI response, obtained from a head to head analysis (Onel E, 2008). **RESULTS:** The response rates for Bio-HA were 71% versus 63% for Hilano. The knee effusions in patients treated with Bio-HA was 0.6% (MX$39) vs. Hilano 8.1% (MX$531). The cost per patient treated for each alternative was MX$7728 and MX$8338 for Bio-HA and Hilano, respectively. The cost per responder patient was lower for Bio-HA than Hilano, MX $10,885 and MX $13,236, respectively. So, the savings generated by Bio-HA are very high. If we consider the 1,000 patients for each alternative, the savings would be MX$610,000 and this money be useful to purchase an extra 122 cycles of treatment with Bio-HA or to be reassign for other therapeutic areas. Considering all the above Bio-HA proved to be a dominant strategy (less costly and more effective). **CONCLUSIONS:** The results of this pharmacoeconomic analysis suggest that the use of Bio-HA in patients with OA is a cost-saving strategy for the institutions of public health in Mexico.

PMS35

A COST-EFFECTIVENESS ANALYSIS OF DENOSUMAB FOR THE TREATMENT OF POST-MENOPAUSAL OSTEOPOROSIS IN GREECE

Athanasakis K[1], Karampli E[1], Hollandezos M[1], Papagiannopoulou V[2], Badamgarav E[3], Intorcia M[4], Kyriopoulos J[1]
[1]*National School of Public Health, Athens, Greece,* [2]*AMGEN Hellas, Marousi, Greece,* [3]*Amgen, Thousand Oaks, CA, USA,* [4]*Amgen S.A., Barcelona, Spain*

OBJECTIVES: To evaluate the cost-effectiveness of denosumab compared to supportive care (no active osteoporosis treatment), alendronate, ibandronate, risendronate and strontium ranelate for the treatment of women with post-menopausal osteoporosis (PMO) in Greece. **METHODS:** An 8-state, 6-month cycle Markov cohort model was developed in order to estimate costs and effects, i.e. reductions in fracture occurrence, of denosumab vs. comparators for a 5year period, from a third-party payer perspective (Euros, 2011). The model was populated according to the characteristics of the FREEDOM clinical trial population (mean age: 72.3, prevalence of vertebral fracture: 23.6%, femoral neck T-score ≤ -2.5), that also provided the data on efficacy of denosumab. Data on efficacy (relative risk of fractures) for the comparators were taken from a published meta-analysis. The model took into account treatment persistence across all comparators, as well as a 2year residual effect of treatment after discontinuation. **RESULTS:** The base-case analysis showed that the incremental cost per QALY gained with denosumab was €18,813, €24,784, €13,727, €18,436 and €11,114 versus no treatment, alendronate, ibandronate, risendronate and strontium ranelate, respectively. The probabilistic sensitivity analysis demonstrated that denosumab was cost-effective in an implicit €30,000 threshold for 81.6% of the iterations versus no treatment and risendronate, 63.4% versus no treatment and alendronate and 88.2% versus no treatment and ibandronate. Univariate sensitivity analyses showed that changes in persistence rates, baseline age and T-score where the factors with the most significant influence in the results. **CONCLUSIONS:** In a disease that entails a significant morbidity and socioeconomic burden, denosumab seems to be a cost-effective alternative to established treatment regimens for osteoporosis in Greece.

PMS36

ECONOMIC ANALYSIS OF ETANERCEPT IN RHEUMATOID ARTHRITIS FROM A PUBLIC PERSPECTIVE IN COLOMBIA

Fernandes RA[1], Tovar DAB[2], Mould JF[3]
[1]*ANOVA - Knowledge Translation, Rio de Janeiro, Brazil,* [2]*Pfizer, Inc., Santa Fe De Bogota, Colombia,* [3]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: Rheumatoid Arthrtis (RA) leads to significant impact on management costs and patient's quality of life if no therapeutic measure is adopted and represents one of five most common incapacity causes in women aged 15-44 years, in Colombia. Biologic treatment after disease-modifying antirheumatic drugs fail is an alternative, but their high cost represents a challenge for decision makers. This study aims to perform cost-effectiveness and cost-utility analysis of biologic alternatives for moderate to severe RA in Colombia, from a public perspective. **METHODS:** An economic analysis was developed through a decision-tree model to

simulate RA evolution after treatment with etanercept (basecase treatment), adalimumab or infliximab as first-line therapies and their associated costs over a 12-month time horizon. Therapy continuation or switch was evaluated at week 24. Effectiveness measures were ACR70 response and quality adjusted life years (QALYs) gained. Direct medical costs included biologics, concomitant drugs, medical follow-up and adverse events management. Clinical response was extracted from published literature, while costs were collected from Colombian public official databases. Probabilistic sensitivity analyses were performed through Monte Carlo Simulation second-order approach. **RESULTS:** In base case analysis estimated effectiveness resulted in [ACR70, QALY]: etanercept [31.3%, 0.79]; adalimumab [18.1%, 0.77] and infliximab [12.8%, 0.73]. Expected mean costs per patient were 23,065USD, 24,869USD and 25,853USD, respectively. In cost-effectiveness and cost-utility analysis, etanercept was the less costly and the most effective alternative being cost-saving in all comparisons: 2789USD less than infliximab(most costly alternative); 18.5% more patients met ACR70 response regarding infliximab(the least effective alternatives); incremental utility reached -0.0576 versus infliximab. Acceptability curves showed that etanercept regardless willingness to pay would be the most cost-effective biologic. **CONCLUSIONS:** Due to its lower costs and favorable effectiveness profile, etanercept is dominant regarding ACR70 response and QALYs gained over other biologic treatments in the management of RA at Colombian public health care system.

PMS37

THE COST EFFECTIVENESS OF GLUCOSAMINE SULPHATE POWDER (GLUSARTEL) FOR THE TREATMENT OF OSTEOARTHRITIS OF THE KNEE

Batty AJ[1], Birrell F[2]
[1]*BresMed Health Solutions, Sheffield, South Yorkshire, UK,* [2]*University of Newcastle, Newcastle, UK*

OBJECTIVES: Oral glucosamine formulations are frequently used as a food supplement for joint maintenance, with little supportive evidence. However, Glusartel, a formulation of glucosamine (produced by Rottapharm), has been shown to increase oral bioavailability and has been studied in over 7,000 patients, showing a significant improvement in joint space narrowing and knee replacement. The cost-effectiveness of the new product was studied compared to both standard of care and other glucosamine products. **METHODS:** A four state (with death as a sink state) Markov model was constructed to investigate disease progression, patient utility (mapped from the Western Ontario and McMaster Universities Arthritis Index (WOMAC)) and cost. Efficacy was taken from two pivotal trials, while costs were taken from standard sources including NHS Reference Costs, PSSRU, and the British National Formulary. All costs were inflated to financial year 2009/2010, with the perspective taken that of NHS Scotland. **RESULTS:** Using a 50 year (lifetime) time horizon, with patients beginning treatment at age 62 (as seen in the clinical trials), patients treated with Glusartel are estimated to cost £1799 more than those treated with standard management (£6443 vs. £4645), but gain an additional 0.15 (2 d.p.) QALYs (9.45 vs. 9.31), generating an ICER of £12,402. Compared with currently used glucosamine treatment, even conservatively assuming equal efficacy, Glusartel produces a cost saving of £700, and is dominant in outcomes when the assumption around treatment efficacy is relaxed. The model is sensitive to the time horizon, utility in mild/moderate arthritis and data source for costs, with the main driver being the efficacy of Glusartel in delaying severe arthritis. **CONCLUSIONS:** From the perspective of NHS Scotland Glusartel is highly cost-effective compared to standard of care, and cost saving compared to other glucosamine products. By revising existing prescribing patterns, NHS Scotland could both improve patient outcomes, and realise cost savings.

PMS38

A STRUCTURED LITERATURE REVIEW OF RHEUMATOID ARTHRITIS ECONOMIC MODELS FOR BIOLOGICS

van Nooten F[1], Gajria K[2], Kansal AR[3]
[1]*United BioSource Corporation, London, UK,* [2]*MedImmune LLC, Gaithersburg, MD, USA,* [3]*United BioSource Corporation, Bethesda, MD, USA*

OBJECTIVES: To review relevant Rheumatoid Arthritis (RA) economic models for biologics; and identify potential model limitations. **METHODS:** Search targeted economic evaluations of RA biologics since 2000 using Medline, EMBASE, and Cochrane databases. Articles were subjected to a two level review process before data abstraction. **RESULTS:** Twenty-six economic evaluations were published assessing costs and outcomes associated with RA biologics. Most models used a payer perspective. Two methotrexate (MTX)-naïve patient models were cost utility analyses (CUA); one was a patient simulation model and one a decision analytic model. Of seventeen models for disease modifying anti-rheumatic drug (DMARD)/MTX failure populations, sixteen were CUAs and one was a cost-effectiveness (CE) model based on cost/ACR improvement achieved; model structures included patient level simulation, Markov, and decision analytic models. Of seven models identified for anti-TNF inhibitor failure populations, five were CUAs and two were CE models where CE was defined by both cost/remission and cost of achieving low disease activity (Disease Activity Score (DAS)−28 ≤3.2); six models employed a simulation structure and one a Markov structure. Results varied widely across studies due to heterogeneity in the time horizon, perspectives, year of costs and comparators. Model Incremental cost effectiveness ratios (ICERs) ranged from $4,849 (2007$)−$47,157 (2007$) per QALY for MTX-naïve, $14,518 (1998$) −$498,420 (2005$) per QALY for DMARD/MTX failure, and $12,869 (2006$)−$76,363 (2008$) per QALY for TNF-failure. Key limitations included limited availability of treatment data over long time horizons, and use of Health Assessment Questionnaire (HAQ) as primary outcome and as determinant of utility. **CONCLUSIONS:** We recommend future modeling efforts evaluate the use of direct utilities versus mapping; advantages of CUA versus CE and simulation approach using patient level data; benefits of longer time horizon; and inclusion of both health related quality of life assessment such as HAQ and disease activity such as DAS-28 as model inputs.

PMS39

ECONOMIC EVALUATION OF TOCILIZUMAB FOR THE TREATMENT OF SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS IN MEXICO

Carlos F[1], Clark P[2], Lechuga D[3]
[1]*R A C Salud Consultores S.A. de C.V., Mexico City, Mexico,* [2]*Hospital Infantil Federico Gómez, Secretaría de Salud, Mexico, Mexico, Mexico,* [3]*Roche Mexico, Mexico, Mexico, Mexico*

OBJECTIVES: Half of patients with systemic juvenile idiopathic arthritis (sJIA) will eventually fail to non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids. Tocilizumab (TCZ) is indicated for patients with refractory sJIA. We aimed to determine the cost and the effectiveness of adding TCZ to conventional treatment for sJIA in Mexico. **METHODS:** We designed two decision models to compare TCZ versus placebo. In each model, two time horizons were analyzed: 12 weeks and one year. Target population consists of patients (2-19 years) with active sJIA and inadequate response to NSAIDs and corticosteroids. The dosing scheme for TCZ was based on body weight: 8 mg/kg for patients ≥30 kg and 12 mg/kg for patients <30 kg. The analysis was performed under the perspective of the public health care system in Mexico. Tocilizumab acquisition cost, infusion fees and standard management of sJIA according to level of response were evaluated. Efficacy was defined in terms of the American College of Rheumatology Pediatric response criteria. Resource use and unit costs were gathered from local sources; efficacy was derived from two phase-3 clinical trials; increase in mortality and utility scores associated with level of response was based on literature. All costs are expressed in 2011 euros (€). **RESULTS:** A markedly higher proportion of patients achieved an ACRPedi70 response with TCZ in both children with the possibility of maintaining methotrexate (71% vs. 8%) and in those without that alternative (75% vs. 13%). The incremental cost per achieving an ACRPedi70 response was around 2400€ in both models. During base-case, the incremental cost per Quality-Adjusted Life Year (QALY) gained with TCZ ranged from 10,636€ to 10,681€. The gross domestic product per capita in Mexico during 2010 was estimated at 7048€. Results were robust to variation in all parameters. **CONCLUSIONS:** TCZ is a cost-effective option to treat sJIA in Mexico.

PMS40

ECONOMIC EVALUATION OF ETANERCEPT IN RHEUMATOID ARTHRITIS FROM THE PUBLIC PAYER PERSPECTIVE IN BRAZIL

Fernandes RA[1], Takemoto MLS[1], Tolentino ACM[1], Takemoto MMS[1], Santos PML[1], Mould JF[2]
[1]*ANOVA - Knowledge Translation, Rio de Janeiro, Brazil,* [2]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: Rheumatoid Arthritis (RA) leads to significant impact on management costs and patient's quality of life. In Brazil, costs associated to RA patient's care are 6.6-fold higher than general population, with greater resources consumption. Biologic treatment after two disease-modifying antirheumatic drugs fail is an alternative, but their high cost represents a challenge for decision makers. Currently, adalimumab, etanercept and infliximab are provided by the Brazilian public healthcare system. This study aims to assess the cost per responder of etanercept versus adalimumab and infliximab, for moderate to severe rheumatoid arthritis treatment from a public payer perspective in Brazil. **METHODS:** A decision-tree model was developed to simulate RA evolution after treatment with etanercept (basecase treatment), adalimumab or infliximab as first-line therapies and their associated costs over a 12-month time horizon. Therapy continuation or switch was evaluated at week 24. Effectiveness measure was ACR70 response. Direct medical costs included biologics, concomitant drugs, medical follow-up and adverse events management. Clinical response was extracted from published literature, while costs were collected from Brazilian public official databases. Probabilistic sensitivity analyses were performed through Monte Carlo Simulation second-order approach. **RESULTS:** In basecase analysis, 31.4%, 18.2% and 12.9% patients met ACR70 response for etanercept, adalimumab and infliximab. Annual costs per ACR70 responder were 147,147USD, 264,097USD and 327,632USD, respectively. Etanercept represented the least costly per ACR70 responder and the most effective alternative in all comparisons: 116,950USD and 180,485USD less than adalimumab and infliximab, respectively; 13.2% and 18.5% more patients met ACR70 response regarding adalimumab and infliximab. **CONCLUSIONS:** Etanercept exhibited incremental clinical effectiveness at a lower cost per ACR70 responders when compared to adalimumab and infliximab, from the Brazilian public health care system.

PMS41

ASSESSING THE COST EFFECTIVENESS OF BROADENING ACCESS TO ALENDRONATE FOR THE PREVENTION OF OSTEOPOROTIC FRACTURE IN AUSTRALIA

Tilden D[1], Jackson D[1], Tay-Teo K[2], Van Bavel J[2]
[1]*THEMA Consulting Pty Ltd, Pyrmont, NSW, Australia,* [2]*Merck Sharp & Dohme (Australia) Pty Limited, North Ryde, NSW, Australia*

OBJECTIVES: Alendronate is subsidised in Australia for patients with a prior fracture or those aged ≥70 with a bone mineral density (BMD) T-score of ≤-3.0. The objective of the analysis was to assess the cost-effectiveness of broadening access to alendronate to individuals aged ≥ 70 with BMD T–score ≤ –2.5. **METHODS:** A cost-utility analysis was constructed using a microsimulation model of a Markov process. The comparator was 'no alendronate' until such time that the individual became eligible for treatment due to a fracture or to BMD T-score reaching -3. The microsimulation transits patients through six health states of a Markov process with the health states defined by treatment status (not eligible, on treatment, discontinued treatment) and fracture status (with or without history of fracture).

As patients advance through the model, their BMD progresses and they are at risk of fracture (hip, vertebral, other) and of death. BMD changes, fracture risks and mortality were all based on the Dubbo Osteoporosis Epidemiology Study (DOES). Utility values were based on the patients fracture status. Evidence for the efficacy of alendronate in the prevention of fracture was the clinical fracture arm of the Fracture Intervention Trial (FIT). **RESULTS:** The incremental cost per QALY of broadening access to alendronate compared with current practice was $34,808 (incremental costs of $783 per patient with 0.0225 QALYs gained). Broadening access to alendronate resulted in fewer fracture-related deaths (301 per 100,000 population), hip fractures (904), vertebral fractures (259) and other fractures (1098). **CONCLUSIONS:** Broadening primary prevention treatment of osteoporotic fracture with alendronate to individuals aged ≥70 years with BMD T–scores ≤ – 2.5 will prevent fractures and save lives at good value-for-money.

PMS42

COST-EFFECTIVENESS OF INCREASING BISPHOSPHONATES ADHERENCE FOR OSTEOPOROSIS IN COMMUNITY PHARMACIES

van Boven JFM[1], Oosterhof P[1], Hiddink EG[2], Stuurman-Bieze AGG[2], Postma MJ[1], Vegter S[1]
[1]University of Groningen, Groningen, The Netherlands, [2]Health Base Foundation, Houten, The Netherlands

OBJECTIVES: Increasing real-life adherence to bisphosphonates therapy is important to achieve the clinical benefits of reducing fractures reported in randomized clinical trials (RCTs). The aim of this pharmacoeconomic analysis was to determine the cost-effectiveness of a pharmaceutical care intervention program in community pharmacies, aimed to increase bisphosphonates adherence for the prevention of osteoporotic fractures. **METHODS:** A decision analytical model was constructed with a time horizon of three years, discounting at 4.0% and 1.5% annually for costs and effects, respectively. A Dutch healthcare provider's perspective was adopted. Adherence and efficacy data were gathered from a Dutch pharmaceutical care program in community pharmacies (the MeMO intervention). The association between bisphosphonate adherence and osteoporotic fractures was modelled using Dutch clinical studies. Recent and upcoming reimbursement policy changes in The Netherlands were modelled with a scenario of therapeutic substitution, characterized by drastically lower drug prices. **RESULTS:** Adherence to bisphosphonates therapy in The Netherlands was 68.3%. The pharmaceutical care intervention program increased bisphosphonates adherence to 83.9% ($P<0.001$). If the intervention program would be introduced nationwide in community pharmacies, 337 osteoporotic fractures would be prevented and 47 quality-adjusted life years (QALYs) would be gained. Additional medication and intervention costs were €1,738,000; the cost-savings due to reduced fractures were €998,000. The cost-effectiveness of the pharmaceutical care intervention was €16,000 per QALY. When drug prices decline following therapeutic substitution policies, the intervention will be cost-saving. **CONCLUSIONS:** Pharmaceutical care programs in community pharmacies, such as the MeMO intervention, can improve bisphosphonate adherence, resulting in a considerable number of osteoporotic fractures being prevented. Therapeutic substitution policies that lower drug prices will increase the cost-effectiveness of interventions that increase adherence. This study demonstrates the value of pharmaceutical care programs in community pharmacies to increase therapy adherence.

PMS43

COST-MINIMIZATION ANALYSIS OF COLLAGENASE CLOSTRIDIUM HISTOLYTICUM COMPARED WITH FASCIECTOMY IN PATIENTS WITH DUPUYTREN'S CONTRACTURE IN PORTUGAL

Inês M[1], Silverio NM[2], Erdogan-Ciftci E[3]
[1]Pfizer Portugal, Porto Salvo, Oeiras, Portugal, [2]Pfizer Portugal, Porto Salvo, Portugal, [3]Erasmus University Rotterdam, Rotterdam, The Netherlands

OBJECTIVES: Dupuytren's contracture (DC) is a progressive disorder that limits hand function and impacts on patient's ability to work or to perform their daily activities. Current standard of care is limited fasciectomy, a surgical procedure that removes part of the affected cord. *Collagenase clostridium* histolyticum (CCH) is the first licensed pharmacological treatment for DC patients with a palpable cord. This study aims to estimate costs of CCH versus fasciectomy in Portuguese DC patients. **METHODS:** A cost minimization approach was adopted, with effectiveness assumed to be equivalent for CCH and fasciectomy. Resource use was elicited through a panel of five Portuguese experts with extensive clinical experience. Fasciectomy' direct costs of included surgery in-patient cost and post-surgery costs: follow up outpatient visits and physiotherapy. CCH' direct costs included vials costs, administration of injection in an outpatient setting and a follow up outpatient visit. Fasciectomy induced indirect costs were estimated by the human capital method. Unit costs were extracted from Portuguese literature and official sources. Societal perspective was adopted. **RESULTS:** Average direct cost per patient for CCH and fasciectomy were respectively 2,099€ and 2,366€. Average saving per patient is 267€, a reduction of 11% direct fasciectomy costs. Although inclusion of indirect costs can introduce some uncertainty due to measurement error, they should be analysed given their relevance to the society: average saving per patient estimate is 1,407€ when we include productivity costs. **CONCLUSIONS:** CCH is a convenient, minimally invasive, effective and generally well tolerated alternative to surgery for DC' patients. Adoption of CCH as an alternative to fasciectomy offers a choice for DC' patients, and provides an efficient approach to the treatment of DC by reducing the demand for physiotherapy and in-patient services. On average, CCH is cost saving in Portugal compared with fasciectomy and induces superior savings when indirect costs are included.

PMS44

COST-EFFECTIVENESS OF DENOSUMAB IN THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS IN SCOTLAND

Davies A[1], Compston J[2], Ferguson S[3], McClosky E[4], Shearer A[5], Taylor A[5]
[1]Oxford Outcomes (UK), Oxford, Oxfordshire, UK, [2]Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK, [3]Amgen Limited, Uxbridge, UK, [4]University of Sheffield, Sheffield, UK, [5]Amgen Limited, Cambridge, UK

OBJECTIVES: Denosumab has been shown to be a cost-effective use of NHS resources for the treatment of postmenopausal osteoporosis in England and Wales. This study assessed the cost-effectiveness of denosumab given Scottish treatment and resource use patterns. **METHODS:** A probabilistic model employed in a recent submission to NICE was used with resource use amended to reflect local expert advice. This indicated zoledronate requires an annual pre-infusion assessment appointment and that patients failing on, or unable to take oral bisphosphonates are referred to secondary care for advice on further treatment. Denosumab is modelled as initiated in secondary care, with subsequent injections in primary care. Fracture risk for 70 year old women with bone mineral density T-score <-2.5 was based on a published algorithm and accounted for prior fracture. Relative efficacy of osteoporosis therapies was based on meta-analysis and adjusted indirect comparison. Utilities reflected patients' age and modelled health states. All therapies' administration was costed using NHS Reference and PSSRU costs. Drug costs were from the British National Formulary. Costs and utilities were discounted at 3.5%. **RESULTS:** Denosumab dominated strontium ranelate and IV ibandronate in both cohorts, and was cost-effective versus raloxifene (£4,339/QALY without prior fracture and dominant in patients with prior fracture). Denosumab was also cost-effective against no treatment: cost/QALY £22,380 and £9,618 in patients without and with prior fracture respectively. IV zoledronate and denosumab each produced very similar QALYs in the two cohorts, however, denosumab's costs were approximately £1,000 lower in each. Zoledronate's cost/QALY ratios against denosumab were £120,000 and £50,000, i.e. zoledronate was not cost-effective against denosumab. Denosumab had the greater probabilities of being cost-effective at threshold values of £30,000/QALY in both cohorts. **CONCLUSIONS:** Denosumab was shown to be cost-effective against all comparators in both primary and secondary care settings. Compared with zoledronate, denosumab may be a better use of NHS resources.

PMS45

COST-UTILITY AND BUDGET IMPACT ANALYSIS OF CERTOLIZUMAB PEGOL PLUS METHOTREXATE FOR THE TREATMENT OF MODERATE-TO-SEVERE ACTIVE RHEUMATOID ARTHRITIS IN GREECE

Maniadakis N[1], Boumpas D[2], Kourlaba G[1], Christou P[3], Anargiros I[3], Smets E[4], Purcaru O[4]
[1]National School of Public Health, Athens, Greece, [2]University of Crete, Heraklion, Greece, [3]UCB A.E, Alimos, Greece, [4]UCB S.A, Brussels, Belgium

OBJECTIVES: To evaluate the cost-utility and budget impact (BI) of certolizumab pegol (CZP) as an add-on therapy to methotrexate (MTX) versus other first line biological DMARDs, in the treatment of adult patients with active RA who did not respond adequately to DMARDs, including MTX, in Greece. **METHODS:** A Markov (cohort health state transition) model was developed to evaluate the cost-utility of CZP versus other TNF-α inhibitors recommended in Greece (etanercept [ETA], adalimumab [ADA] and infliximab [IFX]). Treatment efficacy was measured using the ACR-responses (ACR20/50/70) at 6 months. ACR estimated rates were based on adjusted indirect comparison (MTX as common comparator) of published clinical trials. Utilities were derived from EQ-5D data from CZP RA clinical trials. Clinical history/resource use data came from published literature. Sensitivity analyses were conducted. The BI of CZP as an add-on therapy to MTX was estimated from payer perspective over 2011–2015. The alternatives to CZP include all TNF-α inhibitors recommended in Greece (etanercept, adalimumab, infliximab, golimumab). Epidemiological data were used to estimate the RA population eligible for CZP therapy. Published 2011 hospital unit costs (drug acquisition, administration, monitoring, resources) in both analyses were taken from Greek routine sources/expert opinion. Base case analysis assumed a payer perspective, costs discounted at 3.5% (CU/BI), a lifetime horizon, with outcomes discounted at 3.5% (CU), 75kg patient-fixed average weight (BI). **RESULTS:** Base case analysis indicated that CZP is cost-effective compared with all combination therapies considered (at €60,000(3xGDP/capita) willingness-to-pay threshold), with an incremental cost-effectiveness ratio of €19,181/QALYs, €32,208/QALYs, €22,349/QALYs versus ADA+MTX, ETA+MTX and IFX+MTX, respectively. In terms of BI, the introduction of CZP on the Greek market produced cumulative net savings of €7.68M during 2011–2015. **CONCLUSIONS:** This analysis shows that CZP+MTX is cost-effective versus. the other TNF-α inhibitors recommended in Greece for the treatment of RA and its use is anticipated to result in budgetary net savings.

PMS46

COST-UTILITY ANALYSIS OF CERTOLIZUMAB PEGOL VERSUS ALTERNATIVE TUMOR NECROSIS FACTOR-INHIBITORS, FOR THE TREATMENT OF MODERATE-TO-SEVERE RHEUMATOID ARTHRITIS IN SPAIN

Villoro R[1], Hidalgo A[2], Ferro B[3], Talavera P[3]
[1]Instituto Max Weber, Madrid, Spain, [2]Castilla-La Mancha University, Toledo, Spain, [3]UCB Pharma S.A., Madrid, Spain

OBJECTIVES: To evaluate the cost-utility of CZP compared with standard-of-care first-line administered TNF-inhibitors + MTX in the treatment of moderate-to-severe RA in Spain. **METHODS:** A Markov (cohort health state transition) model was developed to evaluate the cost-utility of CZP versus the other TNF-inhibitors licensed and recommended in Spain (etanercept [ETA], adalimumab [ADA], and

infliximab [IFX]). Treatment efficacy was measured using ACR-responses (ACR20, ACR50 or ACR70) at 6 months. ACR estimated response rates were based on adjusted indirect comparison (MTX as the common comparator) of published clinical trials. Utilities were derived from EQ-5D data collected in CZP RA clinical trials. Clinical history and resource use data came from published literature. Unit costs (drug, administration, monitoring, and resources) were taken from Spanish routine sources or published references (cost year 2009). Base case analysis was conducted from the payer perspective, with a lifetime horizon, annual discounting rates of costs and outcomes of 3.5% and inflation rate for 2009 onwards of 3%. One-way sensitivity analyses were conducted. **RESULTS:** The average lifetime costs for CZP+MTX, ETA+MTX, ADA+MTX and IFX+MTX were €140,971, €141,197, €139,148 and €136,961, respectively. The quality-adjusted life-years (QALYs) gained were 6.578, 6.462, 6.430 and 6.318, respectively. The deterministic cost-effectiveness analysis found that CZP+MTX dominated ETA+MTX (lower cost, greater QALYs), and that CZP+MTX was cost-effective vs ADA+MTX and IFX+MTX at the €30,000/QALY willingness-to-pay threshold (ICERs of €12,346/QALY and €15,414/QALY, respectively). One-way sensitivity analyses showed that ICERs were most sensitive to the change in annual discount rates, the model cycle (evaluation of ACR response at 3 instead of 6 months), the analysis perspective and the estimation of utilities (HAQ-DI mapping instead of direct evaluation from EQ-5D). **CONCLUSIONS:** This analysis shows that CZP+MTX is cost-effective versus the other considered TNF-inhibitors recommended in Spain for the treatment of RA.

PMS47

THE LONG TERM COST-EFFECTIVENESS OF GOLIMUMAB FOR THE TREATMENT OF SEVERE, ACTIVE ANKYLOSING SPONDYLITIS IN ADULTS WHO HAVE RESPONDED INADEQUATELY TO CONVENTIONAL THERAPY

Farrell J[1], Muszbek N[2], Sheppard O[1], Chaudhary M[3], Naci H[4], Kachroo S[5]
[1]*MSD, Hoddesdon, Hertfordshire, UK,* [2]*UBC, Budapest, Budapest, Hungary,* [3]*Merck & Co. Inc, North Wales, PA, USA,* [4]*UBC, London, London, UK,* [5]*MSD, 1 Merck Drive, NJ, USA*

OBJECTIVES: To evaluate the cost-effectiveness of golimumab (Gol) treatment in severe, active Ankylosing Spondylitis (AS). **METHODS:** A Markov model was constructed based upon the literature, to model the progression of a cohort of AS patients treated with Gol and its comparators over a 20 year time frame. The comparators considered were adalimumab (Ada) and etanercept (Eta) and all were compared to standard care which was comprised of a combination of nonsteroidal anti-inflammatory drugs (NSAIDs), disease modifying antirheumatic drugs (DMARDs), Cox-2 inhibitors and physiotherapy. Long-term efficacy was based on regressions estimated from the Gol phase III trial (GO RAISE) and the literature. Short-term comparative efficacy was derived from a mixed treatment comparison. The outcome measure was quality-adjusted life-years (QALYs). Utilities were estimated through use of an algorithm translating BASFI and BASDAI progression to EQ-5D. Costs were based on the literature (long-term) and expert opinion (short-term). Uncertainty was explored through deterministic and probabilistic sensitivity analysis (PSA). **RESULTS:** Compared to conventional therapy, the incremental cost-effectiveness ratios (ICERs) of the biologic TNF-α inhibitors Gol, Ada and Eta were £30,043, £30,187 and £30,810 respectively, with the TNF-α inhibitors having similar QALYs and costs. In the sensitivity analysis, time horizon and baseline BASFI and BASDAI scores had the biggest impact on the results. Gol was seen to provide the greatest net monetary benefit (NMB) of all the TNF-α inhibitors at all willingness to pay (WTP) thresholds up to £30,000 per QALY. **CONCLUSIONS:** Gol is a highly effective and well-tolerated therapy for the treatment of patients with severe, active AS and represents a treatment option with similar cost-effectiveness versus conventional care as the TNF-α inhibitors currently approved by the National Institute for Health and Clinical Excellence (NICE) in the UK.

PMS48

COST-UTILITY OF DENOSUMAB FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS IN SPAIN

Darba J[1], Kaskens L[2], Sorio F[3]
[1]*Universitat de Barcelona, Barcelona, Spain,* [2]*BCN Health, Barcelona, Spain,* [3]*Amgen, Barcelona, Spain*

OBJECTIVES: To estimate the cost-utility of denosumab compared with generic alendronate, generic risedronate, oral ibandronate, strontium ranelate and no treatment to prevent osteoporotic fractures in Spanish postmenopausal women. **METHODS:** A validated Markov cohort model was adapted to the Spanish osteoporotic patient population (women aged 65 years, T-score ≤ -2.5 SD and a prevalence of morphometric vertebral fractures of 36%) to represent the possibility of transitioning through different health states: well, hip fracture, vertebral fracture, wrist fracture, other osteoporotic fractures, post-vertebral fracture, post hip fracture and death. Efficacy data on fracture risk reduction were derived from a phase III trial for denosumab versus placebo and a meta-analysis conducted by NICE for comparators with follow-up of one to three years. The perspective of the Spanish National Healthcare System was used and costs were referred to 2010. The model included treatment persistence during the intended 5-year treatment period and assumed a two year linear decline in efficacy after discontinuation. Persistence data for all treatments were obtained from prescription data and a persistence study. Results were presented in incremental cost-effectiveness ratios (ICERs). **RESULTS:** The base-case ICERs were estimated at €17,345, €25,397, and €14,543 per QALY for denosumab compared with no treatment, generic alendronate, and generic risedronate. Denosumab was dominant against oral ibandronate and strontium ranelate since resulted in lower costs and better efficacy. **CONCLUSIONS:** This analysis showed that denosumab is a cost-effective treatment option compared to oral osteoporosis treatments.

PMS49

COST-EFFECTIVENESS OF RITUXIMAB IN THE TREATMENT OF RA PATIENTS IN THE NETHERLANDS

Diamantopoulos A[1], Kievit W[2], De Vries R[3], Pompen M[4]
[1]*Symmetron Limited, Elstree, Herts, UK,* [2]*Dutch Rheumatoid Arthritis Monitoring register, Nijmegen, Nijmegen, The Netherlands,* [3]*Roche, Woerden, Woerden, The Netherlands,* [4]*Roche, Woerden, Woerden, The Netherlands*

OBJECTIVES: Rituximab (MabThera™) selectively targets B cells and represents an effective therapeutic approach for RA in addition to existing treatments, such as disease-modifying anti-rheumatic drugs (DMARDs) and tumour necrosis factor (TNF) inhibitors. This study explores the cost-effectiveness of rituximab in TNF-IR patients in the The Netherlands. **METHODS:** The analysis reflects efficacy of the compared strategies based on two parameters: ACR response and HAQ score. A network meta-analysis provided evidence on the comparative efficacy of treatments based on ACR response. Evidence from the REFLEX trial and secondary sources are used to project HAQ score changes of patients over time. Cost input for the analysis is derived from local sources in the The Netherlands. Utility data (EQ-5D) from a patient registry is analysed and categorised into six HAQ score bands based on disease severity. All input is synthesised through an individual simulation model that compares three treatment strategies after failure of a first TNF: one sequence containing rituximab, one containing TNF (i.e. TNF-cycling) and one containing abatecept. Uncertainty around model parameters is explored through probabilistic sensitivity analysis. A scenario analysis uses data on loss of productivity to estimate the indirect costs of the comparing strategies. **RESULTS:** In the base-case analysis, the strategy with rituximab dominates the other strategies. The result is the same in probabilistic sensitivity analysis where over 98% of the samples show that the sequence with rituximab dominates both other strategies. **CONCLUSIONS:** The addition of rituximab +MTX in the standard of care of patients with inadequate response to TNF treatment is estimated to be a cost-effective strategy.

PMS50

COST-EFFECTIVENESS OF BIOLOGIC AGENTS COMPARED WITH METHOTREXATE IN THE TREATMENT OF RHEUMATOID ARTHRITIS IN COLOMBIA

Valle-Mercado C[1], Cubides MF[2], Parra-Torrado M[3], Rosselli D[4]
[1]*Universidad de los Andes, Bogota, Colombia,* [2]*Hospital Militar/Universidad de La Sabana, Bogota, Colombia,* [3]*Fedesarrollo, Bogota, Colombia,* [4]*Universidad Javeriana, Bogotá, Colombia*

OBJECTIVES: We developed a cost-effectiveness model of biological therapy (BT) compared with methotrexate (MTX) alone, using a combination of information from 150 patients at Hospital Militar in Bogota, Colombia, and from international trials and economic aggregated data. **METHODS:** We designed a Markov model with five functional states, based on Health Assessment Questionnaire (HAQ). Five simulations were estimated through hypothetical cohorts of patients, with similar characteristics to our observed sample, who initiated treatment in each of the five states defined for the disease. Simulations were run for 10 and 20 years under different scenarios. Utilities, in QALY were taken from Tufts CEA Registry. Discount rates: 6% for costs and 1.5% for utilities. We calculated both direct and indirect costs, converted into US dollars. **RESULTS:** In the ten-year base case, incremental cost effectiveness ratios (ICER) (in US$ per additional QALY gained) for each of the five functional states in increasing severity order, were $153,184; $139,466; $130,281; $134,752 and $109,934,respectively. In the twenty-year base case, ICERs were $119,025; $112,921; $108,124; $110,520 and $98,119, respectively. Total costs were lower with MTX, despite higher indirect costs and complication costs. However, BT treatment represented more QALYs regardless of the initial state. Moreover, it is more cost-effective to start the treatment from advanced disease states. BT would not be cost-effective in Colombia when using WHO cost-effectiveness threshold (3 times per capita GDP of US$6200) and even less so using other thresholds (US$ 50,000; €50,000 or £30,000 per QALY gained). **CONCLUSIONS:** BT compared to MTX provides more QALYs to the patients, but at a high cost. When ICERs were estimated for Colombia, BT would not be cost effective under usual thresholds. A serious dilemma arises. We suggest establishing different thresholds for different conditions, giving priority to chronic diseases that can lead to serious disability.

PMS51

A COST UTILITY ANALYSIS OF ANTI-TNF AGENTS FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

Adams RC[1], Walsh C[2], Schmitz S[3], Barton P[4], Barry M[1]
[1]*National Centre for Pharmacoeconomics, Dublin, Ireland,* [2]*Trinity College Dublin, Dublin, Ireland,* [3]*Trinity College Dublin, Dublin, Dublin, Ireland,* [4]*University of Birmingham, Birmingham, UK*

OBJECTIVES: There are 5 anti-TNF agents licensed for the treatment of RA in Ireland; adalimumab, certolizumab pegol, etanercept, golimumab and infliximab. Reimbursement agencies have issued mixed approvals for their use through either a multiple assessment process or a single technology appraisal process. Significant uncertainties have been identified through these assessments. A multiple treatment comparison of these agents, focusing on the uncertainties previously highlighted, in the Irish health care setting is the focus of this study. **METHODS:** The Birmingham Rheumatoid Arthritis Model 2009 was used to estimate the cost effectiveness of anti-TNF agents in patients with established RA who were non-responders to methotrexate. The perspective taken is that of the Irish Healthcare Payer. Evidence synthesis of HAQ data (via a multiplier), long and short term survival data was performed in WinBUGs and used to inform the effect parameter in the model. Irish cost data was applied. Utility mapping between HAQ, EQ-5D (revised scoring) and SF-6D was used to model utility gain. Probabilistic analysis was

performed. **RESULTS:** Incremental cost effectiveness ratios were calculated for each anti-TNF in comparison to methotrexate. Infliximab is dominated in almost all scenarios, being more costly and less effective. Etanercept and adalimumab are the most effective options and most costly. Golimumab appears less effective and less costly. Sensitivity analysis around utility measure and HAQ improvement assumptions indicate that these are key drivers to the estimates. **CONCLUSIONS:** This CUA focuses on novel methods for data inputs estimation. Both Bayesian and frequentist methods are employed in order to validate the sub models used. The outputs from the cost utility model show that etanercept and adalimumab appear most effective on the cost effectiveness plane. However they are also more costly than both golimumab and certolizumab pegol.

PMS52

ADDITIONAL MEDICAL COSTS DUE TO FALLS/SLIPS AT THREE TEACHING HOSPITALS IN JAPAN

Tsuda Y[1], Hirose M[2], Egami K[1], Honda J[1], Shima H[1], Imanaka Y[3]
[1]*St. Mary's Hospital, Kurume, Fukuoka, Japan,* [2]*Shimane University Hospital, Izumo, Shimane, Japan,* [3]*Kyoto University, Kyoto, Japan*

OBJECTIVES: Falls/Slips cases injured with over the level two and their medical costs for a year of 2008 at 3 teaching hospitals are explored. **METHODS:** There are 2559, 1394, and 4086 incident reports in 2008 collected at St. Mary's Hospital, Shimane University Hospital, and Kyoto University Hospital, Japan. Their reports include 565, 399, and 561 cases for Falls/Slips. The cases are classified 264, 176, and 306 cases with level 2, and 89, 32, and 82 cases with level 3a, and 8, 3, and 5 cases with level 3b, respectively. We explored 963 cases with over level 2 in order to calculate additional medical costs by using their own administrative profiling data. **RESULTS:** According to the injury level, average AMCs are 108 at SMH, 175 at SUH and, 72 USD at KUH (level 2), respectively. Similarly, Average AMCs are 122, 223, and 97 USD (level 3a), and 1,431, 7,745 and 33,357 USD (level 3b), respectively.With regard to clinical services, AMC with diagnostic imaging is the highest (10,118 USD, SMH; 14,090 USD, SUH), but AMC with surgery/treatment is the highest at KUH, 92,115 USD. AMC with surgery/treatment is 6900 USD at SMH, and 8879 USD at SUH, AMC with iv/div is 1275 USD at SMH and 1818 USD at SUH, AMC with laboratory examination is 674 USD at SMH, and 899 USD at SUH, and AMC with drug administration is 455 USD at SMH and 318 USD at SUH. By contrast, AMCs at KUH are 11578 USD (imaging), 11290 USD (examination), 3372 USD (drug administration), and 714 USD (iv/div), because AMC with level 3b and over is the highest by clinical services. **CONCLUSIONS:** Therefore, Hospital administrators and policy makers have to take appropriate measures to prevent patients from Falls/Slips and save money, because this amount is not overlooked.

PMS53

WORK PRODUCTIVITY AND PRODUCTIVITY COSTS OF PATIENTS WITH ANKYLOSING SPONDYLITIS IN THE CZECH REPUBLIC

Kruntoradova K[1], Klimes J[2], Dolezal T[3], Vocelka M[4], Petrikova A[5]
[1]*Czech Technical University in Prague, Faculty of Biomedical Engineering, Kladno, Czech Republic,* [2]*Charles University, Faculty of Pharmacy, Hradec Kralove, Czech Republic,* [3]*Institute for Health Economics and Technology Assessment, Prague, Czech Republic,* [4]*Third Faculty of Medicine, Charles Universitiy in Prague, Praha 10, Czech Republic,* [5]*VFU Brno, Brno, Czech Republic*

OBJECTIVES: To assess the impact of ankylosing spondylitis (AS) on work productivity, to determine factors influencing work productivity and to estimate productivity costs incurred by AS in the Czech Republic. **METHODS:** A questionnaire including Work Productivity and Activity Impairment Questionnaire (WPAI:AS), Health Assessment Questionnaire (HAQ) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) were filled out by 230 patients with AS in productive age. The interdependence between HAQ, BASDAI, disease duration, age and WPAI:AS scores were described by Spearman's rank correlation coefficient. We have analyzed differences between work-active and all patients (work-active + disable) groups, effect of biological treatment and education level on work productivity. Productivity costs were calculated by friction cost approach (FCA) using friction period of 130 work-days and average monthly gross income as denominator. **RESULTS:** Average patients' age was 49.3 years (22-61) and average disease duration 18.0 years. Mean HAQ and BASDAI were 0.99 and 4.43, respectively. We reported significantly greater loss in work productivity (p-value<0,001) and daily activities impairment (p-value<0,001) for disable patients in compare to work-active patients, differences were by 35.6% and 19.6%, respectively. AS in work-active patients group was associated with 40.7% reduction in work productivity and 40.3% reduction in daily activities. Work-active patients group revealed significantly lower age (p-value<0,001), lower BASDAI (p-value<0,001) and lower HAQ (p-value<0,001). Work absenteeism was weakly correlated with BASDAI and HAQ. Work presenteeism and overall work impairment were moderately correlated with BASDAI and HAQ, whereas impairment of daily activities was strongly correlated with all four WPAI domains. Average annual productivity costs per one patient were €2923 in all patients group. **CONCLUSIONS:** HAQ, BASDAI and age significantly influence patients' productivity. Patients on biologics had lower impairment of daily activities and work productivity and revealed lower HAQ and BASDAI as well. Average annual productivity costs per one patient were €2923.

Muscular-Skeletal Disorders – Patient-Reported Outcomes & Preference-Based Studies

PMS54

THE CLINICAL AND ECONOMIC BURDEN OF POOR ADHERENCE WITH OSTEOPOROSIS MEDICATIONS IN IRELAND

Hiligsmann M[1], Mcgowan B[2], Bennett K[2], Barry M[3], Reginster JY[4]
[1]*Maastricht University, Maastricht, The Netherlands,* [2]*Trinity Centre for Health Sciences, Dublin, Ireland,* [3]*National Centre for Pharmacoeconomics, Dublin, Ireland,* [4]*University of Liège, Liège, Belgium*

OBJECTIVES: The economic impact of therapeutic non-adherence has been rarely examined in chronic diseases. This study aims to estimate the impact of non-adherence with osteoporosis medications on clinical and economic outcomes and to evaluate the economic value of improving patient compliance using hypothetical interventions. **METHODS:** A previously validated Markov microsimulation model was adapted to the Irish setting to estimate long-term costs and outcomes (fractures, life years and quality-adjusted life-year (QALY)) for three adherence scenarios: no treatment, real-world adherence and full adherence over 3 years. The real-world adherence employed compliance and persistence data from the Irish HSE-PCRS pharmacy claims database. The number of fractures associated with poor adherence and the incremental cost per QALY gained between the adherence scenarios was estimated. We also investigated the cost-effectiveness of hypothetical adherence-enhancing interventions according to their cost and effect on adherence (improvements between 10% and 50%). **RESULTS:** The number of fractures prevented and the QALY gain obtained at real-world adherence levels represented only 57% and 56% of those expected with full adherence, respectively. Over 3 years, a total number of 3,340 fractures including 1,271 at the hip were estimated to be associated with non-adherence, resulting in a loss of 3,044 QALYs. The costs per QALY gained of real-world adherence and of full adherence compared with no treatment were estimated at €11,834 and €6,341. An intervention to improve adherence by 25% would result in an ICER of €11,392/QALY and €54,182/QALY if the intervention cost an additional €50 and €100 per year, respectively. **CONCLUSIONS:** Poor adherence with osteoporosis medications results in a 50% reduction in the potential benefits observed in clinical trials and a doubling of the cost per QALY gained from these medications. Depending on their costs and outcomes, adherence-enhancing interventions have the potential to be an attractive approach to improve the allocation of resources.

PMS55

PERSISTENCE TO OSTEOPOROSIS TREATMENT AND ITS ASSOCIATION TO THE RISK OF FRACTURE AMONG WOMEN IN TAIWAN

Ling YL[1], Tang CH[2], Huang KC[2], Chang WL[3]
[1]*The University of Texas at Austin, Austin, TX, USA,* [2]*Taipei Medical University, Taipei, Taiwan,* [3]*National Yang Ming University, Taipei, Taiwan*

OBJECTIVES: The present study investigates the treatment persistence of osteoporosis and assesses its impacts on the risk of fractures among women in Taiwan. **METHODS:** This is a retrospective cohort study design. Patients who filled prescriptions of alendronate, ibandrobate, risedronate, zoledronate, raloxifene or teriparatide during 2005-2009 were retrieved from the National Health Insurance Research database. Non-persistence was defined when the patients did not refill prescription within 30 days after the previous osteoporosis prescriptions. Relative risks of fracture incidence within 3 years after the initial prescription date in four persistence groups (<30 days, 1 month-1 year, 1-2 years, 2-3 years) were evaluated based upon survival analysis. **RESULTS:** A total of 1,287,253 patients were included and followed during the study period of 2005-2009. The overall persistence rates among patients with osteoporosis drug treatment were 37%, 29%, 21%, and 9% after 1, 2, 3, and 4 years, respectively. Risks of fractures were higher in the lower persistence group (HR 0.87, p=0.092 in 1 month-1 year persistence; HR 0.61, p<0.001 in 2-3 years persistence). **CONCLUSIONS:** The relatively high non-persistence rates among patients with osteoporosis treatment and the significant negative association between treatment persistence and fracture incidence indicates potential cost-savings and health gains are substantial if improvement in the treatment persistence can be achieved.

PMS56

SUBJECTIVE HEALTH EXPECTATIONS OF RHEUMATOID ARTHRITIS PATIENTS STARTING BIOLOGICAL THERAPY

Gulacsi L[1], Brodszky V[2], Baji P[3], Gulacsi LÁ[4], Péntek M[2]
[1]*Corvinus University Budapest, Budapest, Hungary,* [2]*Corvinus University of Budapest, Budapest, Hungary,* [3]*Maastricht University, Maastricht, The Netherlands,* [4]*Corvinus University of Budapest, Budapest, Budapest, Hungary*

OBJECTIVES: To study self-estimates of rheumatoid arthritis (RA) patients regarding their future health related quality of life and to assess the acceptability of different health problems at certain stages of life. **METHODS:** A cross-sectional survey was performed in 12 rheumatology centres. RA patients initiating first biological therapy were involved. Disease activity (DAS28) was registered, health status (EQ-5D) and functional disability (HAQ-DI) questionnaires were applied. Participants were asked to indicate the health status they expect in 3 months time and for ages 60, 70 and 80 years, using the health problem descriptions of the EQ-5D. Concerns regarding "some" and "severe problems" in the dimensions of the EQ-5D and HAQ-DI were surveyed by age (acceptable from age 30, 40, 50, 60, 70, 80 or never). **RESULTS:** Altogether 116 patients (87.4% females) were involved, mean (SD): age 52.3 (11.7) years, disease duration 9.3 (8.3) years, DAS28 6.17 (0.89), EQ-5D score 0.348 (0.358), HAQ-DI 1.476 (0.653). Expected status after 3 months: EQ-5D 0.759 (0.270), HAQ-DI 0.648 (0.593). Patient expect to have significantly worse EQ-5D scores at ages 60, 70 and 80 than the actual age specific general population has, mean (SD): 0.438 (0.373) versus 0.728 (0.012); 0.240 (0.406) versus 0.682 (0.016) and 0.070 (0.411) versus 0.615 (0.024), respectively. The majority (26.3%-39.5%) pointed that "some problems" in five dimensions of the EQ-5D are acceptable from age 70. The "severe problems" level was rejected as never acceptable (54.3%-68.0%) except the "usual activities" dimension wherat extreme problems were accepted from age ≥80 by 47.1%. Similar outcomes were found with the HAQ-DI. **CONCLUSIONS:** RA patients initiating biological drug expect quick improvement but prognosticate

sharp health deterioration with age. Nevertheless, moderate health problems are considered as acceptable in advanced ages. These findings intend to support compliance research and health gain valuations.

PMS57

PRELIMINARY PSYCHOMETRIC VALIDATION OF THE SLEEP DISTURBANCE AND SLEEP ADEQUACY SUBSCALES OF THE 1-WEEK RECALL MEDICAL OUTCOMES STUDY SLEEP SCALE IN PATIENTS WITH RHEUMATOID ARTHRITIS

Meldahl ML, Sterling KL, Zagar A, Naegeli A
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: Sleep issues have been reported by patients with rheumatoid arthritis (RA) and recently recommended as a clinical trial endpoint. The objective of this study was to conduct a quantitative validation of the sleep disturbance and sleep adequacy subscales of the 1-week recall Medical Outcomes Study Sleep Scale (MOS-SS) in patients with RA. **METHODS:** Participants with self-reported RA were recruited via newspaper or online advertisements in two regions of the US. Participants completed measures in-person, then completed a one-week retest via mail. Internal consistency of the MOS-SS subscales was evaluated using Cronbach's α; test-retest reliability was assessed using Intraclass Correlation Coefficient (ICC). Pearson's correlation coefficient was calculated to assess convergent validity of MOS-SS 1-week subscales with a Sleep Numeric Rating Scale (NRS). Known-groups validity was assessed using ANOVA to compare MOS-SS mean subscale scores with self-reported RA severity (mild, moderate, severe) and general health (very good, good, fair, poor). **RESULTS:** Participants (N=50) were 76% female, 72% White, mean age (SD) 49.4 (13.2) years and mean disease duration (SD) 13.7 (12.0) years. Cronbach's α for sleep disturbance and adequacy subscales were 0.73 and 0.71, respectively. Mean sleep disturbance and adequacy subscale scores were 47.1 and 34.0 at baseline, 47.3 and 32.0 at 1-week follow-up (ICC=0.78 and 0.75), respectively. Correlations of the sleep disturbance and adequacy subscales with the Sleep NRS were r=0.43 (p=0.002) and r=0.45 (p=0.001), respectively. Mean sleep disturbance and adequacy subscale scores across RA severity and health status groups trended as hypothesized but were not significantly different. **CONCLUSIONS:** The MOS-SS sleep disturbance and sleep adequacy subscales demonstrated good internal consistency and test-retest reliability, modest convergent validity, and trended but did not significantly discriminate based on RA severity or general health. Further psychometric analysis in a larger sample of RA patients is needed to determine if these subscales could be useful in clinical trials.

PMS58

PILOT VALIDATION OF THE BRIEF FATIGUE INVENTORY 'FATIGUE AT ITS WORST' ITEM IN PATIENTS WITH RHEUMATOID ARTHRITIS

Naegeli AN[1], Sterling KL[2]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*Eli Lilly, PuDong, Shanghai, China*

OBJECTIVES: Fatigue has been reported by patients as an important symptom of rheumatoid arthritis (RA) and recommended for measurement in clinical trials. The objective was to evaluate the validity of, 'WORST level of fatigue (weariness, tiredness) during the past 24 hours,' item of the Brief Fatigue Inventory (BFI Q3) in a sample of US patients with self-reported RA. **METHODS:** 50 adults with RA were recruited to complete questionnaires at baseline and one week later. Internal consistency reliability of the BFI fatigue severity subscale (questions 1-3) was evaluated using Cronbach's α. BFI Q3 was assessed using Intraclass Correlation Coefficient (ICC) for test-retest reliability; Pearson's correlation coefficient for convergent validity with BFI fatigue severity subscale and Multidimensional Assessment of Fatigue (MAF) global score; and analysis of variance for known-groups discriminant validity with self-reported RA severity (mild, moderate, severe) and general health (very good, good, fair, poor). **RESULTS:** Participants were 76% female, 72% Caucasian, mean age (SD) 49.4(13.2) years and mean disease duration 13.7(12.0) years. Mean BFI Q3 score was 7.3(1.9) at initial and 6.8 (2.3) at retest; ICC=0.58. Correlation with fatigue severity subscale and MAF were r=0.79(p<.001) and r=.02(p=.92), respectively. Cronbach's α for severity subscale =0.84. Mean BFI Q3 scores were 6.0, 7.1 and 7.8 (p=.36) and poor general health were 5.6, 7.0, 7.9, and 9.0 (p=.01), respectively. **CONCLUSIONS:** In a small sample of patients with RA, assessment of worst fatigue severity as measured by BFI Q3 demonstrated validity. Discrimination based on RA severity was not significant, possibly due to low study power, however trended in the hypothesized direction. Test-retest reliability was low but acceptable, and expected due potentially to the episodic nature of fatigue. Further validation of the BFI Q3 in a larger sample is needed to confirm these findings that the measure is useful in the context of RA clinical trials.

PMS59

INADEQUATE PAIN RELIEF IN KNEE OSTEOARTHRITIS AND PATIENT REPORTED OUTCOMES: A SURVEY OF OSTEOARTHRITIS REAL WORLD THERAPIES (SORT) IN THE UNITED KINGDOM

Jameson K[1], Balshaw R[2], Phillips C[3], Martin GR[4], Everett SV[5], Watson DJ[6], Taylor SD[5]
[1]*Merck Sharp & Dohme Ltd., Hoddesdon, Hertfordshire, UK,* [2]*Syreon Corporation, Vancouver, BC, Canada,* [3]*Swansea University, Swansea, Wales, UK,* [4]*Greenwood and Sneinton Family Medical Centre, Nottingham, UK,* [5]*Merck & Co., Inc., Whitehouse Station, NJ, USA,* [6]*Merck & Co., Inc., Upper Gywdnedd, PA, USA*

OBJECTIVES: Osteoarthritis (OA) has significant patient and economic burden. Despite treatments for OA, data on treatment patterns, adequacy of pain relief, and quality of life are limited. SORT was designed to determine the adequacy of pain relief, and compare patterns of clinical care and patient reported outcomes (PROs) in patients with knee OA. **METHODS:** SORT, a 12-month prospective, observational study will enroll 1400 participants (across 6 countries) who use oral or topical analgesics for knee OA symptoms. Participants visiting a primary care physician must be > 50 years old. Clinical history, medications, quality of life and resource use are collected at baseline and months 1, 3, 6, 9 and 12. Inadequate pain relief (IPR) was defined as an average Brief Pain Inventory pain score of "moderate or greater pain" (score >4). This interim assessment reports data from the UK only. **RESULTS:** To date, 141 participants from the UK have provided baseline data: 67% women; median (range) age 68 years (51-90); history of diagnosed knee OA for an average of 6 years and 68% taking oral pain medication only. Hypertension (52%) was the most common co-morbidity. IPR was reported by 64% of the cohort at baseline (90 of 141). Patients reporting IPR and non-IPR were similar in clinical characteristics (p<.05): BMI 31 kg/m2 (20-55), co-existing OA of the hip (16%) & spine (29%). Participants with IPR (vs. non-IPR) differed in their rating of other PROs: WOMAC Stiffness (mean: 127 vs. 81, p< 0.01); Physical Function (969 vs. 499, p< 0.01); SF-12 General Health (fair/poor 42% vs. 12%, p<0.01) and satisfaction with prescribed treatment (less than satisfied 47% vs. 28%, p< 0.01). **CONCLUSIONS:** With 64% of UK participants reporting IPR at baseline, SORT will provide valuable insight into current treatment patterns and PROs for individuals with knee OA.

PMS60

EXPERIENCES OF PATIENTS WITH RHEUMATOID ARTHRITIS IN THE US AND UK: A CROSS-CULTURAL COMPARISON

Sterling KL[1], Bush EN[2], Naegeli A[2], Swinburn P[3], Gallop K[3], Nixon A[3]
[1]*Eli Lilly, PuDong, Shanghai, China,* [2]*Eli Lilly and Company, Indianapolis, IN, USA,* [3]*Oxford Outcomes, an ICON Plc Company, Oxford, Oxon, UK*

OBJECTIVES: The patient perspective has become increasingly important in the field of rheumatology research. Understanding cross-cultural experiences of RA is helpful when designing clinical trials that include PRO measures. Qualitative data from this study were used to compare the experiences of patients with RA in the US and UK. **METHODS:** Patients with RA in the US and UK who met specific inclusion and exclusion criteria were recruited; criteria in UK were less restrictive than in the US. Concept elicitation interviews were conducted and interview transcripts were analyzed with the aid of ATLAS.ti software to identify concepts and explore interrelationships between concepts. Data were collected and analyzed in accordance with the US FDA's final guidance on PRO instrument development and validation. **RESULTS:** A total of 32 participants were recruited (19 in US; 13 in UK), of which the majority were female (74% in US; 77% in UK) and White (68% in US; 77% in UK). Mean age (SD) of the US and UK participants was 65.1 (6.9) and 47.7 (14.7), respectively. Descriptions of RA in both populations were similar and included pain (n=32) and fatigue-like effects of RA (n=17), which impacted daily activity and psychological well-being. Descriptions of pain were similar in US and UK populations: "dull," "shooting," "nagging," and "gnawing." The term "fatigue" was mentioned spontaneously by some (n=5, 26%) of US participants, and was not mentioned spontaneously by any UK participants. The majority of those asked whether fatigue was a term they would use to describe their symptom affirmed the use of fatigue (71.4% in US and 90% in UK). **CONCLUSIONS:** This small, qualitative, study identified few differences in experiences of RA in US and UK patient populations. Qualitative research is useful for identifying whether the use of identical PRO measures is acceptable in multi-national clinical trials.

PMS61

RAPID REDUCTIONS IN FATIGUE AND SLEEP PROBLEMS AND CORRELATION WITH IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES IN PATIENTS WITH ACTIVE RA TREATED WITH CERTOLIZUMAB PEGOL IN THE REALISTIC 12-WEEK PHASE IIIB RANDOMISED CONTROLLED STUDY

Pope J[1], Fleischmann R[2], Dougados M[3], Bingham CO[4], Massarotti E[5], Wollenhaupt J[6], Duncan B[7], Coteur G[8], Weinblatt ME[5]
[1]*Univ of Western Ontario, London, ON, Canada,* [2]*University of Texas, Dallas, TX, USA,* [3]*Hopital Cochin, Paris, France,* [4]*Johns Hopkins University, Baltimore, MD, USA,* [5]*Brigham and Women's Hospital, Boston, MD, USA,* [6]*Klinikum Eilbek, Hamburg, 22081, Germany,* [7]*UCB, Raleigh, NC, USA,* [8]*UCB, Brussels, Belgium*

OBJECTIVES: To determine the impact of CZP on patient-reported outcomes (PROs), including fatigue and sleep problems, among patients (pts) with active RA who participated in the REALISTIC (RA EvALuation In Subjects receiving TNF Inhibitor Certolizumab pegol [CZP]) study. **METHODS:** A total of 1,063 eligible pts were randomised 4:1 to CZP 400mg at Wks 0, 2 and 4 followed by 200mg every 2 wks or placebo injection (control) every 2 wks added to current therapy. PROs included fatigue (Fatigue Assessment Scale [FAS]), sleep quantity and quality (Sleep Problem Index II domain, Medical Outcomes Study sleep scale [MOS-SPI]), pain (visual analogue scale [VAS]), and pts global assessment of disease activity (PtGA, VAS). The % of pts reporting minimal clinically important differences (MCIDs) was determined: ≥1 FAS, ≥6 MOS-SPI, and ≥10mm pain-VAS and PtGA. Correlations between PROs and DAS28 were assessed (Pearson ρ, CZP group only). NCT00717236. **RESULTS:** Baseline (BL) characteristics were similar for both groups. Significant, meaningful improvements, compared with BL, in fatigue were reported with CZP vs control from the first time point at Wk 2 (−1.1 vs −0.2; p<0.001) to Wk 12 (−1.3 vs −0.5; p<0.001). Sleep problems were significantly reduced with CZP vs control from the first assessment at Wk 6 (−7.6 vs −4.8; p<0.05) to Wk 12 (−7.6 vs −4.2; p<0.01). CZP significantly reduced pain and PtGA from Wk 2 (pain: −15.3 vs −2.8, PtGA: −14.7 vs −2.5; p<0.001). At Wk 12, more CZP pts had improvements ≥MCID in FAS (56.4% vs 46.2%, p<0.01), MOS-SPI (49.7% vs 42.5%, p=0.058), pain (59.0% vs 42.0%, p<0.001) and PtGA (59.5% vs 42.5%, p<0.001). Correlations between PROs and DAS28 were moderate (0.3<rho<0.6). **CONCLUSIONS:** CZP was associated with clinically meaningful reductions in fatigue and sleep problems, and improvements in pain and PtGA, in a diverse group of RA pts reflecting those seen in daily clinical practice.

PMS62

IMPROVED FATIGUE AND PHYSICAL FUNCTION ARE CORRELATED WITH HEALTH-RELATED QUALITY OF LIFE IN PSORIATIC ARTHRITIS SUBJECTS TREATED WITH APREMILAST: RESULTS FROM A PHASE 2, RANDOMIZED, CONTROLLED STUDY

Strand V[1], Hu A[2], Zhang F[2]
[1]Stanford University, Portola Valley, CA, USA, [2]Celgene Corporation, Warren, NJ, USA

OBJECTIVES: Psoriatic arthritis (PsA) is an inflammatory arthritis with deleterious effects on health-related quality of life (HRQOL). We evaluated the effect of apremilast (APR) on patient-reported outcomes (PROs) in PsA subjects and the correlation between the 36-Item Short-Form Health Survey (SF-36) domains and disease-specific measures of physical function and fatigue. **METHODS:** A phase II, multicentre, double-blind, placebo-controlled study randomised 204 subjects with active PsA (duration >6 months; ≥3 swollen joints; ≥3 tender joints) 1:1:1 to oral APR 20mg BID (APR20), 40mg QD (APR40), or placebo for 12 weeks. PROs included Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F), Health Assessment Questionnaire–Disability Index (HAQ-DI), pain visual analogue scale (VAS), and SF-36 domain scores. Correlations between the HAQ-DI, pain VAS, and FACIT-F and the SF-36 Physical Function (PF), Bodily Pain (BP) and Vitality (VT) domains were described with statistical significance. **RESULTS:** At week 12, mean change in PF, BP, and VT was −2.1, 2.7, and 3.1 with placebo; 6.2 (P=0.012 versus placebo), 11.5 (P=0.001 versus placebo), and 6.6 (P<0.05 versus placebo) with APR20; and 3.8, 7.9 (P=0.037 versus placebo), and 3.7 with APR40, respectively. Mean change in HAQ-DI was −0.1, −0.2, and −0.2 with placebo, APR20, and APR40. Mean change in FACIT-F was 0.5, −4.1 (P<0.025), and −4.3 with placebo, APR20, and APR40. Mean percent change in pain VAS was 7.4%, −14.5%, and −15.1% with placebo, APR20, and APR40. Moderate (>0.30≤0.60) and statistically significant (P<0.001) correlations were evident between pain VAS and BP (−0.55), HAQ-DI and PF (−0.43), and FACIT-F and VT (0.55). High (>0.60), statistically significant (P<0.001) correlations were observed for FACIT-F versus VT (0.66) with APR20 and HAQ-DI versus PF (−0.73) with APR40. **CONCLUSIONS:** Treatment of PsA with APR20 was associated with statistically significant improvements versus placebo in FACIT-F and HRQOL. Moderate to high correlations were evident among PROs.

PMS63

NEW DEVELOPMENTS IN THE ANKYLOSING SPONDYLITIS QUALITY OF LIFE (ASQOL) SCALE

Mckenna S[1], Wilburn J[2], Crawford S[2], Aryamanesh M[1], Twiss J[3]
[1]Galen Research Ltd, Manchester, UK, UK, [2]Galen Research Ltd, Manchester, Gtr Manchester, UK, [3]Galen Research Ltd, Manchester, UK

OBJECTIVES: The PsAQoL is a measure of quality of life (QoL) specific to psoriatic arthritis (PsA) first published in 2003. Content of the measure was derived entirely from qualitative interviews conducted with UK PsA patients. New language versions have since been developed for several European countries, the US, Canada, Argentina and Brazil. Interest in the PsAQoL has increased lately due to the need to determine changes in QoL associated with new biological treatments. In recent years there has been a move towards conducting clinical trials in developing countries. This has increased interest in adapting patient-reported outcome measures developed in Europe and the United States for use in new regions of the World. An important question remains to be answered; can such measures provide valid assessment of QoL in these regions? **METHODS:** New adaptations are currently being produced for Eastern Europe (4), the Middle East (2), Central and South America (2) and Asia (5). The measures are being translated (using the two panel methodology required for needs-based measures) and tested with local patients by means of cognitive debriefing interviews. **RESULTS:** To date cognitive debriefing interviews have confirmed the adapted measures' acceptability to patients who found it easy to understand and complete. The adaptations also have good internal consistency (alphas > 0.85) and reproducibility (test-retest reliability coefficients: > 0.85). The adaptations also exhibited construct validity by their ability to distinguish groups of PsA patients that varied by perceived disease severity and general health and by correlating as expected (moderately) with the Nottingham Health Profile. **CONCLUSIONS:** It is intended to use Item Response Theory analyses to determine whether respondents in the developing countries answer the PsAQoL in the same way as those in Western countries. This will show whether the scales work validly in the developing countries.

PMS64

SENSITIVITY OF PRO'S TO DETECT CHANGES IN QUALITY OF LIFE IN PATIENTS TREATED WITH A BIOLOGIC AGENT

Pumford N[1], Wade A[1], Crawford G[1], Mcconnachie A[2]
[1]Patients Direct, Glasgow, UK, [2]Glasgow University, Glasgow, UK

OBJECTIVES: To investigate whether patient reported outcomes in patients who had been prescribed etanercept, an anti –TNF inhibitor, by their specialist could detect changes in quality of life over time. A longitudinal evaluation was designed to collect naturalistic data about their condition, medications and health care experience. **METHODS:** The evaluation was conducted throughout the UK using a web-based system supplemented by telephone reporting PROBE (patient reported outcomes based evaluation). Outcome measures included demographic data, the condition, previous treatment, current medications, patients' experiences of their condition, treatment and healthcare and quality of life. **RESULTS:** A total of 344 people participated in the evaluation at baseline, 290 online and 54 by telephone with a mean age of 53 years and 62% female. 191 of these patients had Rheumatoid Arthritis, 44 Psoriatic Arthritis, 43 Ankylosing Spondylitis, 35 psoriasis and 31 other/missing data. Patients were severely affected by their condition as noted on their quality of life measures at baseline. Treatment had a marked beneficial effect for patients as recorded by all measurement tools. All scores given in order. Baseline month 6 mean (SD) clinical global impression 1 worst health 7 best health 3.15 (1.09) to 4.31 (1.50) p<0.001. EQ 5D Questionnaire 0.0 worst health 1.0 best health 0.39 (0.34) to 0.64 (0.27) p<0.001. DLQI 30 worst effect 0 no effect on life 14.57 (6.74) to 3.69 (6.14) p<0.001. HAQ. 0 no difficulty 3 unable to perform action 1.77 (0.63) to 1.25 (0.73) p<0.001. **CONCLUSIONS:** This evaluation shows that patients have significant impairment of their quality of life before commencing a biologic agent across a range of conditions. Treatment with the biologic agent showed a sustained improvement in their quality of life up to 6 months. The PROBE methodology (web-based system supplemented by telephone reporting) successfully captured changes in patient reported quality of life measures.

PMS65

QUALITY OF LIFE FOR THAI HIP FRACTURE PATIENTS: ASSESSMENTS WITH MEDICAL OUTCOMES STUDY, A 36-ITEM SHORT FORM SURVEY (MOS SF-36) AND ONE-YEAR HEALTH CARE RESOURCE UTILIZATION IN A PUBLIC HOSPITAL

Udombhornprabha A[1], Boonhong J[2], Tejapongvorachai T[3], Komoltri C[4], Sermsri S[5]
[1]Program in Clinical Epidemiology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, [2]Department of Rehabilitation Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, [3]Department of Orthopaedics, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, [4]Clinical Epidemiology Unit, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand, [5]Faculty of Social Sciences and Humanities, Graduate School of Mahidol Univeristy at Salaya, Bangkok, Thailand

OBJECTIVES: Hip fracture is a major health burden in Thailand. We determined the health-related quality of life for patients living with hip fracture, correlated factors and relationships with one-year health care resource utilization. **METHODS:** A self-administered Medical Outcomes Study 36-item Short Form Survey (MOS SF-36) questionnaire was mailed to patient after hospital discharge over 6 months. A cross-sectional analysis of MOS SF-36 was carried out among 119 hip fracture patients of Chiangrai Hospital. Healthcare resource utilization was follow-up for one year taken from hospital database. **RESULTS:** Response rate was 67 % and a mortality rate after one year was 14%. The Cronbach's alpha coefficients of eight items symptoms domain, and of two items of summary score components for physical function and mental function of MOS SF-36 Thai questionnaire were 0.769 and 0.831 respectively. The mean ±SD (95 % CI) for summary score components for physical and mental functions were 40.1±11.6 (38.0-42.2) and 48.0±10.2 (46.1-49.9) respectively. There was no significant difference of mean ±SD scores for global health between gender (p=0.103), age (65≤ and >65years) (p=0.798), BMI (20.0≤ and >20.0kg/m2) (p=0.693), hip fracture management types (surgical and nonsurgical) (p=0.386) and types of hip fracture (p=0.188) respectively. Presence of co-morbidity was a highly correlated factor for summary score components for physical (p=0.030), and mental (p<0.001) functions. There was no significant correlation between overall one year healthcare resource utilization with both summary score components for physical (p=0.567) and mental (p= 0.357) functions. **CONCLUSIONS:** Health-related quality of life assessments with MOS SF-36 for Thai hip fracture patients are reliable. Thai hip fracture patients reflect poorer physical functions than mental functions. Presence of co-morbid disease is a factor well correlated with poorer health-related quality of life. There is no significant correlation between one-year health care resource utilization and health-related quality of life for Thai hip fracture patients.

PMS66

CONCEPTUAL MODEL OF THE IMPACT OF HIP FRACTURE ON PATIENTS' LIVES

Kerr C[1], Gallop K[1], Nixon A[1], Naegeli AN[2], Zhao Y[2], Burge RT[2]
[1]Oxford Outcomes Ltd, an ICON Plc Company, Oxford, Oxon, UK, [2]Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: Hip fractures are traumatic and debilitating events which are more common in the elderly, and associated with loss of mobility and independence, mortality, and significantly increased health care resources. Our objectives were to evaluate the impact of hip fractures on patients' lives and summarise the patient experience in a conceptual model. **METHODS:** Twenty-one adults aged ≥50 years who experienced a hip fracture in the previous 2-18 months were recruited to participate in in-depth semi-structured interviews exploring their experience of hip fracture and impacts on their life. Thematic qualitative analysis of interview transcripts was conducted using ATLAS.ti software to identify areas of impact (concepts) and explore the interrelationships between concepts. A conceptual model was developed based on this analysis. **RESULTS:** Participants were mostly female (n=12) with mean age 75 years (range 53-87 yrs), and 5 participants had a hip fracture treated with partial or total hip replacement. Pain and limited mobility were commonly reported by participants and were associated with increased physical inactivity. Mobility limitations included: difficulties walking (distance, speed, up/down stairs), restricted or difficult lower limb movements, getting or standing up and driving. Restrictions to various activities (everyday, physical, leisure and social) were reported as well as wide-ranging impact on patients' sleep, energy levels, independence, emotions, family and other relationships. Moderators of the impact of hip fracture on patients were also identified and incorporated into the conceptual model. **CONCLUSIONS:** The conceptual model summarizes important experiences and related impacts of hip fracture from the patient's perspective and demonstrates the wide-ranging effects in other areas of patients' lives during their recovery.

PMS67

DETERMINING THE TRUE IMPACT OF DUPUYTREN'S DISEASE: A QUALITATIVE STUDY

Wilburn J[1], McKenna S[2], Crawford SR[1], Perry-Hinsley D[3], Bayat A[3]
[1]Galen Research Ltd, Manchester, Gtr Manchester, UK, [2]Galen Research Ltd, Manchester, UK, UK, [3]Manchester Interdisciplinary Biocentre, Manchester, Gtr Manchester, UK

OBJECTIVES: To explore the impact of Dupuytren's Disease (DD) on patients' quality of life (QoL) and identify implications for clinical practice. A search of the literature failed to identify a patient-reported outcome measure for assessing the impact of DD. The study was designed to be the first stage in the development of such a measure. **METHODS:** The needs-based model of QoL was adopted and unstructured qualitative interviews were conducted with DD patients attending out-patients clinics. Data were transcribed and then underwent interpretative phenomenological analysis (IPA) to identify the key impact areas and common themes in individuals' personal experiences. **RESULTS:** Thirty-four DD patients (73.5% male; aged 41-80; mean (SD): 64.2 (12.5) years) were interviewed. The sample had a wide range of duration of DD (0.5-40; mean (SD) 12.6 (9.9) years). A total of 953 statements relating to the impact of DD were identified from the interview transcripts. These statements fell into 3 major categories of impact; emotional impairment (4 themes including having no confidence in hand and being embarrassed), activity limitations (10 themes including dressing, gripping and personal care) and QoL (11 themes including avoiding physical contact, self-consciousness and socialisation). **CONCLUSIONS:** Dupuytren's disease impacts on patients in three main areas; emotional reactions, activity limitations and QoL. In any trial designed to determine the benefits of new interventions for the disease it is important to ensure that each of these areas is assessed. It is intended to develop valid and reliable DD-specific scales to cover each of these outcomes.

PMS68

MEASURING THE HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH ADALIMUMAB IN GREECE: COMPARING THE RESULTS OF ONE GENERIC (EQ-5D) AND ONE DISEASE-SPECIFIC (HAQ) INSTRUMENT

Settas L[1], Papadopoulos N[2], Pikazis D[3], Vasilopoulos D[4], Katsounaros M[2], Latsou D[5], Kritikou P[5], Vlachopioti Z[6], Floros A[7], Yfantopoulos J[5]
[1]*AHEPA General Hospital, Thessaloniki, Greece,* [2]*General Hospital of Thessaloniki, Thessaloniki, Greece,* [3]*Department of Pathophysiology, General Hospital of Athens, Athens, Greece,* [4]*Athens, Greece,* [5]*University of Athens, Athens, Greece,* [6]*Market Access Department, Abbott Greece, Athens, Greece,* [7]*Medical Department, Abbott Greece, Athens, Greece*

OBJECTIVES: Rheumatoid arthritis (RA) has been associated with significant decreases in a patient's health-related quality of life (HRQL). Our objective was to measure the HRQL of Greek RA patients treated with adalimumab. These outcomes were assessed for differences between the results of a generic (EuroQol-5 Dimension [EQ-5D]) and an RA disease–specific (Health Assessment Questionnaire [HAQ]) instrument. **METHODS:** Data were drawn from an observational 52-week, single-arm study that measured the effectiveness of adalimumab in the treatment of patients with moderate to severe RA. Two instruments were implemented for recording the HRQL during the study duration, the EQ-5D and the HAQ. All statistical analysis was performed using SPSS software. **RESULTS:** The outcome measures revealed that adalimumab is effective in treating patients with moderate to severe RA. The mean utility score, as indicated by the EQ-5D questionnaire, increased from 0.433 at baseline to 0.621 after 12 months of treatment. The mean disability index, as indicated by the HAQ, decreased from 1.341 at baseline to 0.624 at the end of treatment. Although both instruments reached the same conclusion, there was only moderate correlation between the instruments (Spearman's correlation at baseline and at 12 months, r=0.659 and r=0.793, respectively). As expected, the HAQ was more closely correlated with disease activity measures (swollen and tender joints, visual analog scale [VAS] for pain assessment, and VAS for general health assessment by both the patient and the physician) than the EQ-5D questionnaire. **CONCLUSIONS:** Adalimumab is effective in the treatment of Greek patients with moderate to severe RA. Caution should be taken in interpreting the changes in HRQL when different outcome measures are used.

PMS69

EFFECTIVENESS THE TREATMENTS WITH NATURAL MINERAL WATER IN LOW BACK PAIN FOR SPONDYLARTHROSIS

Ferreira MI[1], Silva AJ[2], Almeida A[1]
[1]*Universidade da Beira Interior, Covilhã, Portugal,* [2]*Comissão de avaliação técnica no âmbito do termalismo da DGS, Covilhã, Portugal*

OBJECTIVES: Determine whether treatments with Unhais da Serra natural mineral water, a Portuguese spa, are effective in low back pain for spondylarthrosis. **METHODS:** A descriptive, longitudinal, observational, uncontrolled prospective study was conducted. The 51 study participants underwent 14 days of treatment with Unhais da Serra natural mineral water. Assessment criteria were: pain intensity (Visual Analogue Scale), quality of life (SF36v2), disability (ODIv2), absenteeism, acute outbreak/relapse, drug consumption. The evaluation was conducted in four distinct stages: the first day before, 14 days, 3 and 6 months after the thermal treatment. **RESULTS:** The mean age of the sample was 60.53 years, 60.8% were female. The duration of illness was, on average, 7.35 years, 50.9% were retired and 90.2% were from a countryside district. There was a statistically significant improvement ($p < 0.05$) in pain intensity, quality of life, disability, absenteeism and drug consumption, 14 days, 3 and 6 months after thermal treatment compared to baseline. There was no effect on the number of acute outbreak/relapse. Regarding socio-demographic and clinical data, we get no consistent results, only low correlations and some differences in just a few moments of assessment. **CONCLUSIONS:** This research showed that 14 days of treatment with natural mineral water of Unhais da Serra spa, reduced pain, disability and drug consumption, improved quality of life, not influencing the number of outbreaks acute/relapse presented by the participants. All the beneficial effects were observed in the short and medium term (six months). No consistent conclusion could be drawn to the possible influence of socio-demographic and clinical variables. Thus, treatment with Unhais da Serra spa shows up as an effective complementary treatment modality in selected patients with lumbar spondylarthrosis. It seems to be justified and useful to familiarize patients and their physicians with this modality of treatment because the socio-economic impact of the pathology.

Muscular-Skeletal Disorders – Health Care Use & Policy Studies

PMS70

EVALUATION OF PRESCRIBED PAIN MEDICATIONS PRIOR TO THE INITIATION OF DULOXETINE THERAPY IN A COMMERCIALLY INSURED POPULATION

Wu N[1], Peng X[2], Chen SY[1], Bernauer M[3], Cheung M[1], Boulanger L[1], Zhao Y[2]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Eli Lilly and Company, Indianapolis, IN, USA,* [3]*Eli Lily and Company, Indianapolis, IN, USA*

OBJECTIVES: Duloxetine is approved for the treatment of major depressive disorder (MDD) and general anxiety disorder (GAD), and for the management of diabetic peripheral neuropathic pain (DPNP), fibromyalgia (FM), and chronic musculoskeletal pain, as studied in patients with osteoarthritis (OA) and chronic low back pain. This study assessed pain medication use prior to duloxetine initiation among patients with each of these conditions. **METHODS:** US administrative claims were used to identify commercially-insured duloxetine initiators 1/1/2009-3/31/2010 who had any of the 6 medical conditions mentioned above during the 12 months prior to duloxetine initiation (defined as no duloxetine pill coverage in the previous 90 days). Utilization of pain medications including antidepressants, anticonvulsants, opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and muscle relaxants was assessed over the 3, 6 and 12 months prior to duloxetine initiation. **RESULTS:** The study identified 19,546, 5,764, 2,334, 15,362, 12,317, and 27,781 duloxetine initiators in the MDD, GAD, DPNP, FM, OA, and low back pain (LBP) groups. Antidepressant use was high across all conditions over the 12 months prior to initiation, especially among patients with MDD (84.4%) or GAD (79.9%). Anticonvulsant utilization was highest in DPNP (63.1%) and FM (51.9%), lowest in GAD (39.5%), and similar among other groups (range: 42.8%-48.3%). Opioid use varied greatly across groups (54.5-81.6%), with the lowest use among GAD patients and the highest use among LBP patients. GAD patients had the lowest NSAID use (32.9%), while OA patients had the highest utilization (58.1%). The use of muscle relaxants ranged between 29.4% (DPNP) and 56.7% (LBP) at 12 months prior to duloxetine initiation. Pain medication use in the prior 3 and 6 months showed similar trends. **CONCLUSIONS:** Patients used several types of pain medications prior to initiating duloxetine across disease states. The trends in use were consistent 3, 6, and 12 months prior to duloxetine initiation.

PMS71

A POPULATION BASED ASSESSMENT OF OSTEOPOROSIS PREVALENCE AND TREATMENT IN PRIMARY HEALTH CARE IN MADRID (SPAIN)

Sánchez-Piedra C, Parody Rúa E, González-Enríquez J, Imaz I, Sarría Santamera A
Agencia de Evaluación de Tecnologías Sanitarias (AETS), Madrid, Madrid, Spain

OBJECTIVES: Osteoporosis represents a significant burden both to patients that suffers from this condition, given the complications associated with this disease, as well as to the health care system, given the elevated costs to treat this conditions. Different options are considered in the treatment of osteoporosis, but there are scanty assessments of this condition in large populations. The objective of this study is to describe the population patterns of the prevalence of this disease as well as main treatment trends in primary care centres (PCC) in Madrid. **METHODS:** Information was gathered from electronic medical records of PCC of 7 areas of the region of Madrid. Cross-sectional descriptive study from PCC database. This database contains information about 1,318,020 patients who have visited PCC during 2006 and are older than 25 years-old. Patients with diagnosis of osteoporosis have been identified. The use of pharmacological interventions (biphosphonate, raloxifene, calcium) are described and compared considering sex, age, weight, height, comorbidity, concomitant treatments, number of visits to the doctor and other sociodemographic aspects. **RESULTS:** Overall, the prevalence of osteoporosis was 4.4%, being women 89.3% of reported cases. The median age was 64 years-old (interquartile range 73-57). Osteoporotic patients used biphosphonates (33.1%), raloxifene (3.29%), calcium (40,3%). A 14,3% of patients used only calcium. A 45.31% of patients did not use calcium or other pharmacological treatments. The median age of patients who used biphosphonates was 67, whereas the median age of patients who did not use any treatment, including calcium, was 61. A 7.0% of patients were referred to the traumatologist. **CONCLUSIONS:** Different treatment strategies are considered among physicans of PCC in Spain to manage osteoporotic patients. A relevant proportion of patients did not use any pharmacological intervention. The treatment strategies used in osteoporosis seem to vary by age, and should be adapted to individual risk factors.

PMS72

ASSESSMENT OF PRIOR USE OF PRESCRIBED PAIN MEDICATIONS AMONG ELDERLY PATIENTS WHO INITIATED DULOXETINE

Chen SY[1], Peng X[2], Wu N[1], Bernauer M[3], Rao P[1], Boulanger L[1], Zhao Y[2]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Eli Lilly and Company, Indianapolis, IN, USA,* [3]*Eli Lily and Company, Indianapolis, IN, USA*

OBJECTIVES: Duloxetine is approved to treat major depressive disorder (MDD) and general anxiety disorder (GAD), and to manage the symptoms of diabetic peripheral neuropathic pain (DPNP), fibromyalgia (FM), and chronic musculoskeletal pain as studied in patients with osteoarthritis (OA) and chronic low back pain. This study assessed use of pain medications prior to duloxetine initiation among elderly patients with each of these conditions. **METHODS:** Duloxetine initiators aged 65+ with Medicare Supplemental Insurance in 2007, 2008 and during January 1, 2009-March 31, 2010 who had any of the 6 medical conditions listed above during the 12

months prior to duloxetine initiation (defined as no duloxetine pill coverage in the previous 90 days) were identified via administrative claims. The use of pain related medications was assessed during the 6 and 12 months prior to duloxetine initiation. **RESULTS:** The study identified 1682, 308, 1044, 1363, 4255, and 5189 in the MDD, GAD, DPNP, FM, OA, and low back pain (LBP) cohorts in 2009-2010. Antidepressant use during the 12 months prior to initiation was common, and was highest among MDD (87.2%) and GAD patients (83.4%). The use of anticonvulsants was comparable between cohorts, but highest among patients with DPNP (60.0%) and FM (54.7%), and between 47.0-52.4% among other cohorts. There was varied use of opioids across cohorts, ranging from 63.3% (GAD) to 84.7% (LBP). Non-steroidal anti-inflammatory drugs utilization varied with the lowest use among GAD patients (30.2%) and the highest among OA patients (45.8%). Utilization of muscle relaxants widely ranged from 22.0% (DPNP) to 40.4% (FM). Use of pain medication during the 6 months prior was similar, but was generally 10-15% lower. Use patterns in 2007 and 2008 were similar. **CONCLUSIONS:** Across disease states, patients used a variety of medications prior to the initiation of duloxetine. Patterns of use have largely stayed the same from 2007 through 2010.

PMS73

EPIDEMIOLOGY, THERAPY PATTERNS AND FUNCTIONAL STATUS OF PATIENTS WITH JUVENILE IDIOPATIC ARTHRITIS (JIA) IN RUSSIA

Vorobyev PA[1], Alexeeva EI[2], Bezmelnitsyna L[1], Borisenko O[1], Kirdakov FI[3], Hájek P[4]
[1]*Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia,* [2]*National center for Child Health of Russian Academy of Medical Science, Moscow, Russia,* [3]*University Child Hospital of First Moscow Medical University named I.M.Sechenov, Moscow, Russia,* [4]*Pfizer, Praha, Czech Republic*

OBJECTIVES: For distribution biologic agents in patients with JIA in Russia, data about epidemiology, used drugs and their impact on functional status are necessary. **METHODS:** Records were examined for 6 months retrospectively. Data were collected via medical chart review by rheumatologists from 11 regions of Russia. Functional status was assessed with CHAQ questionnaire. Inclusion criteria: age (younger than 18 years), minimum 6 months since diagnosis of JIA and availability of 6 months retrospective data. Recruitment: no more than 30% patients received biologic therapy. Disease-specific criteria: about 50% had oligoarthritis, 30-40% - polyarthritis and 10-20% - systemic form. Analysis was performed with methods of descriptive statistic, parametric and non-parametric criteria. **RESULTS:** Data on 405 patients were obtained. Ratio (male:female) was 1:1.6. Average duration of disease was 5 years. 72% had a disability status caused by JIA. 43% had mild functional disorders; 32% - moderate; 23% - severe disorders, and only 2% had no functional disorders. Seventy-two percent patients in subgroup without functional disorders got biologic therapy, 30% and 28% got biologic agents in subgroups with mild and moderate disorders respectively. In subgroup with severe disorders 41% received biologic therapy; 18% patients with oligoarthritis got biological agents; 40% - with polyartritis, 54% - with systemic form. **CONCLUSIONS:** Prescription of biologic therapy increases in case of more severe form of JIA. Direct relationship between biologic therapy prescription and functional status was not revealed.

PMS74

USE OF DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS FOR RHEUMATOID ARTHRITIS IN QUEBEC, CANADA

Roussy JP[1], Bessette L[2], Bernatsky S[3], Rahme E[3], Légaré J[4], Lachaine J[1]
[1]*University of Montreal, Montreal, QC, Canada,* [2]*CHUL, Quebec, QC, Canada,* [3]*McGill UHC/RVH, Montreal, QC, Canada,* [4]*Arthritis Alliance of Canada, Neuville, QC, Canada*

OBJECTIVES: Disease-modifying anti-rheumatic drugs (DMARDs) are the cornerstone of rheumatoid arthritis (RA) pharmacotherapy and should be initiated promptly after RA diagnosis. We examined trends in DMARD use among RA patients in Quebec, and factors correlated with DMARD initiation in newly diagnosed RA. **METHODS:** Quebec administrative health databases were used to identify RA subjects and their claims for medical and pharmaceutical services between January 1, 2002 and December 31, 2008. To describe DMARD use, cross-sectional analyses were performed on November 1 of each year. For subjects newly diagnosed with RA, multivariable logistic regressions were used to identify possible predictors of DMARD initiation at 12 months and Kaplan-Meier curves to define the probability of initiating a DMARD over time. **RESULTS:** A total of 32,533 subjects were included (mean age: 67.5 years; 70.4% female). Over the study period, the percentage of subjects on a DMARD increased from 42.0% (November 2002) to 43.2% (November 2008). Being followed by a rheumatologist (vs. GP) was the strongest predictor of DMARD initiation (OR=4.39; 95%CI: 3.80-5.08). The use of NSAIDs, corticosteroids, and opioids in the year prior to cohort entry and the calendar year of cohort entry had a positive effect on DMARD initiation, whereas age, comorbidity score, and the use of acetaminophen had a negative effect. For biologics, calendar year was the strongest predictor (OR 2007 vs. 2002=10.78; 95%CI: 2.45-47.37). Of subjects newly diagnosed in 2002, 0.1% had a biologic initiated within one year, while for those newly diagnosed in 2007 the percentage was 1.3%. In any newly diagnosed subjects, averaged over 2002-2007, the probability of having initiated any DMARDs at 12 months was 38.5% (47.8% for those followed by a rheumatologist). **CONCLUSIONS:** Despite encouraging signs for earlier aggressive RA management, DMARD use appears to be sub-optimal in Quebec. Use of DMARDs was much higher among subjects followed by a rheumatologist.

PMS75

EXPLANATORY FACTORS FOR THE RHEUMATOID ARTHRITIS PATIENTS' ACCESS TO BIOLOGICAL AGENTS IN 15 EUROPEAN COUNTRIES

Laires PA[1], Exposto F[2], Barosa P[2], Hormigos B[2], Martins AP[1]
[1]*Merck, Sharp & Dohme, Oeiras, Portugal,* [2]*IMS Health, Oeiras, Portugal*

OBJECTIVES: In the last decade, several biological agents (biologics), including anti-TNFs, have been approved for use in Rheumatoid Arthritis (RA), thus revolutionizing treatment. Despite the widespread availability of these drugs through Europe, patient access differs significantly among countries. We aimed to compare the share of RA patients being treated with biologics in each country and study the factors that influence the different shares, with focus on the market potential for Portugal. **METHODS:** A multivariable linear regression model using SPSS 10.0 was built to identify which factors best explain a country's share of prevalent RA patients treated with biologics. This share was calculated based on IMS Health reported unit sales converted into annualized treatments by applying defined daily doses by WHO. **RESULTS:** A total of 21 independent variables were collected for each of the 15 European countries, including demographic, economic, funding-related, disease-related and biologics-related data. Model results (Adjusted R2= 0,953; SE=0,0456) indicated that a country's share of prevalent RA patients treated with biologics is mostly explained by its GDP per capita (β=0.006; p<0.0001), the share of biologics treatments per dispensing channel - hospital vs. Retail (β=−0.046; p=0.149) and the usage of methotrexate (β=0.26; p=0.05). Based on these variables and their expected evolution we estimated the overall market potential for the Portuguese market, define 4 country clusters and understand Portugal's relative position among the 15 countries. Share of RA prevalent patients treated with methotrexate in Portugal may be standing 5 years behind comparable countries such as UK, France, Germany or Spain, thus impacting the share of patients treated with biologics. **CONCLUSIONS:** Portugal presents the lowest share of RA prevalent patients treated with biologics of all selected countries. Lower GDP per capita, biologics exclusively dispensed in hospital settings and a low consumption of methotrexate are the best explanatory factors for this reality.

PMS76

TREATMENT PATTERNS AMONG PATIENTS WITH SHOULDER OSTEOARTHISTIS

Kozma CM[1], Bhattacharyya SK[2], Palazola P[2]
[1]*Research Consultant/Adjunct Professor, University of South Carolina, St. Helena Island, SC, USA,* [2]*DePuy Mitek, Inc, Raynham, MA, USA*

OBJECTIVES: To assess treatment patterns among patients with shoulder osteoarthritis (OA). **METHODS:** Data from Thomson MarketScan, a large national managed care population, was used to identify patients with a shoulder OA diagnosis in the first 6 months of 2005 (i.e., the index date). The 360 days post index (identification period) was used to establish baseline treatments (i.e., conservative management (pharmaceutical and physical therapy), steroid injections and shoulder surgery). Patients were required to be continuously eligible for 54 months post-index and were excluded if they had a shoulder surgery claim in the identification period. Four cohorts were followed based on the baseline treatments: C1- conservative treatment; C2- conservative treatment and at least one steroid injection; C3- at least one steroid injection; C4- no treatment claims. Progression to additional treatments was evaluated descriptively from day 361 to 1260 in 180 increments. Logistic regression was used to model the odds or having a claim for a treatment. **RESULTS:** A total of 3646 patients met the analysis criteria (C1, n=2,815(77.2%); C2, n=171(4.7%); C3, n=27(0.7%); C4, n=633(17.4%)). The distribution was split evenly between males (50.2%) and females (49.8%). Patients who received steroid injections in the identification period had the greatest likelihood of having a steroid injection in the observation period (C1-19.2%;C2-43.9%;C3-44.4%;C4-14.1%). The percentage with shoulder surgery was 6.4%, 15.2%, 11.1% and 6.5% for C1 to C4, respectively. Patients with steroids in the observation period (C2 and C3) were more likely to have surgery in the first year of observation. Logistic regression showed that females who had steroid injections (C2 and C3 combined) had odds of surgery that were 2.9 times greater than females with no treatments (C1). **CONCLUSIONS:** The most significant predictor of surgery was presence of steroid injections. Rates of steroid injections and surgery differed based on presence of pre-existing treatments.

PMS77

IMPROVING QUALITY AND REDUCING COSTS IN WORKERS' COMPENSATION HEALTH CARE: A POPULATION-BASED INTERVENTION STUDY

Wickizer TM[1], Franklin GM[2], Fulton-Kehoe D[2]
[1]*The Ohio State University, Columbus, OH, USA,* [2]*University of Washington, Seattle, WA, USA*

OBJECTIVES: To evaluate the effect of a quality improvement intervention that provided financial incentives to physicians to encourage adoption of best practices, coupled with organizational support to improve care management. The intervention, implemented at two pilot sites in Washington State, was aimed at reducing work disability for patients with occupational injuries or illnesses treated within the workers' compensation system. **METHODS:** At each pilot site, a Center for Occupational Health and Education (COHE) was established to recruit physicians for the pilot and to implement the intervention. We conducted a prospective non-randomized intervention study, with a non-equivalent comparison group, using difference-in-difference models. The intervention group included patients (31,520) treated from July 2004 through June 2007 by COHE physicians (n > 300). The comparison group included patients (40,176) treated by non-COHE physicians practicing in the pilot target areas. The baseline (pre-intervention) period was specified as July 2001 to June 2003 and included 33,910 patients treated by COHE and non-COHE physicians. We used logistic regression and generalized linear models to analyze four outcomes at one year following injury: off work and on disability, disability days, and disability costs and medical costs per claim. **RESULTS:** COHE patients were less likely to be off work and on disability at one year post injury (OR = .79, P = 0.003). The COHE was associated with a statistically significant ($p < .01$) reduction in disability days (16.5%) and disability costs (23.7%), and with a non-signific0ant ($p = 0.13$) reduction of 6.7% in medical costs. Patients treated by

COHE physicians who more often adopted occupational health best practices had 57% fewer disability days ($p = 0.001$) compared with patients treated by COHE physicians who less frequently adopted best practices. **CONCLUSIONS:** Physician financial incentives, coupled with care management support, can improve outcomes and reduce costs for patients receiving occupational health care.

Muscular-Skeletal Disorders – Research on Methods

PMS78
MEASUREMENT STRATEGY FOR KYPHOSIS: NEW EVIDENCE FROM PATIENTS AND PHYSICIANS

Bayliss MS[1], Miltenburger C[2], Van de Maele C[3], Alvares L[2], Bujanover S[4]
[1]*QualityMetric Incorporated, Lincoln, RI, USA,* [2]*Medtronic International, Tolochenaz, VD, Switzerland,* [3]*Medtronic - Spinal and Biologics Europe, Zaventem, Belgium,* [4]*Medtronic, Inc., Herzliya, Israel*

OBJECTIVES: Kyphosis due at least one vertebral compression fracture (VCF) is prevalent among osteoporotic patients, resulting in well documented symptoms and impact on functioning and well-being. Assessing health outcomes of interventions concentrates on consequences of back pain, omitting relevant aspects of increased morbidity. A three-part study led to development of a conceptual measurement framework for comprehensive assessment of symptoms, impact and treatment benefits in kyphosis. **METHODS:** We developed a literature-based (PubMed, Medline) Disease Model (DM) for kyphosis for selecting and developing outcome measures, as recommended by regulatory agencies. In-depth interviews were conducted among patients (n=10) and physicians (n=10) to test the DM. Physician respondents were PCPs or specialists currently treating patients with osteoporotic kyphosis. Patient respondents were >50 years old with an osteoporotic VCF >= 90 days prior. Relevant Patient-Reported Outcome instruments (PROs) were evaluated for appropriateness in this population. **RESULTS:** The DM included signs, symptoms, causes/triggers, exacerbations, and functional/well-being impact of kyphosis. The DM content was largely confirmed by all respondents, however patients offered new concepts of emotional and functional impact and clinicians discounted psychosocial concepts (well-being and sleep impairment) and added clinical evaluations of the spinal deformity. Related to these findings, PRO instruments lacked adequate content validity or measurement properties for evaluating kyphosis outcomes. Close matches were the IOF Quality of Life questionnaire (Qualeffo-41) and the Osteoporosis Assessment Questionnaire (OPAQ), though neither includes gastrointestinal or respiratory symptoms. **CONCLUSIONS:** This study confirms the need for more comprehensive assessment of health outcomes in kyphosis, because current approaches omit key concepts (gastrointestinal and respiratory symptoms) and functional impact being a major cost-driver. A comprehensive evaluation of the severity and impact of kyphosis requires clinician evaluation of spinal deformity and patient-report of symptoms (spinal, respiratory, GI) and functional impact and a more complete understanding of the unique information provided by different measurements.

PMS79
MIXED TREATMENT COMPARISON OF BIOLOGIC AGENTS IN PATIENTS WITH RHEUMATOID ARTHRITIS WHO HAVE RESPONDED INADEQUATELY TO METHOTREXATE THERAPY IN THE UNITED KINGDOM

Lebmeier M[1], Pericleous L[2], Taylor PC[3], Christensen R[4], Drost P[5], Bergman G[6], Eijgelshoven I[6], Guyot P[6]
[1]*Bristol-Myers Squibb, Uxbridge, Middlesex, UK,* [2]*Bristol Myers Squibb Pharmaceuticals, Uxbridge, UK,* [3]*Imperial College London, London, UK,* [4]*The Parker Institute: Musculoskeletal Statistics Unit (MSU), Copenhagen, Copenhagen, Denmark,* [5]*Bristol-Myers Squibb, Braine-l'Alleud, Belgium,* [6]*Mapi Values, Houten, The Netherlands*

OBJECTIVES: To compare the clinical effectiveness of abatacept and other biologic Disease Modifying Anti-Rheumatic Drugs (DMARDs), as measured by Health Assessment Questionnaire (HAQ) score, in patients with rheumatoid arthritis (RA) who have responded inadequately to methotrexate (MTX-IR) in the UK environment. **METHODS:** A systematic literature review (conducted in line with UK reimbursement environment) identified controlled trials investigating the efficacy of abatacept (3 studies), adalimumab (2), certolizumab pegol (2), etanercept (2), golimumab(1) and infliximab(2) in MTX-IR patients. The identified trials were comparable in design, included patients, and concomitant treatment (MTX). Mixed treatment comparison analyses were performed on HAQ change from baseline (CFB) at 24 and 52 weeks. Results were expressed as difference in HAQ CFB score between treatments and expected HAQ CFB and the 95% Credible Interval (CrI) per treatment at 24 and 52 weeks. **RESULTS:** The analysis of HAQ CFB at 24 weeks showed that abatacept/MTX is more efficacious than MTX monotherapy (−0.30, 95%CrI:−0.42, −,0.16) and shows small numeric differences versus other biologics/MTX (range:−0.11 to 0.9). The expected mean HAQ CFB at 24 weeks for abatacept (−0.57) was superior to placebo (−0.27) and comparable to all the alternative treatments (adjusted mean between −0.46 and −0.65). The findings at 52 weeks are in line with those at 24-weeks, although no data was available for golimumab. Scenario analyses confirmed the robustness of the findings. **CONCLUSIONS:** Abatacept in combination with MTX is expected to result in a comparable improvement in functional status as measured in HAQ score and ACR responses as other biologic agents in MTX-IR RA patients.

Neurological Disorders – Clinical Outcomes Studies

PND1
ESTIMATING NET HEALTH BENEFITS OF INTRAMUSCULAR INTERFERON BETA-1A AND FINGOLIMOD IN TREATING PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS

Szabo SM[1], Dembek C[2], Moore P[3], White LA[4], Wijaya H[3], Levy AR[1]
[1]*Oxford Outcomes Ltd., Vancouver, BC, Canada,* [2]*Biogen Idec GmbH, Wellesley, MA, USA,* [3]*Oxford Outcomes, Vancouver, BC, Canada,* [4]*Biogen Idec, Weston, MA, USA*

OBJECTIVES: Both intramuscular interferon (IM IFN) β-1a and fingolimod slow reduce progression and relapses among patients with multiple sclerosis (MS). In a head-to-head trial, fingolimod demonstrated greater reductions in relapses, but no difference in progression, compared to IM IFN-β-1a; fingolimod-treated patients were at increased risk of some unintended treatment effects, however. Whether the difference in efficacy between fingolimod and IM IFN-β-1a is offset by the increased risk of unintended effects is unknown. The objective was to estimate the net health benefit (NHB) of IM IFN-β-1a versus fingolimod. **METHODS:** A probabilistic Markov risk-benefit model was developed with three-month cycles and a five-year time horizon (ten years in sensitivity analysis). Model inputs were abstracted from the head-to-head trial, and incorporated intended (preventing progression and relapse) and serious unintended (cardiovascular events, serious infections, and neoplasms) effects of treatment. Utilities for these were discounted at 5% annually, and combined using a minimum model. NHB was expressed in quality-adjusted life years (QALYs) per patient, with 95% credible intervals. **RESULTS:** In a cohort of 1000 patients (mean age, 36 years), the NHB of treatment was 3.76 (3.30-4.08) QALYs with fingolimod and 3.73 (3.24-4.07) QALYs with IM IFN-β-1a over five years. Fingolimod-treated patients accrued slightly more QALYs from intended effects (3.88, vs. 3.82 QALYs for IM IFN-β-1a), but had higher QALY decrements from unintended effects (-0.12, vs. -0.09 QALYs for IM IFN-β-1a). Findings were consistent over a ten-year horizon. **CONCLUSIONS:** Even with greater relapse reduction with fingolimod, both treatments have similar positive NHBs. This was driven by similar disease progression rates between the treatments, and additional risks of unintended effects with fingolimod. This model can assist clinicians and decision makers in quantifying the trade-offs between intended and unintended treatment effects, by jointly incorporating the benefits of slowing progression and reducing relapses, with the risks of adverse events.

PND2
COST OFFSETS AND GAINS IN HEALTH EFFECTS IN THE TREATMENT OF RELAPSING–REMITTING MULTIPLE SCLEROSIS WITH LAQUINIMOD: AN ANALYSIS BASED ON THE ALLEGRO TRIAL

Ekman M[1], White RE[2], Buck PE[2], Justo N[3], Lindgren P[4]
[1]*OptumInsight, Stockholm, Sweden,* [2]*Teva Neuroscience Inc, Horsham, PA, USA,* [3]*i3 Innovus, Stockholm, Sweden,* [4]*OptumInsight, San Diego, CA, Sweden*

OBJECTIVES: In the ALLEGRO Phase III clinical trial, 0.6 mg once daily laquinimod, an oral treatment under development for the treatment of relapsing-remitting multiple sclerosis (RRMS), showed a statistically significant 36% reduction in the risk of confirmed disability progression according to the Expanded Disability Status Scale (EDSS) versus placebo, in addition to a significant 23% reduction in the relapse rate. The purpose of this analysis was to investigate health economic implications of these efficacy results. **METHODS:** A computer model was developed to estimate costs and health effects in the treatment of RRMS with laquinimod, allowing for comparison against different treatment alternatives. The model used a 40-year time horizon to capture long-term consequences, assuming that the treatment duration would be 5 years in concordance with many other models in the field. Efficacy data from the ALLEGRO trial and published cost and quality of life data for Sweden were used to populate the model. As there is not yet an established market price for laquinimod, the analysis focused on cost savings and gains in quality of life. Costs and health effects were discounted at an interest rate of 3%. **RESULTS:** Therapy with laquinimod during 5 years resulted in a gain of 0.29 quality adjusted life years and societal cost offsets of EUR 58,000 over the modeled time period (0.11 Euro/Swedish Krona). On average, 0.5 relapses were also estimated to be avoided during the treatment period. Over 40 years, patients spent 1.2 years less at EDSS level 6 and above. The results were stable for reasonable variation of most model parameters. **CONCLUSIONS:** Efficacy data from the ALLEGRO trial and Swedish cost and quality of life data indicated potential cost savings and improved quality of life. The most important driver of these results is the effect on disability progression.

PND3
RISK-BENEFIT ANALYSIS OF THERAPY IN MULTIPLE SCLEROSIS

Qizilbash N[1], Méndez I[2], Sánchez-de la Rosa R[3]
[1]*Oxon Epidemiology Limited, London, London, UK,* [2]*Oxon Epidemiology Limited, Madrid, Madrid, Spain,* [3]*TEVA Pharma SLU, Madrid, Spain*

OBJECTIVES: To undertake a systematic benefit-risk analysis of glatiramer acetate (GA) in relapse-remitting multiple sclerosis and clinical isolated syndrome using controlled studies, according to the EMA guideline. **METHODS:** We searched PubMed, Embase, the Cochrane Trials Register for eligible articles according to explicit criteria to obtain trials and controlled cohort studies. Fixed and random effects meta-analysis techniques were applied for pooling data. Qualitative and quantitative benefit-risk analyses were performed. **RESULTS:** A total of 4451 patients in 15 studies were included in the meta-analysis. The overall reduction in clinical progression was 40% (RR=0.60, 95%CI: 0.48-0.75) for GA compared with placebo/untreated and 23% (RR=0.77, 95%CI: 0.65-0.92) for GA compared with interferons. The rate of patients free from relapse was higher with GA compared with placebo/standard treatment (RR=1.35, 95%CI: 1.21-1.50) and similar compared with interferons (RR=1.04, 95%CI: 0.98-1.11). For GA compared with interferons there was a13% reduction in discontinuation due to all causes (RR=0.87, 95%CI: 0.72-1.04) and a similar proportion of serious adverse events leading to discontinuation (RR=0.89, 95%CI: 0.56-1.41). Based on these results, for being free from disease progression at 24 months against placebo/untreated, the number needed to benefit was of 22.7 and the risk-benefit ratio was 1.69. Compared with placebo/untreated, the relative net benefit-risk was 9% using a multi-criteria decision analysis.

CONCLUSIONS: GA was found to reduce relapses and clinical progression compared with placebo, and clinical progression in comparison with interferons. Serious adverse events were comparable with interferons. Qualitative and quantitative methods demonstrated that the benefits of GA outweigh the risks but the results differ substantially depending on the quantitative risk-benefit model used.

PND4

A META-ANALYSIS OF THE DURATION OF CLINICAL EFFECT OF ONABOTULINUMTOXINA IN CERVICAL DYSTONIA

Marsh W[1], Monroe D[2], Gallagher C[3]
[1]*Shenandoah University, Winchester, VA, USA,* [2]*Allergan, Austin, TX, USA,* [3]*Allergan Inc, Irvine, CA, USA*

OBJECTIVES: Cervical dystonia is a disabling, painful condition involving involuntary movement and posturing of the head and neck. Botulinum toxin injections are the standard of care in the symptomatic management of this condition, but need to be re-administered regularly to maintain a stable improvement. The duration of clinical effect and thus, frequency of need for reinjection may be dependent on the product used and can impact annualized drug and health care utilization costs. **METHODS:** A literature search was undertaken to identify prospective or retrospective studies reporting duration of effect of onabotulinumtoxinA (BOTOX®). A formal meta-analysis was conducted using Comprehensive Meta-Analysis Version 2. Both a fixed effects and random effects model were performed. The quality of each identified journal article was evaluated using the Cho & Bero Quality scoring instrument by two separate investigators. Differences in scores were resolved through conference. Subgroup analyses were performed on several moderating variables including study quality and dose of onabotulinumtoxinA. **RESULTS:** Of the identified potential journal articles, 13 studies met the inclusion criteria and were used for the meta-analysis. The duration of effect of onabotulinumtoxinA in cervical dystonia was found to be 13.7 weeks (95% CI 13.4 – 13.9 weeks) for the fixed effects model and 13.5 weeks (95% CI 12.7 – 14.3 weeks) for the random effects model. A meta-regression found that the higher the quality score, the shorter the duration of effect. Another meta-regression found that doses of onabotulinumtoxinA greater than 200U generally resulted in a longer duration of effect than doses below 200U. **CONCLUSIONS:** Based on the published literature, the duration of effect of onabotulinumtoxinA was 13-14 weeks. This suggests that, in general, patients with cervical dystonia treated with onabotulinumtoxinA should require approximately 4 treatments per year. A dose-effect for duration was also identified.

PND5

EFFICACY AND SAFETY OF IMMUNO-REGULATORY DRUGS, INTERFERONS BETA AND GLATIRAMER IN RELAPSING-REMITTING MULTIPLE SCLEROSIS

Martínez-Férez IM, Flores-Moreno S
Andalusian Agency for Health Technology Assessment, Seville, Spain

OBJECTIVES: To assess the relative efficacy and safety of high (HD) and low dose (LD) beta interferons (IFNβ-1a and FNβ-1b) and glatiramer treatments in relapsing-remitting multiple sclerosis. **METHODS:** Systematic review of literature. A bibliography search was carried out to identify primary studies on MEDLINE and EMBASE until February 2011. Other databases consulted were: Cochrane library, Centre for Reviews and Dissemination, ECRI, ISI Web of Knowledge e INHATA. Inclusion criteria: 1) head to head randomized clinical trials; 2) patients with relapsing-remitting multiple sclerosis; and 3) Outcomes: relapse rate, proportion of relapse-free patients, time to first relapse, expanded disability status scale, magnetic resonance imaging outcomes and adverse effects. A quality assessment was carried out to estimate the internal validity of the selected studies and the quality of their evidence. Indirect comparison were analysed when head to head studies weren't available. **RESULTS:** Eight studies were included in this report, 5 head to head studies between HD and LD IFNβ and 3 studies which compared the HD beta interferons with glatiramer. No studies were found which compared LD beta interferon and glatiramer. The included studies had moderate internal validity. Direct comparison between the three beta interferons LD 1-a, HD1-a and HD1-b showed that all of them were effective and HD IFNβ were better than LD IFNβ. There was weak indirect and direct evidence for similar efficacy between the HD IFNβ. The comparison HD interferons and glatiramer did not show significant differences in their relapse rate and MRI measures. **CONCLUSIONS:** 1) HD interferons showed greater efficacy at short term in reducing relapses than low-dose interferon. Currently, the estimation of the relative efficacy of two high-dose interferons is not possible but there is weak evidence in favor of similar efficacy, and 2) HD interferons and glatiramer showed similar efficacy for relapse measures at 2 years.

PND6

OUTCOMES OF ANTIEPILEPTIC DRUGS USES AT DOSES ABOVE THE RECOMMENDED RANGE AMONG CHILDREN WITH STRUCTURAL-METABOLIC EPILEPSY IN MALAYSIA

Salih M[1], Bahari MB[1], Hassali MAA[2], Shafie AA[2], Al-lela OQB[3], Abd AY[1], Ganesan V[4]
[1]*Discipline of Clinical Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, Minden, Penang, Malaysia,* [2]*Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, Minden, Penang, Malaysia,* [3]*Universiti Sains Malaysia (USM), Pinang, Malaysia,* [4]*Hospital Pulau Pinang, Georgetown, Penang, Malaysia*

OBJECTIVES: To assess the rate and clinical outcomes of using antiepileptic drugs (AEDs) at doses above the recommended range (DARR) in pediatric outpatients with structural-metabolic epilepsy. **METHODS:** Patients were followed-up retrospectively for one year since the first visit. Inclusion criteria were age >2 years; a diagnosis of structural-metabolic epilepsy; AEDs treatment; and three or more visits during the first year from the referral time. Exclusion criteria were epilepsy surgery within the first year from the referral time; and patients not satisfied inclusion criteria. During the period from January to June 2010, the required data were extracted from medical records. Assessment of AEDs doses was based on the recommended drug doses that were mentioned in "Pediatric Protocols for Malaysian Hospitals". **RESULTS:** Of 120 followed-up patients, only 13 (10.83%) of them exposed to AEDs at DARR. In term of visits, 32 (5.68%) visits out of 563 demonstrated DARR. There was no association between the uses of AEDs at DARR with age, gender, race, child development, and seizure type. However, the uses of AEDs at DARR were significantly higher in polytherapy than monotherapy visits (Chi-square, $p<0.001$). Visits included DARR led to higher seizure frequency than visits without DARR (Mann-Whitney, P=0.001). Ultimately, only patients who weren't exposed to AEDs at DARR showed a significant improvement in their seizure control at the last follow-up visit compared with the baseline (Wilcoxon, P=0.001). **CONCLUSIONS:** The low frequency of DARR indicates the knowledgeability and awareness of the in charged pediatric neurologist about consequences of exceeding average effective doses. In term of better seizure control, uses of AEDs at DARR shows no benefit over using these agents at recommended doses.

PND7

DISABILITY PROGRESSION IN PATIENTS WITH RELAPSING REMITTING MULTIPLE SCLEROSIS (RRMS) WHO EXPERIENCE DISEASE ACTIVITY DESPITE PREVIOUS DISEASE MODIFYING THERAPY

Hettle R[1], Murphy J[1], Eckert B[2]
[1]*HERON Evidence Development Ltd, Luton, UK,* [2]*Novartis Pharma AG, Basel, Switzerland*

OBJECTIVES: Patients with RRMS can benefit from disease modifying treatments (DMT) through delayed disease progression and reductions in relapse frequency. For patients who continue to experience disease activity despite DMT, therapeutic options have been limited. Understanding the relative prognosis of these sub-optimally treated (SOT) patients is of considerable interest given the availability of new treatment options. The aim of our study was to evaluate disease progression of SOT and non-SOT patients enrolled to the placebo arm of the FREEDOMS® trial. **METHODS:** SOT patients were identified as patients who experienced either an unchanged relapse rate, or at least one relapse with additional disease activity observed on MRI, despite treatment with a DMT in the prior year. For each patient group (SOT and non-SOT), Markov state transition matrices were derived. Each matrix evaluated the annual probability of patients transitioning between stages of the Expanded Disability Status Scale (EDSS). Comparisons between patient groups included time to disability greater or equal to (≥) EDSS 4 and EDSS 6, time from EDSS 4 to disability ≥EDSS 6 and mean EDSS score over time. **RESULTS:** Median time to EDSS ≥4 and EDSS ≥6 was 5.5 [4.5, 7.5] and 9.0 [7.0, 12.0] years in SOT patients, compared with 10 [8.5, 12.0] and 18.5 [16.0, 22.5] years in non-SOT patients. Median time from EDSS 4 to disability greater than EDSS 6 was 3.4 [1.8, 5.4] years in SOT compared to 5.3 [3.5, 8.0] years in non-SOT patients. Mean EDSS scores at 2, 5 and 10 years post-onset were estimated at 1.05, 2.55 and 3.21 for SOT and 0.95, 2.13 and 3.07 for non-SOT, respectively. **CONCLUSIONS:** The analysis suggests that RRMS patients who experience relapse and MRI activity despite previous treatment with a DMT face faster progression to severe disability states. The analysis highlights the importance of effective treatment options for these patients.

PND8

PREVALENCE AND PROCEDURE FOR VERTIGO FOLLOW-UP IN FRANCE

Taieb C[1], Ruiz F[2], Mansuy L[3]
[1]*PFSA, Boulogne Billancourt, France,* [2]*Clinsearch, Bagneux, France,* [3]*Pierre Fabre, Toulouse, France*

OBJECTIVES: Vertigo is a crippling and stressful symptom. It involves the illusion of movement that manifests itself with an impression of spinning. It is often accompanied by neurovegetative signs, but the patient remains conscious during the attack. Vertigo, often recurrent and sometimes persistent, can strongly alter the quality of life of patients, to the point of preventing the performance of the majority of daily activities. It increases the risk of falling and depression or anxiety. Describe the initial care of patients with vertigo by general practitioners in France. **METHODS:** A total of 1400 general practitioners drawn by lot from the general practitioners practicing in France were contacted, then questioned. **RESULTS:** The prevalence of consultations for vertigo and, this being any type of vertigo, is 5.57%, with one in three is being recurrent vertigo, with an incidence of 2.49%. 45% of the vertigo cases were not associated with an underlying known pathology (for example, a middle ear infection or brain tumour), 40 % of the benign paroxysmal positional vertigos, 9% Ménière's disease, 6% a vestibular neuronitis or neuritis 69% of cases of recurrent vertigo not associated with an underlying pathology are treated by oral an anti-vertigo drugs, 4% are intravenous, 27% benefit from 2 galenic. Fifty-seven percent of the general practitioners directly treat their patients' vertigo, the others refer them to a specialist. **CONCLUSIONS:** The epidemiology of recurrent vertigo (upon the first appearance) has not been studied. It is necessary to point out that vertigo is, for the most part, recurrent. The interest in this work responds to this problem situation.

PND9

THE ROLE OF SPONTANEOUS EVENTS DATABASES FOR BENEFIT-RISK ANALYSIS

Qizilbash N[1], Méndez I[2], Sánchez-de la Rosa R[3]
[1]*Oxon Epidemiology Limited, London, UK,* [2]*Oxon Epidemiology Limited, Madrid, Madrid, Spain,* [3]*TEVA Pharma SLU, Madrid, Spain*

OBJECTIVES: We used the World Health Organisation database (Vigibase) to evaluate the contribution of a global spontaneous adverse event (AE) database for an analysis of benefit-risk for Glatiramer acetate (GA) in multiple sclerosis. **METHODS:** Vigibase is a passive surveillance system that in 2011 contained over 6 million reports of spontaneous AEs suspected of being linked to health care products from regulatory authorities in nearly 90 countries. GA, interferon beta-1a, interferon

beta-1b (interferons) and natalizumab and the reactions suspected of being associated with them were identified. Disproportionality analyses used the Multi-item Poisson Gamma Shrinker method with WHO-ART diagnosis at the preferred term level for all AEs and for the standard combination of all WHO 'critical terms'. Statistical significance for disproportionality was defined as an Empirical Bayesian Geometric Mean lower fifth percentile (EBGM05) >2.0. Comparisons were made between GA versus all other drugs and GA versus interferons and natalizumab. Sales data for GA were available to calculate reporting rates. **RESULTS:** A total of 2,320 cases with 6,680 AEs with a suspected relationship with GA and 20,155 cases with 72,326 AEs for interferons and natalizumab were identified. Compared with all other drugs in Vigibase and with interferons and natalizumab, GA was associated with several statistically significant observations of disproportionate reporting. WHO 'critical terms' combined were not higher for GA versus interferons and natalizumab (EBGM of 0.84 (90% credibility interval 0.79-0.90). The reporting rate of WHO 'critical terms' for GA was 69 events/100,000 person-year. **CONCLUSIONS:** In a risk-benefit analysis of GA based on traditional meta-analysis, the number of AEs in eligible controlled placebo/untreated and head-to-head studies were limited. In such a situation analysis of a global large spontaneous AEs database permitted the assessment of non-common and important risks. However, the biases inherent in these databases need to be addressed.

Neurological Disorders – Cost Studies

PND10

BUDGET IMPACT ANALYSIS OF THE INTRODUCTION OF FAMPRIDINE TO IMPROVE AMBULATION IN PATIENTS WITH MULTIPLE SCLEROSIS (MS) IN THE UK

Pietri G[1], Miller DW[2], White J[3], Moorcroft E[1]
[1]*HERON Evidence Development Ltd, Luton, UK,* [2]*Biogen Idec, Weston, MA, USA,* [3]*Biogen Idec, Zug, Switzerland*

OBJECTIVES: Ambulation is the most highly valued bodily function for MS patients (Heesen et al.), with ambulation problems recorded in up to 75% of patients (Hobart et al.). Fampridine is a first-in-class treatment for ambulation. It improves the conductivity of the nerves where demyelination has occurred. A preliminary budget impact model (BIM) has been created to analyse the impact of introducing fampridine to treat MS patients with walking impairment in the UK market. **METHODS:** The BIM calculates the budget impact from a UK payer perspective of introducing fampridine in addition to usual care to an eligible MS patient population suffering from ambulation problems with an Expended Disability Severity Scale (EDSS) between 4 and 7.5, using a 3 year time horizon and a market forecast. The model conservatively assumes that all patients respond to treatment and there is no effect of fampridine on usual care resource use. A monthly withdrawal rate is also applied. **RESULTS:** The acquisition cost of fampridine is estimated at £3800 per patient per year. An approximate eligible population of 35,000 MS patients is estimated from literature. The market forecast estimates an uptake of 3%, 10% and 16% of the eligible population in the first three years respectively, and the estimated withdrawal rate is 2.2%. Compared to usual care alone, the annual results for the first three years show an additional budget of £3.4million, £10.9million and £18.2million respectively. **CONCLUSIONS:** The model presents conservative estimates whilst still showing a relatively low impact on the payer's budget, demonstrating that a major unmet need of MS patients can be met without a large increase in budget. Further research is required into response rates, effect of fampridine on usual care treatment costs to get a more accurate estimate of the impact fampridine.

PND11

BUDGET IMPACT ANALYSIS OF FIRST-LINE TREATMENT FOR RELAPSING-REMITTING MULTIPLE SCLEROSIS IN SPAIN

Sánchez-de la Rosa R[1], Sabater E[2], Casado MA[3]
[1]*TEVA Pharma SLU, Madrid, Spain,* [2]*Pharmacoeconomics & Outcomes Research Iberia, Pozuelo, Spain,* [3]*Pharmacoeconomics & Outcomes Research Iberia, Pozuelo de Alarcón, Madrid, Spain*

OBJECTIVES: To assess the budget impact of the treatment for Relapsing Remitting Multiple Sclerosis (RRMS), interferons, and glatiramer acetate, from the National Health System (NHS) perspective. **METHODS:** A budget impact model was designed to compare the cost of RRMS treatment in different settings, using a 5 year time-horizon, considering different percentages of administration of each medication. A reference setting o base case using all the available first line treatments (interferons and glatiramer acetate) was compared with 5 alternatives scenarios excluding each one of these treatments. The cost analysis (2010 euros) includes direct medical resources (drugs, administration, visits, disease management, diagnostic tests). Unitary cost data was obtained from the health costs database e-Salud and drugs Catalogue. **RESULTS:** Considering a cohort of 22,255 patients with RRMS, the mean global budget impact per year would be € 260.775.470 in the base case. The setting that excluded glatiramer acetate increases the budget impact in a 3.23% (€ 372 per patient per year). Pharmacological costs were the key drivers of total cost (90%). **CONCLUSIONS:** The use of glatiramer acetate in the first-line-treatment of RRMS patients is a cost-saving strategy, which may decrease the budget impact from the NHS perspective in Spain.

PND12

THE COST OF CORTICOSTEROID-ASSOCIATED ADVERSE EVENTS IN SYSTEMIC LUPUS ERYTHEMATOSUS

Shah M[1], Chaudhari S[1], Mclaughlin T[1], Kan HK[2], Bechtel B[3], Dennis G[4], Molta CT[5]
[1]*Xcenda, LLC, Palm Harbor, FL, USA,* [2]*GlaxoSmithKline, Research Triangle Park, NC, USA,* [3]*GlaxoSmithKline, Munich, Bavaria, Germany,* [4]*Human Genome Services, Rockville, MD, USA,* [5]*GlaxoSmithKline, King of Prussia, PA, USA*

OBJECTIVES: To estimate costs of managing corticosteroid (CS)-related adverse events (AEs) within a systemic lupus erythematosus (SLE) population. **METHODS:** A retrospective claims analysis (January 1, 2000–June 30, 2010) was conducted within an SLE population to evaluate the risk of known CS-related chronic and acute AEs among CS users and non-users by utilizing Cox proportional hazards models adjusting for patient characteristics, SLE severity, other SLE treatments, and AE-related risk factors. Associated costs were computed for AEs where the risk was significantly different among CS users compared to non-users. CS users having a chronic AE were followed for 12 months post-AE date to capture total costs, which were compared to total costs of CS users who did not have a chronic AE during the same time period. Predicted annual costs were generated using generalized linear models controlling for baseline characteristics. The incremental difference in annual costs among the two groups was considered attributable to the AE. For patients having an acute AE, disease-specific costs were calculated over a 12-month timeframe post-AE date. **RESULTS:** SLE patients receiving CS were more likely to develop chronic AEs (ie, cataracts, sleep disturbances, hypertension, type II diabetes, migraine) and acute AEs (ie, pneumonia, herpes zoster, fungal infections, nausea/vomiting). The average annual cost for managing AEs was highest for type II diabetes ($9763), followed by hypertension ($8774), sleep disturbances ($5599), migraine ($3591), cataracts ($2407), herpes zoster ($2079), pneumonia ($1726), nausea/vomiting ($1357), and fungal infections ($857). When applying base rates and increased risk estimates of each AE to the cost estimates, it costs an additional $784/year per CS user to manage known CS-related AEs compared to CS non-users. **CONCLUSIONS:** Within an SLE population, CS treatment is associated with additional costs of $784/year due to management of CS-related AEs. Providers and payers should consider these potential costs of CS when making treatment decisions.

PND13

MANAGEMENT OF FOCAL EPILEPSY TREATED BY POLYTHERAPY IN FRANCE: THE COST OF PHARMACO-RESISTANCE

de Zélicourt M[1], Laurendeau C[1], Levy-Bachelot L[2], Branchoux S[2], Murat C[2], Vespignani H[3], de Toffol B[4], Fagnani F[1]
[1]*Cemka, Bourg la Reine, France,* [2]*Laboratoire GlaxoSmithKline, Marly le Roi, France,* [3]*Centre Hospitalier et Universitaire de Nancy, Nancy, France,* [4]*CHU Bretonneau, Tours Cedex, France*

OBJECTIVES: Approximately 50% of patients do not achieve seizure control with a single antiepileptic drug (AED). With the advent of multiple AEDs in the past 15 years, the choice of optimal polytherapy remains difficult in absence of clinical studies about the effectiveness of various combination therapies. This study aimed at describing the current management of focal epilepsy treated by polytherapy in France and at estimating the extra-costs of pharmacoresistance (PR) as redefined in 2009 by the International League Against Epilepsy (ILAE). **METHODS:** ESPERA is a European multicenter, observational, cross-sectional study conducted in France and Spain in 2010. A random sample of neurologists enrolled prospectively a sample of adult patients treated with at least two antiepileptic drugs (AEDs) in combination for focal epilepsy. The investigators classified their patients according to the new ILAE criteria and this classification was then reviewed by two independent experts. All items of medical resources use associated with epilepsy were collected retrospectively over the last year and valued according to a societal perspective. **RESULTS:** Seventy-one French neurologists collected analysable data on 405 patients. After review by experts, patients were finally classified as PR in 286 (70.6%) of them, in 91 (22.4%) as responsive and in 28 (7%) as undefined. The mean annual epilepsy related direct costs par patient were 4238 € (SD: 3772) in PR patients as compared with 1907€ (SD: 1,739) in responsive patients. AEDs costs were estimated 2602€ and 1544€ respectively and PR patients were significantly more often hospitalized (mean annual cost: 1023€ versus 78€) and had more procedures (mean annual cost: 194€ versus 53€). **CONCLUSIONS:** Despite the number of therapeutic alternatives available in epileptic patients, a large proportion of them remain with uncontrolled seizures yielding to significant extra costs.

PND14

COMPARING EXPECTED COSTS ASSOCIATED WITH THREE SCREENING STRATEGIES FOR CYSTIC FIBROSIS ALONG SPAIN

Ramos-Goñi JM[1], Valcárcel-Nazco C[1], Castilla-Rodríguez I[1], Espada-Sáenz-Torre M[2], Tellería-Orriols JJ[3], Barroso-Guerrero F[4]
[1]*Servicio de Evaluación del Servicio Canario de Salud, Santa Cruz de Tenerife, Tenerife, Spain,* [2]*Departamento de Sanidad.Gobierno Vasco, Bilbao, País Vasco, Spain,* [3]*Universidad de Valladolid/CSIC, Valladolid, Castilla y León, Spain,* [4]*Universidad de la Laguna (ULL), La Laguna, Tenerife, Spain*

OBJECTIVES: To compare the expected costs (EC) of three different screening strategies for cystic fibrosis implemented in Spain: TIR/DNA/DGGE, TIR/TIR/DNA, and TIR/DNA. These strategies correspond to screening programs in Basque Country, Castilla León and Canary Islands. **METHODS:** For each strategy, EC per child screened, also EC per infant with CF and EC disaggregated by type of test was estimated. In addition, sensitivity of each strategy was calculated. Unless there are differences between unit cost along communities, the same unit cost source for all programs was used, in order to allow comparisons. **RESULTS:** The estimated EC per screened neonate were € 3.67, € 4.07, € 4.11 for TIR/ADN, TIR/ADN/DGGE, and TIR/TIR/ADN respectively, showing that TIR/ADN/DGGE is the strategy with lowest EC for its population. Regarding the sensitivity of the three strategies, the results showed similar and high values for all of them, being the strategy of Basque Country which had highest value (99.37%). The ECs per neonate suffering CF were 82.703,48 €, 18.726,29 €, 16.604,10 € for TIR/ADN, TIR/ADN/DGGE, and TIR/TIR/ADN respectively, showing highest cost per neonate with the disease, however the power of this results is still low, and there are differences between incidences along strategies. **CONCLUSIONS:** In this cost comparative study it was obtained that the

most expensive screening program in term of population ECs is TIR/TIR/ADN. However, this strategy has the lowest EC/neonate with CF. In the opposite TIR/ADN has the lowest EC in term of population but the highest cost in term of neonates with CF. However more data are needed in order to increase the power of estimations. It is clear that the factors which have most influences in cost difference between regions are algorithm type used, order of diagnostic tests and cutoff points.

PND15

ECONOMIC BURDEN OF CHRONIC MIGRAINE IN TAIWAN

Tang CH[1], Chen YC[2], Wang SJ[3], Ng K[4]
[1]*Taipei Medical University, Taipei, Taiwan,* [2]*National Defense Medical Center, Taipei, Taiwan,* [3]*Taipei Veterans General Hospital, Taipei, Taiwan,* [4]*Allergan Singapore Pte Ltd, Singapore*

OBJECTIVES: Migraine is associated with significant medical costs in Western countries. However, there is currently limited information comparing the economic burden of different types of migraine including chronic migraine (CM) (≥15 headache days/month), especially in Asia. This study aims to estimate the medical costs associated with chronic migraine in Taiwan. **METHODS:** A retrospective matched cohort study was conducted utilizing data from the Taiwan National Health Insurance Research Database. Cases of chronic migraine were defined as patients with ≥ one neurological outpatient visit with primary or secondary ICD-9-CM code of 346.11, diagnosed by neurologists in medical centers during 2007-2008. The 1st comparison group was other migraine sufferers (346.XX), without any migraine diagnosis before 2007, matched with cases at a 4:1 ratio by age, gender, and hospital setting. The 2nd comparison group was the general population without any migraine diagnosis during 2005-2009, matched with cases at a 4:1 ratio by age, gender, urbanization level of the residence and income. Medical costs within 365 days after the index date were assessed using a two-part model: a logistic regression to predict the probability of use of services and a generalized linear model to predict utilization for users of services. **RESULTS:** A total of 723 and 727 of CM patients were matched with 2384 of other migraine sufferers and 2906 of the general population, respectively. Patient with CM had significantly higher total medical costs versus those with other migraine (NT$52527 vs. NT$41886, difference=NT$10641; $p<0.001$) or the general population (NT$61018 vs. NT$21377, difference=NT$39641; $p<0.001$). The mean drug costs for CM sufferers were higher than those with other migraine (NT$16617 vs. NT$11217, difference=NT$5400; $p<0.001$) or the general population (NT$19691 vs. NT$7105, difference=NT$12586; $p<0.001$). **CONCLUSIONS:** Consistent with a higher burden of illness, CM sufferers in Taiwan had significantly higher medical costs than those with other migraine diagnoses or the general population.

PND16

HEALTH ECONOMICS OF SCLEROSIS MULTIPLEX IN SLOVAKIA

Psenkova M[1], Paluch A[2], Bielik J[3], Novak I[4]
[1]*Pharm In, Bratislava, Slovak Republic,* [2]*General Health Insurance Company, Banska Bystrica, Slovak Republic,* [3]*Trencin University, Trencin, Slovak Republic,* [4]*Novartis Slovakia, Bratislava, Slovak Republic*

OBJECTIVES: The information on Sclerosis Multiplex (MS) health care and social expenditures is not publicly available in Slovakia. The objective of the Cost of Illness study was to establish the current cost of MS in order to provide a basis upon which the economic impact of new treatments can be estimated. **METHODS:** The analysis was performed based on the several data sources. Information on healthcare and social expenditure were obtained from State Health and Social Insurance Funds. As not all detailed data on expenditures were available in a necessary structure, the missing data were collected in the patient research. Both direct and indirect costs were evaluated and dissagregated by the cost type and severity of the disease based on the EDSS score. Capital method is the most common method applied for calculation of Indirect costs in MS and it was used in order to get comparison with the data published in other countries. **RESULTS:** In Slovakia, the prevalence of MS is 112/100 thousands inhabitans. Total yearly MS expenditures in 2010 were 40,7 mill. EUR. Direct costs counted for 57% of total costs and the most of them (95%) were caused by drugs, hospitalisations and diagnostics (mostly MRI) expenditures. The highest share of Indirect costs represented Loss of productivity (58%), followed by Disability pensions (37%) and Sick leave wage compensation (4%). Direct and indirect costs per one patient represent 3770 Eur and 2896 Eur respectively. **CONCLUSIONS:** The evidence of cost-effectiveness of new treatments must be demonstrated in order to get reimbursement in Slovakia. According the Slovak Guidelines only direct costs are accepted in cost-effectiveness submissions and indirect costs are taken into account only in reasonable cases. Indirect costs represent nearly half of total MS costs (43%) and therefore should be considered in assessing the cost effectiveness of new comming innovative MS therapies.

PND17

TREATMENT EXPERIENCE, BURDEN, AND UNMET NEEDS (TRIBUNE) IN MULTIPLE SCLEROSIS STUDY: EXCESS BURDEN DUE TO RELAPSES

Karampampa K[1], Gustavsson A[1], Miltenburger C[2], Eckert B[3]
[1]*OptumInsight, Stockholm, Sweden,* [2]*Former employee at OptumInsight, Stockholm, Sweden,* [3]*Novartis Pharma AG, Basel, Switzerland*

OBJECTIVES: A Multiple Sclerosis (MS) relapse refers to an episode of neurological disturbance during which an acute worsening of function occurs, usually lasting for several days or weeks. The TRIBUNE study provides a detailed exploration of costs and quality of life (QoL) associated with MS relapses. **METHODS:** Patients in five European countries (France, Germany, Italy, Spain, and UK) completed a self-administered web-based questionnaire capturing information on demographics, disease characteristics and severity (EDSS), co-morbidities, relapses, resource consumption, and relevant aspects of QoL. The effect of relapses on the socioeconomic burden was assessed by the difference in costs and QoL incurred by relapsing-remitting MS (RRMS) patients with and without relapse(s) with EDSS score ≤5. **RESULTS:** Out of 1261 patients that completed the questionnaire, 68% had RRMS and 87% reported receiving MS treatment. Nearly half (48%) of the RRMS patients with an EDSS score ≤ 5 reported having at least one relapse during the past year. This sub-group reported a higher consumption of direct medical resources, professional and informal care, and more sick-leave days compared to patients without relapse(s). The difference in costs of patients with relapse(s) compared to those without ranged between €3,321 and €9,430 across countries. Relapses requiring treatment with steroids or hospitalization resulted in higher costs compared with relapses not needing an intervention; €4,062 - €10,589 versus €340 - €5,096 respectively across countries. QoL outcomes were also correlated with relapse(s). **CONCLUSIONS:** The additional burden imposed by relapses is important both in terms of excess cost and the impact on quality of life. The use of effective treatments that reduce the frequency of relapses, in addition to providing clinical benefits, could potentially lessen the clinical and socioeconomic burden of MS.

PND18

RECENT TRENDS IN MUSCULAR DYSTROPHY-RELATED INPATIENT CARE AMONG PEDIATRIC PATIENTS IN THE UNITED STATES

Candrilli SD[1], Bell C[2], Davis KL[1]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*GlaxoSmithKline Research & Development, Research Triangle Park, NC, USA*

OBJECTIVES: Muscular dystrophies (MD) are a group of genetically heterogeneous disorders, characterized by progressive muscle wasting and weakness. The MDs vary in incidence, pattern of inheritance, age of onset (though frequently among pediatrics), muscles affected, and progression. Overall, MD imposes a significant economic burden on both patients and society in general. This study assessed recent trends in pediatric MD hospitalizations in the United States (US). **METHODS:** Data for pediatric (≤20 years) hospitalizations with a primary diagnosis of MD (ICD-9-CM codes 359.0, 359.1, or 359.2) from the 1997, 2000, 2003, and 2006 HCUP Kids' Inpatient Databases, nationally representative databases of pediatric hospitalizations in the US, were analyzed. Weighted estimates of the number of hospitalizations for MD, characteristics of these hospitalizations (e.g., patient demographics), and associated resource-based measures (i.e., charges, length of stay [LOS], and most common primary procedures performed) were derived. **RESULTS:** Between 1997 and 2006, the rate of pediatric MD-related hospitalizations (per 100,000 2010 US pediatric population) has increased, from 3.57/100,000 in 1997 to 4.12/100,000 in 2000, 4.39/100,000 in 2003, and 4.56/100,000 in 2006. Mean LOS decreased appreciably between 1997 and 2000, then remained unchanged through 2006 (10.7 days in 1997, and 9.4 days in 2000, 2003, and 2006). During each year of the study period, continuous mechanical ventilation and dorsal and dorsolumbar fusion (posterior technique) were the most frequently observed primary procedures. Finally, mean total charges (2010 US $) for MD-related stays increased roughly 21%, from $53,739 (1997) to $65,280 (2006). **CONCLUSIONS:** We examined rates of pediatric MD-related hospitalizations in the US, and observed an increase in the rate of hospitalizations over time. LOS decreased from 1997 to 2000, then remained constant through 2006, although total charges increased significantly over this time. These findings provide insight into MD-related hospitalizations in the US and highlight the need to further examine the burden of MD.

PND19

COST OF THE RELAPSE OF MULTIPLE SCLEROSIS IN SPAIN

Gubieras L[1], Casado V[1], Romero-Pinel L[1], Matas E[1], Bau L[1], Martínez-Yélamos S[1], López M[2], Escartín A[2], Arbizu T[1]
[1]*Hospital Universitari de Bellvitge, Barcelona, Spain,* [2]*Hospital de la Santa Creu i Sant Pau, Barcelona, Spain*

OBJECTIVES: Multiple sclerosis (MS) is a prevalent, chronic and disabling disease, affecting mainly young adults. The most common clinical form presents with recurrent episodes of focal neurological deficits, called relapses. The aim of this work is to analyse the socioeconomic cost of an MS relapse. **METHODS:** A prospective observational study performed in 2 MS Units, located in Barcelona (Spain). We included 100 consecutive patients (april 2007 to november 2009) who have had a relapse. Patients were invited to answer a questionnaire after the relapse, with demographic, social, employment status data and clinical aspects, as well as data about the consumption of sanitary and no-sanitary resources during the relapse. The unit costs were calculated according to the Catalan Health Service. **RESULTS:** The mean age was 38.3 years, and 2 out of 3 were female sex. The mean duration of disease was 9.5 years. 94% of patients had recurrent-remitting MS and secondary-progressive 6%. At the time of the relapse 76% had a mild disability, 22% modeate and 2% severe. 63% of patients reported to be employed. The relapse required a mean of 3.1 medical visits, 3.7 days of outpatient hospitalization, 22.5 hours for informal care and 12.4 sick leave days. The MS relapse costs resulted 2.609 euros per patient. This included 1.524 euros of direct costs (medical visits: 183,7 euros, complementary tests: 28,5 euros, hospitalizations days: 32,5 euros, outpatient hospitalization:777,8 euros, displacements:152,9 euros, rehabilitation: 98,9 euros, informale care: 151,7 euros, formal care: 21,5 euros and treatment: 76,5 euros) and 1.085 euros of indirect costs (sick leave days). **CONCLUSIONS:** Total cost of MS relapse resulted (included direct and indirect costs) 2.609 euros per patient. The main contributors to total cost were sick leaves and outpatient hospitalization.

PND20

A COST-OF-ILLNESS ANALYSIS OF AMYOTROPHIC LATERAL SCLEROSIS IN GREECE

Athanasakis K[1], Sideris M[1], Zacharis M[2], Rentzos M[2], Evdokimidis I[2], Kyriopoulos J[1]
[1]*National School of Public Health, Athens, Greece,* [2]*Aeginition University Hospital, National and Kapodistrian University, Athens, Attica, Greece*

OBJECTIVES: To estimate the annual per patient cost of Amyotrophic Lateral Sclerosis (ALS) in Greece from a societal point of view. **METHODS:** Data on direct costs (medications, laboratory/imaging tests, consultations, hospitalizations) were obtained through retrospective chart review of a sample of patients followed-up in Aeginition University Hospital, a reference centre for ALS in Greece. Eligible patients were those that visited the ALS clinic in the previous 6 months and had fully recorded data for the previous year. Patients were also personally interviewed, following consent, based on a strictly-structured questionnaire, with an aim to record indirect costs incurred in the previous year (work absenteeism, professional home help, walking aids). Unit prices for health-resource use were the official NHS prices. Work loss and home help were costed with the hourly rate of the basic salary, in order to obtain a conservative approach. Costs are reported in year 2011 Euros. **RESULTS:** The sample (N=34) was 53% female with an average age of 61.6 years. Total average annual per patient cost was 7450.6€ (standard deviation: 6423€), out of which 4136.3€ (s.d. 1,350€) were direct and 3314.2€ (s.d. 6190€) were indirect expenditure. Medications accounted for 32.7% of the total cost, followed by professional home help (24.4%), work absenteeism (17.7%) and hospitalizations (9.2%). Women had a significantly higher average cost than men (10,004€ vs. 4,347€, $p<0.05$), mostly as a result of indirect expenditures from productivity loss. Age >65 did not have a significant impact on outcomes due to the substitution of productivity losses (<65) by home help, for patients >65. **CONCLUSIONS:** ALS entails a significant per patient economic burden in societal terms. Cost-of-illness data, even for rare diseases, provide important inputs for the decision-making process in health as well as for awareness purposes.

PND21

COST OF ALZHEIMER'S DISEASE IN ROMANIA

Paveliu MS[1], Tudose C[2], Tudose F[3]
[1]*Titu Maiorescu University, Bucharest, Romania,* [2]*Carol Davila University, Bucharest, sect4, Romania,* [3]*Spiru Haret Univ., Bucharest, sect5, Romania*

OBJECTIVES: Alzheimer's disease (AD) is the most common form of dementia. Estimates of the cost of AD in Romania come from external sources and are based on extrapolations and assumptions. We tried to replace some of the assumptions with actual data obtained from official sources and based on data obtained from the Bucharest Memory Center. **METHODS:** This is an empirical investigation of the economic cost of AD in Romania in 2010. Direct and indirect costs are estimated and allocated to the AD by taking in consideration an extrapolation of European data for incidence and prevalence, actual cost for medication provided by National Insurance House for specific medication used in prevention an treatment of AD, actual data provided by Ministry of Labor and Social Security for persons with AD living in nursing home. Cost of care provided by family members were estimated on a telephonic cross-sectional survey, carried out using the database of Bucharest Memory Center. **RESULTS:** The calculated cost of Alzheimer's disease in Romania is 187.022.387 €, direct medical cost of 62 millions €, 7.5 million € for hospitalization, medication of 34.9 million €, ambulatory medical services of 0.4 million €, nursing home costs of 4.6 million €, parapharmaceuticals cost of 15 million € and indirect (informal) cost of 124.5 million €. **CONCLUSIONS:** There is a major discrepancy between the cost obtained by Wimo A. et al in 2010 and ours, which is 10 times smaller. The main difference is due the small number of people hospitalized in specialized centers, only 3%, the small number of people receiving treatment - only 14% of the total number of patients with DA. Romania must strive to remove the inequities concerning informal costs and be prepared for an exponentially increase of costs as the care of patients will normalize.

PND22

A COST-OF-ILLNESS ANALYSIS OF MYASTHENIA GRAVIS IN GREECE

Athanasakis K[1], Glava V[1], Zacharis M[2], Zouvelou V[2], Evdokimidis I[2], Kyriopoulos J[1]
[1]*National School of Public Health, Athens, Greece,* [2]*Aeginition University Hospital, National and Kapodistrian University, Athens, Attica, Greece*

OBJECTIVES: To estimate the annual per patient cost of Myasthenia Gravis (MG) in Greece from a societal perspective. **METHODS:** Data on direct costs (medications, laboratory/imaging tests, consultations, hospitalizations) were obtained through retrospective chart review of a sample of patients followed-up in Aeginition University Hospital, a reference centre for MG in Greece. Eligible patients were those that visited the MG clinic in the previous 6 months and had fully recorded data for the previous year. Patients were also personally interviewed, following consent, based on a strictly-structured questionnaire, with an aim to record indirect costs incurred in the previous year (premature retirement, work absenteeism, decreased productivity, professional home help). Unit prices for health-resource use were the official NHS prices. Productivity losses and home help were costed with the hourly rate of the basic salary, in order to obtain a conservative approach. Costs are reported in year 2011 Euros. **RESULTS:** The sample (N=32) was 56% female with an average age of 57 years (men: 66.6, women: 49.5). Average total annual per patient cost was 4125.4€ (standard deviation: 5287€), out of which 614.3€ (s.d.: 496€) were direct and 3511.5€ (s.d.: 5260.5€) were indirect expenditure. Early retirement, home help, and medications were the major cost drivers of total cost (49%, 31% and 8% respectively), while medications had the biggest influence when focusing on direct costs alone (51%). Women had a higher average cost than men (5173€ vs. 2777€), principally as a result of indirect expenditures from lost productivity. **CONCLUSIONS:** MG is a burdensome disease, in socioeconomic terms, that seems to affect women more heavily, compared to men, most probably due to symptom onset at a younger (and more productive) age. Even in the case of low prevalence- or rare-diseases, cost-of-illness analysis can promote awareness and contribute with the necessary data to health policy decisions.

PND23

COST OF THE INFORMAL CARE OF MULTIPLE SCLEROSIS IN SPAIN

Gubieras L, Casado V, Romero-Pinel L, Matas E, Bau L, Martínez-Yélamos S, Arbizu T, Grupo ECodEM.
Hospital Universitari de Bellvitge, Barcelona, Spain

OBJECTIVES: Multiple sclerosis (MS) is a prevalent, chronic and disabling disease, mainly affecting young adults. The aim of the present work is to analyse the cost of the informal care of MS according to disability, in different Spanish regions. **METHODS:** Patients with clinical diagnosis of MS, from different Spanish regions, were selected between december 2006 and december 2010. The patients were divided in 3 groups based on their disability: mild (EDSS 0-3,5), moderate (EDSS 4,0-6,5) and severe (7,0-9,5). They were invited to answer a questionnaire, with demographic, social, employment status data, clinical aspects, as well as data about the consumption of sanitary and no-sanitary resources during the MS process. The replacement method was used to estimate informal costs. **RESULTS:** We analized 1107 pacients and 317 caregivers. The percentage of patients requiering informal care increased with disability, ranging from 7% (mild disability) to 73% (severe disability) and daily hours of informal care per patient, 0.4 (mild disability) to 11.8 (severe disability). These informal cares can also vary depending on the Spanish region analyzed. The caregiver mean age was 53 years, is mostly the patient's partner (54%) and has been practicing as a caregiver a mean of 10 years. The estimated cost of informal care increased with disability, ranging from 777 euros/patient/year (mild disability) to 26.987 euros/patient/year (severe disability). The cost grew to 45% of the total cost of the disease in advanced stages. **CONCLUSIONS:** The estimated cost of informal care increased with disability, ranging from 777 euros/patient/year (mild disability) to 26,987 euros/patient/year (severe disability). It represented almost half of the total cost of the disease in advanced stages.

PND24

COST OF SYMPTOMATIC DRUG THERAPY IN MULTIPLE SCLEROSIS

Fogarty E, Tilson L, Barry M
National Centre for Pharmacoeconomics, Dublin, Ireland

OBJECTIVES: Drug therapy in Multiple Sclerosis (MS) accounts for a significant proportion of the economic burden of this disease. Expenditure on disease-modifying-therapies (DMT) in Ireland was €32.7 million in 2009, 1.63% of total pharmaceutical expenditure. In addition to DMT, other non-DMT drugs are used to treat MS symptoms. This study describes the patterns and cost of non-DMT (other) drug utilisation in Ireland. **METHODS:** A cohort of patients dispensed a DMT during 2009 were identified from a national prescribing database. An analysis of all other drugs dispensed for this cohort during 2009 was undertaken. **RESULTS:** A cohort of 2749 people on DMT was identified (39.3% of the estimated Irish MS population) 69.0% of whom also received other drugs costing €2.7 million (estimated 7.6% of total MS drug costs). The mean other drug cost per person on DMT was €1417 (SD €1863). Drug classes contributing most to other drug costs were antiepileptics (17.1%) used for neuropathic pain, urinary antispasmodics (8.1%) and muscle relaxants (7.0%). The top 10 drugs by cost included pregabalin, gabapentin, modafinil, tizandine, tolterodine, evening primrose oil, atorvastatin, venlafaxine, baclofen and escitalopram (39.9% of other drug costs). The most commonly prescribed drug classes – antidepressants, analgesics and NSAIDs, dispensed to over 20% of the cohort in each case, accounted for just 12.7% of other drug costs. **CONCLUSIONS:** Characterisation of non-DMT drug use provides useful information for clinicians, healthcare payers, and those undertaking cost-of-illness studies. While these drugs account for a smaller proportion of overall costs than DMT, they are an indication of overall morbidity and wider resource utilisation e.g. urological drugs as an indicator for physiotherapy and incontinence equipment. These results can be considered in the design of future cost-of-illness surveys which often include an exhaustive list of individual drugs.

PND25

USE OF DRUG REIMBURSEMENT AS MARKERS OF DISEASE FOR EPIDEMIOLOGICAL AND DIRECT COST ANALYSIS: THE CASE OF EPILEPSY IN FRANCE

Fagnani F[1], Kusnik-Joinville O[1], de Zélicourt M[1], Levy-Bachelot L[2], Branchoux S[2], Murat C[2], Bertrand M[3], Kahane P[4]
[1]*Cemka, Bourg la Reine, France,* [2]*Laboratoire GlaxoSmithKline, Marly le Roi, France,* [3]*Inserm UMR_S 708, Paris, France,* [4]*Centre Hospitalier de Grenoble, Grenoble Cedex, France*

OBJECTIVES: Population characteristics of patients with epilepsy remain poorly documented in France. Reimbursement databases may be useful to perform cost and epidemiological studies provided that patient diagnoses can be identified either directly, or indirectly through the use of antiepileptic drugs (AEDs) as markers. This study explored the possibility to use the French reimbursement database to determine the prevalence and direct cost of epilepsy. **METHODS:** The "EGB" reimbursement database is a 1/97 representative sample (500,000 individuals) of the population covered under the French General Scheme. Only a fraction of patients fully covered for epilepsy can be identified on a diagnosis basis. The rest of them can only be identified through their treatment by AEDs, but some are not specific to epilepsy (e.g. benzodiazepines). An algorithm was built to identify patients with epilepsy and calculate an estimation of the prevalence. In parallel, total medical expenses of patients were derived on the fully covered sub-population. **RESULTS:** Only patients treated with polytherapy (≥2 AEDs) could be identified in a relevant way by an algorithm based on drug use. The prevalence of epilepsy in this subgroup in 2009 was estimated between 1.83‰ and 2.79‰ (93,000 – 142,000 patients). A proportion of 70.1% to 71.6% were fully covered by insurance for their expenses, with epilepsy alone as a cause in only 27 to 33% of them. The most frequent comorbidities were psychiatric disorders and incapacitating stroke. The annual per capita expenses were in the range of 6601€- 6696€ for patients with polytherapy,

inpatient care and drug costs represented about 50% and 27% respectively of overall expenses. The increase by 24.4% polytherapy patients mean costs as compared to monotherapy raised to 72% [IC 95: 44-106%] after adjustment on age, gender and presence of severe comorbidity. **CONCLUSIONS:** Polytherapy in epilepsy is associated with substantial higher direct costs.

PND26

ESTIMATED COSTS OF FIRST-YEAR MONITORING AND ADMINISTRATION OF MULTIPLE SCLEROSIS THERAPIES IN THE UNITED STATES

Trautman HC[1], Clark JA[2], Huleatt H[1], Oleen-Burkey M[3], Brewster C[3]
[1]*Aventine Consulting, Marblehead, MA, USA,* [2]*Aventine Consulting, University Place, WA, USA,* [3]*Teva Pharmaceuticals, Kansas City, MO, USA*

OBJECTIVES: To develop a tool to estimate the first-year per member and total health plan costs associated with monitoring of MS therapies in the United States. **METHODS:** Data were incorporated into an interactive tool designed to allow a health plan to estimate their costs for monitoring. MS prevalence was based on the literature. The default value for the proportion of MS patients treated with immunomodulators was assumed at 95% and adjusted IMS data were used for default market share inputs. Current Procedural Terminology (CPT) codes corresponding to the monitoring and administration procedures recommended by each product's prescribing information (PI) were identified. Charges associated with each CPT code were assigned using physician fee schedule software based on Medicare charges with default values set at 150%. PI recommendations were used for the proportion being monitored and the frequency of monitoring. In cases where a PI recommended only individuals with specific characteristics undergo monitoring, a database analysis identifying all individuals with a diagnosis of MS in the i3 InVision Data Mart (Ingenix, Eden Prairie, MN) was used to estimate the proportion of patients who may require that specific monitoring. **RESULTS:** The tool yielded average per patient and health plan costs expected with MS therapy monitoring. The tool conservatively estimates that the average per member first-year monitoring and administration costs ranged from $0 for glatiramer acetate to $3279 for natalizumab. Based on default values, the estimated annual costs of monitoring for all MS therapies for a million member health plan is $519,451. **CONCLUSIONS:** Estimating the economic impact of FDA-recommended MS therapy monitoring allows health plans to more closely assess the total cost of MS. This tool allows health plans to individualize inputs to estimate the plan-specific economic impact of MS therapy monitoring.

PND27

ECONOMIC ANALYSIS OF COST PER EPISODE OF CARE FOR ARM SPASTICITY AND CERVICAL DYSTONIA: COMPARISON OF TWO BOTULINUM TOXIN A PREPARATIONS IN 20 COUNTRIES

Roze S[1], Marty R[1], Kurth H[2], Godard A[2]
[1]*HEVA, Lyon, France,* [2]*IPSEN, Boulogne Billancourt, France*

OBJECTIVES: Botulinum toxin A (BTA) injections are indicated for the management of neurological movement disorders, including arm spasticity (AS) and cervical dystonia (CD). This study calculated the cost per care episode for two BTA: Botox® and Dysport®. The analysis was completed for 20 countries around the world. **METHODS:** Doses of BTA are expressed in non-interchangeable units: Botox® is available in "Allergan units" whereas Dysport® is provided in 500 "Speywood units". Recommended dosages were derived from country SmPCs/PIs. Cost analysis was based on official list prices and expressed in 2011 euros, using exchange rates as of end of May 2011. The cost per care episode was calculated using available recommended dosages for each product (country's own or average of other countries) combined with price per vial in each country. **RESULTS:** For AS, recommended total injection dosage per patient for Dysport is 1000 units in all countries where indicated in SmPCs; for Botox®, it is 300U per patient based on recommended dosages in the USA and France. For CD, dosages for Dysport® are 500U per patient; whereas 200U of Botox® is recommended per patient. Considered with the respective prices per vial in each country, Dysport® cost per patient per care episode for AS was less than Botox® in 17 (89%) of the 19 countries (average 15% less across countries). The difference was 20% or higher in nearly half (47%) of countries. In CD, these differences were even greater with Dysport® cost per patient was 40% or less versus Botox in 45% of countries (average 36% less across countries). **CONCLUSIONS:** Considering cost per patient per care episode based on recommended dosages in SmPCs/PIs, Dysport® remains cheaper versus Botox in most countries. When extrapolated to a national level, substantial savings could be realized by using Dysport® in the treatment of AS and CD.

PND28

COST-EFFECTIVENESS ANALYSIS OF INTERFERONS AND GLATIRAMER ACETATE AS FIRST LINE TREATMENTS IN REMITTING-RELAPSING MULTIPLE SCLEROSIS SPANISH PATIENTS

Sánchez-de la Rosa R[1], Sabater E[2], Casado MA[3]
[1]*TEVA Pharma SLU, Madrid, Spain,* [2]*Pharmacoeconomics & Outcomes Research Iberia, Pozuelo, Spain,* [3]*Pharmacoeconomics & Outcomes Research Iberia, Pozuelo de Alarcón, Madrid, Spain*

OBJECTIVES: The aim of this study was to calculate the incremental cost-effectiveness ratio of the different Disease Modifying Drugs (DMD) used as first-line treatments (interferons IM IFNβ-1a, SC IFNβ-1a, SC IFNβ-1b and glatiramer acetate, GA) in Remitting-Relapsing Multiple Sclerosis (RRMS) in Spain. **METHODS:** A Markov model was developed to simulate the progression of a cohort of patients with RRMS, during a period of 10 years. Seven health states, defined by the EDSS, were considered in the model. Patients with an EDSS score of less than 6.0 were assumed to be treated with one of DMD. In addition, all patients were assumed to receive symptomatic treatment. The monthly transition probabilities of the model were obtained from the literature. The analysis was performed from the societal perspective, in which both direct and indirect (losses in productivity) healthcare costs (€, 2010) were included. A discount rate of 3% was applied to both costs and results. **RESULTS:** GA was the less costly strategy (€322,510), followed by IM IFNβ-1a (€ 329.595), SC IFNβ-1b (€ 333.925) and SC IFNβ-1a (€ 348.208). IM IFNβ-1a has shown the best efficacy results with 4,176 quality-adjusted life year (QALY), followed by SC IFNβ-1a (4,158 QALY), SC IFNβ-1b (4,157 QALY) and GA (4,117 QALY). Incremental costs per QALY gained with IM IFNβ-1a were €-1,005,194/QALY, €-223,397/QALY, and €117,914/QALY in comparison to SC IFNβ-1a, SC IFNβ-1b and GA, respectively. **CONCLUSIONS:** First-line treatment with GA is the less costly strategy for the treatment of patients with RRMS. Treatment with IM IFNβ-1a is a dominant strategy (lower cost and higher QALY) compared with SC IFNβ-1a and SC IFNβ-1b. However, IM IFNβ-1a is not a cost-effective strategy versus GA, because incremental cost per QALY gained with IM IFNβ-1a exceeds the €30,000 per QALY threshold, commonly used in Spain.

PND29

COMPARING THE COST-EFFECTIVENESS OF AVONEX AND BETAFERON IN THE MANAGEMENT OF MULTIPLE SCLEROSIS IN IRAN

Imani A, Golestani M, Rasekh H
Shahid Beheshti Medical University, tehran, Iran

OBJECTIVES: Multiple sclerosis (MS) is the neurologic disability that can dramatically affect the quality of life (QoL) of patients and their families. Family life, economic status, and social interaction may be affected by somatic symptoms of the disease. Approximately 70,000 people in the Islamic Republic of Iran are affected by MS. Under budgetary constraints,Cost-effectiveness and cost-utility analyses (CEA/CUAs) are useful tools to assess the tradeoff between the added costs and potential benefits (e.g., improved patient outcomes) of new therapies. **METHODS:** The primary objective of this analysis was to evaluate the cost-effectiveness of Avonex compared with Betaferon from the Iranian Ministry of Health(MoH) over a 2-year time horizon. The relative risk reduction (RRR) method was used to compare reduction in relapse rates and disease progression data from pivotal randomized double-blind placebo-controlled clinical trials of the DMDs. The evaluation was conducted from the perspective of a Iranian health care sector (direct medical costs and indirect cost considered). The primary economic endpoint was cost per relapse avoided . Costs and outcomes occurring in the second year were discounted 3% to bring to 2010 present values. One way sensitivity analyses were conducted on key input variables to assess their impact on cost per relapse avoided. **RESULTS:** The 2-year reductions in clinical relapses for treatment with Avonex,Betaferon were 0.69 and 0.60 relatively. In the base case analysis, Avonex had the most favorable costs per relapse avoided (2652778 Rials) rather than Betaferon. Sensitivity analyses showed that these results were robust to changes in key input parameters, such as the number of relapses and disease progression steps in untreated patients, the progression rates, the average cost of relapse. **CONCLUSIONS:** This evaluation suggests that IFN β-1a SC injection(Avonex) represent the most cost-effective DMDs for the treatment of RRMS, where cost-effectiveness is defined as cost per relapse avoided,rather than Bataferon.

PND30

COST-EFFECTIVENESS OF EARLY VS. NON-EARLY INTERVENTION IN ACUTE MIGRAINE WITH ALMOTRIPTAN IN SPAIN

Slof J
Universitat Autonoma de Barcelona, Bellaterra, Spain

OBJECTIVES: Early intervention in the course of acute migraine attacks has been recently advocated as a way to further reduce the economic burden and suffering of patients due to this condition. The aim of this study was to investigate the cost-effectiveness of such a strategy using almotriptan in the Spanish setting. **METHODS:** An economic evaluation was conducted from the Spanish societal and public health system perspective based on patient-level data collected in the "Act when Mild" study. Incremental cost-effectiveness ratios (ICER) were determined in terms of attack duration, loss of productive time and quality-adjusted life days (QALDs). Monte Carlo simulation was used to derive cost-effectiveness acceptability curves. **RESULTS:** Early treatment led on average to shorter attack duration, less productive time lost, better quality of life, and was overall cost-saving from a societal point of view with a probability of 97%. In terms of publicly reimbursed drug costs only, though, non-early treatment was always slightly less expensive. From the public health system perspective the (bootstrap) mean ICER of early treatment amounted to €0.12 per migraine hour avoided, €0.42 per hour of productive time lost avoided, and €6.62 per QALD gained. Considering willingness to pay values of €1 to reduce attack duration by one hour, €5 to avoid the loss of one productive hour, or €55 to gain one QALD (equivalent to €20,000 per QALY), the probability that early treatment was cost-effective from the public health system perspective was, respectively, 96%, 96%, and 98%. These results remained robust in sensitivity analyses that accounted for the uncertainty surrounding the major elements of the economic evaluation. **CONCLUSIONS:** Compared to non-early treatment, early treatment of acute migraine attacks with almotriptan when pain is still mild is with high probability cost-saving from the Spanish societal perspective and cost-effective from the public health system point of view.

PND31

A MODELLED ECONOMIC EVALUATION OF FIRAZYR® (ICATIBANT) FOR SYMPTOMATIC TREATMENT OF ACUTE ATTACKS OF HEREDITARY ANGIOEDEMA (HAE) IN ADULTS WITH C1-ESTERASE-INHIBITOR (C1-INH) DEFICIENCY

Tilden D[1], Cottrell S[1], Tocchini L[1], Jayaram N[2], Sinani R[3], Barnes D[4]

[1]THEMA Consulting Pty Ltd, Pyrmont, NSW, Australia, [2]Shire Australia Pty Ltd, North Ryde, NSW, Australia, [3]Shire Australia Pty Limited, North Ryde, NSW, Australia, [4]Shire Australia Pty Limited, North Ryde, NSW, Australia

OBJECTIVES: To estimate the cost-effectiveness of subcutaneously self-administered icatibant for the symptomatic treatment of acute attacks of HAE in adults with C1-INH deficiency.versus current clinical practice in Australia i.e., best supportive care, with delayed use of intravenous C1-INH concentrate if required administered in the hospital emergency setting. **METHODS:** An economic model with Markov processes was developed to estimate the costs and benefits of self-administered icatibant compared to current clinical practice in Australia. The model consisted of four health states (free of HAE attack, cutaneous HAE attack, abdominal HAE attack, laryngeal HAE attack) with patients starting in the attack-free health state and transitioning to one of the four health states at weekly cycles over 52 weeks. Variables in the model (probability of attack, probability an attack is treated, duration of attack) were based on evidence from relevant clinical trials and the wider literature. Utility values were derived from a survey of 201 members of the Australian general public using a vignette/health state scenario based approach and standard gamble methodology. Costs were estimated from the perspective of the Australian public health care system. **RESULTS:** Incremental cost per QALY of self-administered icatibant compared with current clinical practice in Australia estimated by the model was $71,026. Incremental costs consisted of an additional $8,864 in icatibant costs relative to C1-INH concentrate costs and a saving of $105 in the costs of attendances to accident and emergency department. The majority of the QALY gains were due to the better quality of life whilst in the attack-free health state, attributed to the "process utility" afforded by having access to self-administration and living in the knowledge that when an attack occurs it can be quickly and easily managed. **CONCLUSIONS:** This represents a reasonable level of cost-effectiveness of icatibant in the context of a small patient population and orphan indication.

PND32

COST-UTILITY ANALYSIS OF ROPINIROLE IN PARKINSON'S DISEASE (PD) TREATMENT

Zerda I[1], Drozdz A[1], Brzyski D[1], Pochopien M[1], Gwiosda B[1], Lisiecka B[1], Barlog D[2], Glogowski C[2], Dziurda D[2], Rys P[1], Plisko R[1]
[1]HTA Consulting, Krakow, Poland, [2]GSK, Warszawa, Poland

OBJECTIVES: To compare cost-effectiveness of controlled release ropinirole (ROP CR) with levodopa (LD) and piribedil (PIR) in treatment of Parkinson's disease in Poland. **METHODS:** Lifetime Markov model from Polish public payer perspective was developed. Two schemes: drug monotherapy (ROP CR vs LD and PIR) and therapy added to levodopa (ROP CR vs LD) were considered. Effectiveness data were taken from the systematic review of randomized clinical trials. Utility was modeled based on the UPDRS values and dyskinesia occurrence. In the model Polish costs of drugs, qualification, monitoring, hospitalization and dyskinesia treatment were included. sensitivity analysis were performed for key model's parameters. **RESULTS:** Estimated lifetime QALYs per patient for comparison of monotherapies were: 8.12 for ropinirole CR, 7.95 for levodopa and 7.89 for piribedil. Differences in QALYs were statistically significant in favor of ropinirole CR for both comparators. Average costs per patient were 76,710 PLN for ropinirole CR, 61,180 PLN for levodopa and 62,860 PLN for piribedil. The ICERs for ropinirole CR were: 94,200 PLN in comparison to levodopa and 59,780 PLN in comparison to piribedil. Estimated lifetime QALYs per patient for comparison of ropinirol CR as add-on to levodopa with levodopa monotherapy in higher doses were: 7.70 for ropinirole CR and 7.16 for levodopa. Differences in QALYs were statistically significant in favor of ropinirole CR. Average costs per patient were 64,110 PLN for ropinirole CR and 18,420 PLN for levodopa. The ICERs for comparison of ropinirol CR with levodopa was 84,920 PLN. **CONCLUSIONS:** Ropinirole is cost-effective in comparison to piribedil and levodopa in monotherapy, and as add-on to levodopa in comparison to levodopa monotherapy in higher doses (threshold of three GDP: 102,045 PLN).

PND33

COST MINIMIZATION ANALYSIS OF FINGOLIMOD COMPARED TO NATALIZUMAB IN PATIENTS WITH RELAPSE REMITTING MULTIPLE SCLEROSIS IN THE NETHERLANDS

Verheggen B[1], Treur M[1], Groot M[2]
[1]Pharmerit International, Rotterdam, The Netherlands, [2]Novartis Pharma B.V., Arnhem, The Netherlands

OBJECTIVES: To assess the costs of oral treatment with fingolimod (Gilenya®) compared to intravenous infusion of natalizumab (Tysabri®) in patients with relapse remitting multiple sclerosis (RRMS) in the The Netherlands. **METHODS:** A cost-minimization analysis (CMA) was used to compare the costs of both treatments. In this analysis drug acquisition costs, drug administration costs, and other costs related to drug treatment were distinguished. Costs were discounted at 4%, and incremental model results were presented over a 1, 2, and 10 year time horizon. The robustness of the model results was determined by means of a number of deterministic univariate sensitivity analyses and a probabilistic sensitivity analysis. Additionally, a break-even analysis was carried out to determine at what IV infusion costs a cost neutral outcome would be obtained. **RESULTS:** When fingolimod was compared to natalizumab, the model predicted discounted incremental costs of -€1,699 (95%CI: -€2,216;-€946), -€4,094 (95%CI: -€5,017;-€2,625), and -€20,218 (95%CI: -€24,192;-€13,977) over a 1, 2, and 10-year time horizon respectively. Results of the sensitivity analyses showed that these predictions were most sensitive to changes in the costs for IV administration of natalizumab. Changing these costs within a range of €217 and €297 per IV infusion, resulted in cost savings varying from €15,831 to €24,606 after 10 years. The additional break-even analysis showed that IV infusion costs needed to be as low as €127 and €73 in order to obtain a cost neutral result after 1 and 10 years respectively. **CONCLUSIONS:** The present analysis showed that treatment with fingolimod resulted in considerable cost savings compared to natalizumab: €20,218 per RRMS patient in the The Netherlands after 10 years of treatment. The robustness of this estimate was confirmed within the sensitivity analyses. The conclusions were in line with cost-utility analysis that has been performed as well, showing cost savings of fingolimod compared to natalizumab.

PND34

COST-UTILITY ANALYSIS OF LACOSAMIDE ADJUNCTIVE THERAPY IN THE TREATMENT OF PATIENTS WITH REFRACTORY IN THE SLOVAK REPUBLIC

Benhaddi H[1], Poliakova Z[2]
[1]UCB Pharma S.A., Brussels, Belgium, [2]UCB s.r.o., Bratislava, Slovak Republic, Bratislva, Slovak Republic

OBJECTIVES: To calculate and compare the incremental cost-utility ratios for standard antiepileptic drug (AED) therapy with and without adjunctive lacosamide in patients with uncontrolled partial-onset seizures in the Slovak Republic. **METHODS:** The model simulated the treatment pathway of a hypothetical cohort of 1000 patients over two years from the third party payer perspective in the Slovak Republic using 2011 pricing. A decision tree was split into four phases of six months each during which patients can become seizure free, experience a seizure reduction (responder defined as ≥50% reduction in seizures), or withdraw due to non-response. The standard therapy arm included five adjunctive therapies: carbamazepine, lamotrigine, levetiracetam, topiramate and valproate. The likelihood of being in a particular health state has been estimated from clinical trials data. The cost of outpatient visits, inpatient and emergency department visits were included. Costs and utility values attached to various health states were taken from the published literature. **RESULTS:** Lacosamide adjunctive therapy was associated with 6730 avoided seizures and a gain of 38 quality adjusted life-years (QALYs), compared with the standard therapy within the 2-year timeframe. Treatment with lacosamide was associated with a cost of €103 per seizure avoided, and €18,402 per QALY gained versus standard therapy over 2 years and falls within acceptable thresholds of cost-effectiveness in Slovakia. Results calculated for 6-, 12- and 18-month follow-up showed respective incremental cost-utility ratios of €20,904, €19,443 and €19,133 and cost per seizure avoided of €276, €127 and €111. Using a willingness-to-pay threshold of €26,500 per QALY, 83% of the simulations fell below this value after 2 years of treatment. **CONCLUSIONS:** Lacosamide was shown to be a cost-effective adjunctive treatment in patients with uncontrolled partial-onset epilepsy in the Slovak Republic.

PND35

BELGIAN COST-UTILITY ANALYSIS OF GILENYA® (FINGOLIMOD) IN THE MANAGEMENT OF ADULTS WITH ACTIVE RELAPSING REMITTING MULTIPLE SCLEROSIS

Drieskens S[1], Moeremans K[2]
[1]Panacea, Brussels, Belgium, [2]IMS Health Consulting, Vilvoorde, Belgium

OBJECTIVES: To assess the cost-utility of oral fingolimod (Gilenya) versus IV natalizumab (Tysabri) in active relapsing remitting multiple sclerosis (RRMS) from Belgian healthcare (RIZIV/INAMI + patient), governmental and societal perspectives. **METHODS:** A 40-year Markov model was developed containing 20 health states describing disability severity based upon the Expanded Disability Status Scale (EDSS): 10 RRMS EDSS states (0-9), 10 secondary progressive MS (SPMS) EDSS states (0-9) and a death state. Per annual cycle, RRMS patients can remain stable, progress to a higher RRMS EDSS state or convert to SPMS at a higher EDSS state. Patients have a fixed annual probability of relapse and death (national age-adjusted mortality). RRMS patients with EDSS score <6.5 are eligible for disease modifying therapies (DMTs). Patients with SPMS or EDSS score ≥ 6.5 receive best supportive care. Transition probabilities were based on the natural history of RRMS and the relative risk of confirmed disability progression and relapse per DMT. Efficacy of natalizumab (AFFIRM) and fingolimod (FREEDOMS) was based upon indirect comparison with adjustment for differences in baseline disease characteristics and demographics. Belgian costs and utilities obtained from literature were assigned to each EDSS level and to relapse. DMT monitoring and administration costs were based upon expert opinion. Costs (3%) and outcomes (1.5%) were discounted. Probabilistic sensitivity analyses covered variability in efficacy, costs and utilities. **RESULTS:** Base-case analyses revealed cost-effectiveness of fingolimod from the health care perspective and dominance from governmental and societal perspective. The probability of fingolimod being cost-effective (<35,000€/QALY) varied between 64% and 70%. Results were sensitive to the hazard ratio of disability progression due to wide and overlapping confidence intervals (indirect treatment comparison). Excluding uncertainty in this parameter resulted in probabilities of cost-effectiveness between 81% and 100%. **CONCLUSIONS:** Treatment of active RRMS with fingolimod was cost-effective from all payers' perspectives versus treatment with natalizumab.

PND36

FACTORS ASSOCIATED WITH UTILITY AND DISUTILITY VALUES IN RELAPSING FORM OF MULTIPLE SCLEROSIS (RMS) PATIENTS USING DATA FROM TEMSO, A TERIFLUNOMIDE PIVOTAL PHASE III TRIAL

O'Connor P[1], Briggs A[2], Carita P[3], Bego-Le-Bagousse G[3]
[1]University of Toronto, Toronto, ON, Canada, [2]University of Glasgow, Glasgow, UK, [3]Sanofi-aventis, Massy, France

OBJECTIVES: Multiple sclerosis (MS) is a neurodegenerative disease associated with significant impairments in health related quality of life. This analysis was to identify patient factors associated with utility in RMS patients and to derive disutility values according to relevant disease stages. **METHODS:** TEMSO (N=1088)

was designed to assess efficacy and safety of teriflunomide, a novel oral disease modifier, in RMS patients. The utility score, a measure of health-related quality of life, was calculated via the EQ-5D questionnaire assessed alongside the trial. Using baseline data, a cross-sectional analysis was performed to identify factors associated with utility scores using a multivariate regression linear model. This model includes the following factors; expanded disability status scale (EDSS) score, type of multiple sclerosis (relapsing remitting (RRMS) versus progressive relapsing (PRMS), region, number or relapses within the past 2 years, previous MS medication, gender, time (years) since first diagnosis of MS and burden of disease defined by magnetic resonance imaging. **RESULTS:** Three variables demonstrated a significant negative impact on utility values: the functional disability level as assessed by EDSS score (when EDSS score increases), PRMS versus RRMS and Eastern European countries versus North American countries. The major influencing factor, consistent with other analyses, was the EDSS score with the following disutility estimates: EDSS[1-2[=-0.021, p=0.52; EDSS[2-3[=-0.081, p=0.0128; EDSS[3-4[=-0.176, p<0.0001; EDSS[4-5[=-0.237, p<0.0001; EDSS[5-6[=-0.231, p<0.0001; EDSS[6-7[=-0.257, p<0.0001]. In addition, disutilities associated with PRMS versus RRMS and Eastern Europe region versus North American were respectively -0.073 (p=0.0028) and -0.038 (p=0.0361). **CONCLUSIONS:** In RMS patients, these results confirm the major impact of functional disability on patients' utility. These analyses also provided disutility estimates per EDSS score, disutilities for PRMS versus RRMS and for Eastern Europe versus North American region. The later probably reflecting cultural differences in health status perception.

PND37

AN EXAMINATION OF RESOURCE UTILIZATION AMONG PATIENTS WITH PARKINSON'S DISEASE TREATED WITH RASAGILINE OR SELEGILINE

Grubb E[1], Castelli-Haley J[1], Lage M[2]
[1]*Teva Pharmaceuticals, Kansas City, MO, USA,* [2]*HealthMetrics Outcomes Research, Groton, CT, USA*

OBJECTIVES: To examine resource utilization associated with the use of Rasagiline or Selegiline, two commonly prescribed MAOB inhibitors for the treatment of Parkinson's Disease (PD). **METHODS:** Data for this retrospective study were obtained from the US i3 LabRx database over the time period from January 1, 2006 through December 30, 2010. Patients were included in the analysis if they were prescribed Rasagiline or Selegiline (with first such date identified as the index date), were diagnosed with PD (ICD-9 code 332.0), and had continuous insurance coverage from 6 months prior through 12 months post index date. Analyses are primarily descriptive in nature, with differences in categorical variables analyzed using chi-square statistics and differences in continuous variables analyzed using t-statistics. **RESULTS:** There were 1242 individuals included in the study - 926 initiated on Rasagiline and 316 initiated on Selegiline. Patients initiated on Rasagiline, compared to those intitiated on Selegiline, were significantly younger (63.2 years vs. 65.4 years; P=0.0020). Patients initiated on Rasagiline were significantly less likely to be diagnosed with chest pain (16.41% vs. 21.52%; P=0.0402) or headaches (4.97% vs. 9.49%; P=0.0037). Patients who intitated on Rasagiline were significantly more likely to visit a neurologist (93.63% vs. 89.24%; P=0.0105). Compared with Selegiline use, initiation on Rasagiline was associated with significantly fewer inpatient visits (1.58 vs. 2.94; P=0.0236) and significantly shorter hospital length of stay (4.71 days vs. 8.78 days; P=0.0216). **CONCLUSIONS:** Results from this retrospective study indicate that, patients who initiated therapy with Selegiline, compared to Rasagiline were more likely to experience side effects of chest pain or headaches. In addition, these patients were more likely to have a greater resource utilization due to the number and significantly longer lengths of hospitalizations.

PND38

INTERNATIONAL COMPARISON OF HUNTINGTON DISEASE (HD) BURDEN

Dorey J[1], De Nicola N[2], Tedroff J[3], Squitieri F[2], Clay E[4], Verny C[5], Zielonka D[6], Cohen J[7], Aballea S[8], Lamure M[9], Toumi M[10]
[1]*Creativ Ceutical, Paris, France,* [2]*Neurogenetics and Rare Disease Centre, Pozzi, Italy,* [3]*NEUROSEARCH, Ballerup, Denmark,* [4]*Creativ Research, Paris, France,* [5]*Centre national de référence des maladies neurogénétiques, Angers, France,* [6]*Poznan University of Medical Sciences, Poznan, Poland,* [7]*Tufts University Center for the Study of Drug Development, Boston, MA, USA,* [8]*Creativ Ceutical, Paris, Ile de France, France,* [9]*University of Lyon I, Villeurbanne Cedex, France,* [10]*University Claude Bernard Lyon1, Lyon, France*

OBJECTIVES: This study aimed to identify the socioeconomic burden of HD in five European countries **METHODS:** The survey was conducted in Germany, Italy, France, Poland and the USA. The following patient data were collected: clinical symptoms (motor, behavioral and psychiatric), functional/independence score, QoL (H-QoLI, SF-36, EQ-5D), resource utilization, GP and specialist visits, other healthcare professional visits, hospitalization, nursing home, social services, allowance, medical device and daily out of pocket expenses. The following data were collected from caregivers: time spent and working days lost caring for the patient, out of pocket expenditure, caregiver quality of life. **RESULTS:** To date, 175, 124, 44, 60 and 134 patients were included in respectively France, Italy, Germany, Poland and US. The populations were reasonably homogeneous regarding sociodemographic characteristics and severity such as age (48-56) and disease duration (6-10 years except for the Poland: 4 years). The average number of monthly visits to GP was 0.76-1.32, to neurologist 0.49-1.12, to physiotherapist 0.09-5.59. The percentage of patients admitted to hospital during the last 6 months was between 1% (USA) and 19% (France). The mean (± SD) health utility (EQ-5D) ranged from 0.25 (0.46) in France to 0.47 (0.37) in Germany. Caregivers spent between 6 (USA) and 22 hours/day (Italy, Poland) caring for patients and their monthly expenses amounted to €295 (Poland) to $2391 (USA). Caregivers also had reduced QoL. **CONCLUSIONS:** The initial results indicated significant differences in access to health care and resource use. France has the largest health care resource consumer by far. Countries that use little health care resources compensate by a significantly larger caregiver involvement. More data will be presented.

Neurological Disorders – Patient-Reported Outcomes & Preference-Based Studies

PND39

HEREDITARY ANGIOEDEMA HEALTH STATE UTILITY VALUATION STUDY FROM THE PERSPECTIVE OF A REPRESENTATIVE SAMPLE OF THE AUSTRALIAN GENERAL PUBLIC

Cottrell S[1], Tilden D[1], Jayaram N[2], Sinani R[2], Barnes D[2]
[1]*Thema Consulting Pty Ltd, Pyrmont, NSW, Australia,* [2]*Shire Australia Pty Limited, North Ryde, NSW, Australia*

OBJECTIVES: The impact of hereditary angioedema (HAE) on patients' health related quality of life (QoL) extends beyond the acute attack period. This study was to value the disutility of living with HAE outside of the acute attack period, according to different emergency treatments available to the patient. **METHODS:** The study used a vignette/health state scenario based approach and standard gamble methodology. The health states described three different circumstances faced by patients with HAE in terms of availability of emergency medications should they suffer a swelling attack: Scenario A: HAE without any effective emergency medication; Scenario B: HAE with effective emergency medication available in hospital; Scenario C: HAE with effective emergency medication available for self-administration. The health state descriptions were based evidence from on relevant clinical trials, burden of disease and QoL studies and HAE treatment guidelines, supported by clinical expert opinion. The standard gamble survey was web based/administered online. Respondents were recruited from an existing consumer research panel. **RESULTS:** A total of 201 respondents completed the survey; 91% were prepared to gamble with death to achieve perfect health in at least one of the three health states. The mean utility weighting elicited for health state C was significantly higher than either weightings elicited for health state B (0.75 [95%CI. 0.71, 0.79] versus 0.64 [95% CI 0.60, 0.69]; p<0.001), or for health state A (0.75 [95%CI. 0.71, 0.79] versus 0.62 [95% CI 0.58, 0.67]; p<0.001). There was no statistical difference between the utilities elicited for health states B and A. **CONCLUSIONS:** The results demonstrate the recognition of and value placed on the QoL benefits provided by the availability of and immediate access to a self-administered emergency medication for HAE over that provided by treatment available only in the hospital accident and emergency treatment setting.

PND40

A STUDY TO ESTIMATE UTILITY VALUES FOR DIFFERENT LEVELS OF SEVERITY OF MIGRAINE PAIN

Hareendran A[1], Ng-Mak DS[2], Stafford MR[1], Insigna RP[3], Reifung X[3]
[1]*United BioSource Corporation, London, UK,* [2]*Merck & Co., Inc, West Point, PA, USA,* [3]*Merck & Co., Inc, North Wales, PA, USA*

OBJECTIVES: Health state utility values are the metric preferred by health care decision makers to examine the relative value of various treatments to treat migraine, including those that reduce the severity of migraine pain. This cross-sectional, observational study aimed to estimate utility values for different levels of migraine pain severity. **METHODS:** One hundred six participants from the UK (UK), diagnosed with migraine, completed the EQ-5D™ to evaluate their health status for mild, moderate, and severe levels of migraine pain severity for a recent migraine attack and for current health (without migraine) defined as health status within 7 days post-attack, with no residual migraine symptoms. T-tests were used to compare mean utility values between each level of severity to evaluate whether there were significant differences in mean utility scores by migraine severity; Wilcoxon signed rank test was also performed. **RESULTS:** Utility scores for each health state were found to be significantly different from perfect health (p<0.0001) and one another (p<0.0001). As severity worsened, utility decreased and the lowest mean utility, -0.20 (95% confidence interval [CI]: -0.27−-0.13), was for severe migraine pain. Compared to current health (without migraine), utility decrements were 0.21, 0.34, and 1.07 for mild, moderate, and severe migraine pain states respectively. The smallest difference in mean utility scores was between mild and moderate migraine pain (0.13) and the largest difference in mean utility scores was between current health (without migraine) and severe migraine pain (1.07). **CONCLUSIONS:** Migraine pain severity was associated with significantly lower utility compared with perfect health, with higher levels of pain severity associated with lower utility. Severe migraine pain was considered a health state worse than death. Our results can be used in cost-utility models examining the relative economic value of therapeutic strategies for migraine in the UK.

PND41

PREDICTING EQ-5D UTILITY SCORES FROM THE HUNTINGTON QUALITY OF LIFE INSTRUMENT (H-QOL-I)

Clay E[1], Briquet B[2], Aballea S[3], Maman K[4], Toumi M[5]
[1]*Creativ Research, Paris, France,* [2]*ISUP, Paris, France,* [3]*Creativ Ceutical, Paris, Ile de France, France,* [4]*Creativ-Ceutical, Paris, France,* [5]*University Claude Bernard Lyon1, Lyon, France*

OBJECTIVES: H-QoL-I is a quality-of-life indicator specific to the Huntington's Disease (HD), with 3 dimensions: motor function, psychology and socializing. It has been validated in several countries (France, Italy, Poland, Germany and United States). We compared several methods for mapping H-QoL-I onto EQ-5D and thus derive utility values from H-QoL-I. **METHODS:** This analysis was based on a sample of 315 HD patients who participated in an international survey on the burden of HD, and completed H-QoL-I and EQ-5D, with help from caregivers if necessary. EQ-5D index scores were calculated based on UK time trade-off tariff. The sample was divided into 70% derivation and 30% validation sets. We compared three methods to estimate patient's utility as a function of 11 H-QoL-I items: ordinary least-

squares (OLS) regression and Tobit regression, with utility score as independent variable, and ordered logistic regression for each item of EQ-5D. Model performance was assessed by comparing predicted and observed mean EQ-5D scores in the validation set, the unadjusted R-squared and the root mean squared error (RMSE). **RESULTS:** The OLS regression had the best predictive performance with R-squared equal to 0.60 and RMSE equal to 0.25. The linear regression model accurately estimated the mean EQ-5D score in the validation set (predicted score 0.32 versus observed score 0.30). RMSE values of 0.26 and 0.31 were obtained with Tobit model and ordered logistic model. Items with the greatest contribution to variance in the OLS model were 'difficulty of tie the laces of my shoes' ($p=0.0018$), 'difficulty to drink without spilling' ($p=0.0156$) and 'difficulty to make precise movements' ($p=0.0165$). **CONCLUSIONS:** EQ-5D utility scores can be reasonably predicted from the H-QoL-I, although item wordings are not directly related. The model based on OLS regression provides the best fitting. Motor functions items contributed the model to utility predictions.

PND42

IMPACT OF RELAPSES LEADING TO HOSPITALISATION ON HEALTH-RELATED QUALITY OF LIFE, FATIGUE AND HEALTH CARE RESOURCE UTILISATION IN A POPULATION WITH A RELAPSING FORM OF MULTIPLE SCLEROSIS (RMS) USING DATA FROM TEMSO A TERIFLUNONOMIDE PIVOTAL PHASE III TRIAL

O'Connor P[1], Goldberg L[2], Bego-Le-Bagousse G[3], Dive-Pouletty C[3]
[1]*University of Toronto, Toronto, ON, Canada,* [2]*Goldberg, MD & Associates, Battle Ground, WA, USA,* [3]*Sanofi-aventis, Massy Cedex, France*

OBJECTIVES: In patients with RMS, assess the impact of relapse(s) leading to hospitalization on Health-Related Quality of Life (HR-QoL), fatigue and Health Care resource utilisation. **METHODS:** TEMSO (N=1088) was designed to assess efficacy and safety of teriflunomide, a novel oral disease modifier, in RMS patients. Patients with no relapse, patients with relapse(s) not leading to hospitalisation and patients with at least one relapse leading to hospitalisation were analysed. The following patient reported outcomes (PROs) were assessed; utility (EQ5D), PCS and MCS (Physical and Mental Health Component Summaries) scores of the SF-36, fatigue (FIS-total score). Also, Emergency Medical Facility Visits (EMFV; a visit to a medical facility/hospital for emergency care not resulting in an admission) was tracked. Changes from Baseline for PROs and annual EMFV rate were analysed for a two-year period. **RESULTS:** Change from baseline (CfB) in utility in patients with no relapse was +0.034, CfB in utility in patients with relapse(s) not leading to hospitalisation was -0.019(*p1<0.01) and CfB in utility in patients with relapse(s) leading to hospitalisation was -0.057(p1<0.001; p2:ns). Similar results were seen for PCS of +1.0, -1.0 (p1<0.01) and -3.1(p1<0.001; p2<0.05) respectively and for MCS were respectively +1.8, -1.0(p1<0.01) and -2.7 (p1<0.001; p2:ns). This same trend was observed with FIS total score, (CfB was respectively: -3.0, +1.4 (p1:ns) and +10.3 (p1<0.001; p2<0.01). The mean annual EMFV rate in patients with no relapse was 0.5 and in patients with relapse not leading to hospitalisation was 0.4 (p1:ns). This rate was increased to 1.2 (p1<0.05; p2<0.001) in patients with relapse leading to hospitalisation. **CONCLUSIONS:** In TEMSO, patients with relapse leading to hospitalisation comparatively have worsening in HR-QoL (EQ-5D, SF-36), fatigue and have a higher number of EMFV. *p1: versus patients with no relapse, p2: versus patients with relapse not leading to hospitalisation.

PND43

VALIDATION OF THE SELF ASSESSMENT OF TREATMENT (SAT) QUESTIONNAIRE

Wyrwich KW[1], Thompson C[1], Holmstrom S[2], Wiklund I[3]
[1]*United BioSource Corporation, Bethesda, MD, USA,* [2]*Astellas Pharma Global Development, Leiderdorp, The Netherlands,* [3]*United BioSource Corporation, London, UK*

OBJECTIVES: The original SAT is a five-item questionnaire developed to assess treatment benefits associated with application of QUTENZA™, a novel high-dose capsaicin patch, in clinical trials among patients with neuropathic pain . The objective of this study was to evaluate the item performance and psychometric properties of the SAT. **METHODS:** The SAT, Numerical Pain Rating Scale (NPRS), SF-36, Brief Pain Inventory and Patient Global Impression of Change (PGCI) scores were measured in two 12 week Phase3 clinical trials. Descriptive statistics, exploratory and confirmatory factor analysis (EFA and CFE) were conducted to assess the item performance and to explore the underlying constructs. Reliability and validity were also examined. **RESULTS:** Pooled data from 698 patients (21-91 years) completing SAT after 12 weeks of treatment were analyzed. From descriptive statistics, EFA and CFA results, a one-factor model combining 4 of the 5 items emerged as the optimal solution with 66% explained variance. The internal consistency reliability was high (Cronbach's alpha = 0.87). Construct validity was demonstrated by moderate to high correlations with change in the NPRS (-0.55 pain now and -0.64 average pain), BPI (-0.59 worst pain, -0.35 activity limitation), SF 36v2 pain subscale (0.43) and PGIC (0.85). SAT scores strongly discriminated patient change groups using the PGIC; mean SAT scores were 1.7 in patients who were very much improved versus -1.0 in patients who were much worse/very much worse. **CONCLUSIONS:** Preliminary analyses indicate that the measurement properties of the four-item version of SAT are valid and reliable for patients self assessment of treatment with QUTENZA™ among patients with neuropathic pain. The item performance suggests that the questionnaire could be further improved with additional patient input to clarify some of the questions as well as revising the response options and recall period to better reflect treatment benefits during the course of a trial.

PND44

VALIDATION OF THE FABRY OUTCOME SURVEY (FOS) PAEDIATRIC HEALTH AND PAIN QUESTIONNAIRE

Raluy M[1], Wiklund I[1], Stull DE[2], Chen WH[3], Ramaswami U[4], Whybra C[5], Kalkum G[5], Pintos-morell G[6], Parini R[7], Rohrbach M[8], Beck M[9]
[1]*United BioSource Corporation, London, UK,* [2]*United BioSource Corporation, Bethesda, WA, USA,* [3]*United BioSource Corporation, Bethesda, MD, USA,* [4]*Addenbrooke's Hospital, Cambridge, UK,* [5]*University Medical Center, University of Mainz, Mainz, Germany,* [6]*University Hospital "Germans Trias i Pujol", Badalona, Spain,* [7]*San Gerardo Hospital, Università Milano Bicocca, Monza, Italy,* [8]*University Children's Hospital, Zurich, Switzerland,* [9]*Children's Hospital, University of Mainz, Mainz, Germany*

OBJECTIVES: The original 40-question Fabry-specific Paediatric Health and Pain Questionnaire (FPHPQ) was developed to understand and assess the symptoms in Fabry Disease (FD) patients as no validated instrument existed. The objective of this study was to evaluate the psychometric properties of the FPHPQ. **METHODS:** FPHPQ data were collected from the FOS, a registry sponsored by Shire HGT for patients with FD who were treatment naive or receiving enzyme replacement therapy with agalsidase alfa. Descriptive statistics and exploratory factor analysis were conducted to assess the item performance and to explore the underlying constructs. Reliability, validity, and responsiveness were also examined. **RESULTS:** Eighty-seven children (aged 4-18 years) from 8 different countries completed the questionnaire. From descriptive statistics and EFA, 23 items in three subscales emerged: Pain associated with heat or exertion; pain associated with cold; abdominal pain and fatigue. Internal consistency reliability for all three subscales was good (Cronbach alpha ≥ 0.84) and high for all age groups (4-7, 8-12, 13-18 years). Test-retest reliability was high for all three subscales (intraclass correlation coefficient ≥ 0.74). Construct validity was demonstrated by moderate correlation with the Brief Pain Inventory (BPI), KINDL, and EQ-5D. Known group validity showed that all subscales were able to discriminate between mild and moderate FD severity as classified by the FOS MSSI (Mainz Severity Score Index). The FPHPQ heat and exertion subscale was responsive to change in symptoms between responders and non-responders as defined by change in EQ-5D index scores between Visits 1 and 2. **CONCLUSIONS:** Preliminary analyses indicate that the measurement properties of FPHPQ are valid and reliable for assessing patient-reported symptoms of FD. The questionnaire could be a useful tool for clinicians to understand the progression of disease and monitor treatment effects. FPHPQ will be further validated and refined as the FOS database is continuously adding more patients.

PND45

DEVELOPMENT AND VALIDATION OF THE MULTIPLE SCLEROSIS RATING SCALE-REVISED (MSRS-R)

Wicks P, Vaughan TE, Massagli MP
PatientsLikeMe, Cambridge, MA, USA

OBJECTIVES: PatientsLikeMe is an online health-data sharing community and research platform for patients with chronic and life-changing health conditions. In developing the PatientsLikeMe online platform for patients with Multiple Sclerosis (MS), we required a patient-reported, multi-dimensional assessment of functional status that was easy to complete. Existing measures of functional status were inadequate; clinician-reported, focused on walking, and burdensome to complete. To develop a longitudinal record accessible to patients using the site, we developed the Multiple Sclerosis Rating Scale (MSRS). **METHODS:** We adapted a clinician-rated measure, the Guy's Neurological Disability Scale, to a self-report scale and deployed it to an online community. As part of our validation process, we reviewed online forum discussions between patients, conducted in-person patient cognitive debriefing, and made minor improvements to form a revised scale (MSRS-R). The MSRS-R was deployed as a cross-sectional survey to 4382 patients with relapsing-remitting MS (RRMS) on the PatientsLikeMe platform. The survey included the MSRS-R as well as a range of comparator MS measures: PRIMUS, MSIS-29, PDDS, NARCOMS Performance Scales, and MSWS-12. **RESULTS:** In total, 816 RRMS patients responded. The MSRS-R exhibited high internal consistency (Cronbach's alpha = 0.86) and 1-week retest reliability (r = 0.91). The MSRS-R walking item was highly correlated with alternative walking measures (PDDS, r = 0.84; MSWS-12, r= 0.83; NARCOMS mobility question, r = 0.86). The MSRS-R correlated well with comparison instruments, and reliably differentiated between participants by PDDS disease stage, relapse severity, and time since diagnosis. Retrospective scoring of most recent relapse suggested a 3-point increase in MSRS-R might usefully identify relapses. **CONCLUSIONS:** The MSRS-R is a concise, multi-faceted measure of MS-related functional disability. It may be useful for describing the impact of MS and can support further inquiry into the factors that relate to variation in outcomes among MS patients.

PND46

THE HUNTINGTON QUALITY OF LIFE INSTRUMENT (H-QOL-I): CROSS-CULTURAL VALIDATION IN GERMANY, POLAND AND USA

Clay E[1], Mraidi M[2], Zielonka D[3], Cohen J[4], Toumi M[5], Auquier P[6]
[1]*Creativ Research, Paris, France,* [2]*Creativ-Ceutical, Les Berges du Lac - Tunis, Tunis, Tunisia,* [3]*Poznan University of Medical Sciences, Poznan, Poland,* [4]*Tufts University Center for the Study of Drug Development, Boston, MA, USA,* [5]*University Claude Bernard Lyon1, Lyon, France,* [6]*Timone University Hospital, Marseille, France*

OBJECTIVES: The Huntington Quality of Life Instrument (H-QoL-I) is a first self-reported specific Health-Related Quality of Life (HR-QoL) instrument developed to assess the QoL of patients suffering from Huntington's disease. It was originally developed and validated in French and in Italian. The instrument is being validated in 11 languages. This study aims to validate the German, Polish and US versions of H-QoL-I cross-culturally. **METHODS:** The original questionnaire was based on 11 items and 3 dimensions. The instrument was translated forwards and backwards by native speakers. It was then reviewed and adjusted by local clinicians and tested for face validity. A survey was conducted with 134 US, 60 Polish and 41 German patients. Face validity was tested through item completion and overall under-

standing. Internal validity was tested, assessing internal consistency, correlation matrix using item/dimension correlation, factorial structure and differential item functioning. External validation was performed versus motor symptoms, behavioral symptoms, and the well-established QoL scale EuroQoL 5D. **RESULTS:** The preliminary analysis supported the validity of the H-QoL-I. Face validity appeared satisfactory (Missing data < 7%); as for the original instrument, a ceiling effect was observed for patients with severe HD. The H-QoL-I showed an acceptable reliability (Cronbach's alpha > 0.85 for each dimension). The factor analysis explained 77% of the total variance and split the items in 3 factors in the same way as the original version. There was no differential item functioning neither between countries nor gender. The Pearson's correlation between the clinical motor score and the motor functioning dimension was 0.89, between EQ-5D score and H-QoL-I total score, 0.71 and between the clinical depression/anxiety score and the psychological dimension of H-QoL-I, 0.63. **CONCLUSIONS:** Test–retest and sensitivity to change remain to be performed, but current data support the validity of the H-QoL-I.

PND47

THE HUNTINGTON CLINICAL SELF-REPORTED INSTRUMENT (H-CSRI): VALIDATION IN GERMANY, POLAND AND USA

Clay E[1], Mraidi M[2], Toumi M[3], Tedroff J[4], Squitieri F[5], De Nicola N[5], Verny C[6], Cohen J[7]
[1]*Creativ Research, Paris, France,* [2]*Creativ-Ceutical, Les Berges du Lac - TUNIS, TUNIS, Tunisia,* [3]*University Claude Bernard Lyon1, Lyon, France,* [4]*Neurosearch, Ballerup, Denmark,* [5]*Neurogenetics and Rare Disease Centre, Pozzi, Italy,* [6]*Centre national de référence des maladies neurogénétiques, Angers, France,* [7]*Tufts University Center for the Study of Drug Development, Boston, MA, USA*

OBJECTIVES: The H-CSRI is the first clinimetric patient assessed scale for patients with Huntington's disease (HD). It was originally developed and validated for France and Italy. Such an instrument offers the advantage of allowing a remote follow-up and getting information on the development of motor, functional and behavioral disorders of HD patients perceived by the patient himself. The objective of this study is to adapt and cross-culturally validate the H-CSRI for Germany, Poland and USA. **METHODS:** The original questionnaire included three subscales assessing the motor (13 Likert-type items in 4 dimensions), functional (7 Yes/No questions) and behavioural ability (13 Likert-type items in 4 dimensions). The instrument was translated forwards and backwards by native speakers. It was then reviewed and adjusted by local clinicians and tested for face validity. A total of 134 US, 60 Polish and 41 German HD patients filled in the H-CSRI questionnaire. Classical test theory and item response theory were used to assess its clinimetric properties.Cross-cultural validation was assessed by diferential item functioning analysis. **RESULTS:** Among 235 patients, item response rates ranged from 86% to 93%. Face validity appeared satisfactory; as for the original instrument, there was a floor effect on items related to psychotic disorder in the behavioral dimension. The H-CSRI showed an acceptable reliability (Cronbach's alphas > 0.80). Factor analyses demonstrated a satisfactory construct validity for the motor dimensions with 76% of explained variance and for the behavioural dimensions with 74% of the explained variance. The differential item functioning analyses showed no item bias between the three countries and between genders. **CONCLUSIONS:** These data support the cross-cultural validity of the H-CSRI to assess the health status for patients with Huntington's disease and integrate the patient perspective for Germany, Poland and US.

PND48

DEVELOPMENT OF A BURDEN QUESTIONNAIRE: FAMILY BURDEN OF ICHTHYOSIS IN INFANTS

Bodemer C[1], Dufresne H[1], Taieb C[2]
[1]*Hopital Necker, Paris, France,* [2]*PFSA, Boulogne Billancourt, France*

OBJECTIVES: Ichthyoses form a group of ailments for which the main part of treatment aims to reduce hyperkeratosis and to control sensory, articular and psychological complications. In infants, dermatologists do not restrict their treatment to the cutaneous involvement, but endeavour to prevent the consequences of these severe and obvious afflictions for the future of these patients. To explore the handicap, in the largest sense, generated by ichthyosis using a questionnaire to express the burden of the illness on the daily life of patients and their family, in order to anticipate and treat it more effectively. **METHODS:** The questionnaire was developed following a strict methodological process involving a multidisciplinary team incorporating various players (doctors, nurses, social workers) who are involved in the treatment of patients and caring for their families in order to guarantee its credibility and reliability. A review of the literature and discussions with the children and their families were conducted in order to identify the concepts related to the pathology. **RESULTS:** Exploratory assessments showed that the concept of burden could be structured around five components: feeling of pain, daily life, family and personal relationships, work and psychological impact. Ninety-six preliminary items were identified at the end of the first discussion. A first analysis managed to reduce these items to 40 whilst conserving the 5 components but making it easier to use the analysis. The creation of a "child module" aimed at children who are able to provide answers independently proved necessary. **CONCLUSIONS:** Chronic pathologies such as ichthyosis, which remains a rare and incapacitating illness, are difficult to assess by clinical or quality of life aspects alone as their impact can be multidimensional. "Family Burden Ichthyosis" takes them all into consideration in order to explain every angle of the handicap generated.

PND49

INITIAL PSYCHOMETRIC PROPERTIES OF THE EURODOLMED QUESTIONNAIRE: A NEW INSTRUMENT TO MEASURE NEUROPATHIC PAIN IN PATIENTS WITH SPINAL CORD INJURY (SCI) BASED ON PAIN INTENSITY, PAIN INTERFERENCE AND PAIN DESCRIPTORS

Taylor JS[1], Ruiz MA[2], Soler MD[3], Bouhassira D[4], Poole H[5], Jauregui ML[6], Eurodolmed SG[7], Finnerup NB[8]
[1]*Hospital Nacional de Parapléjicos SESCAM, TOLEDO, Spain,* [2]*Universidad Autonoma de Madrid, Madrid, Spain,* [3]*Hospital de Neurorehabilitació Institut Guttmann, Badalona, Barcelona, Spain,* [4]*Hôpital Ambroise Paré, Boulogne-Billancourt, France,* [5]*Walton Centre, Liverpool, Liverpool, UK,* [6]*Hospital Cruces, Barakaldo, Bizkaia, Spain,* [7]*Hospital Nacional de Parapléjicos, Toledo, Toledo, Spain,* [8]*Aarhus University Hospital, Århus C, Århus, Denmark*

OBJECTIVES: To develop a new instrument measuring neuropathic pain at and below the level of spinal cord injury (SCI) based on pain intensity, pain interference and pain descriptors. **METHODS:** An expert panel composed of pain specialists, physiologists, rehabilitation doctors, neurologists, psychologists and methodologists was created to generate the items and to supervise the questionnaire construction, following Classic Test Theory assumptions. A total of 12 Likert items, 2 multichoice items, 7 dichotomous indicators and 23 pain descriptors were proposed. They were measured for at and below level pain in patients with traumatic SCI between the C3 and T10 level. A subgroup of items was assessed for constant pain, paroxysmal pain, and evoked pain. Item analysis, structural validity (exploratory factor analysis) and reliability (Cronbach's alpha) were assessed. Correlation with DN4, NPSI, BPI and MHI5 was studied for convergent validity. Cluster analysis and multidimensional correspondence analysis were also used to study pain descriptor behavior. **RESULTS:** A total of 153 patients recruited at 4 specialized hospitals in Spain and Denmark. Women were 26%, and mean age 43 years (SD=12.4). Thirty five percent experienced below SCI level pain, 26% at level, and 39% both. Factor analysis below SCI suggested that pain intensity and QoL interference were related to constant non-evoked pain, while paroxysmal pain was related to night disturbance and temperature-evoked pain. Scale reliability was 0.76 below and 0.80 at SCI level. Exploratory correlations with other standard diagnostic tools were moderate. Descriptor clustering disclosed 5 main groups of pain types covering most of the items used frequently in other instruments (DN4 or NPSI). Pain at and below level differed in specific aspects. **CONCLUSIONS:** Initial psychometric properties of the EuroDolMed are good and support the use of this new instrument to explore neuropathic pain in patients with SCI, although an effort should be made to shorten it without losing precision.

PND50

PUBLIC PREFERENCES FOR THE PREDICTIVE GENETIC TEST FOR ALZHEIMER'S DISEASE IN THE UNITED STATES

Huang MY, Perri M
University of Georgia, Athens, GA, USA

OBJECTIVES: To assess public preferences for the predictive genetic test for Alzheimer's disease in the United States. **METHODS:** A rating conjoint analysis was conducted using an anonymous online survey distributed by Qualtrics® to a general population panel in April 2011 in the United States. The study design included three attributes: Accuracy, Treatment Availability, and Anonymity. A total of 12 scenarios were used to elicit people's preference by adopting an 11-point scale. The respondents also stated their highest willingness-to-pay (WTP) for each scenario by answering the open-ended questions. **RESULTS:** A total of 295 responses were collected over four days. The results showed the most important attribute for the aggregate model was Accuracy, contributing 64.73% to the preference rating. Treatment Availability and Anonymity contributed 20.72% and 14.59% to the preference rating, respectively. The most preferred scenario was the test with a 100% chance of being correct, a cure for AD is available and the test result is anonymous. The median WTP for the highest-rating scenario (Accuracy 100%, a cure is available, test result is anonymous) was $100 (mean WTP was $276). The median WTP for the lowest-rating scenario (Accuracy 40%, no cure but drugs for symptom relief, not anonymous) was zero (mean WTP was $36). Four groups were identified using cluster analysis revealing different patterns of importance among the three attributes. **CONCLUSIONS:** The results of this study highlight the attributes consumer find important when making the decision to obtain an AD genetic test. These results should be of interests to policy makers, genetic test developers and health care providers.

PND51

THE RELATIONSHIP BETWEEN PATIENT-REPORTED HEALTH-RELATED QUALITY OF LIFE AND DISABILITY STATUS AMONG PATIENTS WITH MULTIPLE SCLEROSIS

Khalaf KM[1], Globe D[1], Armstrong E[2], Malone D[2], Coyne K[3]
[1]*Allergan, LLC, Irvine, CA, USA,* [2]*University of Arizona, Tucson, AZ, USA,* [3]*United BioSource Corporation, Bethesda, MD, USA*

OBJECTIVES: Previous research suggests that the Short Form 36 (SF-36) may capture some of the broad effects of MS that are not reflected in the Kurtzke Expanded Disability Status Scale (EDSS) and may be appropriate when evaluating overall health-related quality of life (HRQL). The purpose of this study was to explore the relationship between an EDSS-correlated self-reported disability measure, the Patient Determined Disease Steps (PDDS), and SF-36 health domain scores. **METHODS:** A convenience sample of US-residing participants with MS were recruited through web-based patient advocacy organizations. Participants responded to questions pertaining to demographics, disease history, productivity, urinary symptoms, and HRQL. Disability status was measured using the PDDS, an 8-point ordinal scale ranging from "Normal" to "Bedridden," and general HRQL was measured using the SF-36 version 2, a 36-item questionnaire comprised of 8 health domain subscales and 2 summary scores normalized for direct comparison to the US general population. Spearman rank correlation coefficients were calculated to assess the relationship between SF-36 health domain scores and PDDS scores. **RESULTS:** Among the sample of 1052 participants who completed the survey, 19% were men and the mean age was 48 years. All 8 SF-36 subscales were significantly

positively correlated with one another (0.20<r<0.73), and significantly negatively correlated with PDDS scores (-0.82<r<-0.07). The physical functioning domain correlated most strongly with PDDS scores (r=-0.82, p<0.001). Strong correlations were also noted among the role-physical (r=-0.58, p<0.001), social functioning (r=-0.37, p<0.001), and bodily pain (r=-0.28, p<0.001) domains. The domains correlating most weakly with PDDS scores were vitality (r=-0.23, p<0001) and mental health (r=-0.07, p=0.03). **CONCLUSIONS:** As expected, the patient-rated PDDS scores were more strongly associated with domains related to physical health status. To capture the broader psychosocial impact of MS on patient HRQL, additional patient-reported outcomes need to be utilized.

PND52

RESPONSIVENESS OF THE MULTIPLE SCLEROSIS INTERNATIONAL QUALITY OF LIFE AND SHORT FORM-36 QUESTIONNAIRES TO EXPANDED DISABILITY STATUS SCALE SCORE CHANGES IN SUBJECTS WITH MULTIPLE SCLEROSIS: FINAL 24-MONTH RESULTS FROM AN INTERNATIONAL OBSERVATIONAL STUDY

Fernandez O[1], Baumstarck-Barrau K[2], Butzkueven H[3], Flachenecker P[4], Idiman E[5], Pelletier J[2], Stecchi S[6], Verdun di Cantogno E[7], Milner A[7], Auquier P[2]
[1]*Hospital Regional Universitario Carlos Haya, Málaga, Spain,* [2]*Timone University Hospital, Marseille, France,* [3]*Royal Melbourne Hospital, Melbourne, Australia,* [4]*Neurological Rehabilitation Center Quellenhof, Bad Wildbad, Germany,* [5]*Dokuz Eylül University, Ýzmir, Turkey,* [6]*Multiple Sclerosis Unit, Department of Neuroscience AUSL, Bologna, Italy,* [7]*Merck Serono S.A., Geneva, Switzerland*

OBJECTIVES: Quality of life (QoL) is an important measure in multiple sclerosis (MS), complementing clinical assessments such as the Expanded Disability Status Scale (EDSS). The MS International QoL (MusiQoL) questionnaire is a validated, MS-specific instrument. This multicentre, observational study assessed responsiveness of MusiQoL versus the Short Form-36 version 2 (SF36v2) to changes in EDSS score over 24 months in subjects with MS (≥18 years; EDSS ≤7.0; treated/untreated). **METHODS:** MusiQoL, SF36v2 and EDSS scores were recorded at baseline (BL) and 6-monthly intervals to month 24 (M24). Primary endpoint: change in MusiQoL index score and effect size (ES) to M24. Secondary endpoints included change in MusiQoL and SF36v2 scores and ES (BL–6-monthly assessments). **RESULTS:** Six hundred subjects enrolled in 12 countries; 452 had evaluable BL and M24 EDSS and MusiQoL index data. BL mean (SD) EDSS score was 2.9 (1.9), mean (SD) MusiQoL index score was 68.5 (14.3), and mean (SD) MusiQoL subscale scores ranged from 59.8 (25.0) to 85.5 (18.2). EDSS score worsened by M24 in 89 subjects (19.7% vs expected 30%); mean (SD) change in MusiQoL index score was 0.30 (12.3) in non-worsened (ES: 0.02) and –2.3 (11.6) in worsened (ES: –0.17) subjects. At M24, larger (mean [SD]; ES) changes were seen in MusiQoL Relationship with Healthcare System (–6.0 [16.9]; –0.40) and Sentimental and Sexual Life (–6.4 [26.2]; –0.22) subscale scores for worsened subjects; in Psychological Well-Being (+4.8 [21.6]; 0.20) subscale score for non-worsened subjects; and in the SF36v2 physical component (–2.5 [6.7]; –0.24), physical functioning (–3.3 [7.6]; –0.28), bodily pain (–3.1 [10.3]; –0.28) and emotional (–2.8 [14.1]; –0.22) subscale scores for worsened subjects. **CONCLUSIONS:** MusiQoL index score detected poorer QoL in subjects with worsening EDSS scores. Most MusiQoL scores decreased over 24 months in subjects with more severe disability, indicating poorer QoL and confirming the utility of the MS-specific MusiQoL questionnaire in rating QoL.

PND53

THE PATIENT-REPORTED BURDEN OF IMPAIRED WALKING IN MULTIPLE SCLEROSIS

Moorcroft E[1], Kennedy K[1], Miller DW[2], White J[3], Sidovar M[4]
[1]*HERON Evidence Development Ltd, Luton, UK,* [2]*Biogen Idec, Weston, MA, USA,* [3]*Biogen Idec, Zug, Switzerland,* [4]*Acorda Therapeutics, Hawthorne, NY, USA*

OBJECTIVES: Walking impairment is recognised as one of the most distressing disabilities for people with Multiple Sclerosis (MS) and is reported in approximately 75% of patients. The objective of this analysis is to assess the impact of impaired walking on quality of life, and on direct and indirect costs to society. **METHODS:** The NARCOMS registry is a voluntary MS patient self-report database operating mainly in the US. The registry collects MS related data semi-annually through web-based and mail questionnaires, and periodically administers additional surveys on specific topics of interest, such as mobility. One of the main measures used for assessing walking impairment is the Multiple Sclerosis Walking Scale 12 (MSWS12). The Patient Determined Disease Step (PDDS) scale is used to measure the level of disease progression. NARCOMS data collection also addresses patient reported quality of life through the EuroQol-5 Dimensions (EQ-5D) and the 12-item Short-Form survey (SF-12), as well as patients' physical activities, work life, and healthcare resource use. We used descriptive statistics, and univariate analyses to describe and quantify the cross-sectional relationship between walking impairment and other patient outcomes. **RESULTS:** A total of 2276 patients were randomly selected from the NARCOMS database, of which 1838 (81%) were female. The sample population had a mean age of 46 years, and a mean PDDS score of 3.0. Univariate analysis demonstrated that increases in MSWS-12 scores (decrease in ambulation) were negatively correlated with quality of life as measured by EQ-5D. An increase in MSWS-12 score was also associated with increases in visits to MS neurologists and physiotherapists, increases in caregiver visits, as well as reduced productivity. **CONCLUSIONS:** MS patients with less severe walking impairment showed better quality of life, lower health care utilization and higher productivity. Additional research using multivariate models should be encouraged to further characterize the impact of impaired walking on MS patients.

PND54

QUALITY OF LIFE IMPAIRMENT, DISABILITY, AND ECONOMIC BURDEN ASSOCIATED WITH CHRONIC DAILY HEADACHE FOCUSSING ON CHRONIC MIGRAINE WITH OR WITHOUT MEDICATION OVERUSE: A SYSTEMATIC REVIEW

Lantéri-Minet M[1], Duru G[2], Mudge M[3], Cottrell S[3], Tilden D[3]
[1]*Département d'Evaluation et Traitement de la Douleur, Pôle Neurosciences Cliniques du CHU de Nice - Hôpital Pasteur, Nice, Alpes-Maritimes, France,* [2]*Claude Bernard University, Lyon, Villeurbanne ced, France,* [3]*Thema Consulting Pty Ltd, Pyrmont, NSW, Australia*

OBJECTIVES: To evaluate the evidence for quality of life (QoL) impairment, disability, healthcare resource use, and economic burden associated with chronic daily headache (CDH), particularly chronic migraine (CM). **METHODS:** Systematic review and qualitative synthesis of studies of patients/subjects with CDH (≥15 headache days/month) that included CM, reporting QoL or disability outcomes, healthcare resource utilisation or associated direct costs. **RESULTS:** Thirty-four studies were included: 25 of patients; 9 of subjects from the general population; 16 reporting QoL and 14 reporting disability outcomes; 4 reporting on healthcare resource utilisation and/or costs. Data were not amenable to statistical pooling. In studies reporting QoL using SF-36 or SF-12 instruments: CDH was consistently associated with lower QoL compared to normative/healthy control (5/5 studies) or episodic headache (EH) (6/6 studies); 3/4 studies showed CDH with migraine was associated with lower QoL than CDH without migraine; 3/5 studies showed CDH with medication overuse headache (MOH) was associated with lower QoL than CDH without MOH; 4/4 studies suggested a significant negative QoL impact when CDH was with a comorbidity. In studies reporting disability using the MIDAS instrument, CDH was consistently associated with greater disability and productivity (D&P) loss than EH (7/7 studies), 1/2 studies showed CDH with migrainous features was associated with greater D&P loss than CDH without migraine, 1/1 studies showed CDH with MOH was associated with greater D&P loss than CDH without MOH and 1/1 studies suggested a significant negative impact when CDH was with a named comorbidity. In the two most comprehensively reported economic studies, CDH was associated with more consultations, more or longer hospitalisations and higher direct costs compared to EH. **CONCLUSIONS:** The findings underline the disabling nature and QoL detriment of CDH, and in particular of CM and CDH with MOH, and negative impact on workplace productivity compared to other headache types.

PND55

THE PREDICTORS OF HEALTH-RELATED QUALITY OF LIFE IN PEDIATRIC EPILEPSY: A SYSTEMATIC REVIEW

Stevanovic D[1], Tadic I[2], Novakovic T[3]
[1]*General Hospital Sombor, Sombor, Serbia and Montenegro,* [2]*Belgrade University, Belgrade, Serbia and Montenegro,* [3]*Galenika a.d., Belgrade, Serbia and Montenegro*

OBJECTIVES: A number of studies evaluated different predictors of health-related quality of life (HRQOL) in children and adolescents with epilepsy, but the findings of these studies were often contradictory and it was not possible to draw general conclusions. Therefore, this review was organized with the aims to identify in a systematic way the predictors of HRQOL in pediatric epilepsy. **METHODS:** Searches of the literature in Pubmed, Scopus, and Web of Science, with searches of relevant journals were performed. In total, 14 studies met the inclusion criteria (participant aged up to 18 years, HRQOL was assessed with an epilepsy specific and/or generic questionnaire/s, HRQOL predictors were identified using regression models, and the study was published in a peer-review journal). The methodological quality of the studies was assessed using predefined criteria. **RESULTS:** All identified studies were cross-sectional with the quality scores ranging 7 (low) – 14 (high) points. Strong evidence was found for age at epilepsy onset (younger age), a number of antiepileptic drugs (AEDs), and parental depression as HRQOL predictors in both, children and adolescents. Moderate evidence was found for attention problems, overall intelligence (lower) and family (i. e. structure, parental anxiety, etc.). Specific to adolescents with epilepsy, seizure worry/concerns and side effects of AEDs were found as strong predictors and epilepsy severity, while a number of AEDs as moderate. Weak evidence and inconclusive data exist for other predictors (i.e. social skills, duration of epilepsy, seizure frequency and severity, neuropsychiatric comorbidity, side effects of AEDS, autonomy, social support, victimization, economic status, and so forth). **CONCLUSIONS:** This systematic review identified age at epilepsy onset, a number of AEDs, and parental depression as strong HRQOL predictors in pediatric epilepsy, but specific to adolescents only, seizure worry/concerns and side effects of AEDs were identified. Other predictors were of lesser importance or were unimportant.

PND56

QUALITY OF LIFE ASSESSMENTS IN ADULTS WITH ATTENTION DEFICIT/HYPERACTIVITY DISORDER - A SYSTEMATIC REVIEW

Marfatia S[1], Shroff K[2], Munshi S[1], Tiwari A[1]
[1]*pharmEDGE, Syosset, NY, USA,* [2]*New Horizons Community Service Board, Columbus, GA, USA*

OBJECTIVES: A growing body of evidence suggests that symptoms of attention-deficit/hyperactivity disorder (ADHD) persist into adulthood and are associated with ongoing impairments in quality of life (QoL). The objective of the study was to identify the most commonly used QoL instruments in adults with ADHD and to examine their psychometric properties. **METHODS:** A systematic literature review was conducted to identify articles from 1990 to May 2011 using PUBMED and ProQoLID. The search was limited to English language and key search terms included but were not limited to ADHD, quality of life, psychometrics, questionnaires, and adults. Identified articles were screened further to exclude clinical studies not measuring QoL, review articles relating to ADHD and QoL, and studies with n < 30. **RESULTS:** The search yielded a total of 89 articles of which 16 were included in the final review. The Adult ADHD Quality of Life (AAQoL) and the ADHD Impact Module

– Adult (AIM - A) were the most commonly used disease specific instruments used in clinical trials. Both, AAQoL and AIM-A have demonstrated good construct validity, responsiveness to changes in ADHD symptom severity, and internal consistency of 0.93 and 0.83, respectively. Generic instruments like the SF-36 and the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) were used in 3 RCTs to evaluate QoL. The Q-LES-Q has also demonstrated good internal consistency of 0.88 among adults with ADHD. **CONCLUSIONS:** Given the strong psychometric properties and ability to discriminate between patients with varying degrees of symptom severity, the AAQoL and AIM-A justify their use in clinical practice. These scales can be used in conjunction with diagnostic scales like the Conner's Adult ADHD Rating Scale in making effective treatment decisions on a per patient basis. Future efforts need to focus on increasing the awareness and uptake of these scales in regular clinical practice.

Neurological Disorders – Health Care Use & Policy Studies

PND57

EFFECT OF TREATMENT TIMING ON RISK OF INSTITUTIONALIZATION AMONG PATIENTS WITH ALZHEIMER'S DISEASE

Geldmacher DS[1], Kirson NY[2], Birnbaum HG[2], Kantor E[2], Eapen S[2], Joish VN[3]
[1]*University of Alabama - Birmingham, Birmingham, AL, USA,* [2]*Analysis Group, Inc., Boston, MA, USA,* [3]*Bayer HealthCare Pharmaceuticals, Inc, Wayne, NJ, USA*

OBJECTIVES: Recent research on biomarkers for Alzheimer's disease (AD) suggests possibilities for earlier diagnosis and treatment. Existing treatments, however, focus on symptomatic relief, and controlled clinical trials have shown little effect on disease progression and time to institutionalization. This study assesses effects of treatment timing on risk of institutionalization of AD patients in a real-world setting. **METHODS:** Retrospective analysis of administrative claims data for New Jersey Medicaid patients (1997-2009). Patients were included if they had ≥2 claims with AD diagnosis, or ≥1 claim and a prescription for AD treatment (donepezil, galantamine, memantine, rivastigmine, or tacrine); N=5,790. The index date was defined as the earliest claim with any dementia/memory loss diagnosis (ICD-9-CM: 290, 291.2, 292.82, 294, 331, 780.93), possibly preceding AD diagnosis. Institutionalization was defined as ≥90-day stay in a long-term care facility. The effect of treatment on institutionalization risk was estimated at the patient-quarter level using logistic regression with repeated measures, controlling for a quadratic time-trend and baseline characteristics. The model was used to predict the conditional probability (hazard rate) of institutionalization by prior treatment and quarter following index diagnosis. In turn, predicted hazard curves were constructed for different treatment scenarios. **RESULTS:** Median interval to treatment was 7 quarters (21 months) from index date diagnosis. Treatment in prior quarters reduced institutionalization risk [OR 0.88, CI 0.78-0.99]. Older age on index and AD diagnosis in prior quarters increased institutionalization risk. The predicted hazard curves imply that initiating treatment at the earliest observed onset of memory-loss symptoms could delay institutionalization by ~4 months, compared with median observed initiation. **CONCLUSIONS:** Treatment in earlier periods is associated with a small statistically significant delay in time to institutionalization among AD patients, possibly due to reduction in symptom burden. These findings may be especially relevant in light of new criteria facilitating earlier diagnosis of AD.

PND58

A REAL WORLD EVALUATION OF THE TIME ASSOCIATED WITH ADMINISTRATION OF A SINGLE EPISODE OF TREATMENT IN PATIENTS WITH HEREDITARY ANGIOEDEMA (HAE) IN THE HOME AND HOSPITAL ENVIRONMENT

Farragher A[1], Keetley M[2], Marshall S[2]
[1]*Manchester Royal Infirmary, Manchester, UK,* [2]*pH Associates, Marlow, UK*

OBJECTIVES: To describe the time associated with administration of icatibant and C1 esterase inhibitor concentrate (C1) in patients with HAE when given in hospital and self administered at home. **METHODS:** A local service evaluation was conducted in a single UK hospital Trust between January and May 2011. Direct time and motion observation was used to measure the time associated with set-up, administration and post-administration activities for icatibant and C1 in hospital. Times associated with home administration were reported by the patient or care-giver. The product and dose received were recorded. As dose of C1 is body weight dependent, the time for administration of 1000U was also recorded for comparison. **RESULTS:** Fifteen HAE episodes (hospital: 3 C1, 0 icatibant and home: 9 C1 and 3 icatibant) were observed in 8 patients (Hospital 3 C1: 0 icatibant, home 3 C1: 2 icatibant). Patients received 30mg icatibant and between 1000U-1,500U C1. Mean set-up time (min:sec): Home - C1 15:47 v icatibant 1:43; Hospital - C1 20:44. Mean administration time (min:sec): Home - C1 Total dose 7:28, C1 1000U 5:32 versus icatibant 2:06; Hospital - C1 Total dose 12:18, C1. 1000U 9:54. Mean time post administration (min:sec): Home - C1 6:30 v icatibant 1:34; Hospital - C1 4:36. Mean total time (min:sec): Home - C1 Total dose 29:46; C1 1000U 27:50 v icatibant 5:23; Hospital - C1 Total dose 37:38; C1 1000U 35:14. **CONCLUSIONS:** Total time associated with administration of therapy for HAE is shorter for icatibant than C1 in the home setting. Further the total time associated with administration of either therapy at home is less than C1 in hospital. Therefore encouraging home administration and offering choice of therapies may offer significant NHS resource use savings and patient preference benefits in appropriate patients.

PND59

A COMMON ROAD MAP FOR RATIONAL CLINICAL AND POLICY DECISIONMAKING: APPLICATION OF THE MCDA-BASED EVIDEM FRAMEWORK TO GROWTH HORMONE USE IN PATIENTS WITH PRADER-WILLI SYNDROME

Tony M[1], Goetghebeur MM[2], Khoury H[2], Wagner M[2], Deal CL[3], Battista R[1]
[1]*University of Montreal, Montreal, QC, Canada,* [2]*BioMedCom Consultants Inc., Dorval, QC, Canada,* [3]*CHU Sainte-Justine Research Center, Montreal, QC, Canada*

OBJECTIVES: Apply a MCDA-based model to support and streamline policy and clinical decisionmaking for growth hormone (GH) therapy in patients with Prader-Willi syndrome (PWS), a rare genetic disorder with serious long-term consequences including short stature and morbid obesity. **METHODS:** An extensive literature review was performed to identify and synthesize available evidence on GH for PWS for 19 criteria of the EVIDEM framework using a standardized methodology. Evidence tables, quality assessment of studies, and synthesis of data by criterion, were validated by a wide range of experts using an interactive web site. The framework was used to develop CPG questions and structure development of international recommendations during a consensus workshop. **RESULTS:** The web site provided transparent access to synthesized evidence at 3 levels of detail for 13 scientific criteria of the EVIDEM MCDA model including: disease severity, size of population, therapeutic context and unmet needs, treatment outcomes (efficacy/effectiveness, safety, patient-reported outcomes), type of treatment benefit at population and individual levels, and economic impact on medical and non-medical expenditures. Quality assessments of studies were hyperlinked to synthesized evidence. Evidence for the six contextual and ethical criteria, including utility, efficiency, fairness, system capacity, stakeholder pressures, and political/historical context, was synthesized. CPG questions were developed following this format. **CONCLUSIONS:** The "by criteria" web model provides a pragmatic means for systematic consideration of a wide range of criteria, seamless access to information and development of CPGs to guide evidence-based decisions. This work will serve to structure deliberations of a pan-Canadian taskforce to examine the conditions for successful implementation (obstacles and facilitating factors) of evidence-based CPG. The ultimate goal is to bridge the gap between researchers, policy decision-making, clinical practice and patient concerns to optimize resource allocation and health care system sustainability.

PND60

AN EXAMINATION OF MEDICATION TREATMENT PATTERNS AMONG PATIENTS WITH PARKSINSON'S DISEASE WHO UTILIZE RASAGILINE OR SELEGILINE

Grubb E[1], Castelli-Haley J[1], Lage M[2]
[1]*Teva Pharmaceuticals, Kansas City, MO, USA,* [2]*HealthMetrics Outcomes Research, Groton, CT, USA*

OBJECTIVES: To examine utilization of Rasagiline and Selegiline, two commonly prescribed medications for the treatment of Parkinson's Disease (PD). **METHODS:** Data for this study were obtained from the US i3 LabRx database over the time period from January 1, 2006 through December 30, 2010. Patients were included in the analysis if they were prescribed Rasagiline or Selegiline (with first such date identified as the index date), were diagnosed with PD, and had continuous insurance coverage from 6 months prior through 12 months post index date. Analyses are primarily descriptive in nature. **RESULTS:** There were 1242 individuals included in the study - 926 who initiated on Rasagiline and 316 who initiated on Selegiline. Patients initiated on Rasagiline, compared to Selegiline, were significantly younger (63.2 years vs. 65.4 years; P=0.0020); less likely to have a gap in therapy for at least 60 days (0.86% v 2.85%; P=0.0088; associated with a higher medication possession ration (MPR) (0.62 vs. 0.52; P<0.0001); and associated with a longer persistence of use (259 days vs. 229 days; P=0.0013). Despite the fact that Selegiline is approved only as adjunctive use, there was no statistical significant difference in the percentage of patients using the medication in combination with another PD medication (75.96% vs. 73.43%; P=0.3783). **CONCLUSIONS:** Results from this retrospective study indicate that the two medications are both used primarily as adjunctive medications. Furthermore, approximately 25% of patients who initiate on Selegiline were found to not have used other PD medications adjunctively in the 1 year post initiation. Rasagiline use, compared to use of Selegiline, was found to be associated with fewer gaps in therapy, a higher MPR and longer persistence in therapy.

PND61

IMPACT OF PATIENT COST-SHARING ARRANGEMENTS FOR DISEASE MODIFYING THERAPIES ON TREATMENT COMPLIANCE AMONG PATIENTS WITH MULTIPLE SCLEROSIS IN THE UNITED STATES

Palmer LA[1], Fowler R[1], Shi N[2], Dastani H[3], Abouzaid S[3], Kim E[3]
[1]*Thomson Reuters, Washington, DC, USA,* [2]*Thomson Reuters, Cambridge, MA, USA,* [3]*Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA*

OBJECTIVES: Treatment restrictions because of patient financial burden may have unintended consequence on management of multiple sclerosis (MS). The goal was to evaluate MS treatment compliance among patients enrolled in insurance plans with various cost-sharing arrangements for disease modifying therapies (DMT). **METHODS:** Thomson Reuters MarketScan® Commercial and Medicare databases (January 1, 2004-December 31, 2009) were used to identify adult patients with MS (ICD-9-CM: 340) and on DMT (claim for first DMT was the index event). Patients were assigned to three mutually exclusive cohorts based on DMT insurance plan cost-sharing levels: $0-, low- and high-cost-sharing. Median cost-sharing for DMTs, standardized to 2010 US dollars, was used to determine threshold between 'low' and 'high'. Medication possession ratio (MPR) and persistence (time to discontinuation of DMT) were evaluated during 12-months following index. **RESULTS:** A total of 14,718 patients were identified and had cost-sharing arrangements as follows: $0 cost-sharing (n=1,361, 9.2%), low cost-sharing (n=6,044, 41.1%) and high cost-sharing (n=7,313, 49.7%). Majority were female (77%) and mean age was 46.1 years. Patients in $0 cost-sharing plans had significantly higher MPR values (0.83) than patients in both the low cost-sharing (0.81; p=0.037) and high cost-sharing plans (0.79; p<0.001). Discontinuation rates were also lower among patients in $0 cost-sharing plans (34.1%) versus patients with any cost-sharing (35.5% for low and

37.2% for high cost-sharing; p<0.001). **CONCLUSIONS:** Patients in plans with no cost-sharing have greater adherence and are less likely to discontinue treatment in the 12-month period following DMT initiation. These results suggest that patients with MS are sensitive to the financial costs associated with DMT and may make treatment decisions based on this burden. Manufacturer co-pay assistance programs designed to reduce patient financial burden were not considered in this analysis. Therefore, these results may underestimate the effects of benefit design on medication adherence and persistence.

PND62

WHAT ARE THE KEY DRIVERS FOR CHANGING HTA DECISIONS? EXAMPLE OF ALZHEIMER'S DISEASE TREATMENT IN GERMANY, FRANCE AND UK

Ackermann J[1], Toumi M[2]
[1]*Creativ-Ceutical, Paris, France,* [2]*University Claude Bernard Lyon 1, Lyon, France*

OBJECTIVES: Since launch, HTA agencies from Germany, France and UK have repeatedly reviewed the use of Alzheimer's disease (AD) treatments and issued recommendations, which have changed over time. The aim of this study was to understand the drivers of agency decisions and whether these too have changed over time. **METHODS:** We reviewed HTA appraisals by IQWIG, HAS and NICE for three acetylcholinesterase inhibitors (AChEI) donepezil, galantamine, rivastigmine and memantine, an NMDA receptor antagonist from marketing authorisation to today and identified arguments leading to recommendations. **RESULTS:** Between 1997 and 2002, the EMA approved donepezil, rivastigmine and galantamine for mild to moderate AD and memantine for moderate to severe AD. We identified 2 multiple technology assessments (MTA) and 3 single technology assessments (STA) by IQWIG, 1 MTA and 16 STAs from HAS and 3 MTAs from NICE. Germany: IQWIG ascribed the AChEI class a modest clinical benefit. Following two negative assessments of memantine, the decision was reversed based on post-hoc analysis of initial registration studies. France: HAS initially assigned all treatments an important clinical added value (AMSR II) acknowledging high innovation. Later HAS reviewed the compounds in a new comparative setting (after withdrawal of tacrine) and assigned only a minor clinical added value (ASMR IV). UK: NICE recommended AChEIs in 2001, restricted their use in 2006 and in 2011 again recommended them, while memantine received two negative recommendations followed by a positive recommendation. The last review was based on additional data from randomized clinical trials and the Assessment Group's model demonstrating delay to institutionalisation. **CONCLUSIONS:** The agencies revised assessments based on post-marketing data. Differing national approaches led to different decisions: IQWIG emphasises patient relevant benefit, HAS the clinical added value versus similar medicinal products and NICE cost-effectiveness. Although agency decisions changed, decision drivers were consistent across evaluations.

PND63

DRUG PRESCRIPTION IN AND HOSPITALIZATION OF REFRACTORY FOCAL EPILEPSY PATIENTS IN THE GERMAN NEUROTRANSDATA (NTD) NEUROLOGISTS' NETWORK – IS THERE AN UNMET NEED?

Bergmann A[1], Jochum D[2], Sigl K[1], Peickert A[1], Dieterle L[1], Goesswein KH[1]
[1]*NTD study group Neuburg, Neuburg/Donau, Germany,* [2]*GlaxoSmithKline GmbH & Co. KG, Munich, Germany*

OBJECTIVES: To quantify annual drug costs and hospitalization rates (HR) of adult refractory focal epilepsy patients in Germany. **METHODS:** We retrospectively estimated the annual HR and medication for refractory focal epilepsy patients based on the NeuroTransData epilepsy database (input from 79neurologists, 34centers, 1240patients). Inclusion criteria (at least 1year of disease history; documentation and treatment period of at least 6months; treatment with at least 1anitepileptic drug [AED] in patient history; at least 1seizure during 6months of monitoring) led to the identification of 70 patients. Average ambulatory daily therapy costs among all prescribed drugs included were based on public prices (2011) considering clawbacks and average dosing (real world setting [RWS] vs. daily defined dosing [DDD]). HR were based on number of patients hospitalized. **RESULTS:** On average 2.1AEDs per patient were prescribed, mainly generic drugs or branded drugs close to loss of patent protection. Average daily costs per prescribed drug ranged from 0.65€ (Valproate) to 9.51€ (Lacosamid). Daily drug costs per patient ranged between 7.01€ (RWS) and 6.16€ (DDD). Annual total drug costs per patient were on average 2,557.44€. An ambulatory consultation rate of 2.1visits per patient within 6months was recorded. Average HR was 44%, taking into account various reasons: 56% emergency, 20% new adjustment for medication, 18% documentation of seizure, 4% rehabilitation, 2% pre-surgical diagnostics. Mean duration was 34.9 (CI: 20.2-49.6; median 17.8) days per patient hospitalized. Due to the potential selection bias and the low number of analysed patients these results must be seen as indicative. **CONCLUSIONS:** A 44% HR and a high average number of inpatient days (~1month) within 1year point to an unmet need for treatment optimization in refractory focal epilepsy patients. It indicates that patients receiving combination therapy of conventional drugs are often not well controlled, supporting the consideration of using more innovative drugs.

Neurological Disorders – Research on Methods

PND64

COST-MINIMIZATION ANALYSIS OF IFNB-1B AND FINGOLIMOD AMONG MULTIPLE SCLEROSIS PATIENTS IN GERMANY

Pan F[1], Goh J[2], Wang C[3], Meinhardt M[4]
[1]*United Biosource Corporation, Bethesda, MD, USA,* [2]*United BioSource Corporation, Bethesda, MD, USA,* [3]*Bayer Healthcare Pharmaceuticals, Montville, NJ, USA,* [4]*Bayer Vital GmbH, Leverkusen, Germany*

OBJECTIVES: Several disease-modifying therapies (DMTs) including IFNB-1b have been approved for patients with multiple sclerosis (MS) to delay disease progression and reduce the incidence of relapses. Fingolimod, the first oral formulation of DMT, was recently approved in several nations around the world including Germany. This study aims to conduct a cost-minimization analysis to estimate the cost impact of MS treatment with Fingolimod versus INFB-1b in Germany from the societal perspective. **METHODS:** A Markov model is developed to follow the natural history MS patients from time of diagnosis through disease progression and up to 20 years. MS patients receive either IFNB-1b or Fingolimod treatment but share the same efficacy on disease progression and relapse rate due to the absence of head-to-head comparison data. Fingolimod patients are assumed to have 10% higher treatment adherence due to the oral formulation. In the model, DMTs costs (IFNB-1b: €19,444/year and Fingolimod: €30,584/year) are based on AVP pharmacy retail price, while other cost items are estimated from published literatures or local databases. Main model outcomes include direct costs, indirect costs, and total costs. All costs are inflated to 2010 Euros and discounted annually at 5%. **RESULTS:** In the short-term analysis, Fingolimod costs additional €8,929 per patient in one year and €29,550 per patient in 5 years compared to IFNB-1b. Long-term analysis (20 years) shows that cost savings associated with IFNB-1b is €41,593 per patient, which mainly occurs when MS patients are still receiving treatment. The cost advantages of IFNB-1b in the long-term analysis are attributed to its lower drug cost (€50,342 vs. €92,873), serious adverse events management (€6.7 vs. €102.4), and clinical monitoring (€8.8 vs. €438.2). **CONCLUSIONS:** Compared to Fingolimod, MS treatment with INFB-1b leads to substantial cost savings from both societal and payer perspectives in Germany, with similar treatment effectiveness.

PND65

DESCRIBING AND COMPARING UTILITY FROM EQ-5D AND SF-6D IN A HUNTINGTON'S DISEASE POPULATION

Clay E[1], Perthame E[2], Maman K[2], Dorey J[3], Toumi M[4]
[1]*Creativ Research, Paris, France,* [2]*Creativ-Ceutical, Paris, France,* [3]*Creativ Ceutical, Paris, France,* [4]*University of Lyon, Lyon, France*

OBJECTIVES: The SF-6D and the EQ-5D are two widely used questionnaires to generate utility scores. The objective of this study is to describe and compare utilities derived from EQ-5D and SF-6D in Huntington's disease population. **METHODS:** We used data from Euro-HDB, a multicenter cross-sectional study conducted in France, Italy, Poland and Germany. In several subpopulations, with different degrees of severity, we used paired-samples t-test to identify significant differences and calculated the Pearson's correlation between SF-6D and the EQ-5D utilities. **RESULTS:** The overall sample included 278 patients: 96 from France, 32 from Gemany, 103 from Italy and 47 from Poland. For the overall population, mean utility scores were significantly different (EQ-5D: 0.34 (sd=0.446); SF-6D: 0.62 (sd=0.135); p<0.0001). However values were strongly correlated (r = 0.79, p<0.001). This difference was also significant when considering subpopulations (as discriminated with score of clinical motor scale, and depression scale), with higher values for SF-6D. The difference between EQ-5D and SF-6D utility scores was higher in severe population than in moderate for most of the studied criteria (severe motor impairment: EQ-5D: 0.62; SF-6D: 0.69; moderate motor impairment: EQ-5D: 0.00; SF-6D: 0.51). The SF-6D scores distribution was found to be approximately normal whereas the EQ-5D distribution was negatively skewed. **CONCLUSIONS:** In our study, EQ-5D tends to generate lower scores in all Huntington's disease subpopulations. EQ-5D appears to be more sensitive than SF-6D. The choice of utility measure is likely to have a strong impact on incremental cost-effectiveness ratios of interventions slowing the progression of Huntington's disease.

PND66

CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE BRAZILIAN VERSION OF THE FATIGUE SEVERITY SCALE (FSS)

Toledo FO, Junior WM, Speciali JG, Sobreira CFDR
Sao Paulo University, Ribeirao Preto, Sao Paulo, Brazil

OBJECTIVES: The aim was to perform a cross-cultural adaptation and validation of the Fatigue Severity Scale (FSS) for use in Brazilian patients with myopathy and who complains of precocious muscular fatigue. **METHODS:** The FSS presents nine items measured on a Likert scale ranging from 1 (completely disagree) to 7 (completely agree), where higher scores indicate higher level of fatigue. The process of cross-cultural adaptation included: two independent translations for Portuguese spoken in Brazil; the development of a consensual translated version; application in a pilot group (n=14) of patients with myopathy; evaluation by an expert committee for content validation; a back-translation by one bilingual translator whose native tongue was English, but who was fluent in Brazilian Portuguese. The two English versions (original and back translated) were analyzed by two of the authors and a final Brazilian version was obtained. Twenty one patients with muscular disease following at the outpatient clinic from a University Hospital answered the Brazilian version of the FSS, the visual analogue scale (VAS) and the Chalder fatigue questionnaire (CFQ). The following analyses were performed: exploratory factorial analysis; internal consistency (Cronbach's alpha); construct validity through of the correlation with VAS and CFQ (physical and mental components). **RESULTS:** The FSS scale obtained in the process of cross cultural adaptation was comprehensible to individuals in the pilot population. The twenty one patients who participate in the validation process were aged 21 to 65 years. The exploratory factor analysis determined one factor, as the original version. Reliability analysis indicated satisfactory internal consistency (0.93). Construct validity of the FSS (total score) with VAS and CFQ demonstrated moderate correlations (0.60 and physical=0.56, respectively). The FSS didn't correlate with mental component of the CFQ (0.31).

CONCLUSIONS: The FSS scale is an instrument reliable and valid to measure muscular fatigue in Brazilian patients with myopathy.

PND67

A MIXED-EFFECTS PIECEWISE LINEAR MODEL OF THE RATE OF LUNG FUNCTION DECLINE BEFORE AND AFTER THE CLINICAL USE OF DORNASE ALFA IN AN OBSERVATIONAL STUDY OF CYSTIC FIBROSIS

Pasta DJ, Millar SJ, Rasouliyan L
ICON Late Phase & Outcomes Research, San Francisco, CA, USA

OBJECTIVES: To evaluate lung function decline before and after the initiation of dornase alfa (DA) through a multivariable mixed-effects piecewise linear model using data from the Epidemiologic Study of Cystic Fibrosis (ESCF). **METHODS:** Patients aged 8-38 years enrolled in ESCF for 2 or more years prior to initial treatment with DA were selected if they remained on treatment for at least 2 years. A comparator group included cystic fibrosis patients not yet reported to have received DA. FEV1 percent predicted (pp) was analyzed before and after an index measurement within 30 days of either DA initiation (DA group) or an encounter within 1 year following the 8th or subsequent even-numbered birthday (comparator group). For each patient, we fit a regression line to FEV1 pp separately for the pre-index and post-index periods (both 2 years in duration) using a mixed-effects piecewise linear model adjusted for age, gender, pulmonary exacerbations, respiratory therapies, and nutritional supplements. Patients were categorized by age group or by age-adjusted deciles of the index FEV1 pp. **RESULTS:** The DA group (n=2,230) had a lower FEV1 pp at index and a more rapid decline during the pre-index period. There was an acute improvement in FEV1 pp (change in intercept) associated with the initiation of DA therapy. Furthermore, the mean rate of FEV1 pp decline was more attenuated for the DA group than for the comparator group (n=5,970) across age groups and deciles. **CONCLUSIONS:** The use of DA for a 2-year period is associated with both an acute improvement in FEV1 pp (previously shown in clinical trials) and a reduction in the rate of FEV1 pp decline (shown for the first time). These results demonstrate the value of using mixed-effects piecewise linear models in observational studies to evaluate the effect of instituting a therapy on both the slope and intercept of a continuous outcome.

PND68

SOCIAL ECONOMIC BURDEN AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH RARE DISEASES IN EUROPE (BURQOL-RD PROJECT). METHODS OF SELECTION OF 10 DISEASES FOR A EUROPEAN SURVEY

Linertová R[1], López-Bastida J[2]
[1]*Fundación Canaria de Investigación y Salud (FUNCIS), Las Palmas de Gran Canaria, Spain,* [2]*Universidad de Castilla - La Mancha; Servicio de Evaluación del Servicio Canario de la Salud, Santa Cruz de Tenerife, Spain*

OBJECTIVES: The BURQOL-RD project is intended to develop a disease based model capable of quantifying the socio-economic burden and Health-Related Quality of Life (HRQOL) for patients with rare diseases (RD) and their caregivers in Europe. We described the methodology used to select a set of 10 RD to be approached in a pilot study. **METHODS:** BURQOL-RD project counts with 20 partners, from 8 European countries: Spain, UK, France, Germany, Sweden, Italy, Hungary and Bulgaria. A two-round Delphi process was used to generate consensus in the selection of the 10 RD among the project participants. The wide variability and dispersion of the responses received in the two Delphi rounds of prioritization suggested that an additional procedure should be implemented to improve the representativeness of selected diseases. A Lewis Carroll's trilateral diagram was applied based on three determinants. **RESULTS:** The two rounds of Delphi panel yielded into a prioritised list, to which the Carroll diagram was applied, taking into account three determinants: prevalence, availability of effective treatment and need for carer. The final set of RD was obtained to be targeted in the pilot study of BURQOL-RD: Cystic Fibrosis, Prader-Willi Syndrome, Haemophilia, Duchenne Muscular Dystrophy, Epidermolysis Bullosa, Fragile X Syndrome, Sclerodermia, Mucopolysaccharidosis, Juvenile Idiopathic Arthritis and Histiocytosis. **CONCLUSIONS:** This methodology permitted to obtain an equilibrated set of RD for the pilot study of BURQOL-RD project. The model that will be generated will not only be suitable to apply in a wide range of RD but it will also be sufficiently flexible to identify and adapt to the challenges faced by the different health and social care systems of EU member states.

Urinary/Kidney Disorders – Clinical Outcomes Studies

PUK1

BELATACEPT VERSUS TACROLIMUS: RESULTS OF AN INDIRECT ANALYSIS FROM A SYSTEMATIC REVIEW OF IMMUNOSUPPRESSIVE THERAPIES FOR KIDNEY TRANSPLANT RECIPIENTS

Sidhu M[1], Odeyemi AO[2], Hart WM[2], Dada BR[2]
[1]*Astellas Pharma Europe, Staines, UK,* [2]*EcoStat Consulting UK Ltd, Bow, London, UK*

OBJECTIVES: To systematically identify and summarise the evidence of renal transplant outcomes, toxicity and adverse effects in order to determine the most effective options. In particular, comparing tacrolimus, the cornerstone of renal transplantation therapy, with newer therapies that have been introduced since 2003. **METHODS:** An electronic literature search of MEDLINE, Current Contents and the Cochrane Library databases was conducted, plus manual reference checks of all articles involving controlled trials of kidney transplants and immunosuppressive therapy between 2003 and July 2010. Studies were assessed for eligibility and quality by two reviewers who extracted data independently. Studies were classified according to CNI avoidance or reduction, steroid avoidance, and induction therapies. Results were expressed as risk ratio (RR) with 95% confidence intervals (CI). Where necessary, indirect comparison techniques were used to compare different forms of tacrolimus with belatacept. **RESULTS:** Thirty-five studies from an initial list of 2895 citations were included in the analysis. Results show CNI avoidance leads to higher incidence of acute rejection (RR 2.52, 95% CI 1.11–5.75), which is a known predictor for graft loss, but reduced chronic allograft nephropathy. Tacrolimus produces better rejection prophylaxis compared with ciclosporin (RR 0.38, 95% CI 0.21–0.70), and ciclosporin produces lower acute rejection compared with belatacept (RR 0.32, 95% CI 0.19–0.55). Indirect analysis shows that tacrolimus is superior to belatacept in acute rejection prophylaxis (RR 0.18, 95% CI 0.08–0.39), but leads to more cases of a decrease in glomerular filtration rate (GFR) (RR 1.37, 95% CI 0.92–2.03); however, the long-term impact of a reduction in GFR in the context of a CNI-free regimen is not clear at present. **CONCLUSIONS:** Direct and indirect comparisons demonstrate that CNIs, and in particular tacrolimus, remain superior even against more recent compounds for preventing acute rejection. However, more research needs to be done to find the optimum combination of therapies.

PUK2

COMPARATIVE EFFECTIVENESS OF INVESTIGATIONAL COMPOUND FERUMOXYTOL FOR THE TREATMENT OF IRON DEFICIENCY ANAEMIA IN CHRONIC KIDNEY DISEASE: SYSTEMATIC REVIEW AND MIXED TREATMENT COMPARISON

Stradwick S[1], Hartmann J[2], Morgan A[3], Freemantle N[4]
[1]*BresMed Health Solutions, Sheffield, South Yorkshire, UK,* [2]*Takeda Global Research & Development Centre (Europe) Ltd, London, City of Westmins, UK,* [3]*Sheffield University, Sheffield, South Yorkshire, UK,* [4]*University College London, London, Hampstead, UK*

OBJECTIVES: To evaluate the comparative effectiveness of investigational compound ferumoxytol for the treatment of iron deficiency anaemia (IDA) associated with chronic kidney disease (CKD) compared to alternative iron replacement therapies (IRT). Primary interest was the improvement in haemoglobin (Hb) from baseline levels. **METHODS:** A comprehensive systematic review was conducted to identify any randomised controlled trials investigating the efficacy of IRTs for the treatment of IDA in CKD where efficacy is defined as Hb change from baseline and IRTs included intravenous (IV) and oral treatments. Twelve electronic databases were searched up to November 2010 (language unrestricted). Two reviewers independently assessed each identified reference and conducted subsequent data extraction. Method quality of each included trial was also independently assessed in accordance with NICE guidelines. A standard meta-analysis comparing oral iron to ferumoxytol was initially conducted, reflecting the trial programme. The full network of evidence that included IV and oral iron therapies was synthesised using a mixed treatment comparison (MTC). The random effects model showed 'predicting superiority' to the fixed effects model and was thus utilised. Mean efficacy was estimated through analysing standardised effect sizes of trials and back-transforming data to Hb values via weighted average standard deviation. **RESULTS:** Seventeen published trials and one unpublished clinical study provided the heterogeneous trial base for MTC analysis. Ferumoxytol was significantly favoured when compared to oral iron therapy by conventional meta-analysis (0.61; 95% CI=0.44,0.79; P value=<0.0001) which was supported by results from the MTC efficacy analysis (0.48; 95% CI=−1.24,2.2). Significant differences in efficacy were not observed between ferumoxytol and any of the alternative IV iron therapies. **CONCLUSIONS:** The results from the conventional meta-analysis showed that the model favoured investigational compound ferumoxytol, in terms of increasing Hb, in comparison to oral iron therapy and suggested a modelled equivalence to currently approved alternative IV iron treatments.

PUK3

SOURCES OF HETEROGENEITY AMONG OVERACTIVE BLADDER CLINICAL TRIAL ESTIMATES OF TOLTERODINE AND FESOTERODINE REDUCTIONS OF URGENCY URINARY INCONTINENCE EPISODES RELATIVE TO PLACEBO

Snedecor SJ
Pharmerit North America, LLC, Bethesda, MD, USA

OBJECTIVES: Explore potential sources of heterogeneity among estimates of tolterodine (TOL) and fesoterodine (FESO) efficacy relative to placebo (PBO) in patients with overactive bladder and urgency urinary incontinence (UUI) from randomized clinical trials (RCTs) published from 2001 – 2010. **METHODS:** RCTs evaluating TOL 4mg, solifenacin 5mg and/or 10mg, or FESO 4mg or 8mg compared to PBO reporting mean reduction of UUI episodes/d from baseline to endpoint were identified. Treatment effects (treatment response minus PBO response) and PBO responses were tested for heterogeneity using Cochran's Q statistic. Where heterogeneity was present, other study variables (baseline UUI, baseline micturitions, gender, age, diary evaluation days, publication year, and study duration) were evaluated for potential confounding using linear regression methods. **RESULTS:** Statistical heterogeneity was found among the 17 PBO responses (mean reduction of UUI) of the included studies. PBO response increased with publication year, which accounted for more than 27% of response variation. Publication year ($p<0.02$), gender ($p<0.003$), and study duration (6-week vs. other) ($p<0.006$) were significant predictors of PBO response (adj. $R2=0.6261$). TOL and FESO 8mg treatment effect estimates were also heterogeneous. Among the nine TOL trials, treatment responses remained constant over publication year while PBO responses increased, resulting in a net decline in TOL treatment effect ($p=0.0928$). The majority of this decline was explained by publication year and study duration (adj. $R2=0.7703$). The four FESO 8mg UUI responses also displayed a publication year-dependent decrease leading to a decreasing treatment effect relative to PBO. However, this trend was almost fully predictable by differential baseline UUI episodes (adj. $R2=0.9721$). **CONCLUSIONS:** Publication year, gender, 6-week duration, and baseline UUI were found to be significant predictors of PBO response or treatment effect. Additional research should be done to understand why PBO response has increased over time

and future trials should compare to real-world treatments wherever possible to demonstrate clinically-meaningful differences.

PUK4

COMPARING PROJECTED OUTCOMES OF RENAL TRANSPLANT RECIPIENTS BASED ON TRIAL ENDPOINT OF RENAL FUNCTION AND RECEIVING DIFFERENT IMMUNOSUPPRESSIVE REGIMENS IN THE UNITED STATES

Levy A[1], Briggs A[2], Johnston K[3], Schnitzler M[4], LItalien GJ[5], Yuan Y[6], Kasiske B[7]
[1]Dalhousie University, Halifax, NS, Canada, [2]Glasgow Universrity, Glasgow, UK, [3]Oxford Outcomes Ltd, Vancouver, BC, Canada, [4]St Louis Unversity, St. Louis, MO, USA, [5]Bristol Myers Squibb, Wallingford , CT, USA, [6]Bristol-Myers Squibb, Plainsboro, NJ, USA, [7]Hennepin County Medical Center, Minneapolis,, MN, USA

OBJECTIVES: Enhancements in renal transplant have led to reduced rates of acute rejection leading to a shift to kidney function as an accepted endpoint in efficacy trials. Characterizing long-term benefits requires modeling to project long-term outcomes of treatment based on kidney function. The goal of this study was to project rates of graft failure and quality adjusted life years over the lifetimes of hypothetical patients receiving belatacept (a recently-introduced selective co-stimulation blocker), cyclosporine or tacrolimus. **METHODS:** We developed a simulation with two phases that integrated trial-based information with a long-term four-state Markov model (functioning graft, graft failure on dialysis, functioning re-graft, and death). In the first phase, three-year distributions of patients in four estimated glomerular filtration rate (eGFR) categories (>60, 45-59, 30-44 and 15-29, with graft failure assumed at eGFR <15 mLs/min/1.73m2) were estimated using a mixed treatment comparison of cyclosporine, belatacept, and tacrolimus. The Markov phase was populated using transplant recipient data from the United States Renal Data System (n=34,130). Utilities for adjusting life-years were obtained from a study of US renal transplant patients. **RESULTS:** Over a 20-year modeled time-horizon for 1,000 hypothetical patients, belatacept was associated with 551 graft failures,and 9.6 quality-adjusted life years. Relative to cyclosporine, belatacept was associated with 0.9 additional quality-adjusted life years, and 56 fewer graft failures. Relative to tacrolimus, belatacept was associated with 0.9 additional quality-adjusted life years, and 18 fewer graft failures. **CONCLUSIONS:** This is the first long-term follow-up model of renal transplant patients to be based on trial-based graft function endpoints and include all relevant comparators. This long-term extrapolation of differences in kidney function observed at three years shows clinically important differences between treatments. While validation of these models will require long-term follow-up of patients, modeling based on renal function may prove to be a useful method of projecting long-term outcomes.

PUK5

MIXED TREATMENT COMPARISONS OF IMMUNOSUPPRESSANTS FOLLOWING RENAL TRANSPLANT

Thurston S[1], Kalsekar A[2], LItalien GJ[3], Sennfält K[4]
[1]Pharmerit Ltd, York, UK, [2]Bristol-Myers Squibb, Princeton, NJ, USA, [3]Bristol Myers Squibb, Wallingford , CT, USA, [4]Bristol-Myers Squibb, Rueil Malmaison, Other, France

BACKGROUND: Belatacept is a first in-class co-stimulation blocker developed for primary maintenance immunosuppression following renal transplantation. Data is widely available comparing belatacept to cyclosporine, limited data is available comparing it with other immunosuppressants. **OBJECTIVES:** Estimate belatacept's efficacy and safety relative to tacrolimus. **METHODS:** A systematic review was conducted of randomised controlled trials (RCTs) published between January 1990 and September 2010. Data extraction captured study duration, quality, baseline data, treatment and clinical outcomes. Efficacy and safety outcomes included glomerular filtration rate (GFR), graft- and patient-survival, and acute rejection (AR). The data were analysed with fixed- and random-effects models. Linear models with outcome of mean difference were applied for GFR because GFR (ml/min) is a continuous measure, unlike the other variables which are dichotomous in nature. Logistic models were used for these other outcomes (summary measure being odds ratios). Sensitivity analyses (SAs) were conducted based on trial durations and sub-populations. **RESULTS:** We identified twenty-six RCTs comparing cyclosporine with tacrolimus, three RCTs comparing cyclosporine with belatacept, and no trials comparing tacrolimus with belatacept. Most trials were 12 months in duration (range: 6 to 60 months). MTC results using 36 month belatacept data suggested benefits with belatacept on patient survival (OR=0.62 95%CI: 0.31,1.24), and difference in GFR (8.50 ml/min/1.73 m2; 95% CI (− 4.22,20.44), versus tacrolimus, with AR outcomes favouring tacrolimus (OR=2.43; 95%CI 1.08,5.34). MTC results indicated reduced graft-survival with belatacept at 36 months (OR=1.18 95%CI: 0.51,2.85). However, SAs using data at 12 months post-transplant demonstrated a benefit for belatacept on graft-survival (OR=0.89 95%CI: 0.36,2.16). Benefits on graft-survival were also seen at 12 and 24 months in the standard-criteria donor population. SAs on the other outcomes resulted in similar conclusions to those of the base case. **CONCLUSIONS:** Belatacept showed improved renal function and benefits in graft- and patient-survival in comparison to tacrolimus despite increased risks for AR.

PUK6

BPH PATIENTS TREATED WITH PHYTOTHERAPY IN PORTUGAL: RESULTS AT SIX MONTHS

Perrin P[1], Auges M[2], Rahhali N[2], Taieb C[2]
[1]Lyon Sud, Pierre Benite, France, [2]PFSA, Boulogne Billancourt, France

OBJECTIVES: Assess the impact of the treatment of urinary disorders of the lower urinary tract related to benign prostatic hypertrophy (BPH) using medical treatment under actual conditions of use. **METHODS:** A pragmatic cohort of patients treated medically, was followed up for 6 months, using validated questionnaires: IPSS and MSF4. **RESULTS:** Fifty-one patients treated with Serenoa Repens (hexanic extract) were evaluated, the mean age was 61.51± 8.11 years, and on average the diagnosis had been made 3.6 months previously.At 6 weeks, the IPSS was significantly improved ($p<0.0001$). This improvement in the IPSS score between 6 weeks (10.15±5.36) and inclusion (13.76±6.03) was 3.6 points. An improvement was also observed at 3 months. At 6 months, the p-value was also significant ($p<0.0001$). The improvement in the IPSS score between 6 months (6.90±3.46) and inclusion (12.93±6.09) was 6 points.The MSF4 was unchanged. **CONCLUSIONS:** We observed an improvement in the IPSS score from the sixth week; this statistical improvement was confirmed by a significant clinical improvement in the sixth month.

Urinary/Kidney Disorders – Cost Studies

PUK7

3 YEARS FOLLOW UP OF THE PHARMACOTHERAPY COST OF PATIENTS WITH KIDNEY TRANSPLANTATION IN BULGARIA

Georgieva SS[1], Stoimenova A[2], Petrova G[3]
[1]Aleksandrovska Hospital, Sofia, Bulgaria, [2]Medical University Sofia, Faculty of Pharmacy, Sofia, Bulgaria, [3]Medical University, Faculty of Pharmacy, Sofia, Bulgaria

OBJECTIVES: To analyze the cost savings after the consecutive introduction of the generic immunospressants Azathioprine, Mycophenolic acid and Ciclosporin for patients with transplanted kidney in Bulgaria. **METHODS:** Prospective observational study of the pharmacotherapy cost of patients after kidney transplantation during 36 months (Mar 2008 – February 2011) was performed; 528 patients switched to at least one of the generic immunosupressors were followed. Patients were classified in 3 periods – beginning, during and after the switch. It was also followed the changes in the whole pharmacotherapy as an indicator for switch compliance. Mean cost per patient and cost saving were calculated. **RESULTS:** A total of 433 patients were treated with combined immunosuppressive therapy containing at least one of the 4 originators (Imuran, Myfortic, Cellcept, Sandimmune) through the Period 1 and then consecutively they increase to 528. Per patient cost of therapy with the observed medications differs among the age groups and among the periods with low cost for age group of up to 70 years old. The introduction of generic Azathioprine in 2009 reduced the mean pharmacotherapy cost for all patients with 6% from 4814 - 4539 BGN (2461 - 2321EUR). At the same time the introduction of generic mycophenolic acid's derivates and appearance of generic ciclosporin in 2010 reduced the mean pharmacotherapy cost of the observed patients more than 2 times (119%) from 4539 – 2076 BGN (2321 – 1061 EUR). Total reduction of the mean pharmacotherapy cost (Period 1 vs. Period 3) was 132% from 4814 – 2076 BGN (2461 – 1061 EUR). No other changes in the pharmacotherapy were observed, as well as no back transfer to originator products. **CONCLUSIONS:** The introduction of generic immunosuppressors significantly decreased the mean cost of therapy and let to high cost savings for the hospital budget without any additional changes in the patients' pharmacotherapy.

PUK8

CHRONIC KIDNEY DISEASE BURDENS PATIENTS, HEALTH CARE SYSTEMS, AND EMPLOYERS

Davis K[1], Sood V[2], Hogue S[1], Braun LA[1], Copley-Merriman C[3], Lieberman B[2]
[1]RTI Health Solutions, Research Triangle Park, NC, USA, [2]Mitsubishi Tanabe Pharma America, Inc., Warren, NJ, USA, [3]RTI Health Solutions, Ann Arbor, MI, USA

OBJECTIVES: To elucidate patient and economic burden associated with chronic kidney disease (CKD) across countries. **METHODS:** A targeted literature review using PubMed and desktop research was performed. Currency conversions were adjusted to 2010. **RESULTS:** North American, European, and Asian studies were identified; most reports were from the United States (US). Advanced CKD (stages 3-5) adversely affects outcomes. As patient-reported outcomes (PROs) deteriorate, resource utilization (RU) and costs escalate. Across studies, patients with CKD report cognitive impairment, dementia, sleep disturbance, and emotional and physical dysfunction (PD), with PD being most pervasive. Compared with general populations across countries, Health-related Quality of Life (HRQOL) and other PROs decline in patients with CKD. Age, female gender, less education, lower income, unemployment, limited exercise, and comorbid illness are predictors of reduced HRQOL. RU and costs to healthcare systems and employers increase with CKD severity. Prior to (12-24 months) dialysis initiation, costs increase substantially due to hospitalization. Annual US total cost per patient (c/p/p) with CKD (stages 3-5) range from $6,026 (€4,927) to $30,398 (€24,855); annual Germany total c/p/p (stages 1-4) is €3,581 ($4,379), compared to €1,272 ($1,555) in those without CKD. The cost burden of CKD is rising. From 1993 to 2007, Medicare costs for patients with CKD increased by ~5-fold. High healthcare costs (HC) and reduced productivity due to CKD, burdens employers. For employees with CKD (US), HCs range from $1,187 (€971) (stage 3) to $21,826 (€17,846) (stage 5) and work-hours missed per week often exceeds 10. The impact of CKD on patient and economic burden across countries is evident. **CONCLUSIONS:** Patient and economic burden associated with CKD is considerable across countries. With disease progression and kidney-function decline, unfavorable outcomes arise. As evidenced by the high patient and economic burden of CKD, a large unmet need exists for new therapies and employee CKD-management programs.

PUK9

COMPARATIVE COST ANALYSIS OF TREATMENT FOR RENAL ANEMIA WITH METHOXY POLYETHYLENE-GLYCOL ERYTHROPOIETIN BETA (MIRCERA®) VERSUS ERYTHROPOIETIN BETA (NEORECORMON®)

Medina Gómez JL
ISSSTE, Mexico City, Mexico, Mexico

OBJECTIVES: Evaluate if the use of Methoxy polyethylene-glycol erythropoietin beta (MPG-beta) offers better health outcomes and costs with respect to erythropoietin beta multidose presentation (50,000 IU). **METHODS:** Analysis of incremen-

tal cost-effectiveness based on a decision tree to simulate the costs of treatment, with a time horizon of 12 months (nominal cost).The monthly dose of erythropoiesis stimulating agents was adjusted according to hemoglobin levels, if the concentration is greater than 12.5 g/dl 10.000 IU/month of erythropoietin beta or 0.6 mcg/kg/month of MPG-beta, for 11 -12.5 g/dl 20.000 IU/month of erythropoietin beta or 1.2 mcg/kg/month of MPG-beta and concentrations below 11 g/dl 40.000 IU/month of erythropoietin beta or 1.5 mcg/kg/month of MPG-beta. Each scenario has a cost based on usual care of these patients. The direct costs were taken from the current rates for 2010 apply to medical services provided by IMSS. We determined the risk of not being in an ideal range of hemoglobin (11-12.5 g/dl), also known as hemoglobin excursions and associated costs. **RESULTS:** MPG-beta maintains a more stable hemoglobin concentration when compared with erythropoietin beta, so that at 6 months of treatment remain in the ideal range 94% versus 80% with erythropoietin beta. With the use of erythropoietin beta there is a greater risk of having excursions. The incremental cost-effectiveness analysis shows a 13% increase in effectiveness for only an additional $30 USD annually using MPG-beta compared with erythropoietin beta, this derived from the stability of hemoglobin. The ICER is $2.3 USD per incremental percentage of effectiveness. **CONCLUSIONS:** These results demonstrate that MPG-beta offers better health outcomes against an almost insignificant cost increase being as a cost effective treatment.

PUK10

COST-EFFECTIVENESS ANALYSIS OF SOLIFENACIN VERSUS OXYBUTYNIN IMMEDIATE-RELEASE IN THE TREATMENT OF PATIENTS WITH OVERACTIVE BLADDER IN THE UNITED KINGDOM

Hart WM[1], Munro V[2], Retsa P[2]
[1]*EcoStat Consulting UK Ltd, London, London, UK,* [2]*Astellas Pharma Europe Ltd, Staines, Middlesex, UK*

OBJECTIVES: To carry out a cost-utility analysis comparing initial treatment with solifenacin 5 mg/day versus oxybutynin immediate-release (IR) 15 mg/day for the treatment of patients with overactive bladder (OAB) from the perspective of the UK National Health Service (NHS). **METHODS:** A Markov model with six health states was developed in EXCEL to follow a cohort of OAB patients treated with either solifenacin or oxybutynin during a one year period. Costs and utilities were accumulated as patients transited through the health states in the model including a drop-out state. Some of the solifenacin patients were titrated from 5mg to 10mg/day at 8 weeks. A proportion of drop-out patients were assumed to continue treatment with tolterodine ER. Utility values were obtained from a Swedish study and pad use was based on a multinational clinical trial. Adherence rates for individual treatments were derived from a UK database study. For pad use and utility values, the drop-out state was split between those patients who were no longer receiving treatment and those on second-line therapy. Patients on second-line therapy who drop-out were referred for a specialist visit. Results were expressed in terms of incremental cost-utility ratios. **RESULTS:** Total annual costs for solifenacin and oxybutynin were £504.30 and £414.10 respectively. First-line drug use represents 49% and 16% of costs and pad use represent 23% and 35% of costs for solifenacin and oxybutynin respectively. Differences between cumulative utilities were small but were greater for solifenacin (0.7020 vs. 0.6907). The baseline incremental cost-effectiveness ratio was £7,921/QALY. **CONCLUSIONS:** Under our baseline assumptions, solifenacin is cost-effective with an incremental cost-utility of less than £20,000/QALY. However, small differences in utility between the alternatives and the large number of drop-outs means that the results are sensitive to small adjustments in the values of utilities assigned to the drop-out state.

PUK11

PRELIMINARY COST-MINIMIZATION ANALYSIS OF CONTINUOUS VERSUS INTERMITTENT RENAL REPLACEMENT THERAPY IN INTENSIVE CARE PATIENTS EXPERIENCING ACUTE RENAL FAILURE

Banz K[1], Harenski K[2], Brunner M[1], von Czettritz T[2]
[1]*Outcomes International, Basel, Switzerland,* [2]*Gambro Hospal GmbH, Gröbenzell, Germany*

OBJECTIVES: To compare 1-year treatment cost of initial continuous renal replacement therapy (CRRT) vs. intermittent daily hemodialysis (IHD) or slow extended daily dialysis (SLEDD) in critically ill patients with acute renal failure in Germany. **METHODS:** As differences in hospital survival rates among the evaluated renal replacement therapies (RRT) are not evident, a cost-minimization model was developed to compute potential direct medical costs associated with dialysis for each treatment group. The preliminary analysis has been performed from the perspective of the German statutory health insurance. Model input data was derived from published literature and complemented by expert opinion in case of missing information. **RESULTS:** Total estimated average per-patient hospital costs were found to be similar for the evaluated hypothetical RRT cohorts, amounting to €12,380 for CCRT, €12,650 for IHD, and €12,528 for SLEDD. Whereas costs of disposables are substantially higher for CRRT than for IHD/SLEDD, these incremental costs were largely offset by an expected average ICU stay reduction of one day owing to assumed minor treatment benefits for CRRT. As sufficiently powered, randomized comparative trials are currently lacking, we assumed equivalent hospital mortality for each analyzed RRT treatment group as shown in meta-analyses, but a slightly higher renal recovery rate at discharge for CRRT than for IHD/SLEDD (87.8% vs. 80.0%) as indicated by several studies. Consequently, follow-up costs involving chronic RRT in survivors remaining dialysis dependent after discharge were lower for CRRT than for IHD/SLEDD resulting in total first year average per-patient costs of €14,020 vs. €16,527/€16,374, respectively. Findings from multivariate sensitivity analyses support the robustness of these preliminary outcomes. **CONCLUSIONS:** In the absence of published data, our exploratory economic analysis provides first indications of potentially lower total first-year costs for initial CRRT than for IHD/SLEDD. To corroborate these findings, supplementary and consistent clinical and resource use data is warranted.

PUK12

MEDICAL RESOURCE USE IN US PATIENTS DIAGNOSED WITH CHRONIC KIDNEY DISEASE WITH AND WITHOUT DIABETES MELLITUS

Le TK, Sierra-Johnson J
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: Chronic kidney disease (CKD) afflicts up to 26 million people in the US, but limited information exists about the associated health care costs, especially in earlier stages of CKD patients with diabetes mellitus (DM). The objective of this study was to evaluate the medical resource use in US patients diagnosed with CKD with and without DM. **METHODS:** A large administrative claims database (MarketScan) was used to conduct this retrospective study. Patients aged 18+ diagnosed for CKD between January 1, 2007 to December 31, 2008 with 12 months of continuous pharmaceutical and medical benefit coverage were identified. CKD patients with DM were defined as receiving a diagnosis code for DM or ≥1 prescription filled for an antidiabetic medication during the 12-month follow-up period. Multivariate analysis was conducted controlling for baseline differences between CKD w/DM and CKD w/o DM cohorts. **RESULTS:** There were 116,512 patients that met inclusion criteria with mean age of 65 years and 56% male. Forty-five percent of CKD patients had a diagnosis for DM during the follow-up period. CKD w/DM had more CKD related and non-CKD related medical visits in 12 months than CKD w/o DM (12 vs. 9 mean visits, 38 vs. 25 mean visits; all $p<0.0001$). Additionally, adjusted CKD related medical costs for CKD w/DM were $11,431 annually ($p<0.0001$), compared to $8,975 for CKD w/o DM. Mean pharmacy costs for CKD w/ DM were also significantly higher than CKD w/o DM ($7,206 vs. $5,941, $p<0.0001$). Thus, total mean adjusted costs (medical & drug) for CKD w/DM were 9% higher than CKD w/o DM ($38,262 vs. $34,759, $p<0.0001$). **CONCLUSIONS:** In this retrospective study, the annual medical visits and total healthcare costs were significantly higher for CKD patients with diabetes compared to CKD patients without comorbid diabetes. This was particularly evident in the very early and late stages of CKD.

Urinary/Kidney Disorders – Patient-Reported Outcomes & Preference-Based Studies

PUK13

PREVENTION IN PREDIALITIC STAGE HAS BETTER RESULTS IN HEALTH

Carlos F[1], Lechuga D[2]
[1]*R A C Salud Consultores S.A. de C.V., Mexico City, Mexico,* [2]*Roche Mexico, Mexico, Mexico, Mexico*

OBJECTIVES: Evaluates if modifying the epidemiology of renal disease, more patients in predialysis and less in dialysis, improves the quality of life Chronic Kidney Disease (CKD) is a long-term condition described as the gradual loss of kidney function over time There are various stages of chronic renal failure prior to dialysis which are also considered as kidney failure. Those in stages III and IV present a significant percentage of complications from CKD which damage the renal function and accelerate the need of dialysis. Medical literature suggests early treatment of renal anemia, proteinuria and hypertension in patients who have not reached the renal replacement therapy Preventing complications, through adequate care of known progression factors (diabetes, hypertension, correction of anemia, and proteinuria), of CKD in predialysis stages reduces the progression of renal disease. Progression of renal damage can be slow down through early intervention preventive treatments such as control of glucose levels, anemia, hypertension and proteinuria in the early stages of the disease. **METHODS:** We developed a simulation of 1000 patients from predialysis stage coming to dialysis in a period of 30 months. **RESULTS:** Without prevention treatment 57% of the patients will require dialysis, 1% will be transplanted and 9.1% will die, while with the prevention treatment only 25% will require dialysis, 0.5% will be transplanted and 4% will die during this period. **CONCLUSIONS:** The early treatment of patients provides better quality of life and significant savings compared with dialysis. Transplantation as a form of replacement therapy is the best choice for quality life and cost.

Urinary/Kidney Disorders – Health Care Use & Policy Studies

PUK14

TRENDS IN RATE AND COST OF HOSPITALIZATIONS DUE TO CHRONIC KIDNEY DISEASE (CKD) IN THE UNITED STATES

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: To understand the trends in rate and cost of hospitalizations due to Chronic Kidney Disease (CKD) in the United States. **METHODS:** We analyzed last five years of hospitalizations with ICD-9 diagnosis codes of CKD and End Stage Renal Disease (ESRD). The annual number of hospitalizations for specific diagnosis were obtained from AHRQ's National In-patient Sample (NIS) databases of 2005-2009. Data were also analyzed for length of stay (LOS), charges and cost of hospitalization. **RESULTS:** During last five years the number of hospitalizations with diagnosis of CKD and ESRD have increased 4.1 and 4.6 fold, respectively. In 2009, an estimated 1,634,422 and 931,641 hospitalizations were with diagnosis of CKD and ESRD, respectively. The mean LOS for patients with CKD has increased from 4.9 to 5.5 days, during 2005-2009. The mean LOS for patients with ESRD has remained steady at ~6 days during 2005-2009. The cost of hospitalization with diagnosis of CKD has increased 31% during 2005-2009. The cost of hospitalization with diagnosis of ESRD has increased 21% during 2005-2009. In 2009, the mean cost of hospitalization for patients with CKD and ESRD were $11,209 and $21,358, respectively. **CONCLUSIONS:** Hospitalizations due to CKD and ESRD have signifi-

cantly increased during last five years. There is a need for prevention, treatment and disease management programs to lower the medical and socioeconomic burden of this disease.

Urinary/Kidney Disorders – Research on Methods

PUK15

A SIMULATION MODEL OF THE EFFECTS OF TREATMENTS FOR SECONDARY HYPERPARATHYROIDISM ON MORTALITY

Iannazzo S[1], Pradelli L[1], Chiroli S[2], Pétavy F[3], Briggs A[4]
[1]*AdRes HE&OR, Turin, Italy,* [2]*Amgen (Europe) GmbH, Zug, Switzerland,* [3]*Amgen Ltd, Uxbridge, UK,* [4]*Glasgow University, Glasgow, UK*

OBJECTIVES: Secondary hyperparathyroidism (SHPT) is a common condition in dialysis, characterized by high levels of associated laboratory parameters (LABS): parathyroid hormone (PTH), serum calcium (Ca) and phosphorous (P). Cinacalcet can be effective in controlling LABS in SHPT. Objective of this study was to develop a model to simulate the impact of cinacalcet versus standard treatment (ST) on patient mortality. **METHODS:** The model used the latest data on cinacalcet efficacy in lowering LABS from the OPTIMA and ADVANCE interventional trials together with the estimated relationship between LABS and mortality from the ARO observational study on 7970 haemodialysis patients treated in European Fresenius Medical Care facilities. Patient-level data from the 6-month OPTIMA and 12-month ADVANCE studies were pooled and regression models were fitted with post-treatment values as the response to derive functions predicting 12-month LABS values from their starting values, patient characteristics and treatment. After 12 months LABS were assumed constant except for PTH in ST (assumption of a 170 pg/ml per year increase). Mortality was calculated as that of the dialysis population multiplied by relative risks as function of LABS. The model was compared with a Block observational study analyzing mortality rates (26-month follow-up) in 19,186 haemodialysis patients treated at the DaVita dialysis provider in the US. The simulation was run with patient characteristics replicating the DaVita cohort and base mortality rates from the US Renal Data System. **RESULTS:** The simulated death rates (year 1: cinacalcet 18.4%, ST 22.6%, RR=0.81; year 2: cinacalcet 32.9%, ST 40.8%, RR=0.81) were close to the observed data in the Block study (year 1: cinacalcet 15%, ST 20%, RR=0.75; year 2: cinacalcet 30%, ST 37%, RR=0.81). **CONCLUSIONS:** The model showed effects of cinacalcet on mortality similar to those observed in the DaVita US cohort. This mortality model will be a useful tool for future health-economic analyses of cinacalcet in SHPT.

PUK16

KNOWN-GROUP VALIDITY OF THE SPANISH VERSION OF THE SHORT-FORM OVERACTIVE BLADDER HEALTH RELATED QUALITY OF LIFE QUESTIONNAIRE (OABQ-SF) IN SUBJECTS WITH OVERACTIVE BLADDER

Arlandis-Guzmán S[1], Ruiz MA[2], Errando-Smet C[3], Villacampa-Aubá F[4], Arumi D[5], Lizarraga I[6], Ruiz L[7], Rejas J[7]
[1]*Hospital Universitario La Fe, Valencia, Spain,* [2]*Universidad Autonoma de Madrid, Madrid, Spain,* [3]*Department of Urology, Fundación Puigvert, Barcelona, Spain,* [4]*Department of Urology, Hospital 12 de Octubre, Madrid, Spain,* [5]*Pfizer Inc., Madrid, Spain, Alcobendas, Madrid, Spain,* [6]*Medical Unit, Pfizer España, Alcobendas, Madrid, Spain,* [7]*Pfizer España, Alcobendas/Madrid, Spain*

OBJECTIVES: To explore the known-group validity of the Spanish version of the self-administered OABq-SF questionnaire, which feasibility, reliability and construct and criterion validities have previously been shown. **METHODS:** The culturally adapted Spanish version of OABq-SF was administered on two occasions 3 months apart to a set of patients of both genders, >18 years, diagnosed of OAB according with standard criteria and a score > 8 in OAB-V8 scale and able to understand and filling-in PRO instruments written in Spanish. Patients were recruited consecutively at clinics of Urology all over the country. Known-groups validity was explored using the sample of patients classified in quartiles according to their responses in the OAB-V8 scale at the baseline visit. Patients were compared in the OABq-SF: symptom bother and HRQoL. For known-group testing purposes, baseline scores in the OABq-SF questionnaire were used. ANOVA, descriptive statistics and Pearson's r coefficients were computed for data analysis. **RESULTS:** The study enrolled a total of 246 OAB patients (mean age 57.7 years; 76% women, 99% Caucasian, 37% active workers and 36% primary schooling) at 18 urological. OAB-V8 scores significantly correlated (Pearson's r coefficient) with OABq-SF domains; +0.790 and −0.659 for symptom bother and HRQoL domains, respectively ($p<0.001$ in both cases). Mean (95% CI) of the OABq-SF domain scores were significantly different between OAB-V8 quartile groups; 39.1 (36.0-42.3), 48.0 (44.5-51.5), 56.7 (53.6-59.8) and 74.6 (71.4-77.7) points for 1st, 2nd, 3rd and 4th quartile groups, respectively ($F=10.5$, $p<0.001$) in symptom bother domain, and 66.8 (6.1-70.5), 60.5 (56.4-64.6), 53.5 (49.9-57.2) and 37.8 (34.0-41.6) points average score, respectively ($F=32.9$, $p<0.001$) in HRQoL domain. **CONCLUSIONS:** The Spanish version of the OABq-SF instrument provided evidence of known-group validity according with patient-rated severity of symptom bother in the OAB-V8 scale.

POSTER SESSION II
HEALTH CARE USE & POLICY STUDIES

Health Care Use & Policy Studies – Consumer Role In Health Care

PHP1

IMPROVING PATIENT SAFETY IN THE UK AND ENGAGING PATIENTS IN RESEARCH: A NEW MODEL FOR THE NHS?

Cascade E[1], Collier D[2], Kula-Przezwanski C[3]
[1]*MediGuard.org, Rockville, MD, USA,* [2]*William Harvey Research Institute, Barts & The London Queen Mary University of London, London, UK,* [3]*MediGuard.org, Bracknell, Berkshire, UK*

OBJECTIVES: The purpose of this study was to determine awareness of and interest in research amongst members of a web-based medicines monitoring service and to solicit opinions on whether this service should be offered by the NHS. **METHODS:** In May 2011, we surveyed 150 uk.MediGuard.org members: 50 in England, Scotland, and Wales. uk.MediGuard.org is a free medicines monitoring service covering over 2.5 million patients, including 100,000 in the UK. **RESULTS:** Ninety-one percent of respondents rate the MediGuard service as good or excellent and 99% are unaware of similar services in the UK. When asked whether the National Health Service (NHS) should introduce MediGuard to all patients, 93% responded yes and 89% said that offering the service would positively impact their impression of the NHS (43% significantly, 46% somewhat positive impact). While only 12% have ever enrolled in a trial, 71% were at least somewhat interested in participating in the next 12 months (23% extremely, 17% very, 31% somewhat interested). The primary reason why patients have not enrolled in a trial is lack of awareness (68%); only 16% mentioned lack of participation due to concerns about an experimental drug. **CONCLUSIONS:** Survey results show that engagement in a medicines monitoring service is an effective method for improving outcomes and increasing awareness of clinical trials; pilot studies are now underway. Historically, the NHS has been slow to pursue public-private partnerships, however, NHS efforts to stimulate on-line patient engagement have not been a huge success (e.g., HealthSpace enrolled 3,000 in the first year at a cost of £8 million). Recognizing that all UK countries have initiatives to increase participation in research, perhaps it is time for the NHS to reconsider the role of partnerships to leverage the explosion of web-based applications as a method for stimulating research.

PHP2

RELATION BETWEEN CONSUMER BEHAVIOUR AND DRUG SAFETY MONITORING IN FRANCE

Furet J[1], Genane C[2], Ando G[3], Marinoni G[2]
[1]*IHS, PARIS, France,* [2]*IHS, Paris, France,* [3]*IHS, London, UK*

OBJECTIVES: This study aimed to assess the opinion of the French population on the publication of a list of 77 medicines under regulatory monitoring (surveillance list, published following market withdrawal of diet adjuvant benfluorex) in France and more specifically evaluate its impact on consumer behaviour. **METHODS:** A total of 928 French individuals answered a phone questionnaire consisting of 37 closed questions and 3 open-ended questions. Respondents were aged 30 and over since this age group is expected to be more prone to diseases and chronic pathologies. The study, carried out in March 2011, was compliant with the French National INSEE quota methodology. **RESULTS:** Around 7% of the sample population declared using at least one of the products included in the French surveillance list. Of these, over one in three persons indicated their intention to stop or suspend their treatment in reaction to their medicine's regulatory surveillance while one in three persons did not intend to change their treatment intake. Meanwhile, in the larger study sample, nearly one in six persons declared considering reducing their medicine purchasing patterns as a result of the surveillance list publication, a figure in line with studies conducted prior to the publication of the list. Finally, treatment compliance was reported at 85.8% pre-surveillance list publication and 83.5% post-surveillance list publication. **CONCLUSIONS:** French consumer confidence in pharmaceuticals in general is mostly unaffected by the new surveillance list. However, consumer behaviour is strongly affected by product inclusion onto the surveillance list, especially for those patients treated with at least one listed treatment. Furthermore, consumer confidence in healthcare regulators, off-label prescribing and pharmaceutical companies was negatively affected by the benfluorex case. Prescribers will have a pivotal role in maintaining overall confidence through patient communication and information.

PHP3

PATIENT PREFERENCES CONSIDERING THE CHOICE OF HEALTH CARE PROVIDERS IN HUNGARY– RESULTS FROM DISCRETE CHOICE EXPERIMENT

Baji P[1], Pavlova M[1], Gulacsi L[2], Groot W[1]
[1]*Maastricht University, Maastricht, The Netherlands,* [2]*Corvinus University Budapest, Budapest, Hungary*

OBJECTIVES: We use discrete choice experiment to analyze which attributes (quality, access, and price) influence patients' choice between health care providers. We also estimate the willingness-to-pay of respondents for the improvement of health care characteristics. **METHODS:** Data was collected via household survey conducted by face-to-face interviews in Hungary, 2010. Respondents were selected based on multistage random probability method. In total, 1037 respondents filled in the questionnaire. In DCE, eight choice set for the physician and eight for hospital services were presented to the respondents in the form of alternative and basic profiles that contained combinations of attributes of health care services. Attributes and attribute levels were developed on the basis of literature review. For the analysis binary probit regression with random effects was used including attribute differences as well as interactions of attribute differences and socio-economic characteristic as independent variables. Marginal rates of substitution (MRS) were calculated to indicate the willingness-to-pay of the respondent for the improvements in the attribute levels. **RESULTS:** The response rate of the survey was 67%. Significant negative regression coefficients ($p<0.1$) of the interactions between price and social economic characteristics show that respondents from a village or the capital, with low education and bad health status were more sensitive to changes in the price attribute when choosing between health care providers. MRSs show that respondents are willing to pay the most for the good skills and reputation of the physician and the attitude of the personnel, followed by modern equipments and maintenance of the office/hospital. Access attributes (travelling and waiting time in front of the office) were less important. **CONCLUSIONS:** DCE

method is useful to reveal patient preferences, and might support the development of evidence-based and sustainable health policy on patient charges in Central-and Eastern European countries.

PHP4

THE APPROPRIATE USE OF THE EMERGENCY DEPARTMENT FOR PAEDIATRIC PATIENTS

Benahmed N, Laokri S, Cohen L, Zhang WH, Alexander S, De Wever A
Université Libre de Bruxelles, Brussels, Belgium

OBJECTIVES: To determine the factors associated with paediatric inappropriate use (IU) of the accident and emergency department (A&E) **METHODS:** An observational prospective survey was performed. All the patients attending A&E in 12 Belgian hospitals during 2 weeks in 2010 were included. The use of A&E was considered appropriate if, at least, one of the following criteria was met: child referred by a doctor or the police, brought by ambulance, need for a short stay[i], need for technical examination or orthopaedic treatment, in patient admission, death. **RESULTS:** The median age of the 3220 children included was 3.3 years old (0-15.9); 39.3% of the visits were not appropriate according to the definition above. Five determinants were included in a multivariate analyze: age, having a family doctor, night or week-end use of A&E, parents' perception of severity for child's illness and insurance status. Two factors were associated with a decrease of IU: parents' perception of high severity for child's illness (Adjusted OR 0.6; 95% IC 0.4-0.8) and having a family doctor (Adjusted OR 0.6; 95% IC 0.4-0.9). Two other factors were associated with an increase of IU: children age less than 2 years (Adjusted OR 1.8; 95% IC 1.5-2.2) and night or week-end use of A&E (Adjusted OR 1.4; 95% IC 1.1-1.7). After adjustment, the insurance status has no more impact on the appropriateness of A&E use. **CONCLUSIONS:** In a country like Belgium, where it is not compulsory to be registered with a family doctor, the risk of an IU is mainly due to the failure of outpatient care for children <2 years and the use of A&E during night or weekend. Parents' perception of high severity for child's health status and having a family doctor were associated with the appropriateness of A&E use.

Health Care Use & Policy Studies – Diagnosis Related Group

PHP5

ANALYSIS OF LINKED MEDICAL CLAIMS DATA FOR PREINVESTIGATION IN MODELING STUDIES

Einzinger P[1], Zauner G[2], Popper N[2], Endel G[3], Breitenecker F[4]
[1]*Dwh Simulation Services, Vienna, Vienna, Austria,* [2]*Dwh Simulation Services, Vienna, Austria,* [3]*Main Association of Austrian Social Security Institutions, Wien, Wien, Austria,* [4]*Vienna University of Technology, Vienna, Austria*

OBJECTIVES: Medical databases that contain comprehensive claims data linked to individual patients can be an important source for the parameterization of decision-analytic models. Moreover, they are useful for preliminary studies that aim to identify promising research questions and crucial health problems. The goal of this research was on the one hand to analyze health care utilization of children and adolescents using claims data of Austria's social health insurances and on the other hand to gain insight into the general usefulness of the data for further modeling studies. **METHODS:** The database contains all claims data from the insured population during two years (2006 and 2007). We selected patients who were alive and under 20 years old on 1 January 2007. These represented the base population for the analyses. As the database contains no medical diagnoses in ambulatory care we used the drug prescription data and statistically identified links between ATC codes on level 3 and ICD-9 groups (Weisser et al., 26th PCSI Conference, Munich, 2010). **RESULTS:** The basic population consisted of 1, 885, 037 individuals. Antiinfectives for system use (ATC code "J") were by far the most prescribed drug group with 1,231,496 prescriptions. Based on medical prescriptions 646 790 / 685,946 persons were linked to acute respiratory infections in 2006 / 2007. As expected the provider types with most consultations were general practitioners, dentists and pediatrists. **CONCLUSIONS:** The first step for preinvestigation – the identification of relevant diseases and related subpopulations – requires a linkage of reimbursement claims to diagnoses (in this case via drug prescriptions). Afterwards it is possible to analyze the health care utilization and to identify further medical events of the subpopulation as long as all the data is linked to individuals. Our results on child and adolescent health care utilization can point out further directions for future modeling studies.

Health Care Use & Policy Studies – Drug/Device/Diagnostic Use & Policy

PHP6

REGIONAL VARIABILITY IN THE GENERIC ANTIDEPRESSANT MARKET IN SPAIN

Espinós B, Vieta A, Hurtado P, Badia X
IMS Health, Barcelona, Barcelona, Spain

OBJECTIVES: The Spanish antidepressant market is the 7th market in volume in Spain, and represented 475 million Euros in 2010. As a measure to contain pharmaceutical expenditure and promote rational drug use, the Spanish Autonomous Regions (AR) have implemented, among other policies, prescription quality indicators for generics (PQIG). The objective of this study was to analyze the generic antidepressant market in those AR with and without PQIG and to assess whether the AR with PQIG have higher generic sales than those without indicators. **METHODS:** We identified the AR with PQIG, through their health services web pages. We obtained the sales of branded and generic antidepressants (SSRIs, NSMRIs, MAOIs and other antidepressants) in volume (units) for each AR for the period 2007-2010 – data obtained from IMS Health® Regional database. Sales were adjusted per one million population – data obtained from National Statistics Institute. From these data, we estimated generic prescription and compared growth for the period 2007-2010. **RESULTS:** Nine out of the 17 AR have PQIG (Andalusia, Balearic Islands, Catalonia, Castilla-La Mancha, Castilla-León, Madrid, Basque Country, La Rioja and Valencia). Generic prescription increased 8 points from 2007 to 2010, both groups having similar growth (8 and 7 points in the PQIG and non-PQIG group, respectively). In 2007, the mean generic prescription in the AR with PQIG was the 14%, whereas in the non-PQIG group was 10%. In 2010, it was 22% in the AR with PQIG and 17% in the non-PQIG ones. Andalusia and Catalonia were the AR with the highest percentage (38% and 28%, respectively) and Murcia and Country Basque were the lowest (11% and 14%, respectively). **CONCLUSIONS:** The PQIG had an overall positive impact in generic prescription, although other factors, such as PQIG implementation approach may influence the real impact of indicators in sales.

PHP7

ORPHAN DRUGS FOR RARE DISEASES IN THE EUROPEAN UNION: BRIDGING THE GAP BETWEEN DRUG DEVELOPMENT AND UNMET MEDICAL NEEDS?

Catalá-López F[1], Peiró S[1], Gènova-Maleras R[2], Garcia-Altés A[3], Sanfélix-Gimeno G[1], Álvarez-Martín E[4], Morant-Ginestar C[5], Ridao M[6]
[1]*Centro Superior de Investigación en Salud Pública (CSISP), Valencia, Spain,* [2]*Primary Care General Directorate, Regional Health Council, Madrid, Spain,* [3]*Catalan Agency for Health Information, Assessment and Quality (CAHIAQ), Barcelona, Spain,* [4]*Rey Juan Carlos University, Madrid, Spain,* [5]*Regional Health Council, Madrid, Spain,* [6]*Instituto Aragonés de Ciencias de la Salud (I+CS), Zaragoza; Centro Superior de Investigación en Salud Pública (CSISP), Valencia, Spain*

OBJECTIVES: Orphan drug legislations have been introduced to encourage the development of orphan drugs. In the European Union (EU), orphan drugs are used for the diagnosis, prevention or treatment of life-threatening or serious conditions that affect ≤ 5 in 10,000 people. It is estimated that approximately 7000 rare diseases exist. We assessed the characteristics and outcomes of the new drug development for rare diseases in the EU. **METHODS:** Data on therapeutic indications for the cohort of orphan drugs authorised in the EU were extracted from the European Public Assessment Reports of the European Medicines Agency (EMA) and the European Commission Register of medicinal products (up to June 2011). **RESULTS:** Overall, 64 orphan drugs were authorised in the EU since 2000, corresponding to a total of 77 indications. Median time from orphan designation to EMA authorisation was 2.6 years (P25-P75: 1.5-4.5 years). Sixty percent of the total indications were for the treatment of rare diseases that affect ≤ 1 in 10,000 people. By therapeutic area, the percentage of indications with a marketing authorisation was heterogenous (e.g., 45% for malignant neoplasms, 32% for blood and endocrine disorders, 6% for cardiovascular diseases, 6% for neurological and mental conditions, or 3% for perinatal conditions, among others). **CONCLUSIONS:** Regulatory reform efforts have contributed to the development of orphan drugs. Further research is needed to explain whether unmet needs are being addressed among patients with rare diseases.

PHP8

ATC CLASSIFICATION AND ITS ROLE IN PRICING POLICIES

Edathodu AS[1], Mukku S[2], Wild L[3]
[1]*Double Helix Consulting Group, London, UK,* [2]*Double Helix Consulting, London, London, UK,* [3]*Double Helix Consulting, London, UK*

OBJECTIVES: Originally intended for drug utilization studies, ATC classification is now increasingly used worldwide as a tool for controlling prices of pharmaceutical products. This research looked at how select markets within Europe and Latin America have incorporated ATC classification into their pricing policies to drive down prices of similar drugs. **METHODS:** The research was conducted through in-depth secondary analysis and primary research. National and regional level payers from 10 countries within Europe and Latin America were interviewed using structured discussion guides to explore the role of ATC classification in their respective countries. **RESULTS:** ATC classification is used in varying degrees to inform the pricing and reimbursement decision-making within the 10 countries that were included in the study (EU5, Sweden, Denmark, Mexico, Brazil and Argentina). In countries such as Italy and Spain, ATC 3rd and 4th level classification is an important determinant of reimbursement status of drugs for many chronic diseases. In Germany and Denmark, price comparators for a new drug are sometimes chosen from within the 4th level ATC classification. There are exceptions to this when it comes to biologics, innovative products and orphan drugs. In Latin America, ATC classification plays a less influential role in pricing and reimbursement and is mostly used in organisation of drug lists on the national formulary. **CONCLUSIONS:** ATC classification plays a significant role in many countries in Europe as a tool for supporting pricing and reimbursement decisions. Often overlooked, ATC classification is an important consideration for pharmaceutical companies at launch when determining the price of drugs.

PHP9

TEMPORARY USE AUTHORIZATIONS: THE ECONOMIC AND CLINICAL FUTURE OF DRUGS USED IN THE FRENCH COMPASSIONATE PROGRAM

Degrassat-Théas A[1], Paubel P[2], Parent de Curzon O[3], Le Pen C[1], Sinègre M[3]
[1]*Dauphine University, Paris, France,* [2]*Centre Hospitalier Sainte Anne, Paris, France,* [3]*General Agency of Equipments and Health Products (AGEPS), Paris, France*

OBJECTIVES: In 1992, the French law introduced a legal framework for the provision of drugs without a French market authorization (MA) for compassionate use, called temporary use authorization (ATU). This specific French program, aimed to facilitate early access to innovative drugs, is suspected to be inflationary as ATUs bypass public bodies in charge of health technology assessment and of pricing. Moreover, the national health insurance fully reimburses ATU expenditures. The objective of this work was to explore the economic status of previous ATUs before and after they got a MA, in regards of their clinical benefits. **METHODS:** A retrospective descriptive analysis was performed on all ATUs that obtained a French MA

between 2005 and the 30th of June 2010. We observed their administrative path. Among those available in the first teaching hospital group in France (42 hospitals), we evaluated the potential variables associated with the unit price growth rate before and after MA. **RESULTS:** During the study period, 77 ATUs obtained a MA, mostly after a European approval. Cancer represented the major therapeutic area with 21 drugs. After MA, 9 previous ATUs (12%) were not considered by the High commission for health (HAS) to have neither major nor important medical benefit and 19 (25%) were not supposed to bring some benefits compared to existing therapies. For the price growth rate's analysis, 57 drugs were retrieved (9 previous free ATUs were excluded): 68.4% had a decreasing price after MA whereas 17.5% increased and 14% were stable. Overall mean price growth rate was -12.1% ± 22.6%. The improvement in medical benefit assessed by HAS was not a predictor of the growth rate (p=0.392). **CONCLUSIONS:** From these results, pharmaceutical companies seem marketing these compassionate drugs, for which the benefit/risk ratio is only presumed, at a price that guarantees a margin for future negotiations.

PHP10

TWO PHASES STUDY ON THE PERSPECTIVE OF HEALTH CARE PROFESSIONALS ON CURRENT MECHANISMS FOR AUTHORIZING THE PRESCRIPTION OF SPECIFICALLY CONTROLLED MEDICINES IN SPAIN

Orozco D[1], Basora Gallisa J[1], Garcia L[2], Paz S[3], Lizan L[3]
[1]*Sociedad Española de Medicina de Familia y Comunitaria, Barcelona, Barcelona, Spain,* [2]*Novo Nordisk Pharma S.A., Madrid , Madrid, Spain,* [3]*Outcomes'10, Castellon, Castellon, Spain*

OBJECTIVES: An inspection system that controls the prescription of specific groups of pharmaceutical products exits in Spain. It requires certain prescriptions to be authorized by a medical inspector. Traditionally, it has been carried out manually. Currently, the implementation of an electronic system has modified the whole process of prescription and dispensation of medicines countrywide. This study aims to explore health care professionals' views on the impact of the implementation of an electronic system on the prescription and dispensation of specifically controlled medicines in the country. **METHODS:** Observational, exploratory, two phases study. This abstract reports on phase 1 that included a literature review, a review of current legislation, and telephone, audio-tape recorded semi-structured interviews with primary care physicians, endocrinologists, pharmacists, medical inspectors and regional health authorities from urban and rural areas across country until data saturation. A content analysis of interview transcriptions was conducted. Data triangulation was performed. **RESULTS:** A total of 58 interviews were conducted (21 primary care physicians, 11 endocrinologists, 6 pharmacists, 9 medical inspectors, 11 health authority representatives). Three mechanisms for authorizing the prescription of specifically controlled medicines exist across regions: manual, electronic, and linked to electronic dispensation. The electronic system speeds up the process and favors that the prescription of treatments more strictly adjust to the clinical condition they have been authorized for. From health authorities' and medical inspectors' perspective, the inspection of prescription contributes to avoiding medicines misuse. From the physicians' view, the inspection system mostly serves to control the spending on medicines. Alternative strategies based on professional training and education would more effectively contribute to preventing treatments mishandling. **CONCLUSIONS:** Electronic mechanisms for authorizing the prescription and dispensation of specifically controlled medicines vary across regions. Differences on the perceived ultimate value of the inspection system exist amongst physicians, medical inspectors and health authorities.

PHP11

FACT OR FALLACY: DOES MEDICAL TECHNOLOGY DRIVE HEALTH CARE SPENDING?

Sorenson C[1], Drummond M[2], Bhuiyan-Khan B[1]
[1]*London School of Economics and Political Science, London, UK,* [2]*University of York, Heslington, York, UK*

OBJECTIVES: Health care spending has risen steadily in most countries, becoming a concern for decision-makers worldwide. Commentators often point to the diffusion of new medical technology as a key driver for burgeoning expenditures. This paper critically appraises this conjecture, based on an analysis of existing literature, with the aim of offering a more detailed and considered analysis of the impact of technological innovation on spending. **METHODS:** Key databases (e.g., PubMed, EMBASE) were searched to identify relevant literature. Several categories of studies (e.g., multivariate analyses, policy analyses) were included to cover different perspectives and issues regarding the relationship between medical technology and costs. Applicable abstracts were identified and selected articles reviewed. A standardised template was developed to extract relevant information from the select literature, which was then analysed for key themes across: impact of technology on costs, factors influencing this relationship, and noted methodological challenges in measuring such linkages. **RESULTS:** A total of 150 studies were reviewed. The analysis suggests that the relationship between medical technology and spending is complex and often conflicting. Study conclusions were often contingent on varying contextual factors, such as the sector examined, availability of other interventions, population trends, and the methodological approach employed. Moreover, the impact of medical technologies on costs differed across technologies; some (e.g., cancer drugs, invasive devices) had significant financial implications, while others were cost-neutral or cost-saving. Several studies examined technology in general, making it difficult to tease out the contribution of different types of interventions. **CONCLUSIONS:** Ascertaining the impact of technological advances on spending is difficult to quantify (and qualify). Issues of causality and incomplete knowledge of the interactions between technology and other factors affecting expenditures often constrain the reliability of analyses. We argue that it would be more productive to ask if investments in medical technology result in better value in health care.

PHP12

THEN AND NOW: THE EVOLUTION OF INTERNATIONAL REFERENCE PRICING GLOBALLY

Bharath A[1], Ando G[2]
[1]*IHS, London, London, UK,* [2]*IHS, London, UK*

OBJECTIVES: This study assesses the evolution of international reference pricing (IRP) across 34 countries, from 2006 to 2011. Its current influence on innovative drug pricing in the leading five European Union (EU) markets was also considered. **METHODS:** An international reference pricing matrix was created and reviewed to see if the basket of countries referred by nations to price their pharmaceuticals had changed. Pharmaceutical prices were also used to review 2011 prices of five randomly selected innovative blockbuster molecules across EU-5 countries; the molecules in question were bevacizumab, adalimumab, etanercept, rosuvastatin and infliximab. **RESULTS:** The EU-5 markets lead the reference basket used by countries in their price setting process both in 2006 and 2011. Countries that reference these markets are varied and not limited to economically similar markets both within and outside the EU. While there have been additions and deletions, many countries have largely maintained their reference basket of countries. Since 2006, more emerging markets have become IRP prescribers. Unlike Brazil, and Turkey, which followed IRP prior to 2006 and exclusively use developed country prices to price their own products, the newer emerging market followers have also chosen to include neighbouring countries and/or economically similar country prices in their mechanism. A comparison of 2011 prices across the EU-5 markets showed less price variation between countries that followed IRP compared to those that followed free pricing, but prices were not necessarily lower. **CONCLUSIONS:** Countries using IRP still rely on EU-5 drug prices to price their medicines. However, new adopters of the mechanism are including similar and neighbouring countries to arrive at affordable rates and prevent parallel export. With more emerging markets rolling out IRP, it is notable that in the absence of a set formula that identifies the lowest prices, this technique is one of cost harmonization rather than cost containment.

PHP13

A SURVEY OF PRICING TRENDS AROUND THE WORLD

Reinaud F[1], Ando G[2]
[1]*IHS, Paris, France,* [2]*IHS, London, UK*

OBJECTIVES: We surveyed pharmaceutical prices in 18 countries (mix of developed and emerging countries). The goal of the survey was to analyze and compare drug prices in an attempt to determine the countries where drug pricing procedures are more favorable or more stringent, as well as the countries where price cuts are common and where price increases can still be expected. **METHODS:** The methodology was based on estimated ex-manufacturer pricing data from PharmOnLine International, looking at current and historical drug prices in 18 countries. For each country, all prescription drugs by average manufacturer prices were looked at, as well as by therapeutic area. Several case studies were also analyzed. **RESULTS:** With countries having their own legislation and standards when it comes to drug pricing, significant price differentials are seen between countries. By far, conditions are still most favorable in the US. Legislation is more restrictive in other markets, notably in the European Union. Our data finds that the ongoing pricing reform in Germany has already had a significant impact on drug prices, which are dropping. Conditions are more attractive for innovative drugs in certain emerging countries - including Brazil or Russia - where pharmaceutical companies are increasingly investing as demonstrated with the large number of innovative drugs marketed in those countries. Additionally, a significant number of case studies demonstrate that innovative drugs are highly priced and that price increases can still be expected in those countries. **CONCLUSIONS:** With stringent pricing legislations in developed countries, opportunities are now seen in emerging countries where pharmaceutical companies increasingly invest. In these markets, the challenge is seen at the reimbursement and volume levels. Nevertheless, with governments enhancing their healthcare systems, the data points to the conclusion that the basket of drugs funded will increase in the near future.

PHP14

MULTIPLE INDICATION PRICING, REIMBURSEMENT AND FUNDING DYNAMICS: THE CASE OF ORPHAN INDICATIONS

Wild L, Forster L
Double Helix Consulting, London, UK

OBJECTIVES: Indication expansion is a commonly utilized strategy to maximize return on investment for novel pharmaceuticals. As orphan drug designation can confer pricing, reimbursement and funding benefits, such indications can provide attractive targets for launch or follow-on indications. We aim to understand how expansions into or out of orphan indications affect a product's total pricing and reimbursement opportunity. **METHODS:** Centering our research on orphan indications, we explored three potential scenarios that could be reached when expanding a products indication (from highest to lowest frequency of occurrence): 1) Orphan (current) to Orphan (indication expansion); 2) Non-Orphan (current) to Orphan (indication expansion); and 30 Orphan (current) to Non-Orphan (indication expansion). We conducted analogue analysis across a variety of key global markets to understand the implications on pricing and reimbursement for a product moving between these groupings. **RESULTS:** The analogue analysis indication expansion between orphan indications is relatively common, particularly in oncology. Expansion in this way did not significantly impact product funding or access restrictions, although pricing can be affected by the increased patient population size. Further-

more, regulatory requirements stipulate that a new orphan status application must be submitted for each indication. Under EMA regulations, orphan and non-orphan indications cannot be granted under the same marketing authorization. Although expansions between orphan and non-orphan indications are more common in the US, no examples of expansion from a non-orphan to orphan indication were identified by the authors. **CONCLUSIONS:** While indication expansion between orphan indications is relatively common, examples of expansion into or out of orphan indications are less frequent due to the regulatory restrictions. Pricing and reimbursement dynamics in all cases are reflective of the trade-offs between price potential and population size across indications.

PHP15

PRICE NEGOTIATIONS IN KOREAN PHARMACEUTICAL BENEFIT SYSTEM: HOW COMPATIBLE WITH CEA?

Kwon H
National Health Insurance Corporation, Seoul, Seoul, South Korea

OBJECTIVES: Korea introduced a new positive list system in 2007 together with a price negotiation procedure. Importantly, these two systems are run by two different, independent organizations, namely the Health Insurance Review & Assessment Service (HIRA) and the National Health Insurance Corporation (NHIC). HIRA reviews the cost-effectiveness data in submissions and makes listing decisions, then NHIC takes over and sets the reimbursement price via negotiations with manufacturers. The aim of this study is to compare the difference in price after cost-effectiveness appraisal by HIRA and price negotiation by NHIC, and to analyze the factors that NHIC has considered to determine the reimbursement price. **METHODS:** All 35 submissions made to the NHIC between August 2007 and June 2008 were reviewed. 19 submissions concluded with agreement, 15 failed and one case was suspended. In this review only 15 cases of successful negotiations were included. The level of the reimbursement price compared to the submitted price for both essential drugs and non-essential ones and factors affecting the final price were analyzed. **RESULTS:** The discrepancy between reimbursement price and cost-effective price was about 12.33±11.44% on average. For 3 essential drugs, the price level was almost equal to the submitted price whereas the average level was 84.94 ±11.21% of the cost-effective price for non-essential drugs. The major factors affecting negotiations to determine the final price were narrowed down to total cost of substitutes, the foreign price, and the pharmaceutical budget impact. **CONCLUSIONS:** Our findings have demonstrated that drug pricing within the new environment has been done independently of cost-effectiveness appraisal. The payer has exhibited limited bargaining power for essential drugs. Overall, 87.67% of the cost-effective price was accepted during price negotiations, and the total cost of substitutes, foreign prices and pharmaceutical budget impact were considered equally when fixing the reimbursement price. A limitation of this study is that the result may not be generalized because of insufficient cases.

PHP16

EXTRAPOLATING STRATEGIC INSIGHTS THROUGH MARKET SEGMENTATION: A CONCEPTUAL FRAMEWORK

Forster L, Wild L
Double Helix Consulting, London, UK

OBJECTIVES: Primary research is often only conducted in a limited number of key markets despite a product being launched across a wider range of countries. In order to understand the implications of research findings across geographies, markets can be grouped by common underlying factors. **METHODS:** Market segmentation frameworks were developed based on key decision drivers which can be applied at different points in a product lifecycle. Within each framework, markets can be segmented in up to two domains to distinguish segments. In-depth secondary research was conducted in EU27 markets to understand key pricing, reimbursement, access and uptake processes. Qualitative analysis of these findings permitted us to place markets in the segmentation framework, allowing extrapolation of findings across similar markets. **RESULTS:** Markets can be segmented in several domains, depending on areas of interest for the research in question. For example, in the case of peri-launch segmentation, most new pharmaceuticals aim to secure optimal pricing and reimbursement – therefore an understanding of similarities and differences in these areas are of greatest interest. Markets can be assessed in terms of HTA data requirement, degree of centralization of decision making, pricing regulations (fixed vs. 'free' pricing) or pricing decision drivers. This approach was applied to understanding market similarities for a novel, hospital administered product in a rare disease area. All 27 EU markets were segmented by level of price regulation into three groups: price set by manufacturer, price set through negotiation or strict price regulation. Understanding pricing drivers in each group allowed results from primary research undertaken in only 6 of these markets to be used by the manufacturer in all EU27 markets. **CONCLUSIONS:** Applying these conceptual frameworks to drive market segmentation, key similarities and differences between markets can be used to extrapolate findings from primary market research, or determine what strategic options are applicable to a given market.

PHP17

CHARACTERISTICS OF HIGH COST AMBULATORY DRUGS IN FRENCH HEALTH CARE SYSTEM

Gridchyna I, Aulois-Griot M, Pulon C, Maurain C, Bégaud B
Université Bordeaux Segalen, Bordeaux, France

OBJECTIVES: In 1994, in French health care system, a supplement status for ambulatory reimbursement drugs, called "exception drugs", was established. This status enables to reimburse only specified indications of particularly costly drugs. In this study we analyze what characteristics a drug should possess in order to be considered as an "exception drug". **METHODS:** Included in the study, were drugs that had status of "exception drugs" as of April 2011. The clinical (actual benefit, improvement of actual benefit) and economic (amount reimbursed by National Health Insurance) characteristics were collected from official and publicly available websources, as well as supplement restrictions for prescription (any prescription or only the first one must be accomplished by a hospital practitioner; prescription must be accomplished by a specialist; or prescription requires specific following during the treatment). **RESULTS:** As of April 2011, there were 56 "exception drugs" in trade name and 30 in generic name. The drugs from 9 ATC classes level I were presented; the most numerous were A16 (Other alimentary tract and metabolism), H01 (Pituitary and hypothalamic hormones and analogues), B03 (Antianemic preparations). Supplement restrictions for prescription was applied to 33 drugs. Some "exception drugs" (10) had also the status of drugs financed out of DRG payment system. Most of the drugs, 91.07% (51/56) had high level of actual benefit. Around half of the "exception drugs", 42.86% (24/56) had level of improvement in actual benefit from I to III. In 2009, part of reimbursed amount of "exception drugs" was 7.73% from all reimbursed drugs, whereas in 2004 it was 2.85%. Interestingly, in 2009 four "exception drugs" constituted about 1% of the reimbursed amount each, and 40 – less than 0.1%. **CONCLUSIONS:** The analyzed types of characteristics, both economic and clinical, can be used as criteria for establishing the status of "exception drug".

PHP19

DOES PHARMACEUTICAL PRICE REGULATION AFFECT THE ADOPTION OF GENERIC COMPETITION IN THE OECD?

Varol N[1], Costa-i-Font J[2], McGuire AJ[3]
[1]*United Biosource Corporation, London, UK,* [2]*London School of Economics and Political Science, London, UK,* [3]*LSE Health and Social Care, London, UK*

OBJECTIVES: Generic competition is an effective cost-containment mechanism that improves static efficiency and stimulates pharmaceutical innovation. No prior study has empirically analysed the relative delays in adoption of generic competition within the OECD. This study aims to investigate how price regulations in the OECD affect timing of generic adoption following the first global generic launch. **METHODS:** Drawing upon data from 1999 to 2008, we estimate the impact of ex-ante price and market size expectations on the probability of generic launch using discrete-time duration modeling with cloglog and logit regressions. The econometric strategy employs both parametric and non-parametric duration dependence and includes controls for local generic competition, firm characteristics and molecule heterogeneity. **RESULTS:** Ex-ante profit expectations result in faster adoption; both expected price and market size increase the probability of launch. Our findings suggest that neither molecule nor firm characteristics have a significant effect on generic adoption across different specifications. **CONCLUSIONS:** Evidence indicates that regulation has a significant impact on timing of adoption; however, generic competitors tend to follow a locally oriented strategy in contrast to research-intensive pharmaceutical firms.

PHP20

MARKET ACCESS BARRIERS FOR BIOSIMILARS IN SPAIN AND GERMANY: EPOETIN ALFA EXAMPLE

Hurtado P, Vieta A, Espinós B, Badia X
IMS Health, Barcelona, Barcelona, Spain

OBJECTIVES: Biosimilars are predicted to reduce prices of biologicals. Among biosimilars, epoetin alfa has the largest market penetration in Germany and Spain. The aim of this study was to describe the political, technological, economical and social factors that impact on epoetin alfa sales and price in both European countries, which greatly differ in their generic market size. **METHODS:** Revisions of regulatory legislation and policies regarding biosimilars at country and European levels have been conducted. Estimations of market shares in units for epoetin alfa originator and biosimilars plus darbopoetin alfa, a second generation biological, were calculated. Epoetin alfa pricing trend was followed. All data was extracted from IMS MIDAS database, using standard units and ex-manufacturer price. **RESULTS:** Both countries are under the same regulatory framework and have policies that promote generic penetration, although automatic biosimilar substitution is banned. Price of first launched biosimilar was approximately 30% below originator price in both countries. In Germany, originator price decreased about 16% after launch of second biosimilar, whereas in Spain, originator price trend have no changes to date. Regarding originator market shares, they did not change after launch of biosimilars in Spain, while in Germany marked reductions were observed along with biosimilars market share increases. In Spain, market shares of darbopoetin alfa were reduced when epoetin alfa biosimilar sales started, but no changes of the kind were documented in Germany. **CONCLUSIONS:** Although both countries face similar political and technological factors; in Spain, social and economical ones could negatively impact stakeholder perception. In this country, the introduction of biosimilars do not modify market share of the originator despite it has a price about 30% higher. In Germany, stakeholders pose minimum resistance to biosimilars, as market share and price of originator are immediately reduced after the entry of biosimilars.

PHP21

ADOPTION OF NEW MEDICINES IN THE OECD: REGULATION, INNOVATION AND SCALE

Varol N[1], Costa-i-Font J[2], Mcguire AJ[3]
[1]*United Biosource Corporation, London, UK,* [2]*London School of Economics and Political Science, London, UK,* [3]*LSE Health and Social Care, London, UK*

OBJECTIVES: Most OECD countries employ pricing controls to contain rising health care expenditures. The recent financial crisis has resulted in further pressure to

enact more stringent price controls. The purpose of this study is to provide empirical evidence on how price regulations in the OECD affected the adoption speed of new patent-protected pharmaceutical technologies during 1999-2008. **METHODS:** We use discrete time duration modelling with parametric and semi-parametric duration dependence to examine how price expectations shape the probability of launch, controlling for competition, market size expectations, firm and molecule heterogeneity across the major OECD markets during 1999-2008. A sub-sample analysis including only EU countries also investigates the impact of price interdependencies and potential firm strategies in launch and pricing decisions. **RESULTS:** The empirical analysis suggests there is a statistically significant and robust price and market size effect in the adoption of new pharmaceutical technologies. A unit increase in the log expected launch price and the log of expected market size increases the probability of launch by 0.003 and 0.002 respectively. Concentrated therapeutic subgroups, reflecting market crowding constitutes a significant barrier to entry. Sub-sample findings from the EU market suggest strategic firm behaviour with firms delaying launch in low-priced markets and attempts to maintain price differentials across interdependent markets to a minimum due to price complementarities. Firm economies of scale and the therapeutic importance of innovations are other important drivers of early adoption. **CONCLUSIONS:** A significant and robust price and market size effect is observed in the likelihood of new pharmaceutical adoption. Price regulations slow down pharmaceutical adoption on a global scale and may impose welfare losses, particularly when the innovations that are delayed are cost-effective from a societal perspective. Due to scale advantages observed in international roll-out strategies, price controls may increase incentives for mergers and acquisitions, further increasing concentration levels and barriers to entry.

PHP22

ARE HOSPITAL MEDICINES PRICES INFLUENCED BY DISCOUNTS AND REBATES?

Vogler S[1], Zimmermann N[1], Leopold C[1], Habl C[1], Mazag J[2]
[1]*Gesundheit Österreich GmbH / Austrian Health Institute, Vienna, Austria,* [2]*State Institute for Drug Control (ŠÚKL),, Bratislava, Slovak Republic*

OBJECTIVES: To understand the role of discounts/rebates impacting medicines prices in hospitals. **METHODS:** Qualitative survey with competent authorities and hospital pharmacists about purchasing strategies for hospital medicines with all EU Member States and two further European countries (Norway, Turkey) Price survey (study visits) of 12 active ingredients in 25 hospitals in Austria, the The Netherlands, Norway, Portugal, Slovakia. **RESULTS:** Of a total of 27 European countries, 25 countries reported about the practice of discounts and/or rebates (ex-post price reductions). The range of the discounts varied among the countries and with regard to the products. Apart from Italy with mandatory discounts to the NHS, discounts were always commercial and as such usually kept confidential. Free-cost medicines (i.e. medicines provided without payment) were reported to be a practice in six countries, whereas it is legally forbidden in another six countries. In Austria, the The Netherlands, Portugal, and Slovakia discounts were granted in individual negotiations between suppliers and hospitals for some of the surveyed products (e.g., for cardiovascular medicines where generics were available; however no discounts for all oncology medicines of the sample). In Norway, discounts played no role since medicines were tendered centrally. In Austria and Slovakia medicines were provided cost-free to some/all hospitals (only in the indication of cardiovascular treatment). In Portugal, unit prices of nearly € 0.00 were surveyed for a few cardiovascular medicines attributable to rebates. **CONCLUSIONS:** In the in-patient sector, confidential discounts, and, to a lesser extent, rebates and cost-free medicines are common in some countries. Discounts are more likely to be provided where there are (off-patent) therapeutic alternatives available. Large discounts and cost-free provision appear to be a practice for "strategic products" which account for high volume and expenditure in the out-patient sector.

PHP23

ORPHAN DRUG ACCESS IN MEDICARE PLANS IN THE UNITED STATES

Sepulveda B, Doyle J
Quintiles, Hawthorne, NY, USA

OBJECTIVES: The increase in premium-priced orphan drugs coupled with health care budget constraints will pressure managed care plans to consider restricting market access. Coverage and reimbursement of ten FDA-designated orphan drugs (ceramide, alglucerase, modafinil, lamotrigine, laronidase, nitisinone, alpha-glucosidase, galsulfase, idursulfase, bosentan) were analyzed for ten popular Medicare PDP (AARP, Cigna, CVS Caremark, Humana, Medco, RxAmerica, EmblemHealth, UniCare, WellCare, FirstHealth. **METHODS:** Formulary tier structure, out-of-pocket costs (OPC), monthly retail costs and utilization restrictions (UR)—pre-authorization (PA), quantity limits (QL) and step therapy (ST)—were obtained from CMS (www.medicare.gov). UR were assigned point values reflecting most to least restrictive—PA, 3; ST, 2; QL, 1; 6 possible points per drug per plan unless excluded from formulary. OPC is the percentage of the drugs' costs paid by patients—an average of deductible, initial, gap, and catastrophic OPC. Disease incidences were obtained from a variety of sources. **RESULTS:** Monthly retail prices ranged from $19.56 (lamotrigine; generic) to $5,946.37 (bosentan). The drugs excluded from the most formularies were alglucerase and myozyme (3 each). Lamotrigine, the least expensive drug, had the highest OPC as a percentage of its retail price (57.58%) on average among the plans; however, this may be because of its low retail price. Bosentan had the lowest OPC (36.48%). There was no correlation between drug price and UR points (r2=0.030). There were a slight positive correlation between disease incidence and drug price (r2=0.219) and between disease incidence and OPC (r2=0.380). There were slight negative correlations between a drug's UR points and its OPC percentage (r2=0.163) and between its retail price and OPC (r2=0.423). **CONCLUSIONS:** URs on orphan drugs were prevalent in Medicare plans, with patients bearing 40-60% of the OPC. The extent of restrictions was not proportional to the drugs' price, suggesting that more research is warranted to investigate the factors related to orphan drug access.

PHP24

HOW DOES THE COMMITTEE TO EVALUATE DRUGS (CED) MAKE DECISIONS ABOUT AMBULATORY PHARMACEUTICAL FUNDING IN ONTARIO?

Sim J, Speicher J, Evans G, Mahar AL, Johnson A
Queen's University, Kingston, ON, Canada

OBJECTIVES: Pharmaceutical drug costs represent a large portion of government health care spending. A national standard to regulate the process of public financial reimbursement for drugs does not exist in Canada and variations in practices are evident across the country. The purpose of this study was to provide a comprehensive overview of how drug-funding decisions are made in Ontario. **METHODS:** Access to Ontario's Committee to Evaluate Drugs (CED) meeting minutes (July 2009-July 2010) was granted. A data abstraction form was created based on the framework established by Johnson et al. (2009). For each criterion, importance to the final decision, strength of evidence and quality of evidence were recorded. Two reviewers independently extracted the information and consensus was achieved. **RESULTS:** Forty-four submissions were included. Five main observations: 1) the CED considered certain criteria more frequently than others (e.g., clinical benefit was considered for all decisions, while societal values were discussed less frequently); 2) the relative impact of each criterion on the CED's recommendation varied (e.g., overall clinical benefit, efficacy, value for money, and need had the largest influence); 3) the CED was more likely to discuss the strength of evidence when its recommendation did not support public funding (e.g., the strength of cost evidence was discussed 3 times more often for those drugs not recommended for funding); 4) the frequency with which the CED considered criteria varied according to whether or not the CED believed there was an established need; and 5) the majority of the comments made by the CED about the strength of evidence indicated that the quality of the data was low. **CONCLUSIONS:** This review identified trends in the influence of different criteria involved in the CED's drug assessment process. These results may promote the development and application of a comprehensive, consistent, and transparent framework for reimbursement decision-making.

PHP25

DESIGNING FEASIBLE MODELS FOR AN OPTIMAL PHARMACEUTICAL CONSULTATION PROGRAM USING A SYSTEMATIC REVIEW

Medina-Artom T[1], Bramli S[2], Shavit O[3]
[1]*JDC-Brookdale Institute, Jerusalem, Israel,* [2]*JDC-Brookdale Institue, Jerusalem, Israel,* [3]*The Hebrew University of Jerusalem, Jerusalem , Israel*

BACKGROUND: Pharmaceutical consultation (PC) aims to maximize the successful outcome of a drug treatment. Although its benefits are well documented, several different PC models are implemented in various healthcare settings (HCS) and no optimal model has been identified. **OBJECTIVES:** To analyze the characteristics of PC models most relevant to key clinical, monetary, and social objectives, and to design PC models that optimize them and could be implemented in various HCS and in primary care in Israel. **METHODS:** We systematically reviewed studies of PC programs published from 2000–2010. We analyzed the programs by their organizational characteristics and defined a scale for measuring their success that incorporated the clinical, monetary and social objectives. Their results were then scored accordingly. We calculated the association between each of the key organizational characteristics and the success score to identify the characteristics that maximize the program's success. **RESULTS:** The analysis revealed three core patterns: consultation to patient and physician, patient alone, and physician alone. For each pattern, three feasible models for optimal PC were found. The organizational characteristics of each model included the subject and location of the consultation, target population, consultant's profession, communication method, incentives, duration, financing, and the PC process steps. **CONCLUSIONS:** This method for optimizing a model for PC program could be implemented in a variety of HCS to maximize successful drug treatment reflected in the prevention and control of illnesses, improved clinical outcomes, enhanced well-being of the population and maximum economic benefits. Interviews with a sample of key players in HCS could reveal preferences and benefits, which then will be combined with the results of the previous analysis to optimize a PC program for primary care in Israel and for other HCS.

PHP26

HEALTH OUTCOMES AND ECONOMICS RESEARCH FOR REGENERATIVE MEDICINE AND CELLULAR THERAPIES: LESSONS FROM A MULTI-MARKET HEALTH TECHNOLOGY ASSESSMENT AND REIMBURSEMENT REVIEW

Faulkner EC[1], Fernandez M[2], Spinner DS[1]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*RTI Health Solutions, RTP, NC, USA*

OBJECTIVES: Regenerative medicines, which include cellular and gene therapies, offer to shift the focus of healthcare from one of palliative care to curative treatment. Because these technologies are novel, more complex than standard biopharmaceuticals, and often costly, they are anticipated to face heavy scrutiny for market access and adoption. The objective of this analysis was to evaluate published HTAs and reimbursement policies on regenerative medicines for select global markets, compare them to existing biopharmaceuticals, and evaluate lessons for HEOR and market access planning. **METHODS:** A search of HTAs and reimbursement policies from Australia, Canada, France, Germany, Sweden, the UK (UK) and the United States (US) was conducted to identify reimbursement recommendations and key HEOR considerations for this new field. A review of the literature, including

the Cochrane Library and PubMed was also conducted using relevant MeSH terms and text words to identify additional reimbursement and HEOR issues associated with regenerative medicines. **RESULTS:** Although considered a nascent field, over 40 HTAs and coverage policies on cellular therapies and regenerative medicines were available from the key Australian, European and North American HTA agencies and payers considered in the assessment. Many of HTAs and coverage policies identified gaps in effectiveness data, particularly the lack of compelling comparative trials and long-term outcomes, and uncertainty surrounding cost-effectiveness. **CONCLUSIONS:** While HTAs and payer policies on regenerative medicines reflected decision factors commonly associated with biopharmaceuticals, other key market access factors beyond clinical- and cost-effectiveness were identified that are specific to this field. These factors include involvement of multiple reimbursable technologies in cell extraction, processing and administration; cell handling steps that may engage multiple healthcare budgets; and requirements to characterize the value of the entire procedure versus the regenerative medicine alone. Key considerations for HEOR and market access planning are considered.

PHP27

DIFFUSION OF INNOVATIONS IN HEALTH CARE: DOES THE DUAL MARKET PHENOMENON EXIST?

Arbel R[1], Yogev G[2], Greenberg D[1]
[1]*Ben-Gurion University of the Negev, Beer-Sheva, Israel,* [2]*Tel Aviv University, Tel Aviv, Israel*

OBJECTIVES: The diffusion of innovative technologies and specifically the difference between early and mainstream adopters during the product's life-cycle (also known as the chasm/saddle phenomena), has been studied empirically. It has been demonstrated that given a dual-market structure (e.g. early vs. mainstream adopters) cost has a substantially higher negative impact on mainstream adoption rate than on early adoption rate. Previous studies focused primarily on the consumer electronics industry. We examined whether the phenomena of dual-markets exists also for medical technologies. **METHODS:** We analyzed the diffusion of innovation patterns of 11 medical interventions using a recent mathematical model: the Change of Dominance (CD) model, which analyzes the dynamics between the early and mainstream adopters. Previous research concluded that influences on adoption and subsequent diffusion rates are very different for various health categories, technologies, and geographies. Therefore, our empirical dataset covered three major medical intervention categories: interventional procedures (e.g. coronary stents), pharmaceuticals (e.g. beta-blockers), and diagnostic technologies (e.g. CT scans). The dataset was collected from five countries: United States, UK, Korea, Canada and New Zealand. **RESULTS:** The CD model has an excellent fit (>90%) to all of the technologies analyzed. Nine of the 11 technologies examined (82%) reached major market adoption. The median time of change of dominance for these nine technologies was seven years, very similar to that found for consumer electronics. The adoption rate at the time of CD is ~25%, which is higher than the rate in consumer electronics markets. The CD time of interventional technologies (e.g. coronary stents, bypass surgery) was substantially lower (3 vs. 8.5 years) compared to pharmaceuticals or diagnostic technologies. **CONCLUSIONS:** The dual market phenomenon seems to occur in the health care, with similar patterns to the consumer electronics industry. Both technology manufacturers and health planners should consider these findings when attempting to promote the use of innovative technologies.

PHP28

DRUGS FOR RARE DISEASES: INFLUENCE OF OPRHAN DESIGNATION STATUS ON PRICE

Picavet E[1], Dooms M[2], Cassiman D[2], Simoens S[3]
[1]*Katholieke Universiteit Leuven, Leuven, Belgium,* [2]*University Hospital Leuven, Leuven, Belgium,* [3]*K.U. Leuven, Leuven, Belgium*

OBJECTIVES: The literature indicates that the expenditure on orphan drugs will be increasing over the coming years. The market for orphan drugs has inherent market characteristics that sometimes result in high prices. The aim of this study was to analyse whether awarding orphan designation status has an influence on the price setting of drugs for rare disease indications. **METHODS:** To this effect, prices of designated orphan drugs were compared with other non-designated drugs for rare disease indications. We identified 28 designated orphan drugs and 16 comparable non-designated drugs for rare disease indications for which we collected official hospital prices (per defined daily dose) in Belgium in 2010. **RESULTS:** Orphan-designated drugs had a higher median price (€138.56 [interquartile range; IQR €406.57]) than non-designated drugs (€16.55 [IQR €28.05]) for rare disease indications ($p < 0.01$). **CONCLUSIONS:** In conclusion, our results suggest that awarding orphan designation status in itself is associated with higher prices for drugs for rare disease indications. In order to gain full insight into orphan drug pricing mechanisms, future research should focus on collecting information about the different factors influencing orphan drug pricing.

PHP29

IMPACT OF DIFFERENT PHARMACEUTICAL DISTRIBUTION SYSTEMS ON THE ACCESS TO PHARMACEUTICAL PRODUCTS IN SIX EUROPEAN COUNTRIES

Walter E, Dragosits A, Said M
Institute for Pharmaeconomic Research, Vienna, Austria

OBJECTIVES: The pharmaceutical-sector is vital for the society and economy as a whole. Wholesalers are essential for the distribution-chain because they bridge time and space between supply and demand. Thus, the study aims to draw a comprehensive picture of the Pharmaceutical-Wholesale-Industry, outlining its socio-economic importance compared to other forms of distribution with qualitative and quantitative methods, focusing on Germany, U.K., France, Italy, Spain and the The Netherlands. **METHODS:** The necessary data was obtained from different sources: an online-questionnaire was directed to pharmacies, annual GIRP and IMS-Health statistics; a questionnaire was directed to GIRP-full-member associations and Wholesale companies (return rate 81%); and systematical literature research which verified the empirical findings. **RESULTS:** If pooling of medicines would not be ensured by Wholesalers, each pharmacy would have to contact each Manufacturer in order to obtain a complete assortment of medicines. The continuous supply of medicines involves more than 4.5bn transactions between Pharmacies, Wholesalers and Manufacturers each year. Without Wholesalers this number would dramatically increase to 99.4bn transactions per year. On average Wholesalers are bundling products of 21.84 Manufacturers per delivery. The process-costs of a several order from Wholesalers are €7.98; from Manufacturer €11.36 (cost differences of 21.84 supplies from direct sales: €240.11). These additional costs have to be paid by Manufacturers, Pharmacies and finally by Patients. Furthermore, Wholesalers pre-finance (Ø €11.5bn for 46d) the entire medicine-market and secure the cash-flow of the social-insurers. Regarding satisfaction with different distribution-models, the results of the online-questionnaire show that pharmacists are not satisfied with the new models (satisfaction Wholesalers: 85.17%; Manufacturer: 39.75%; RWA: 9.50%; DTP: 12.2%). **CONCLUSIONS:** A reduction in number of Wholesalers will result in a slower supply of medicines, so the existence of the current distribution system is vital to the European health care sectors, as Pharmaceutical Wholesalers help reducing transaction-cost, secure a safe, rapid and continuous supply of medicines.

PHP30

BIOSIMILARS IN THE EUROPEAN MARKET

Lindner L[1], Gimenez E[1], Rovira J[2], Espin J[3], Olry A[3], Leticia G[3]
[1]*IMS Health, Barcelona, Barcelona, Spain,* [2]*Barcelona, Spain,* [3]*Escuela Andaluza Salud Publica, Granada, Granada, Spain*

OBJECTIVES: To describe the evolution of biosimilars in the EU Member States (MS) and to identify the key parameters of the EU biosimilars market dynamics across countries: time to market entry, prices and market penetration. **METHODS:** A quantitative analysis of the EU biosimilar market from 2007 to 2010 was conducted for 26 EU MS. Data was obtained from European Medicines Agency (EMA) and IMS MIDAS database, including at country level: Date of market entry of reference products and biosimilars, unit sales and prices (estimated using official prices) of existing biosimilars and their respective reference products. Descriptive statistics were applied to summarize the results. Multivariate regression analysis was applied to identify statistical associations between: 1) time period between the EMA's approval and market entry; 2) market penetration (in monetary value); 3) biosimilars DDD prices and the following independent variables: Pharmaceutical market value, population, Gross National Income, Price Level Index of medicines, total expenditure on health as % GNI, total expenditure on health in absolute terms, government expenditure on health and Generic Price Control, International Price Comparison, Tendering-like practices, Pharmacists generic substitution, INN prescribing, Procedure for pricing and/or reimbursement decision, and Reference Price System. **RESULTS:** The market penetration of biosimilars for the three reference molecules (somatropin, epoietin and filgrastim) rose from 0.33% in 2007 to 15,52% in 2010. The multivariate analysis show an association between the price level index, the total and governmental expenditure on health and an earlier market entry. **CONCLUSIONS:** Biosimilars hold a certain promise to help bring down the cost of biologicals to health systems. Existing evidence in the EU is still limited and the results do not show a clear pattern of market dynamics, although it becomes evident that biosimilars will attain smaller price reductions and market penetration than conventional generics.

PHP31

THE ECONOMIC IMPACT OF SWITCHES OF PRESCRIPTION DRUGS TO THE OVER-THE-COUNTER STATUS (RX-TO-OTC): A SYSTEMATIC LITERATURE REVIEW

Karray SM[1], Plich A[2], Flostrand S[3], Toumi M[4]
[1]*Creativ-Ceutical, Tunis, Tunisia,* [2]*Creativ-Ceutical Ltd., London, UK,* [3]*Creativ-Ceutical, Paris, France,* [4]*University Claude Bernard Lyon1, Lyon, France*

OBJECTIVES: To review economic evidence supporting Rx-to-OTC switches. **METHODS:** A systematic search of the EMBASE, Pubmed, ISPOR conference abstracts databases and industry associations websites was conducted. The search was limited to years 2000–2010 and to North America and European countries. Two independent reviewers selected eligible studies. **RESULTS:** The search identified 14 reviews, 12 model publications, 12 database analyses, 5 prospective observational studies and 11 other. Most articles originated from the US. In 5/6 database analyses and in 8/9 budget impact models (BIM) that quantified cost consequences of Rx-to-OTC switching, it was shown to generate savings to healthcare budget holders, mainly due to Rx-drug acquisition savings. Other key direct savings included avoided: doctor's visits to obtain a prescription; emergency room visits or hospitalisations due to easier access to an effective or safer therapy. Employers' benefits included less time-off work to obtain a prescription and less absenteeism and presenteeism due to easier access to therapies that improve employee productivity. Cost consequences of potential misuse due to lack of doctor's supervision were frequently acknowledged but rarely quantified. The key factors determining the extent of savings were: uptake rates of the OTC drug among different types of populations (i.e. those on Rx drugs, other Rx drugs, OTC-treated, untreated and undiagnosed), therapeutic area and presence of disreimbursement policies. The only European BIM is old (2004) and showed potential annual savings of €16.4 billion, assuming that 5% of Rx drugs are switched to the OTC status. However, its use is limited as it is not specific to any drug/disease area and took a simplistic

approach to costing and uptake among populations considered. **CONCLUSIONS:** Rx-to-OTC switches are a real opportunity to realise savings for budget holders and productivity gains for employers. More robust economic models are required to estimate the impact of the switches in Europe.

PHP32

MARKET ACCESS VARIATION FOR LIFESTYLE DISEASE DRUGS IN EUROPE

Bastian AW[1], Gea-Sanchez S[2], Tangari M[1]
[1]*Bridgehead International, London, UK,* [2]*City London University, London, UK*

OBJECTIVES: Health policy and funding for medications classed as 'lifestyle' have received considerable scrutiny by public health officials as well as politicians. This has limited public funding and reimbursement for these products in many European countries. A detailed assessment of the variation in payer coverage polices for lifestyle medications across Europe was conducted. **METHODS:** The top 'lifestyle' indications and associated medications were identified from a literature search using WHO, PubMed, and ScienceDirect. Selection criteria for the medications included being first-to-market in the identified indication or being referenced as the only off-label treatment for the specified use. Public reimbursement databases (16) were used to analyze the health technology assessment and reimbursement decisions across European countries (14) for each lifestyle indication. Reimbursement was classified as favourable (broad/restricted but accessible) or no coverage (not funded). Where available, justifications for coverage decisions were analysed to determine the drivers of positive and negative coverage decisions. **RESULTS:** Lifestyle indications where products have achieved high levels of reimbursement include Dyspepsia (100%), Delaying Menstruation (91%), Restless Leg Syndrome (87%), and Alcohol Dependence (85%). Those with the worst coverage are Hair Loss (0%), Hypoactive Sexual Desire Disorder (0%), Erectile Dysfunction (13%), and Weight Loss (15%). Of the 14 countries researched, those offering the most favourable coverage environments for lifestyle treatments were: Belgium (70%), France (69%), and Austria (69%). The countries with the most limited (no available) coverage for lifestyle drug therapies were The Netherlands (13%) and Sweden (25%). Four general characteristics are associated with better access to market: Cross-Usage in Other Indications, Areas with High Societal Costs, Diseases that Affect Family Planning, and Older Therapy Areas. **CONCLUSIONS:** With pressure on public health resources, European payers are resistant to the allocation of funds for medications with lifestyle indications. Despite this, barriers to reimbursement vary substantially across European markets.

PHP33

IMPACT OF 2011 GERMAN HEALTH CARE REFORM ON GLOBAL MARKET ACCESS STRATEGIES

Honoré AC[1], Marinoni G[2], Ando G[2]
[1]*IHS, Zurich, Switzerland,* [2]*IHS, London, UK*

OBJECTIVES: This study seeks to evaluate the impact of the 2011 German healthcare reform (AMNOG) on the global pricing and reimbursement landscape and its influence, if any, on global market access strategies. **METHODS:** Key local regulators were interviewed to understand the scope and mechanism of the mandatory early benefit assessment as well as its implications in terms of pricing and market access on a national and global level. Primary research consisted of in-depth phone interviews with six regulatory stakeholders and industry representatives in Germany. Secondary research was based on data from national and regional healthcare authorities, national statistics offices and IHS Global Insight Healthcare and Pharmaceutical services. **RESULTS:** AMNOG has put an end to free pricing in Germany by correlating price to added therapeutic benefit scores and opening the reference pricing system to all patented medicines. The total transparency of the early benefit assessment and pricing processes can influence prices not only in Europe but also worldwide. The availability of results from the Federal Joint Committee (G-BA)'s benefit assessment can affect the pricing and reimbursement status of pharmaceuticals worldwide, while international reference pricing can put downward pressure on prices in at least 22 other countries. **CONCLUSIONS:** The German reform will have an impact beyond the country's borders. Germany has traditionally been an early pharmaceutical launch market but the end of free pricing and the prospect of lower price levels for products of no and minor-to-moderate added value may require a complete reconsideration of the optimal launch sequence. While AMNOG has revolutionized the pricing and reimbursement landscape in Germany, from a global perspective, the reform is not particularly innovative. Germany's new pricing process is comparable to the French model whereby perceived degree of innovation directly impacts medicine prices, and comes near to the Swiss and Austrian models.

PHP34

PRICING INSIGHTS ACROSS THERAPY AREAS AND EUROPEAN COUNTRIES - A DISCUSSION OF INTERNATIONAL PRICE REFERENCES AND IMPLICATIONS FOR PARALLEL TRADE AND PRESCRIPTION PATTERNS OF PHARMACEUTICAL PRODUCTS

Frenzel A[1], Haas G[1], Pechstein M[1], Degans C[2]
[1]*IMS HEALTH, Frankfurt/Main, Germany,* [2]*IMS HEALTH, London, UK*

OBJECTIVES: This analysis compares pricing levels across 15 European countries and 10 therapy areas in 2010. The differences in the price levels are related to parallel imports and the innovativeness of prescriptions. **METHODS:** From IMS PRICING INSIGHTS pricing information for pharmaceutical products is accessed at the pack level from 15 countries (EU5-Austria-Ireland-Sweden-Norway-Denmark-Portugal-Greece-Poland-Hungary-Romania) for 2010. Currency rates are fixed at 2010 levels. For the ten therapy areas, product baskets are constructed for the comparisons: The therapy areas are defined as Anatomic-Therapeutic-Chemical (ATC) classes at level 2. The top 100 products by sales in the EU5 in these classes enter the comparisons. Prices are compared at the manufacturer and the public sales levels. IMS MIDAS identifies imports related to the products in the baskets. The innovativeness of products is operationalized as the number of months between the overall first introduction and the introduction in the countries. **RESULTS:** The first result is that international drug price comparisons are extremely sensitive to methodological issues, e.g. sample selection, exchange rates. Differences in price build-up structures between countries would dominate cross-country price differences, if not accounted for. Differences between countries exist at the ex-manufacturer-level, differences between public sales levels tend to be larger. Price level differences between countries are not consistent across all analyzed therapy areas. Higher price levels are related to parallel trade rates across countries and to an earlier access to new pharmaceutical products. **CONCLUSIONS:** The analysis shows price differences across countries related to manufacture pricing and regulation structuring the price build-up and taxes. Higher price levels are linked to an earlier access to innovative products. Parallel trade flows into countries with higher price levels, usually from countries with lower price levels, causing scarcities. Differences in economic development and purchasing powers need to be analyzed to evaluate these differences in pricing levels.

PHP35

IS VALUE BASED PRICING EXECUTED IN REAL LIFE SITUATION? – GLOBAL PERSPECTIVES

Mukku S[1], Mallinson M[2]
[1]*Double Helix Consulting Group, London, UK,* [2]*Double Helix Consulting, London, UK*

OBJECTIVES: Value assessment of interventions is conducted in some form or the other, although the importance given to different domains of decisions differ by markets. The research is aimed to analyse how perspectives on value assessment of pharmaceuticals or device interventions vary across regions. The research also analysed how products at launch increase the chances of approval, shorten time to reimbursement and remain competitive within the value based pricing agenda. **METHODS:** The research involved desk research as well interviews with key influencers and decision makers in major markets beyond Europe. More than 25 telephone or face to face interviews with key stakeholders were conducted. **RESULTS:** The research indicated that most countries, other than those that use international price referencing for setting prices use some form of value assessment method before fixing the reimbursement level and price of the product. The decisions are predominantly based on level of unmet needs, severity of diseases, level of innovation, clinical differentiation of the new product against its comparators and how well the product finds it natural place in the treatment pathway. Many forward regions claim to use value based assessments to set the price of new launches, most operate within boundaries. In principal value based pricing should not be fenced with limitations such as cost/QaLY thresholds, budget impact and price-volume agreements. However in real life these measures are common in markets all over the world, the main reason being the limitations in health care budgets. **CONCLUSIONS:** It is very challenging to reward products based on their intrinsic value without introducing other hurdles within the current economic environment. However it also is critical to reward innovation for future investments in R&D of new drugs. Health care reforms in the future will raise the bar of innovation and differentiation making it more challenging for the Pharmaceutical industry and all those involved in developing new medicines.

PHP36

PERCEPTIONS OF POLICY MAKERS AND SCIENCE ADVICE BODY STAFF ON SCIENCE ADVICE IN HEALTH IN EUROPE

Conde Espejo P, Palma Ruiz M, Sarria-Santamera A, Segovia C
Instituto de Salud Carlos III. Ministry of Science and Innovation, Madrid, Spain

OBJECTIVES: EuSANH is a network of science advisory bodies in Europe. The project Eusanh-ISA is funded by 7th framework programme of DG Research. It aims to improve the quality, effectiveness and efficiency of science advice for health across Europe. Within this project the objective of this work is to learn about the perceptions of policy-makers (PM) and science advise bodies' (SAB) staff concerning the relationship between these two groups, and the current use of science advice (SA) in policy making. **METHODS:** Two questionnaires were designed targeting both PM involved in developing health policy (such as government ministers, officials and senior public servants within national and/or local health services) and senior staff with extensive experience working in a SAB. The questionnaire was sent to 25 PM and to 29 SAB staff. Descriptive analysis was carried out. **RESULTS:** Nineteen PM (3 Belgium, 1 Czech Republic, 1 Lithuania, 2 the The Netherlands, 2 Poland, 1 Romania, 5 Spain, 3 Sweden and 1 UK) and 25 SAB staff (1 Belgium, 1 Czech Republic, 1 Italy,1 Lithuania, 4 the The Netherlands, 1 Poland, 3 Romania, 11 Spain, and 2 from Sweden) responded the questionnaire. Factors seen as barriers for the relationship between PM and SAB are the differences in timing, interest, and difficulties to translate policy problems into research questions. The communication was seen as informal. PM and SAB considered that usefulness of SA could be improved with more clarity, brevity, simplicity and concise reporting. Transparency, independency, existence of procedures to adequately deal with conflict of interest, rigor and systematization of knowledge are factors ranked with highest value. **CONCLUSIONS:** Proposals to improve the SA process are "organising regular high level meetings" and "improve the trust between decisors and researchers".

PHP37

REGIONAL DRUG EVALUATION IN SPAIN: A COMPARISON AMONG COMMITTEES

Hernández-Pastor LJ[1], Huerta A[2]
[1]*Glaxosmithkline, Tres Cantos, Madrid, Spain,* [2]*GlaxoSmithKline, Tres Cantos, Madrid, Spain*

OBJECTIVES: Fifteen committees currently undertake drug evaluations at the regional level in Spain that serve as the basis for pharmaceutical policy decisions within primary care or specialized care above single hospitals. The objective of this study was to examine the quality of the assessment procedures under which drug evaluations are undertaken by these regional committees. **METHODS:** We analyzed the quality of the assessment procedures on the basis of 4 criteria: whether operating procedures (OP) are public, whether there is dialog with the marketing authorization holder (MAH) during the assessment, whether drug assessments are public, whether a full economic evaluation (EE) (i.e. costs and health outcomes are taken into account) is undertaken. We reviewed all the public information regarding OPs and drug assessments undertook by these committees. Search was conducted in Google, official bulletins and official Regional Health Systems websites, with no limits. **RESULTS:** In primary care, 2 out of 8 committees follow a public OP when assessing a new drug and explicitly have interaction with the MAH during the assessment. All the committees publish their assessments but none of them undertake full EEs (e.g. only drug costs are considered). Within specialized care 3 out of 7 committees follow a public OP, 2 of which interact with the MAH. 3 committees publish their assessments and also 3 undertake full EEs. Overall 33% of committees follow a public OP, 27% have interaction with the MAH during the assessment, 73% publish their assessments and 20% undertake a full EE. **CONCLUSIONS:** There is room for improvement in the work undertaken by regional drug evaluation committees regarding transparency of OPs, dialog with the MAH and use of EE as a tool for informing decision making.

PHP38

MARKET ACCESS FOR PHARMACEUTICALS IN UK: NUMBER AND SPEED OF DRUG REVIEWS TO IMPROVE AFTER INTRODUCTION OF VALUE BASED PRICING

Izmirlieva MA[1], Ando G[2], Bharath A[2]
[1]*IHS Global Insight, London, UK,* [2]*IHS, London, UK*

OBJECTIVES: This study seeks to evaluate the impact on market access for pharmaceuticals in the UK following the introduction of Value Based Pricing (VBP). **METHODS:** SMC advice and final NICE guidance issued between 1 June 2010 and 31 May 2011 were assessed to determine the number and outcome of total appraisals, of Single Technology Appraisals (STAs), and of appraisals based on a manufacturer submission. The current duration of a NICE STA review and the time required to provide guidance under the NICE Scientific Advice Programme were also reviewed. **RESULTS:** Under VBP, all new originator drugs entering the market and all new indications of existing medicines will be reviewed: as is the case currently in Scotland. Over the 12-month period, the SMC reviewed a total of 101 new drugs or indications, of which 18 were resubmissions, so a total of 83 original reviews were performed. NICE – which only reviews treatments it is commissioned to review by the DH – conducted 28 STAs. Some 47% of SMC drug reviews resulted in positive guidance – rising to 58% among reviews based on a manufacturer submission. The average length of a NICE technology appraisal is 18 months; however, NICE scientific guidance can be provided in as little as 15 weeks. **CONCLUSIONS:** Pharmaceutical market access in England and Wales will potentially improve following the introduction of VBP as more products are reviewed in a more timely manner. Three times more originator medicines or new indications will be reviewed in comparison to the number currently reviewed by NICE. The average duration of an appraisal under VBP could to be just 15 weeks – 19.2% of the time currently required. On the negative side, manufacturers would be expected to offer products at an acceptable price – calculated in accordance with yet-to-be-finalised criteria – in exchange for gaining reimbursement.

PHP39

TOWARD A BETTER DRUG PRICING POLICY IN KOREA: LINKS BETWEEN PRICE REGULATION AND R&D ACTIVITIES

Jo C
Hallym University, Chuncheon, Kangwon-Do, South Korea

OBJECTIVES: Many countries have to face policy dilemma between cost containment policy and industry policy which may encourage pharmaceutical firms in terms of R&D. This study is trying to investigate the following issues: firstly, it tries to figure out the major determinants of R&D investment of pharmaceutical firms. Secondly, it compares the effects of those determinants on R&D intensity between U.S. and the rest of the world. **METHODS:** Using a 10 year panel dataset extracted from several sources such as Compustat, KISINFO, PhRMA, and JPMA, this study empirically investigates whether US pharmaceutical market which is relatively unregulated has higher profitability and cash flows than its counterparts where drug prices are regulated by government agencies. Employing OLS, random-effects, and fixed-effects specifications for established R&D investment models from the literature, the study tries to explore the links between pharmaceutical price regulation and firm R&D investment intensity. **RESULTS:** Data from 32 major pharmaceutical firms have been collected for the years 2000 through 2009, and several models of the determinants of R&D investment were estimated. The regression results show that expected profits and lagged cash flows are principal determinants of firm R&D-to-sales ratios. It has been argued that pharmaceutical price regulation influences R&D investment through both of these channels, resulting in an expected-profit effect and a cash-flow effect. The former influences R&D contemporaneously while the latter effect operates with at least 1 year lag. From a comparison of effects on R&D intensity, U.S. has about 4 or 5 times higher profitability effect than non-U.S. where pharmaceutical price regulation is so strictly implemented. **CONCLUSIONS:** A slower R&D growth as a consequence of price regulation may be politically acceptable because current consumer can benefit, but we can predict that the cost to the future generations is substantial.

PHP40

PERCEPTION STUDY OF UNDERGRADUATES TOWARDS MEDICINES – A SURVEY

Udupa N[1], Dharmagadda S[2], Ligade V[2], Muragundi PM[2]
[1]*Manipal University, Manipal, Karnataka State, India,* [2]*Manipal College of Pharmceutical Sciences, Manipal, India, India*

OBJECTIVES: To know the perception of undergraduate students about various aspects (Cost, quality and safety) of over-the-counter and prescription medicines. **METHODS:** Structured, non-disguised, pretested self-administered questionnaire was used for the study. The total sample was 200 undergraduates (Group 1 – 100 science graduates and Group 2 – 100 arts graduates). 't' Test was used to analyze the data. **RESULTS:** Most of the science graduates (78%) have expressed the cost of medicines were affordable and feel appropriate. They expressed Research and Development and manufacturing requires huge money and time, hence the cost. On the quality front, most of the respondents (68%) were satisfied. However, as far as safety is concerned, many respondents (79%) have expressed that they are safe as they pass through several phases of clinical trials. They were in an opinion that over-the-counter medicines are safer than the prescription medicines. Whereas most of the arts graduates (84%) have said that cost of medicines are higher and were not having any idea about the research, development and manufacturing costs involved. Many respondents (87%) said that quality is just acceptable. Quite a few respondents (69%) said that medicines are not safe and have to be taken with caution, whether it is over-the-counter or prescription medicines. **CONCLUSIONS:** Significant differences were noted between two groups of respondents. Sciences graduates feel the cost charged on medicines is appropriate, are of right quality and often safe. Whereas arts graduates were affirmative to quality and safety aspect but were in opinion that costs charged on medicines are higher.

PHP41

IMPROVING USE OF MEDICINES IN THE COMMUNITY THROUGH INTERVENTIONS

Mandal SC[1], Mandal M[2]
[1]*Directorate of Drugs Control, Suri, West Bengal, India,* [2]*J.C.Ghosh Polytechnic, Kolkata, West Bengal, India*

OBJECTIVES: It has been reported that 50-65 % of the Indian population has no access to essential medicines, whereas a small portion of the population using medicines, do so irrationally and unnecessarily. Irrational use of medicines leads to wastage of national wealth and also emerging Adverse Drug Reactions (ADRs) and developing resistance to some drugs especially antibiotics. In order to improve the situation, several interventions have been suggested. One such intervention is promoting the concept of Rational Use of Medicines (RUM) through conducting workshops and seminars involving all stake holders in the health care system. This study was conducted to determine the effect of an intervention on drug use pattern in a community. **METHODS:** Study was conducted in the semi urban areas covering three districts of West Bengal, India. Community pharmacies mainly serving the prescriptions of private practioners were involved in this study. Prescriptions were collected from community pharmacies, serving prescriptions of private practitioners in a semi urban area within a month. 30 prescriptions each from 10 pharmacies were collected from the area where workshop/seminars were conducted during the last two years. 30 prescriptions each from 10 pharmacies were collected where no such workshop/seminars were organized for the past two years. **RESULTS:** Results show that the average number of medicines prescribed per encounter reduced from 2.84 to 2.18. % of prescriptions for generics improved significantly from nil to 22.78. % of prescriptions for antibiotics and vitamin tonics reduced significantly, i.e. from 54.33 to 34.66 and from 16 to 12 respectively, % of prescriptions for injections reduced from 3.66 to 0.33 .Average number of FDCs reduced from 1.13 to 0.55. **CONCLUSIONS:** It reveals from the result mentioned above that medicine use indicators have improved significantly by intervention i.e. disseminating information on rational use of medicines amongst the stake holders of a health care system.

PHP42

DRUG CONSUMPTION IN BOSNIA AND HERZEGOVINA - COMPARISON TO NEIGHBORING COUNTRY

Krehic J[1], Gavrankapetanovic F[1], Djapo M[2], Agic N[3]
[1]*Clinical Center University of Sarajevo, Sarajevo, Bosnia,* [2]*Health Insurance Fund, Canton Sarajevo, Sarajevo, Bosnia,* [3]*Federal Health Insurance Fund, Sarajevo, Bosnia*

OBJECTIVES: To identify differences in drug consumption in two neighbouring countires, B&H with decentralized HC system and Croatia with centralized HC system. **METHODS:** In this research we have studied 12 reimbursement lists in B&H and 1 in Croatia. In 2009, in B&H, the total drug consumption was 467 mBAM, or 37.6% of drug consumption in the same year in Croatia (43.6% if adjusted for number of inhabitants, and 37.9% if adjusted for VAT and number of inhabitants). All drugs were included in the analysis irrespectively of the co-payment and prescription status (retail or hospital) and were grouped based on ATC level 3 and INN. Top ten ATC 3 groups with highest expenditure in 2009 were identified and cross referenced with top ten in HR. For these groups BH spent 45% of its combined medicine budget and HR spent 37%. **RESULTS:** The most significant differences in the share of relevant ATC 3 group in the total drug expenditure were observed for antihypertensive drugs: C09B (5,9% BH; 3,0% HR), C09A (4,6% BH; 2,5% HR), anxiolytics: N05B (3,4% BH; 1,0% HR) and beta-lactam antibiotics: J01C (3,2% BH; 1,5% HR). High share of drug expenses related to C09B and C09A groups can be explained by very high cardiovascular mortality rate, causing 2,5 time more deaths each year than malignant diseases. In BH we also observed very low consumption share of statins C10A (2,0% BH; 4,5% HR) and antipsychotics N05A (1,8% BH; 3,7% HR). In spite of restrictive policies regulating availability of oncology medicines to patients, we did not observe significant difference in L01X (4,3% BH; 5,2% HR).

CONCLUSIONS: Cardiovascular diseases are still leading cause of death in BH, so we suggest deeper analysis of all guidelines, programs and interventions focused to decreasing CV mortality and making Government(s) expenditure in CV drugs more efficient.

PHP43

INTRODUCTION OF A PRESCRIPTION CHARGE ON THE COMMUNITY DRUG SCHEME IN IRELAND – WHAT IMPACT HAS IT HAD ON DRUG UTILISATION?

Usher C[1], Bennett K[2], Barry M[1]
[1]National Centre for Pharmacoeconomics, Dublin, Ireland, [2]Trinity Centre for Health Sciences, Dublin, Ireland

OBJECTIVES: In October 2010, the Irish healthcare payer (i.e. the Health Service Executive, HSE) introduced a €0.50c charge on all prescription items dispensed under the General Medical Services (GMS) scheme, the largest of the community drug schemes in Ireland covering approximately 40% of the population. We investigated whether this charge was associated with changes in drug utilisation. **METHODS:** Monthly prescription dispensing was analysed from September 2009 to September 2010 (pre-intervention period) and then from November 2010 to March 2011 (post intervention period). In addition to utilization (prescription items) and cost information the database classifies drugs according to whether they are generic, off-patent or patent. The volume of drugs dispensed in each class was calculated and trends in utilsation and expenditure from the pre intervention period were compared with those in the post intervention period using segmented regression analysis. All analyses were performed using SAS (v9.1, SAS Institute Inc. Cary, US). Statistical significance at $p<0.05$ is assumed throughout. **RESULTS:** No effect was noted following the introduction of the prescription charge on prescription items in the post intervention period. A decrease in ingredient cost was noted however, for generics in the month post the intervention ($p<0.01$). A change in the overall trend for ingredient cost of off-patents was noted also in the post intervention period ($p<0.05$). The intervention had no significant effect on utilization and expenditure of patented medicines. **CONCLUSIONS:** The study findings suggest that the recent introduction of a prescription charge has had no significant effect on utilization of prescription medicines, while decreased expenditures could be attributed to changes in the pricing mechanisms for generics and off-patents occurring around this time. Further analysis is warranted to determine if the effect on utilization is sustained over time.

PHP44

INAPPROPRIATE PRESCRIPTIONS BASED ON BEERS CRITERIA IN ELDERLY PATIENTS TREATED AT HOME

Imai H[1], Nakao H[2], Sata F[2]
[1]National Institute of Public Health, Wako-shi, Saitama-ken, Japan, [2]National Institute of Public Health, Wako-shi, Japan

OBJECTIVES: Various studies have been performed on potentially inappropriate medications (PIM) in the elderly. In developed countries, Beers criteria or Zhan criteria are widely utilized. We developed a Japanese version of Beers criteria and are using it in clinical practice. Almost no epidemiological surveys have been performed on PIM in Japan. However, it is clear that dangerous prescriptions including unnecessary and multidrug prescriptions are often written. The objective of this study is to clarify the prevalence of PIM in elderly people 65 or older treated at home. **METHODS:** The subjects were elderly people 65 or older under home care in the Tokyo area who were prescribed drugs in routine practice. The survey was conducted in 300 randomly sampled pharmacies. The survey forms were distributed to the pharmacists by mail. After the pharmacists entered the drug prescription information, they returned the forms by post. **RESULTS:** Replies were obtained from 130 pharmacies (recovery rate: 43.3%). The 84 patients included 30 men and 54 women with a mean age of 82. Medical conditions included hypertension (56%), cognitive impairment (21.4%), ischemic heart disease (16.7%) and diabetes (11.9%). Drugs prescribed based on the Japanese version of Beers criteria accounted for 52.4% and included famotidine (30%), digoxin (5%) and ticlopidine (3.3%). Drug types included peptic ulcer drugs (48.3%), vasodilators (8.3%) and anti-Parkinsonism agents (6.7%). **CONCLUSIONS:** In the first epidemiological survey on PIM in the elderly undergoing home care in Japan, PIM were evident in 52.4%, a high percentage compared data on PIM to date. Peptic ulcer drugs were the most common and prescriptions of ticlopidine were also high when compared with other countries. This survey had several limitations such as being limited to Tokyo and relatively few subjects. In the future, we hope to perform a survey with greater precision in more subjects in the future.

PHP45

PREDICTABILITY OF PHARMACEUTICAL SPENDING USING CLINICAL RISK GROUPS IN THE VALENCIAN COMMUNITY IN VALENCIA

Uso Talamantes R[1], Caballer Tarazona M[1], Buigues Pastor L[1], Trillo Mata JL[1], Guadalajara Olmeda N[2], Vivas Consuelo D[2]
[1]Conselleria de Sanidad, Valencia, Spain, Spain, [2]Universidad Politecnioca de Valencia UPV, Valencia, Spain, Spain

BACKGROUND: The Valencian Community, with 5,000,000 inhabitants, is implementing a system of pharmaceutical management to reduce costs. This system is based on classifying patients in groups using the case mix system, Clinical Risk Groups. An electronic tool has been developed based on www to manage patients with chronic conditions and monitor pharmaceutical expenditure in primary health care. GPs receive a report on the real pharmaceutical cost that is being incurred and the optimum cost adjusted by CRG. **OBJECTIVES:** To evaluate the predictive ability of the Clinical Risk Group System in predicting pharmaceutical expenditure in the Valencian Community. **METHODS:** We ran a generalized linear model to examine the predictive validity of the CRG system and report the correlation between the predicted and observed expenditures. We reported mean predictive ratios across medical condition and cost-defined groups. **RESULTS:** The CRG system predicted pharmaceutical expenditure with precision, excepting for groups 8 and 9 of ACRG3. A new weight adjusted model has been developed to better fit pharmaceutical expenditure in primary health care to the real situation in Valencia. **CONCLUSIONS:** In order to use the CRG system to estimate pharmaceutical expenditure in primary health care, the groups of greater clinical risk must be weight adjusted, as the pharmaceutical consumption of these groups is hospital-based.

PHP46

MARKET UPTAKE OF ORPHAN DRUGS – A EUROPEAN ANALYSIS

Picavet E[1], Cassiman D[2], Simoens S[3]
[1]Katholieke Universiteit Leuven, Leuven, Vlaams-Brabant , Belgium, [2]University Hospital Leuven, Leuven, Vlaams-Brabant , Belgium, [3]K.U. Leuven, Leuven, Belgium

OBJECTIVES: The principle of equitable treatment establishes that everyone has the right of access to preventive health care and the right to benefit from medical treatment. Variations in market uptake of orphan drugs have important implications with respect to access to care and inequality of treatment. Therefore, the aim of this descriptive study is to examine the uptake of orphan drugs in Europe. **METHODS:** We analyzed both the sales and volume uptake from 17 orphan drugs in 24 European countries from 2001 until the beginning of 2010 using the IMS Health database. Countries were clustered based on differences in demographics, gross domestic product (GDP) and patent protection law. **RESULTS:** This study shows that there is a difference in the uptake of orphan drugs across European countries. Not only does the number of orphan drugs launched differ, the sales on orphan drugs and the share of orphan drugs sales on total market sales also vary strongly. Additionally, the volume uptake and the share spent on orphan drugs during the first year after the launch are highest in countries with high GDP and strong patent laws. **CONCLUSIONS:** The uptake of orphan drugs could be promoted through a variety of mechanisms such as the harmonization of European patent laws, the implementation of conditional reimbursement mechanisms, and the introduction of non-binding EU scientific assessment reports on the clinical added value of orphan drugs.

PHP47

EVALUATION OF GENERAL PUBLIC'S EXPENDITURE ON HEALTH PRODUCTS

Alhaddad MS[1], Hassali MA[2], Maghrabi I[3]
[1]Taif University, Taif, Saudi Arabia, [2]Universiti Sains Malaysia, Penang, Malaysia, [3]Taif Universiy, Taif, Saudi Arabia

OBJECTIVES: Most countries including Malaysia are facing escalating healthcare expenditures. The purpose of this study was to evaluate general public's expenditure on health products. **METHODS:** A cross-sectional study using convenience sampling technique was used in this study. 800 questionnaires were distributed to the general public in the state of Penang Malaysia. All data were analysed using descriptive and appropriate inferential statistics at alpha value of 0.05. **RESULTS:** A total of 56.73% of total 704 respondents felt that branded medicines were expensive or moderate, while 56.53% of them felt that the cost of generic medicines were moderate. In terms of private market, the costs of health products sold in community pharmacies were perceived to be cheaper as compared to private clinics and private hospitals. The mean of monthly expenditure per household on moderns medicines, vitamins and non-herbal health supplements, and herbal products were RM 171.80, RM 125.41 and RM 61.03, respectively (1 USD = RM3.30). Respondents' age, gender, race and income were found significantly affecting on patients' responses. **CONCLUSIONS:** This study has highlighted the need to control the medicines prices in the private market especially in private clinics and private hospitals. There is a need to promote generic products and to educate patients about the evidence based medicine since a good proportion of their income is monthly spent on herbal products.

PHP48

CROATIAN PHARMACEUTICAL EXPENDITURE BEFORE AND AFTER HEALTHCARE REFORM – COMPARISON TO EU COUNTRIES

Pogorilic S, Vitezica P, Bolanca S
CARPC (Croatian Association of Research Based Pharmaceutical Companies), Zagreb, Croatia

OBJECTIVES: To assess the impact of pharmaceutical part of the health care reform in Croatia as compared with trends observed in EU countries. **METHODS:** Detailed historical pharmaceutical expenditure was analysed using MIDAS, an IMS Health proprietary database, as well as a variety of other published secondary data sources. Croatian trends have been compared with those of a number of benchmark countries, categorised either as Peer Countries (Slovakia, Czech, Hungary) and Aspirational Countries known to have systems that have been ensuring excellent health care outcomes (France, The Netherlands, Austria). **RESULTS:** Although total health expenditure in Croatia, as percentage of GDP is at EU level (7.8%), total pharmaceutical spend per capita is very low, 128€, with more than 80% coming from public funding. Pharmaceutical expenditure is not driving the overall health cost growth; in fact, pharmaceutical spend as a % of total health expenditure has been declining since 2003. The complex set of cost containment measures, including limitation of GP's prescriptions, imposed by Croatian Health Insurance Institute is the likely cause of this trend. The most relevant finding of this study is that Croatia has been historically very low in drug use in terms of 'volume per capita' compared to benchmark countries. In 2010 Croatian patients consumed approx. 20-25% less prescription medicines per capita than the average of peer and aspirational countries. **CONCLUSIONS:** If the observed trends are allowed to continue, it will be difficult for Croatia to keep pace with its peers in providing adequate phar-

maceutical health care standards and outcomes. Without close monitoring of key health care indicators and outcomes, volume (prescription) limitations introduced by the recent Healthcare Reform can have adverse and inevitable long term impact.

PHP49

THE PHARMACIST'S PERCEPTION OF THE SPLITTING EXTENDED RELEASE AND ENTERIC-COATED FORMULATION DRUGS

Jang HM, Lee EK
Sookmyung Women's University, Seoul, South Korea

OBJECTIVES: Extended release and enteric coated formulations make up 7.8% of all drugs, and the most frequently used drug is an agent affecting circulatory, digestive system. The objective of this study is to analyze of extended release and enteric coated drugs on pharmaceutical reimbursement item list in Korea and evaluate the dispensing of extended release and enteric coated drugs, which is enforced by the National Health Insurance. **METHODS:** The analysis used a questionnaires survey for 169 pharmacists in the hospital pharmacy and community pharmacy(Response rate: 73.8%). The questions include; prescribing change after enforcement by National Health Insurance, prescription correction, change of pharmacy works, expansion of the range of enforcement, provision of information and prescribing error prevention. The statistics methods use Chi-square, AVOVA, t-test, McNemar test by STATA/SE10.($p<0.05$). **RESULTS:** Of extended release and enteric coated formulations, 33.9% were not available in other dosage forms. After enforcement by National Health Insurance, the rate of splitting and crushing of extended release and enteric coated drugs decreased, but pharmacies in tertiary care hospitals had increased workload because of prescription corrections. Prescription was not changed, because patients take medicines for a long time. Most of pharmacists agreed on the expansion of drug range, but 65.7% of pharmacists wanted the enforcement only for hospitals. When pharmacists corrected their prescribing error, the biggest problem was a lack of other dosage forms. To prevent extended release and enteric coated from splitting and crushing, pharmacists want in the following ways; prescribing code prohibits into order computer system, warnings and alerts on prescribing, developing many other dosage forms. **CONCLUSIONS:** What is needed are medication-use system improvements and the creation of lists with suggestions for alternative products on the formulary. Also, pharmaceutical companies should make an effort to develop other dosage forms.

PHP50

IRRATIONAL USE OF INJECTABLE FORM OF DEXAMETHASONE: A WARNING FOR HEALTH SYSTEM IN IRAN

Soleymani F[1], Haerizadeh M[2], Dinarvand R[3]
[1]*Tehran University of Medical Science, Tehran, Iran,* [2]*Minitry of Health, tehran, Iran,* [3]*Tehran University of Medical Sciences, Tehran, Iran*

OBJECTIVES: Irrational prescribing of injections is widespread in Iran. According to statistics of National Committee of Rational Drug Use (NCRUD), based on data from insured prescriptions, more than 40% of prescriptions have at least one injection in which injectable dosage form of dexamethasone is on the top of list. The aim of this study is to describe the prescribing pattern of dexamethasone in general practitioners' prescriptions from 2006 to 2009. **METHODS:** A retrospective cross-sectional study was done on insured prescription during 4 years. All insured prescriptions which were collected in special software called Rx Analyst during the study period in the NCRUD were reviewed for prescriptions included injectable dosage form of dexamethasone. **RESULTS:** A total of 150,630,381 Prescriptions were reviewed in which 73,808,887 were detected to be included at least one injection. Among prescriptions with injections, there were more than 30 percent of prescriptions which had at least one injection form of dexamethasone making it the first prescribed medicine by general practitioner. An overall increasing linear trend in prescribing pattern of injectable dosage form of dexamethasone was evident over the observation period. The percent of general practitioners' prescriptions which had injectable dosage form of dexamethasone is 15.46 in 2006, 15.93 in 2007, 16.64 in 2008 and 16.94 in 2009. **CONCLUSIONS:** Irrational prescribing pattern of dexamethasone injection is obviously determined according to the results of this study. It seems that general practitioners are trying to substitute pain relievers' drugs by injectable dosage form of dexamethasone. A multi-interventional policy is needed to correct the pattern use of dexamethasone.

PHP51

PILL BURDEN IN SOUTH AFRICAN PATIENTS WITH MULTIPLE RISK FACTORS FOR METABOLIC SYNDROME

Burger JR, Lubbe MS, Serfontein JHP
North-West University, Potchefstroom, South Africa

OBJECTIVES: Metabolic syndrome is a cluster of several common metabolic disturbances, including inter alia hypertension, hyperglycaemia and dyslipidaemia. Each of these risk factors requires multiple agents to reach desired therapeutic goals. The aim was to determine the average pill burden level in patients treated concurrently with antidiabetic-, antihypertensive- and lipid-lowering agents. **METHODS:** A retrospective, quantitative drug utilization review was conducted utilizing national medicine claims data obtained from a South African Pharmaceutical Benefit Management company for the period of January 1, 2008 to December 31, 2008. Average pill burden (AvPB) was calculated as the average number of tablets received per prescription over the study period divided by the number of days medication was supplied for. Combination products were counted once. As-needed-medication and other chronic medication were excluded from the analysis. Data for 17 866 patients were analysed using the SAS for Windows 9.1® programme. **RESULTS:** Patients had an overall AvPB of 2.7±1.20 per prescription, with a rate of 2.8±1.21 among males (n = 9 632) vs. 2.6±1.18 for females (n = 8 234). Patients aged 0-15 years (n = 2) had an AvPB of 1.2±0.30 per prescription, vs. 2.3±1.49 for those aged 16-30 years (n = 53), 2.6±1.11 for those 31-45 years (n = 992), 2.8±1.18 for those 46-60 years (n = 5 768), 2.8±1.23 for those 61-75 years (n = 7 641) and 2.5±1.17 for those older than 75 years (n = 3 410). **CONCLUSIONS:** Metabolic syndrome patients are prescribed multiple drug therapies. Our results show that the average pill burden among private health care South African patients receiving antidiabetic-, antihypertensive- and lipid-lowering agents concurrently were the highest among men, and increased progressively with age to peak in those aged 61-75 years. Further studies are necessary to determine the influence of pill burden on adherence, drug interactions and treatment cost.

Health Care Use & Policy Studies – Equity And Access

PHP52

INEQUALITIES IN THE UTILIZATION OF HOME HOSPICE SERVICES IN HUNGARY

Turcsanyi K[1], Domján P[1], Pakai A[1], Gombos G[1], Ágoston I[2], Vas G[2], Molics B[2], Éliás Z[2], Kriszbacher I[2], Boncz I[2]
[1]*University of Pécs, Zalaegerszeg, Hungary,* [2]*University of Pécs, Pécs, Hungary*

OBJECTIVES: Hospice service appeared in 1991, when Hungarian Hospice Foundation was established. More and more hospice institutions were started their works in this period, which type was home care, palliative hospital ward and complex, which provides both of them. In our study we are analyzing the spatial distribution of Hungarian hospice service. **METHODS:** In 2008, number and activities of hospice service was examined and we have been drawn attention for financial data by our survey with data of National Health Insurance Fund and Central Statistics Office. We analyzed the county and regional distribution of hospice services. **RESULTS:** Thirty hospice care providers were reimbursed by the National Health Insurance Fund Administration in 2008. The total number of nursing days were 53,113 in Hungary. The number of nursing days per 10,000 populations showed a significant difference across the regions with a national average of 52.88 days: Western Transdanubian Region (86.64), Northern-Hungarian Region (83.84), Southern-Transdubian Region (81.28), Southern Great-Plain Region (77.31), Central-Transdanubian Region (59.62), Central Hungarian Region (32.23) and Northern Great-Plan Region (1.68). At county level we found similar within country differences with the highest value in Nógrád county (190.83 days/per 10,000 population) and the lowest in county Jász-Nagykun-Szolnok and Fejér (< 7 days/per 10,000 population). **CONCLUSIONS:** The regional differences in hospice care are high among Hungarian regions and counties. A further analysis is required to explore the reasons behind these huge differences.

PHP53

ASSESSMENT OF THE ATTITUDES OF THE GENERAL PUBLIC TOWARDS SUPPLEMENTARY CRITERIA TO BE USED IN P&R DECISION MAKING PROCESS IN POLAND

Kolasa K[1], Lees M[2]
[1]*Bristol-Myers Squibb, Warsaw, Poland,* [2]*BMS, Uxbridge , UK*

OBJECTIVES: To explore the attitudes of the general public towards the principle of QALY maximization in pricing and reimbursement decision-making process in Poland. **METHODS:** Cross sectional survey of a random representative sample of 1000 residents was preformed. Face-to-face interviews were conducted using a structured questionnaire. The final format of the questionnaire included refinements based on a pilot survey. Respondents rated statements concerning attitudes to equity on a Likert scale. Two hypothetical experiments were designed to elicit preferences for QALY maximization. In the first experiment, responders had to allocate a given limited budget to 400 patients with non-fatal disease, 100 patients with fatal disease, or a combination of patients with fatal and non-fatal disease. The QALY gain per patient was assumed the same for both groups. In the second experiment, responders prioritized a given treatment to either 100 patients with eight years or 100 patients with two years of baseline life expectancy. The survival gain per patient resulting from the new treatment was eight years for first group and varied from two to eight years for the second group. **RESULTS:** The study indicated strong support for the statements about equity (42% agreed and 44% strongly agreed). In the first experiment, 75% chose to allocate budget to both groups of which 50% preferred equal distribution. In the second experiment, if survival gain per patient was equal for both groups, 57% chose treatment for group with shorter baseline life expectancy. If survival gain per patient was larger for group with longer baseline life expectancy, 49% still chose treatment for group with shorter life expectancy. **CONCLUSIONS:** General support for statements expressing equity was confirmed by two experiments. Instead of QALY maximization, a significant group of responders took into consideration needs of both patients' groups irrespective of costs and disease severity irrespective of QALY gain.

PHP54

PREDICTORS OF AVOIDABLE EMERGENCY ROOM VISITS AMONG HIGH COST MEDICAID ENROLLEES

Ganduglia C[1], Franzini L[1], Dunn K[2]
[1]*University of Texas Health Science Center Houston, School of Public Health, Houston, TX, USA,* [2]*University of Texas Health Science Center Houston, School of Biomedical Informatics, Houston, TX, USA*

OBJECTIVES: Research has shown that Medicaid enrollees in the USA are the most frequent users of the Emergency Department (ED) services. Several studies have demonstrated that a high proportion of the ED visits could be avoided. The purpose of this analysis is to examine the demographic and health system delivery characteristics that are associated with avoidable ED visits (AEDV) among a high risk, high cost Medicaid population between 2008 and 2009. **METHODS:** One year claims dataset of a sample of high cost, high risk Medicaid enrollees in Houston, Texas was used for the analysis. This was design following the Andersen-Aday theoretical

framework for studying access to health care. ED visits were classified into avoidable or not using the New York University algorithm. Patient complexity was measured using the Chronic Illness Intensity Index (CI3), an index used to measure need of case management intensity. We performed logistic regression models to test for significant association between AEDV, and population at risk and health care delivery characteristics. **RESULTS:** We found that 69% (179) of our population had an ED visits during 2008-2009. Of these visits, 60% were classified as AEDV. The analysis showed that women were 33% less likely to have an AEDV per month. Age was negatively associated, with younger patients being more likely to have AEDV. More complex patients were 6.6% more likely to have an AEDV. For every extra physician a patient visited, the probability of having an AEDV per month increased by 2.4%, however this was not significant ($p = 0.06$) at 95% confidence interval. **CONCLUSIONS:** Among high cost, high risk Medicaid patients there are certain patient characteristics that can allow us to identify those at higher risk of having an AEDV. This information could be use to identify groups that would benefit from interventions to reduce ED utilization.

PHP55

A REVIEW OF THE NICE APPEALS PROCESS

Eaton JN[1], Hawkins N[2]
[1]*Oxford Outcomes Ltd, Oxford, Oxon, UK,* [2]*Oxford Outcomes Ltd., Oxford, UK*

OBJECTIVES: Formal systems of health technology appraisal (HTA) can directly inform resource allocation in healthcare systems and have contributed to the equitable and efficient allocation of such resources. To engender and maintain support from a wide range of stakeholders it is important that HTA systems are seen a socially just, particularly in the face of contentious decisions. Effective appeals processes, internal or judicial, can have an important role in meeting this goal, enabling stakeholders to directly question the evidence considered, its interpretation, and the decision making process. We conducted an empirical review of the results of all appeals made to the National Institute for Clinical Excellence (NICE) between the years 2000 and 2010, and consider whether NICE fulfills these requirements. **METHODS:** A retrospective review of all completed NICE technology appraisals published between March 2000 and October 2010 was conducted. Each technology appraisal was investigated for appeals. Published appeals were then categorized by appeal substance, stakeholder, and outcome. The results were presented as absolute numbers and proportions of overall responses. **RESULTS:** In this study 29% of appraisals resulted in a published appeal of which 41% were upheld. The most common ground for an appeal, 59% of total, was perversity of the decision, the main substance for those appeals was misinterpretation of the clinical or cost-effectiveness evidence. By proportion of appeals upheld the most successful appeal point was that the HTA did not meet the scope or was deemed to be inequitable. Appeals involving a professional body or patient group were also more likely to be successful. **CONCLUSIONS:** Examination of appeals to NICE would suggest that a socially just and effective appeals process is in place. Decisions are reversible and transparent and stakeholders can both participate in and question the decision process.

Health Care Use & Policy Studies – Formulary Development

PHP56

THE EMERGENT ROLE OF THE SPECIALIST PHARMACIST AS AN IMPORTANT STAKEHOLDER IN MARKET ACCESS

Edathodu AS[1], Ismail A[2]
[1]*Double Helix Consulting Group, London, UK,* [2]*Double Helix Consulting, London, London, UK*

OBJECTIVES: Over the last decade, specialist pharmacists across Europe have seen an emergent role in many areas of the healthcare pathway. This research examined four key domains - clinical, policy, education and research - of influence of specialist pharmacists with goal of understanding how they can impact market access of drugs. **METHODS:** Structured interviews with 25 specialist oncology pharmacists from EU5 exploring various aspects within the four identified domains of influence. **RESULTS:** A selection of the most important roles of the specialist pharmacist by domain is presented below: Clinical: 1) Coordinate safe and timely administration of drugs and supportive treatment; 2) Coordinate outpatient supportive care focusing on management of symptoms; and 3) Help develop treatment guidelines to ensure optimal use of supportive care medications. Policy: 1) Provide formulary review for new drugs, and 2) Facilitate reimbursement for a more efficient practice. Education: 1) Educate patients and members of the HC team about drugs and their expected side effects and management, and 2) Educate members of the public about prevention strategies and recommendation for screening and early detection. Research: 1) Conduct internal treatment protocol audits to optimise patient care pathway, and 2) Participate in institutional review board for approval of clinical trials as well as scientific review and monitoring committees. **CONCLUSIONS:** A cornerstone of market access is identification of important stakeholders within a health care economy with the goal of understanding the roles they play in the care pathway. The specialist pharmacist is an often overlooked, but increasingly important stakeholder in the European health care system. The multitude of roles played by the specialist pharmacist is in itself evidence of increasing importance of the role. Pharmaceutical companies will need to engage more closely with specialist pharmacists to ensure better patient outcomes through appropriate use of drugs leading ultimately to increased market access.

PHP57

CENTRALIZED DRUG ASSESSMENT IN CATALONIA: WHERE WE HAVE GONE SO FAR?

Paladio Duran N, Solà Morales O, Sunyer Carreras-Candi B, Almazán Sáez C, Elvira D
Catalan Agency of Health Information Assessment and Quality, Barcelona, Spain

OBJECTIVES: The Committee for the Assessment of Hospital Drugs, led by the Catalan Agency of Health Information Assessment and Quality, has provided evidence-based information to regional health care decision-makers in Catalonia about the added therapeutic value (ATV) of centralized approved drugs fit into the orphan or advanced therapies category or have conditional approval or were approved in exceptional circumstances. This study describes the committee's activity since its creation. **METHODS:** Systematic reviews of efficacy, safety and cost-effectiveness are conducted upon request from the Pharmacy Directorate and results are appraised by expert panels. **RESULTS:** A total of 22 drugs (24 indications) for an estimated population of 1.100 patients have been assessed. Most drugs were granted approval for two major therapeutic areas: onco/hematological (41%) and metabolic diseases (32%). Orphan designation had been given to 70% of all indications. Only 8 indications were given positive opinion based on 2 clinical trials. Most pivotal studies were randomized phase III trials and were considered to have moderate (63%) to high (25%) risk of bias. Placebo was the most frequent comparator in controlled studies but was only considered appropriate in half. Primary endpoint was a surrogate/intermediate endpoint in 94% of studies. Relevance of efficacy results was difficult to interpret due to design flaws, small samples and short-term follow-ups. Scarce or no data on effectiveness was available. Information on comparative safety was also scant and limited by short-term follow-ups. At time of assessment cost-effectiveness data was missing in 66% of the indications. Reported base-case incremental cost-effectiveness ratios from manufacturers ranged from 16.000-565.000€/QALY. **CONCLUSIONS:** Defining ATV of new entities at the time of introduction proved a challenge because of low quality studies and lack of information about relative effectiveness. Registers and/or risk-sharing schemes may be an alternative to gather more information new about drugs and establish their real ATV while facilitating access.

Health Care Use & Policy Studies – Health Care Costs & Management

PHP58

TOWARDS COST-EFFECTIVENESS ANALYSIS OF THE HEALTH AND WELLBEING BENEFITS OF URBAN GREEN SPACE: A MAPPING REVIEW

Harnan SE, Jorgensen A, Tsuchiya A, Goyder L, Woods HB
The University of Sheffield, Sheffield, South Yorkshire, UK

OBJECTIVES: Urban green spaces (UGS) are thought to impact on health and wellbeing. Cost-effectiveness analysis (CEA) can help to determine if provision or interventional use of urban green spaces can contribute to population health in a cost effective manner. This mapping review aims to characterise the study designs, independent variables, outcomes and outcome measures reported in the literature. **METHODS:** Key health and medical databases were searched. Studies of any design (except reviews) which attempted to value the health and wellbeing effects of UGS were included. One reviewer selected studies with a proportion checked by a second and third reviewer. Data were extracted from abstracts using a standardised form. Data were coded using a grounded theory approach and synthesised in graphical and tabular form. **RESULTS:** A total of 189 citations were included. The most common study design was cross sectional regression analyses; there were only three randomised controlled trials. Many putative independent variables were identified, including psychological, socio-economic, environmental and interventional variables. Settings and populations also varied. Outcomes coded as health behaviours included physical activity, visit frequency, nutrition and social interaction; those coded as health outcomes included general health, mental health, quality of life, wellbeing, mortality, obesity and cardiovascular indices amongst others. Outcome measures were generally not compatible with CEA. Amongst 61 economic studies, the most common study type was hedonic pricing. Only one limited CEA analysis was identified. **CONCLUSIONS:** Few randomised studies have been performed and available evidence would not allow a traditional CEA. Existing trials have limited external validity according to criteria normally used in health contexts. Current evidence may better lend itself to logic modelling, as the causal pathways are long and complex and green space is likely to act at both the individual and population level. To aid CEA, future research should carefully choose study design, outcomes and outcome measures.

PHP59

ESTIMATION OF INCREASES IN DIRECT MEDICAL EXPENDITURES ASSOCIATED WITH MEDICATION NONADHERENCE AND POTENTIAL SAVINGS FROM INCREASED ADHERENCE

Hicks KA[1], Karve SJ[1], Vlahiotis A[2], Frazee SG[2], Tian Y[2], Earnshaw SR[1]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*Express Scripts, Inc., St. Louis, MO, USA*

OBJECTIVES: We estimated increases in medical expenditures due to medication nonadherence and potential savings of increasing adherence for members of a prescription-drug benefit plan taking medications in four drug therapy classes (TCs). **METHODS:** We used data from the Medical Expenditure Panel Survey (MEPS) to estimate functional relationships between adherence and resource utilization for patients taking medications in four TCs. Resource use included all-cause and disease-specific annual hospitalizations and emergency room (ER) visits. TCs included depression, diabetes, high blood cholesterol (cholesterol), and high blood pressure or heart disease (heart). Adherence was estimated using the medication possession ratio (MPR). MPR less than 80% was considered nonadherence. Average medication expenditures, by TC, was obtained from a large prescription-drug database. Expenditures per hospitalization and ER visit were estimated from MEPS. Unit costs and functional relationships between adherence and resource use were applied to estimate annual resource use and medication expenditure. Increased expenditures due to nonadherence were estimated for nonadherent patients ver-

sus those with 80% adherence. Total expenditures considered expenditures from inpatient admissions, ER visits, and medications. Potential savings was defined as reduction in total expenditures due to increasing adherence. **RESULTS:** Nonadherence resulted in increased all-cause total expenditures in diabetes, cholesterol, and heart by $240 million (M), $150M, and $47M, respectively. Increasing adherence by 2% reduced increases in all-cause expenditure by 11% to 21%. Nonadherence resulted in increased disease-specific hospitalization and ER visit expenditure for depression ($6M), diabetes ($44M), and cholesterol ($5M). However, increases in the disease-specific hospitalization and ER expenditures were offset by lower medication expenditure, thus resulting in overall lower disease-specific expenditure among the nonadherent patients. Overall, increases in medication adherence resulted in savings in all-cause expenditure but not in disease-specific expenditure. **CONCLUSIONS:** Medication nonadherence can be costly to payers. Increasing adherence even by small amounts may result in significant savings.

PHP60

DRUG-RELATED MORBIDITY – MODELING THE COST-OF-ILLNESS IN SWEDEN USING PHARMACISTS' OPINION

Gyllensten H[1], Hakkarainen KM[1], Jönsson AK[2], Andersson Sundell K[1], Hägg S[2], Rehnberg C[3], Carlsten A[1]
[1]*Nordic School of Public Health, Gothenburg, Västra Götaland, Sweden,* [2]*Linköping University, and the County Council of Östergötland, Linköping, Östergötland, Sweden,* [3]*Karolinska Institutet, Stockholm, Stockholm, Sweden*

OBJECTIVES: The aim of this study was to estimate prevalence and preventability of drug-related morbidity in Sweden based on pharmacists' expert opinion. Furthermore, the aim was to estimate the cost-of-illness (COI) of drug-related morbidity. **METHODS:** Probabilities of therapeutic outcomes of medication therapy were estimated by an expert panel of pharmacists (N=29) using a two-round delphi-methodology and a conceptual model of drug-related morbidity based on a decision tree. We used an American conceptual model adjusted to the Swedish context. In the model, drug-related morbidity included new medical problems (adverse drug reactions, drug dependence and intoxications by overdose) and therapeutic failures (insufficient effects of medicines and morbidity due to untreated indication). The cost-of-illness analysis included all direct costs applying a health care perspective, using national statistics on costs. **RESULTS:** The expert panel estimated that 61±14% (mean ± SD) of all patients visiting health care suffered from drug-related morbidity, of which 29±8% suffered from new medical problems, 17±6% from therapeutic failures, and 14±7% from a combination of both types. Of patients with drug-related morbidity, 44±18% suffered from preventable drug-related morbidity. Participants estimated that 7-39% of patients with drug-related morbidity do not require further attention, but a majority requires health care resources due to the drug-related morbidity. The direct costs were calculated to EUR 575 (2009 value) per patient, which corresponds to an annual cost of EUR 4 billion to the Swedish health care system. The largest component in the COI of drug-related morbidity was hospitalizations, with 50% of the total cost. Advanced specialist care represented 20%, and prolonged hospital stay 11% of the resulting costs. **CONCLUSIONS:** Drug-related morbidity is perceived frequent and often preventable. The estimated health care costs for this morbidity are extensive, and comparable in magnitude to the cost of dispensed medicines in Sweden. Effective and cost-efficient methods to reduce the drug-related morbidity are needed.

PHP61

MODELING PHARMACEUTICAL COSTS IN PRIMARY HEALTH CARE ACCORDING TO CHRONIC CONDITIONS

Trillo-Mata JL[1], Guadalajara-Olmeda N[2], Barrachina-Martínez I[2], De la Poza-Plaza E[2]
[1]*Valencian Community Government. Health Department., Valencia, VALENCIA, Spain,* [2]*Universitat Politècnica de València, Valencia, VALENCIA, Spain*

OBJECTIVES: Controlling pharmaceutical costs has been the subject of research and analysis in many studies in health economics which have shown that the chronic conditions of patients are an important factor. The present work models pharmaceutical expenditure by different health districts and gender according to the characteristics of chronic conditions. **METHODS:** An analysis was made of pharmaceutical expenditure between November 2008 and October 2009 of four health districts of the Autonomous Valencian Government, with an assigned population of 625,246. Those who had followed treatments for chronic conditions were identified associating the pharmaceutical groups (ATC codes) with 24 chronic conditions, according to electronic prescription data. Multivariate regression analysis was used, where the pharmaceutical expenditure in primary health care was explained through the gender, pharmaceutical co-payment status and the number of chronic conditions, varying from 1 to 8 or more. **RESULTS:** The percentage of patients with chronic conditions obtained was of 27.82%, who constituted 58.2% of the total pharmaceutical cost. Pharmaceutical co-payment status was excluded from the model due to its high correlation with the number of chronic conditions. The goodness of fit obtained for explaining the expenditure of the whole population was of 57.2%. The models obtained by health district explained between 56.5 and 60.6%, improving in the models obtained solely for the male population, where they reached 62% for one of the districts studied. Men's pharmaceutical expenditure was the 68.31% of women's. However, the number of chronic conditions has a greater impact on men's pharmaceutical expenditure than women's. **CONCLUSIONS:** Although for the whole population the proposed model explained the 57.2% of the pharmaceutical expenditure, differences can be observed between models obtained for each district or for gender. These models may be more suitable than the general model for cost management and establishing incentives for general practitioners in the different districts.

PHP62

ESTABLISH DRUGS OPTIMAL PURCHASE MODEL

Chang YT[1], Chang TH[1], Chien HY[1], Tai SW[2], Chuang CH[2]
[1]*Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan, Taiwan,* [2]*Taipei Medical University, Taipei, Taiwan, Taiwan*

OBJECTIVES: Taipei Medical University Shuang-Ho Hospital officially opened on July 1, 2008. Due to limited revenue during the initial period, hospital emphasized more on cost control. With the great demand of medication from the growing numbers of outpatients visits and inpatients, pharmacy aim to establish an optimal purchase model to minimize drug inventory management cost. **METHODS:** Economic Order Quantity (EOQ) model were applied to find out the best quantity and frequency on medication purchase order. We analyzed the high-cost medications in which the top 50% of cumulative drug cost in year 2010, and intravenous antineoplastic drugs were excluded. **RESULTS:** The study evaluate drug cost, labor cost and inventory cost. Forty-six high-cost medications were selected to determine EOQ model in this study. The optimal frequency to order each drug estimated by EOQ model was three to ten times per month. The estimated cost of inventory management reduced substantially when order more frequently within 10 times a month. However, after considering the practicability in real practice, the order frequency was adjusted to one to four times per month. The best estimated quantity for each drug was also adjusted by previous fluctuation of purchase orders during 2010. Therefore, the estimated inventory management cost in year 2011 could reduce 500,000 to 700,000 NTD **CONCLUSIONS:** Our inventory management currently purchase drug twice a month. In order to optimize inventory turnover rate, without increasing pharmacists work loading and management cost, we recommend adjusting quantity and frequency of ordering medication based on our finding to achieve the minimal and rational cost on inventory management.

PHP63

SAVINGS ON PHARMACEUTICAL EXPENDITURE IN GREEK NHS HOSPITALS UNDER THE SHADOW OF THE INTERNATIONAL MONETARY FUND (IMF)

Karapanos N[1], Androutsou L[1], Dede Z[1], Geitona M[2]
[1]*Ministry of Health and Social Solidarity, Athens, Greece,* [2]*University of Peloponnese, Athens, Greece*

Due to the financial crisis, Greece was forced by the International Monetary Fund and the European Community (Troika) to implement cost containment measures in the health care sector. **OBJECTIVES:** The objective of the study is to present the measures taken in order to control and reduce the pharmaceutical expenditure in all NHS hospitals and evaluate the respective savings emerging in 2010. **METHODS:** The data derive from the Ministry of Health and Social Solidarity (MoH) database, covering all NHS & IKA hospitals operating in the 7 Regional Health Authorities (RHA) of Greece. Data compare the NHS hospital pharmaceutical expenditure between 2009 and 2010. **RESULTS:** Numerous cost-containment measures have been gradually implemented in all NHS hospitals according to the IMF and MoH guidance, targeting at: 1)creation of NHS database network (esy.net); 2)transfer of the pharmaceutical pricing regulation from the Ministry of commerce to the MoH; 3)unification of the NHS electronic coding system, for ordering and prescribing of pharmaceuticals; 4)hospital packsize; 5)electronic patients files; and 6)increase in the use/penetration of generics & off patent medicines. Although the above measures are still not fully implemented, they reduced hospital pharmaceutical expenditure by 10.51%, from €1.466 million in 2009 to €1.312 million in 2010. At regional level, savings ranged from 8% in the 2nd RHA (covering Pireaus & islands) up to 16% in 6th RHA (Peloponnese & Western Greece). Moreover, in the 1st RHA covering the highest share of NHS hospitals of pharmaceutical expenditure was reduced by 15%. **CONCLUSIONS:** The new cost containment measures implemented in Greek NHS hospitals started presenting results by fulfilling the savings imposed by IMF & Troika). The same picture is presented in the overall HC sector, hospitals & social security funds. The goal of €350million savings by the NHS hospitals seems to be able to be achieved by the end of 2011.

PHP64

REORGANISATION OF HOSPITAL EMERGENCY SERVICES: A BUSINESS CASE FOR QUALITY IMPROVEMENT

Eichler K[1], Senn O[2], Rüthemann I[1], Bögli K[3], Sidler P[3], Brügger U[1]
[1]*Winterthur Institute of Health Economics, Zurich University of Applied Sciences, Winterthur, Switzerland,* [2]*Institute of General Practice and Health Services Research, University of Zurich, Zurich, Switzerland,* [3]*Stadtspital Waid, Zurich, Switzerland*

OBJECTIVES: In Switzerland, emergency care has no gatekeeping system and emergency wards are increasingly overcrowded by walk-in patients. This leads to inefficient use of spezialised resources. Treatment costs are paid by public sources and, beyond some co-payment, reimbursed by health care insurances via tariffs. Given the problems above, a public hospital (Stadtspital Waid; Zurich; catchment population 180'000 people) reorganised its emergency service in 2008. A nurse led triage system and a General Practitioner-led emergency service was implemented beside the conventional emergency ward. To better understand the impact, we assessed quality of service provision and total treatment costs. **METHODS:** From the public payer perspective, we compared annual treatment costs for ambulatory emergency care in 2007 with 2009. In a pre-post study, all consecutive ambulatory emergency patients were included during one month in each year. Treatment costs (CHF) were calculated (e.g. nursing time multiplied with wages) and extrapolated to one year. Waiting times and patient satisfaction were used as indicators for service quality. Clinical outcome was not directly measured. **RESULTS:** The annual number of ambulatory patients increased from n=10'440 (2007) to n=16'035 (2009). Service provision improved with reduced waiting times (mean: 120 min vs. 60 min), persistently high patient satisfaction and more efficient resource use (additional diagnostic testing: 71% vs. 56%). Comparison of the annual local budget spent for

treatment of 16,035 patients in 2009 (7,150,000 CHF; new service) with 2007 (7,184,000 CHF; old service, adjusted to 16,035 patients) showed slightly reduced costs (-34,000 CHF; 95%-CI: +60,000 to -127,000). **CONCLUSIONS:** The cost reduction of 0.5% is a conservative estimate as wages have increased since 2007. The reorganisation has the potential to be a dominant intervention: While quality of service provision improved, treatment costs slightly decreased against the secular trend of increase. Data has to be confirmed in follow-up measurements for decision makers.

PHP65

PHARMACEUTICAL EXPENDITURE IN PORTUGAL – POLICIES AND IMPACT

Teixeira I, Mendes Z, Ribeiro S, Costa S
Centre of Health Research & Evaluation (CEFAR), Contract Research Organization (CRO) National Association of Pharmacies (ANF), Lisbon, Portugal

OBJECTIVES: The Stability and Growth Pact approved by the Portuguese Government in 2010 limits the expenditure growth in 1% for reimbursed pharmaceuticals in outpatient sector. The Memorandum of Understanding signed in May 2011 between the Government and the International Authorities subsequently has increased the requirements to reduce public expenditure. Considering the pricing and reimbursement changes, this study aims to: 1) analyze public expenditure trends on medicines, and 2) identify the main factors and impacts. **METHODS:** We have analyzed the database sales and prescription data from Portuguese community pharmacies, and performed simulations to measure the impact of policy measures. The statistical analysis of monthly data by product was performed with SAS. **RESULTS:** The NHS expenditure in outpatient medicines has increased 5.6% in 2010. The legislation approved in June 2009, that established generics reimbursement at 100% for some pensioners (withdrawn in June 2010), was responsible for more 26.8 million euros of NHS spending in 2010. Nevertheless 117.1 million euros were explained by new molecules reimbursed in the last three years. After July 2010 and due to the 1% VAT increase, the expenditure had increased 7.5 million euros. The Health Subsystems (special security schemes for certain professions) had also contributed positively: in December about 7.4 million euros were transferred from the 'ADSE' (civil servants subsystem) for NHS. At the end of 2010, the Government adopted further measures to control public expenditure, such as 6% prices deduction and several reductions in pharmaceuticals reimbursement levels. Immediately the NHS medicines expenditure decreased 21.2% in the four first months of 2011. In opposition the hospital market is growing 3.5%. **CONCLUSIONS:** Besides price and reimbursement administrative reductions, with limited impact in the short run, it would be important to consider measures, that should be assessed on a periodic basis to identify the best strategies to promote rationality and efficiency in the outpatient and hospital sector.

PHP66

IMPACT OF TYPE OF DRUG INSURANCE ON THE USE OF HEALTH CARE SERVICES AMONG USERS OF ANTIDEPRESSANTS

Blais L[1], Perreault S[2], Lalonde L[3], Bérard A[2], Moisan J[4], Rahme E[5]
[1]*Université de Montréal, Montreal, QC, Canada,* [2]*Université de Montréal, Montréal, QC, Canada,* [3]*Faculty of pharmay, Montréal, QC, Canada,* [4]*Laval University, Québec, QC, Canada,* [5]*McGill University Health Centre, Montreal, QC, Canada*

OBJECTIVES: To compare the use of health care services between patients with private and public drug insurance among users of anti-depressants. **METHODS:** A matched retrospective cohort study was conducted using databases for Quebec residents with private (reMed database) or public (RAMQ database) drug insurance. The study included 194 reMed and 1923 RAMQ patients aged 18 to 64 years who filled at least one prescription of an antidepressant between December 2007 and September 2009. Patients were matched on age, sex and date of 1st filled prescription of an antidepressant. The primary outcomes were the number of outpatients medical visits, emergency department (ED) visit (yes/no) and hospitalization (yes/no) for all causes over one year. The secondary outcome was the average antidepressant cost per patient per month. Linear or logistic regression was used to compare the outcomes between patients with private and public drug insurance, while adjusting for potential confounders. **RESULTS:** Patients with private drug insurance (21.3% males) had 8.1 outpatient medical visits on average, 17.5% had an ED visit and 8.8% were hospitalized over one year. Corresponding figures were 6.6, 20.0% and 8.5% for patients with public drug insurance (23.6% males). Patients with private drug insurance were found to have more outpatient medical visits than patients with public drug insurance (adjusted mean difference= 1.2; 95%CI: 0.2 to 2.3), but were not more likely to have an ED visit (adjusted OR= 0.7; 95% CI: 0.5 to 1.1) or a hospitalization (OR=0.9; 95%CI: 0.5-1.6). Average cost per patient per month for antidepressants was $48.50 (95%CI: 44.97-52.02) and $33.73 (95%CI: 32.94-34.51) for patients with private and public drug insurance, respectively. **CONCLUSIONS:** Little differences were found in the use of health care services between users of antidepressants with private and public drug insurance, while important differences were observed for the cost of antidepressants.

PHP67

TENDERING FOR OUTPATIENT PRESCRIPTION PHARMACEUTICALS: WHAT CAN BE LEARNED FROM CURRENT PRACTICES IN EUROPE?

Dylst P[1], Vulto A[2], Simoens S[3]
[1]*Katholieke Universiteit Leuven, Leuven, Vlaams Brabant, Belgium,* [2]*Erasmus University Medical center, Hospital Pharmacy, Rotterdam, The Netherlands,* [3]*K.U. Leuven, Leuven, Belgium*

OBJECTIVES: To explore the current status (2010) of tendering programs for outpatient pharmaceuticals in the European countries and how these programs operate. **METHODS:** A survey was designed to assess the features of tendering programs in European countries. All 27 countries of the European Union plus Norway were included in the study. The survey was sent to national representatives of authorities and organizations and to academic researchers with expertise in the domain. **RESULTS:** Nineteen of the 28 countries have responded to the questionnaire (68%). Seven countries have adopted tendering programs for pharmaceuticals in ambulatory care. Tendering was more popular in countries with a mature generic medicines market (54%) than in countries with a developing generic medicines market (12.5%). Authorities with financial interest for possible savings issued the tenders and the lowest price/best offer was amongst the criteria to award the tender in most cases. The frequency varied from only once to once every two weeks and the number of winners was between one and four. The objectives of achieving cost savings were achieved in the short term but results on long term are still unclear. **CONCLUSIONS:** Tendering programs can achieve savings in the short term, but the effects in the long term are still unclear. It can be concluded that the policy can work, but the features of the programs such as the legal framework, the criteria to grant the tender, the number of winners, the reward of the winner and the frequency, have to be well-thought-out.

PHP68

ASSESSMENT OF THE NHS HOSPITALS' PRODUCTIVITY IN THE REGIONAL HEALTH AUTHORITY OF THESSALY IN GREECE

Androutsou L[1], Geitona M[2], Yfantopoulos J[3]
[1]*Ministry of Health and Social Solidarity, Athens, Greece,* [2]*University of Peloponnese, Athens, Greece,* [3]*National and Kapodistrian University of Athens, Athens, Greece*

OBJECTIVES: To assess the performance in seven homogenous specialty clinics across all NHS hospitals in the Regional Health Authority of Thessaly (RHAT), over the period 2002-2006. **METHODS:** Data Envelopment Analysis by using the Malmquist Productivity Index and its decompositions have been applied in order to measure the technical efficiency and productivity. Clinics were considered to transform inputs labour (medical and nursing staff) and capital (hospital beds) into health services, approximated by the number of in-patient discharges and in-patient days, used as outputs. The model is output oriented and assumes variable return to scale. Data were collected from hospitals' records. **RESULTS:** Overall productivity progressed in all clinics, led by technical change rather than technical efficiency. Over the whole period the size of the clinics influences the overall effects on hospital performance and the maximum level of outputs produced has not been achieved using the given labour and capital inputs, except orthopaedic clinics. The highest productivity changes were achieved by the gynecology (22.5%), the urology (15.7%) and the paediatric clinics (15.4%). All clinics experienced high technological change level, except general medicine clinics which drops by 6.5%. The highest technological changes were experienced by gynecology clinics (48.4%), the paediatrics (26.2%) and ophthalmology (22.1%). **CONCLUSIONS:** Homogeneity in assessing hospitals' performance provides evidence on the efficiency and productivity gains among clinics and suggests improvements in those which appear inefficient. The difficult economic situation Greece is facing nowadays makes the assessment of NHS hospitals' performance a priority in the decision making.

PHP69

CAN WE INCREASE HOSPITAL REVENUE WITH DIFFERENT NEUROMUSCULAR BLOCKERS? AN ANALYSIS OF SAVING COST FOR HOSPITAL BUDGET WITH TIME SAVING EFFECT OF DIFFERENT NEUROMUSCULAR BLOCKERS IN SHORT OPERATIONS

Kockaya G[1], Daylan Kockaya P[2], Wertheimer A[3], Ozbagrýacýk O[4], Oba S[4]
[1]*General Directorate of Pharmaceuticals and Pharmacy, Ankara, Turkey,* [2]*Polatlı Duatepe Hospital, Ankara, Turkey,* [3]*Temple University School of Pharmacy, Philadelphia, PA, USA,* [4]*Sisli Etfal Education and Research Hospital, Istanbul, Turkey*

OBJECTIVES: Muscle relaxants are used in anesthesia to obtain adequate muscle relaxation. Our aim is obtaining improvement in hospital budget by selecting adequate neuromuscular blocking agents for short-term (under 60 minutes)pediatric operations for hospital managements. **METHODS:** There is a basic investigation of the duration to recovery time of atracurium and rocuronium administrations during anesthesia induction in ASA I-II children. In order to evaluate the effect on hospital budget, direct expenses were used. **RESULTS:** The mean time to reach TOF75 in recovery with rocuronium and atracurium were calculated 38 and 51 minutes, respectively. In atracurium group, time to reach TOF75 was 51 minutes, but operation time was 46 minutes(as rocuronium groups)and patients needed an additional 5 minutes for recovery. During additional minutes, patients were kept in the operation room(OR), thus preparation for the next patient was delayed. After extubation of patients, to determine the period of preparation of an OR for the next patient, a questionnaire was administered. This preparation was determined to be 14 minutes. These means, in the rocuronium and atrocurium groups one needs 60 minutes (46+14) and 65 minutes (51+14), respectively from the start of an operation to the start of next operation. In a pediatric surgery department, lower abdominal and urogenital surgery unit income with rocuronium or atracurium are the same but, rocuronium brings extra time for an average of 15 operations lasting shorter than 1 hour. **CONCLUSIONS:** Study showed that if a hospital works with 100% performance and has no other problems (shortage of bed,personnel,etc), such a hospital may perform, in a month, an extra 15 pediatric surgical operations less than 1 hour can, by using rocuronium. Thus rocuronium may lead an additional income of US$ 2436 per month for one OR. In other words, in short operations, using rocuronium rather than atracurium may lead to savings which is 30-35% of total cost.

PHP70

VALUE BASED PRICING (VBP): IS THIS THE WAY FORWARD FOR THE UK NHS?

Comberiati U[1], Dass RN[2], White N[1]
[1]*Cranfield University, Cranfield, UK,* [2]*PriceSpective, London, UK, UK*

OBJECTIVES: The British government has decided to impose a system of value based pricing (VBP) in England as part of a wide-ranging national health care system (NHS) reform. The outcomes from this decision will have a number of consequences for the NHS and the pharmaceutical industry alike. The objective of this poster is to evaluate the impact of VBP implementation on the NHS and pharmaceutical industry specifically with regards to drug access, health care drug expenditure and promoting innovation. **METHODS:** A literature review was conducted in order to understand health economists' evaluations about VBP and stakeholders' reaction to proposed reform. Ten stakeholders from academia, the pharmaceutical industry and representative members of the NHS, were involved in qualitative interviews to compare and contrast the views of health care workers, NICE and the pharmaceutical industry about NHS reform and concept of value as it pertains to VBP. **RESULTS:** VBP as expected has been quite a contentious and controversial issue for the pharmaceutical industry with regards the proposed NHS reform. NICE's position on value based pricing based on cost-effectiveness analyses is arguably not perfect, but it does define outcomes for the pharmaceutical industry in a more transparent manner. Clinician stakeholders, including the proposed GP commissioning groups will have difficulty in determining value without prescribed criteria and specified guidelines based around innovation and value. It is also questionable whether VBP would indeed spur innovation of drug development or in fact hamper research and development due to increased market access requirements and decreased profitability in the pharmaceutical sector. **CONCLUSIONS:** The definitions of innovation and value in the pharmaceutical industry and the NHS have different meanings for different stakeholders. A clearer understanding of VBP and its expected outcomes would be helpful to bridge the gap between the pharmaceutical industry and the NHS.

PHP71

EFFECT OF SIADH ON PATIENT OUTCOMES AND HEALTH CARE RESOURCE UTILIZATION IN HOSPITALIZED PATIENTS

Amin A[1], Deitelzweig S[2], Lin J[3], Christian R[4], Baumer D[5], Lowe T[6]
[1]*University of California-Irvine, Orange, CA, USA,* [2]*Oschner Medical Center, Jefferson, LA, USA,* [3]*Novosys Health, Flemington, NJ, USA,* [4]*Otsuka America Pharmaceutical, Inc., Rockville, MD, USA,* [5]*Premier Research Incorporated, Charlotte, NC, USA,* [6]*Premier Healthcare Alliance, Charlotte, NC, USA*

OBJECTIVES: Syndrome of inappropriate antidiuretic hormone hypersecretion (SIADH) is a common cause of hyponatremia contributing to 30-50% of hyponatremia cases. Little is known of the influence of SIADH on health care resource utilization. This study assessed the effect of SIADH on inpatient total and intensive care unit (ICU) cost and length of stay (LOS), the likelihood of ICU admission, and 30-, 90-, and 180-day readmission. **METHODS:** The Premier hospital database was utilized to identify US hospital inpatients discharged between January 1, 2007 and June 30, 2009. Hyponatremic/SIADH patients were identified using primary or secondary ICD-9 codes (n=430,731) and were matched to a control group (n=430,731) using exact matching on age, gender, provider region and 3M™ APR-DRG assignment. Matching was further refined using propensity scores based on additional patient and hospital covariates. Due to the contribution of congestive heart failure and cirrhosis on hyponatremia development, these patients were excluded from the analysis. The final analytic sample contained 65,973 SIADH patients and 407,874 non-hyponatremia/SIADH patients. Cost was analyzed using gamma regression, LOS with negative binomial regression. ICU admission and hospital readmission were analyzed using multivariate logistic regression. **RESULTS:** In contrast to non-SIADH patients, patients with SIADH had significantly higher total inpatient cost (55.53%,CI=52.53-58.60;p<.0001), ICU cost (38.07%;CI=33.18-43.15;p<0.0001), total LOS (45.11%,CI=43.20-47.03;p<0.0001), and ICU LOS (42.72%,CI=38.36-47.23; p<.0001). SIADH patients were significantly more likely to be admitted to the ICU (OR=2.131;p<.0001), and readmitted at 30- (OR=1.399;p<0.0001), 90- (OR=1.495; p<0.0001), and 180-days (OR=1.459;p<0.0001) in comparison with non-SIADH patients. **CONCLUSIONS:** The presence of SIADH in hospitalized patients is significantly associated with increased total and ICU cost and LOS, likelihood of ICU admission, and likelihood of readmission.

PHP72

EVIDENCE-BASED PRIORITY SETTING FOR THE NATIONAL HEALTH DEVELOPMENT PLAN OF THAILAND

Patcharanarumol W, Bundhamcharoen K, Poungkantha W, Prakongsai P, Tangcharoensathien V
International Health Policy Program, Nonthaburi, Thailand

OBJECTIVES: To describe how Thailand use evidence on country's burden of disease and cost-effectiveness of health interventions from the 2nd edition Disease Control Priority in Developing Countries (DCP2) to set priorities in health sector investment in the National Health Development Plan. **METHODS:** The study applies comprehensive literature reviews, secondary data analyses, interview of key informants and meeting among stakeholders to answer four specific **OBJECTIVES:** a) burden of disease (BOD) priorities; b) health interventions currently implemented in Thailand against what recommended by DCP2; c) costs of top-ten BOD in terms of medical expenditure, productivity loss due to life loss and morbidity; and d) assessment of medium term economic framework in different scenario. **RESULTS:** Since 1999 there has been an increasing trend in BOD attributable from alcohol and tobacco consumption, consumption of high fat high calorie diet, lack of fibre food and physical activities, increasing incidence of diabetes mellitus, hypertension and high blood lipid, traffic injuries, overweight and obesity. Evidence from the share of DALY loss, productivity loss and absenteeism from morbidity indicates three national health priorities: HIV/AIDS; traffic injuries and diabetes mellitus. Total health expenditure in 2009 was 179 USD per capita, 4.3% of GDP, and mostly spent on curative services, only 4.5% of that was for disease prevention and health promotion. **CONCLUSIONS:** Thailand can invest more on health of the population, in particular on disease prevention and health promotion to address three national health priorities: HIV/AIDS, traffic injuries and diabetes mellitus through cost effective interventions in and outside the health sector. The most probable scenario for increasing investment in health promotion and disease prevention is to double the amount of investment for health promotion and disease prevention. Also, resources can be mobilized from local administrations and communities, and should be managed by efficient and accountable agency with effective mechanisms.

PHP73

GOVERNMENT REDUCES PUBLIC PHARMACEUTICAL EXPENDITURE IN HUNGARY: RATIONAL DECISIONS IN CHALLENGING ECONOMIC TIMES?

Inotai A[1], Merész G[1], Kalo Z[2]
[1]*Syreon Research Institute, Budapest, Hungary,* [2]*Eötvös Loránd University, Budapest, Hungary*

OBJECTIVES: Scarcity of public resources, especially in challenging economic times, draws attention to the expenditure on pharmaceuticals. Over the next 3 years the Hungarian government plans to reduce the public pharmaceutical spending by 35%. Our objective was to assess the current level of pharmaceutical expenditure in Hungary by taking into account the economic status of the country and benchmarks from other OECD countries with special focus on Visegrad countries (Czech Republic, Slovakia, Poland, Hungary). **METHODS:** We completed international cross sectional and cluster analysis based on OECD Health Data 2010 and longitudinal analysis of public pharmaceutical expenditure in Hungary. **RESULTS:** The cluster analysis indicates that pharmaceutical spending is relatively higher in middle-income countries compared to high income countries above 30'000 USD GDP/capita (1.89 vs. 1.41% of GDP%, p=0.04; 23.58% vs. 14.14% of total health expenditure, p<0.001), as prices of pharmaceuticals are not adjusted to local price levels as opposed to prices of other health care services. International trends of the global pharmaceutical market are also valid in Hungary. The public pharmaceutical spending is close to the average of Visegrad countries, but the private pharmaceutical spending is the highest. The annual real growth rate of public pharmaceutical spending was only 1.0% between 1994-2010, whilst increased private funding (mainly out of pocket payments) was the major growth driver of total pharmaceutical expenditure in Hungary. **CONCLUSIONS:** Cost-containment of public pharmaceutical spending was very successful in the last 15 years. The burden of pharmaceutical market growth has been shifted to private households. The proposed public budget cut translates to over 30% decrease in real public pharmaceutical spending from 1994 to 2014. As morbidity and mortality indicators of the Hungarian population are extremely unfavourable, current evidences and international benchmarks do not justify significant reduction of the public pharmaceutical budget.

PHP74

CONSIDERABLE POTENTIAL SAVINGS FROM CHANGE IN DISTRIBUTION CHANNEL FOR SERIOUS DISEASES PRODUCTS IN GREECE: THE CASE OF OGA SOCIAL SECURITY FUND (SSF)

Georgiadou G[1], Tsikalaki E[2], Makridaki D[3], Argyri S[4], Kousoulou F[4], Geitona M[5]
[1]*OGA Social Security Fund, Athens, Greece,* [2]*Syngros Hospital, Metamorfosis, Greece,* [3]*Sismanoglio Hospital / PEFNI Organization, Vrillisia, Greece,* [4]*General Secretary of Social Security Funds, Athens, Greece,* [5]*University of Peloponnese, Athens, Greece*

Greek law (3816/2010) sets a list for serious diseases products (89 in total) which can be dispensed either through public hospitals or retail pharmacies for non hospitalized patients. Each distribution channel incurs different costs for the NHS (public hospitals/SSFs). **OBJECTIVES:** Estimate potential savings for GR NHS (Social Security Funds & Hospitals) through dispensing products of serious diseases through hospital pharmacies instead of retail pharmacies. **METHODS:** Data derived from drug reimbursement database of OGA (Agriculture SSF) covering 20% of the GR population. The data represent actual reimbursement amounts to private pharmacies, from January to April 2011, extrapolated for the whole 2011. The price calculations were based on the following formulas: 1) Public hospitals buy at hospital price (HP) +VAT from pharmaceutical companies; 2) Public hospitals charge wholesaler price +3% premium to SSFs; and 3) Retail pharmacies charge SSFs retail price (calculated as hospital price +2,5%wholesaler margin +18% pharmacy margin +VAT). **RESULTS:** Based on the mean of 5950 prescriptions per month the average value paid by OGA to the retail pharmacies was €1042 per prescription. By changing dispensing channel, via hospital, the mean cost per prescription for OGA was estimated at €930.93. Since both SSFs & hospitals are part of NHS, the actual cost of NHS/prescription is the hospital cost estimated at €818.72 and the estimated hospital gain per prescription is €112.21. The actual gain for NHS per prescription is €223.28. The extrapolated gain for OGA for 2011 is estimated at €7,930.398 while for NHS is €15,942.192. **CONCLUSIONS:** Distribution of products for serious diseases via hospital pharmacies, leads to considerable savings for NHS and SSFs while ensuring considerable gains for hospitals, under specific conditions (hospital personnel, budget, immediate payment by SSF). The expansion of the list is of absolute priority for reducing the NHS spending. More savings can be achieved by dispensing L3816 products through the newly formed unified health care fund (EOPYY) covering 90% of total population.

PHP75

THE COST PER DAY OF INTENSIVE CARE UNITS (ICU) IN FRANCE: THE CRRÉA STUDY

Garrigues B[1], Lefrant JY[2], Bazin J[3], Bardoulat I[4], Tagdichti K[5], Courtial F[5], Maurel F[6], Pribil C[7]
[1]*CH du Pays d'Aix, Aix-en-Provence Cedex1, Aix-en-Provence, France,* [2]*CHU Nîmes, Nimes, France,* [3]*CHRU de Clermont-Ferrand, Clermont-Ferrand, France,* [4]*IMS Health, Puteaux Cedex, France,* [5]*IMS Health, Puteaux, France,* [6]*IMS Health, 92807 Puteaux Cedex, France,* [7]*GSK France, Marly le roi, France, France*

OBJECTIVES: To estimate the daily cost of intensive care unit (ICU) stay in France using a microcosting methodology. **METHODS:** A multicentre prospective cost analysis study was carried out among 23 French ICUs randomly selected from the French National Hospital database stratified by hospital category (regional, university and private non profit). Each ICU enrolled 5 adult patients admitted from May to October, 2009, selected at random, with a simplified acute physiology score (SAPSII)≥15 at admission and with at least 1 reanimation medical act. All healthcare resources used by each patient over a 24-hour period were recorded, as well as the time spent by all hospital staff involved in the patient's management. All resources identified were valued from a hospital perspective (reference year 2009) based on unit cost data provided by each centres. Bi-variant analyses were carried out to identify potential cost-drivers. **RESULTS:** A total of 104 patients were enrolled by 21 ICUs (14 polyvalent, 3 surgical and 4 medical) were included. The mean age of patients was 62.3 years (SD 14.9); 64% were male; 86% were mechanically ventilated and the median Sequential Organ Failure Assessment (SOFA) score was 6 (SD 4.3). The average daily cost of ICU per patient was €1,424 (SD €520). Staff time represented the largest component of this cost (43%) followed by overheads, capital, hotel and nutrition assigned to the ICU (22.9%). Medication and consumables used accounted for 18.6% of the total cost. The majority of the cost (59%) was patient-dependant. The two main patient-dependant factors associated with significantly higher costs were: a high SOFA score and being on continuous mechanical ventilation. **CONCLUSIONS:** This first French microcosting study in ICU demonstrates that the cost per day of ICU care is substantially depends on the patient's medical profile and mainly driven by labour components.

PHP76

THE LACK OF BIA METHODOLOGY IN THE CZECH REPUBLIC LEADS TO INAPPROPRIATE PUBLIC HEALTH INSURANCE BUDGETING

Heislerova M[1], Zizalova J[2], Fuksa L[3], Baloghova K[2]
[1]*Ministry of Health, Prague, Czech Republic,* [2]*Ministry of Health, Prague1, Czech Republic,* [3]*General Insurance Company of the Czech Republic, Praha, Czech Republic*

OBJECTIVES: Budget impact analysis (BIA) is a tool used to predict and understand the potential financial impact of introducing a new health care intervention into a health care system that has finite financial resources. Czech laws only prescribe duty to attach BIAs to the applications for new drug reimbursements without specifying guidelines how to prepare BIA. We analyzed the differences between the BIA in the applications and the real expenditures of the public health insurance. **METHODS:** We have selected 3 applications of new drugs (romiplostin, lenalidomid, bevacizumab) submitted in year 2009 (or an established drug in new indication) and compared submitted BIA estimates for year 2010 with the real expenditures in the same year. We also compared the methods in the submitted BIAs with the Impact Analysis Guidelines published by Patented Medicine Prices Review Board (Canadian National Drug Reimbursement Authority) to identify potential reasons of differences. **RESULTS:** We found differences in the predicted number of patients, average cost of drug application and total impact on the public health insurance. **CONCLUSIONS:** The comparison with standard guidelines identified the key areas to be addressed in the future Czech legislative to improve the quality of submitted BIAs. The inaccuracies were mainly caused due to a) Lack of data sources and their transparency; b) Inaccurate or misapplied assumptions; c) Inappropriate choice of comparators; and d) Overall quality, e.g. false interpretation of referenced studies conclusions.

PHP77

EXPLORING DIFFERENT HRQOL MEASURES AS PREDICTORS OF FUTURE HEALTH CARE EXPENDITURES

Gatwood J, Erickson S
University of Michigan, Ann Arbor, MI, USA

OBJECTIVES: To assess the relative ability of several health-related quality of life (HRQOL) measures to predict future health care expenditures. **METHODS:** Data from the Medical Expenditure Panel Survey (MEPS) for years 2003 (Panel 4, Round 2) and 2004 were used for study purposes and weighted in order to gain a population-level analysis. Applying the Model of Health Services Use, predisposing (age, gender, race, years of education, and marital status) and enabling (insurance type, employment status, family size, and annual household income) variables were combined with varying need variables (SF-12 PCS, SF-12 MCS, EQ-5D Index, EQ-5D VAS, single-item core questions of perceived physical and mental health status, or a combination thereof) and used to predict overall healthcare expenditures, one year after survey, in multivariate linear regression models. The individual R2 values were used for model comparison. **RESULTS:** The final dataset was composed of 9304 respondents, representing over 186 million US residents. The base model of only predisposing and enabling covariates resulted in an R2 value of 0.067. The model using both the SF-12 PCS and MCS values as need variables resulted in the highest R2 value of all models run: 0.094. Use of the SF-12 MCS or the single-item perceived mental health core item as need variables only marginally out-performed the base model, both resulting in R2 values of 0.069. The EQ-5D VAS and Index as well as the physical health perception core measure values were similar, ranging from 0.0821 to 0.0868. **CONCLUSIONS:** The combined use of the SF-12 MCS and PCS measures as need variables in the Model of Health Services Use performed better than the other HRQOL measures in the MEPS dataset in predicting future health care expenditures.

PHP78

CONVERGENT TENDENCIES IN BUDGET IMPACT ANALYSIS ACROSS EUROPE AND BEYOND: GERMANY - DON'T LOSE OUT ON THE "ZEITGEIST"!

Bechtel B, Welte R
GlaxoSmithKline, Munich, Germany

OBJECTIVES: On January 1, 2011, the rapid benefit assessment (RPA) as basis for central price regulations was introduced for new drugs in Germany. It requires the pharmaceutical manufacturer to submit a value dossier. The objective was to investigate converging trends in budget impact analysis (BIA) requirements in selected countries and to compare them to the German RPA. **METHODS:** We conducted a systematic review of national guidelines on BIA requirements for the pricing and reimbursement process of pharmaceuticals in 14 countries across the western world (Europe, North America, Israel). Where needed informal stakeholder interviews were used to supplement lacking information. The information was extracted and evaluated based on 10 characteristics obtained from the "ISPOR Principles of Good Research Practice for Budget Impact Analysis" (Mauskopf et al. 2007). **RESULTS:** All of the investigated countries except for Germany, Scotland and Norway consider the direct medical budget impact of new pharmaceuticals in their reimbursement decision making. In Germany, only the maximum annual direct intervention costs have to be stated. Although Norway and Scotland request no BIA from a payer's perspective the drug's impact on the change in medical resource consumption is analyzed as part of the pharmacoeconomic and comparative effectiveness analyses. 8 countries demand a self-contained BIA complementary to the broader health economic evaluation, while 3 countries deal with financial consequences as part of the economic evaluation. In all countries except for Germany economic consequences for the healthcare budget have to be presented for at least 2-5 years on an annual basis to capture medium to long term savings and expenditures associated with changes in the medical resource utilization following a drug's availability in the market. **CONCLUSIONS:** All investigated countries except Germany consider changes in the resource consumption and their financial consequences (even for a medium term period) for decision making.

PHP79

WHAT ARE THE RESEARCH PRIORITIES IN THE SPANISH NATIONAL HEALTH SYSTEM? A COMPARISON OF ECONOMIC EVALUATIONS OF HEALTH CARE INTERVENTIONS AND PUBLIC-FUNDED RESEARCH

Catalá-López F[1], Garcia-Altés A[2], Gènova-Maleras R[3], Álvarez-Martín E[4], Morant-Ginestar C[5], Peiró S[1]
[1]*Centro Superior de Investigación en Salud Pública (CSISP), Valencia, Spain,* [2]*Catalan Agency for Health Information, Assessment and Quality (CAHIAQ), Barcelona, Spain,* [3]*Primary Care General Directorate, Regional Health Council, Madrid, Spain,* [4]*Rey Juan Carlos University, Madrid, Spain,* [5]*Regional Health Council, Madrid, Spain*

OBJECTIVES: The efficient use of resources requires explicit criteria for setting health care research priorities. We assessed whether economic evaluations of healthcare interventions are directed to priority diseases in the allocation of public-funded research in the Spanish National Health System. **METHODS:** We analyzed data from a systematic review of economic evaluations performed in Spain (period 1983-2008). Reports were grouped according to the source of funding. We included a representative sample of public funds allocated to research projects (2006/2007 calls of the Instituto de Salud Carlos III, Spanish Ministry of Science and Innovation). Both economic evaluations and research projects were classified according to the main disease causes, following the classification proposed by the World Health Organization in its Global Burden of Disease study. We calculated Spearman correlation coefficients (r) between the public funds and economic evaluations. **RESULTS:** A total of 1410 research projects (equivalent to €125.6 million) and 477 economic evaluations were identified and could be categorized in 20 groups and 40 specific causes of diseases. For major groups (n=20), the associations were: total economic evaluations ($r=0.80$, $p<0.001$), economic evaluations funded by for-profit organizations ($r=0.77$, $p<0.001$) and those funded by nonprofit organizations ($r=0.85$, $p<0.001$). For specific disease-causes (n=40): total economic evaluations ($r=0.52$, $p=0.001$), economic evaluations funded by for-profit organizations ($r=0.38$, $p=0.016$) and funded by nonprofit agencies ($r=0.61$, $p<0.001$). **CONCLUSIONS:** The distribution of priorities is similar between economic evaluations and public research funds allocated to specific diseases. However, the optimal level of these distributions could be determined with additional analyses on the impact of research results in reducing the burden of disease in the population.

PHP80

WHERE A CHEAP MEDICINE IS NOT THE SAME AS A GENERIC MEDICINE: THE BELGIAN CASE

Dylst P[1], Vulto A[2], Simoens S[3]
[1]*K.U.Leuven, Leuven, Vlaams Brabant, Belgium,* [2]*Erasmus University Medical center, Hospital Pharmacy, Rotterdam, The Netherlands,* [3]*K.U. Leuven, Leuven, Belgium*

OBJECTIVES: The aim of this study is to describe the experience with the Belgian policy that obliges physicians to prescribe minimum quota of cheap medicines and to document the outcomes of this policy using publicly available data. **METHODS:** Data were obtained from yearly feedback reports of the policy on the website of the Belgian third-party payer (RIZIV/INAMI) which were sent to all physicians. Data were derived from Farmanet, a database where all data of prescriptions of reimbursed medicines from all physicians in Belgium are collected. **RESULTS:** All groups of general practitioners, specialists and dentists reached their minimum percentages every year from 2006 until 2009. The percentage of cheap medicines (in DDD) increased from 22.9% in January 2005 to 44.2% of all prescribed medicines in ambulatory care in December 2009. The percentage of generic medicines increased from 12.10% in 2004 to 24.03% of all prescribed medicines in ambulatory care in 2008. When a physician prescribed a cheap medicine, this was an original medicine whose price had dropped to the reference price level in 41.5% of cases in August 2009. **CONCLUSIONS:** The policy of prescribing quota for cheap medicines was not only associated with increased prescribing of generic medicines during 2004-2008, but also increased prescribing of original medicines whose price had dropped to the reference price level. The potential for prescribing generic medicines has not

yet been fully met in Belgium. Despite the success of the policy, adjustments are desirable, especially with respect to the broad definition of cheap medicines. Given the fact that all groups of physicians reached their minimum quota quite easily together with the increased possibility of prescribing cheap medicines due to the entrance of new, generic medicines, the government decided to raise the minimum criteria in 2011.

PHP81

FUNDING SOURCES ANALYSIS RESULTS (REGIONAL AND FEDERAL LEVELS) OF PHARMACEUTICAL MARKETS PER REGIONS OF RUSSIAN FEDERATION

Borisov D[1], Pechenkin A[2]
[1]Laboratory of Pharmacoeconomics and outcomes research, First MGMU named after I. M. Sechenov, Moscow, Moscow, Moscow, Russia, [2]Non-Commercial partnership, Moscow, Moscow, Russia

OBJECTIVES: To analyze state funding sources of drug provision all over RF for the period of 2009-2010. **METHODS:** Different sources of drug funds were summed up during this research. All materials were taken from the open sources: results of auctions of the federal and regional level, orders of the Ministry of Public Health and Social Development, analysis of regional programs of the drug provision and etc. **RESULTS:** Interactive map of the RF was developed due to this analysis of the collected data, it shows information on each region of the RF, the number of privileges people, population of the region, sum of the budget by the ONLS (reimbursement) programs, the sum of the budget according to the regional reimbursement, sum of the hospital budgets, sum of the special programs of the region (if such programs approved in the region), sum of the budget by the program "7 nosologies" (special reimbursement program), with the detailed separation of the budget according to the nosologies. Such map clearly demonstrates difference in the funding system between regions. The ranges of color distinction by regions were put into the map for more convenient usage, it allows visually demonstrate difference in funding on the territory of the RF. Several pilot regions of the RF were chosen where data was validated, this process showed complete conformity of the existing data with the official budgets of the regions. **CONCLUSIONS:** Nowadays this research represents unique product in acceptance of administrative decisions for the administrators of health sector of the RF. Also for the further improvement of the given analytical system it is necessary to adjust the collecting of the corresponding data for 2011 and to analyze the budget of regions on the Federal Health Modernization Program 2011-2012.

PHP82

A STUDY EXPLORATING THE GENERAL PUBLIC PERCEPTIONS TOWARDS MEDICINES

Alhaddad MS[1], Hassali MA[2], Maghrabi I[3]
[1]Taif University, Taif, Saudi Arabia, [2]Universiti Sains Malaysia, Penang, Malaysia, [3]Taif Universiy, Taif, Saudi Arabia

OBJECTIVES: General public perceptions will affect on their behavior towards medicines. Therefore, this study aims to evaluate the general public perceptions towards medicines in the state of Penang Malaysia. **METHODS:** A cross sectional study using convenience sampling technique was used. Appropriate descriptive and inferential statistics were used to find the differences among the respondents. All data were analyzed at alpha value of 0.05. **RESULTS:** Seven hundred respondents were successfully responded to the survey. More than one third of the respondents 37% stated that they understand what is meant by conventional medicines, whereas 18.6% understand traditional medicines and only 3% understand what is meant by generic medicines. On the other hand, 36% see doctor once they have minor illness and 30% prefer to go to get OTC drugs from the community pharmacy. Furthermore, 62% believe that more expensive drugs are of better quality, and more than 50% believe that advertising affect on their perceived quality of medicines as well as the country of the manufacturer affects on their selection of the drugs. Previous experience, physician's recommendations, pharmacist's recommendations, friend's recommendations, cost of the medicine and medical insurance coverage were the main factors that affect on their perceptions. **CONCLUSIONS:** General public in Penang are very concerning about the medicine chosen. General public education on various types of medicines is important to correct misconceptions and give them the knowledge that they need to make an informed decision. Hence, physicians, pharmacists and other health care providers play vital roles in educating the general public about medicines.

PHP83

THE ECONOMIC BURDEN OF DISEASE RELATED MALNUTRITION IN EUROPE

Kalo Z[1], Inotai A[2], Nuijten M[3]
[1]Eötvös Loránd University, Budapest, Hungary, [2]Syreon Research Institute, Budapest, Hungary, [3]Ars Accessus Medica/Erasmus University Rotterdam, Jisp, The Netherlands

OBJECTIVES: Disease related malnutrition (DRM) is a frequent but often unrecognised problem, even in the developed world. The objective of this study was to estimate the burden of disease related malnutrition (BoDRM) in Europe. **METHODS:** An Excel model was developed to estimate direct incremental health care costs and health burden (including increased mortality and reduced quality of life) due to DRM. The monetary value of the health burden was calculated by multiplying the QALY loss with explicit or implicit (2x GDP/capita) cost effectiveness thresholds in each country. Collection of input variables involved a wide spectrum of current data sources: international databases, PubMed, congress abstracts, references from published papers. Ten primary diseases were incorporated into the model: stroke, breast cancer, COPD, dementia, depression, colorectal cancer, musculoskeletal disorders, head and neck cancer, coronary heart disease, chronic pancreatitis. **RESULTS:** For the 835 million European citizens, the direct financial BoDRM is over 31 billion EUR annually. The estimated annual health burden is approximately 5.7 million life years or 9.1 million QALYs. The total monetary value of the health and financial BoDRM is 306 billion EUR. The health burden in chronic diseases is greater than in acute diseases, and is also greater than the financial burden. In acute diseases, the financial burden is greater than the health burden. **CONCLUSIONS:** In Europe, DRM is a considerable health and financial burden and represents a significant contribution to the total burden of disease, estimated by WHO to be 255 million DALYs annually. Therefore, there is a need to improve nutritional care in all aspects of patient management. The availability of scientific data on DRM is limited, especially regarding the relative mortality risk and quality of life impact. Policy makers should support programmes to extend the clinical and economic evidence base for nutritional care.

PHP84

ASSESSING PRODUCTIVITY AND ACTIVITY IMPAIRMENT DUE TO ILLNESS IN POLAND: EMPLOYEES VERSUS EMPLOYERS VIEW

Wrona W[1], Hermanowski T[2], Jakubczyk M[1]
[1]Department of Pharmacoeconomic, Medical University of Warsaw, Warsaw, Poland, [2]Grant Leader, Department of Pharmacoeconomics, Medical University of Warsaw, Warsaw, Poland

OBJECTIVES: The inclusion of lost productivity costs in pharmacoeconomic studies is still a subject of considerable debate. The aim of this study was to quantify the work impairment due to general health status in population of employees and employers (i.e. owners and managers). **METHODS:** Data were obtained from a survey that incorporated the WPAI-GH questionnaire and questions on costs of worker replacement (including hiring and training process). The survey was conducted in cooperation with Employers of Poland – the largest and oldest organisation of employers in Poland in the framework of research grant no N N405 115034 offered by the Ministry of Science and Higher Education of the Republic of Poland. **RESULTS:** The non-representative population comprised 196 subjects in paid jobs (156 employees and 40 employers), 167 of whom were currently employed in government-owned corporations (with 250+ employees). Employees reported 7.4% of work time missed due to health problems (absenteeism) during the past 7 days (0.8% for employers; $p=0.052$). Impairment while being at work (presenteeism) amounted to 12.2% of total time for employers (5.4% for employers; $p<0,05$). Percentage of overall work impairment due to health problems for employees and employers were 5.7% vs. 18.3%, respectively ($p<0.05$). On average more than 50% of overall work impairment was compensated by other employees in the company with a general tendency of a higher compensation of employees' responsibilities. Mean time of hiring and training new worker to achieve 50% of expected productivity was 76 days and 216 days to achieve full productivity. **CONCLUSIONS:** Productivity loss measured by WPAI-GH is higher among employees than employers in analyzed sample in Poland, with a tendency of a higher compensation among employees. Preliminary data suggest that overall work impairment can be completely compensated within a one year from a single employer perspective and support friction cost approach.

PHP85

A SYSTEMATIC REVIEW OF AUTOMATED DOSE DISPENSING IN PRIMARY HEALTH CARE

Sinnemäki J[1], Sihvo S[2], Isojärvi J[2], Blom M[1], Airaksinen M[1], Mäntylä A[3]
[1]University of Helsinki, Helsinki, Finland, [2]National Institute for Health and Welfare, Helsinki, Finland, [3]Finnish Medicines Agency, Kuopio, Finland

OBJECTIVES: An automated dose dispensing (ADD) service is implemented in primary health care in some countries, particularly in the Nordic countries. In this service, regularly used medicines are machine-packed into unit-dose bags for each point of administration. The aim of this study is to review the evidence of the ADD's influence on the appropriateness of medication use, medication safety and costs in the primary health care. **METHODS:** A literature search was performed on the most relevant databases, including the Medline, Embase, and Cochrane Library. An article was included in the review if the study was conducted in primary health care or nursing home settings and medicines were dispensed in unit-dose bags. All study designs were approved and control groups were not required. Studies applying outcome measures that were related to the appropriateness of medication use, medication safety or costs were included. **RESULTS:** Out of 278 abstracts, six studies were found to be acceptable. The prevalencies of potential inappropriate drug use (IDU) were higher among ADD users than non-ADD users. After controlling for confounding factors, ADD reduced the probability of long-acting benzodiazepine use among women and drug-drug interactions among women and men. The ADD users aged ≥65-79 years had more problems with potential IDU than older ones (≥80 years). The risk of administration errors was lower if medicines were supplied by the ADD service. The ADD service also reduced discrepancies in the documentation of patient medication records. Any costs were not investigated in the studies. **CONCLUSIONS:** The evidence of the influence of ADD on appropriateness of medication use and medication safety is limited, and missing on costs. The findings of this review suggest that the ADD service may improve medication safety in primary health care, but does not effectively reduce potential IDU.

PHP86

INCORPORATING THE PATIENT PERSPECTIVE INTO THE HEALTH CARE PROCESS: EXPERIENCE FROM THE C.A.T. HEALTH SYSTEM

Rebollo P[1], Castejón N[1], Cuervo J[1], Igarreta M[2], Ortega F[3]
[1]BAP Health Outcomes Research, Oviedo, Spain, [2]SaluMetrics S.A., Oviedo, Spain, [3]Hospital Universitario Central de Asturias, Oviedo, Spain

OBJECTIVES: To evaluate the feasibility of the C.A.T-Health system (a computerized adaptive test which evaluates generic Health-Related Quality of Life-HRQoL) in a university hospital, at different levels of the health care process. **METHODS:** The C.A.T-Health system has been developed and validated within a 3 years research

project. The system is implemented in software to fill in the test through a touch screen. According to Item-Response Theory, items showed to the respondent are selected from a pool of items based on the answers to the previous questions. The test can vary from 5 to 15 questions. The C.A.T-Health system was installed during 1 week at 3 locations at the Hospital Central de Asturias: Hemodialysis Unit (HDU), Nephrology Hospitalization Unit (NHU) and Nephrology Outpatient Consultancy (NOC). Patients visiting each of these locations were allowed to answer the questionnaire, though they were not asked to do it. The sanitary staff and the patients' relatives were also allowed to answer the test. The percentage of patients who started and finished answering the C.A.T-Health system, the time of completion and the number of items showed were collected. **RESULTS:** 597 subjects started answering the C.A.T-Health system. 366 subjects (61.31%) completed the test: 96 patients, 180 sanitary staff and 80 patients' relatives. The percentage of patients who spontaneously answered the test was 64% and 55%, with respect to the total number of patients visiting HDU and NHU, respectively. The median number of items was 10 (HDU), 9 (NHU) and 8 (NOC). The median time of completion was 118.5 (HDU), 124.9 (NHU) and 113.13 seconds (NOC). The worst C.A.T-Health mean score was that of patients visiting HDU. **CONCLUSIONS:** The C.A.T-Health system is a feasible innovative HRQoL questionnaire which allows the use of patients' perceived health as an outcome variable in the evaluation of the health care process.

PHP87

PATIENT-CENTERED HEALTH CARE DELIVERY SYSTEMS: A DISCRETE CHOICE EXPERIMENT

Mühlbacher AC[1], Bethge S[1], Schulman K[2]
[1]*Duke University, Durham, NC, USA,* [2]*Duke Clinical Research Institute, Durham, NC, USA*

OBJECTIVES: Patient-centered care, in which health services are customized on the basis of patients' needs and values, is seen as a critical factor in a high-performance health care system. This project seeks to characterize patients' needs and values for specific features of health care delivery systems. **METHODS:** Quantitative data were obtained by means of a discrete choice experiment (DCE). Alternatives were described by specific attributes that described certain features of a health care delivery system. Each set included six attributes with three specific levels. The DCE was divided into four blocks based on thematic mapping (DCE 1, patient involvement; DCE 2, point of care; DCE 3, personnel; DCE 4, organization). **RESULTS:** In preliminary results, N=663 respondents have completed the survey so far. The feature "out-of-pocket costs" was the most important attribute across all 4 DCEs (DCE 1 coefficient, 0.59025; DCE 2 coefficient, 1.20715; DCE 3 coefficient, 0.99938. DCE 4 coefficient, 0.99079). In DCE 1 regarding patient involvement, "trust and respect" (0.50411) and "attention to personal situation" (0.33664) were of greatest importance. In DCE 2 addressing preferences at the point of care, "shared decision making" (0.77153) and "access to patient record" (0.51370) were nearly equally valuable to patients but of highest relevance. In DCE 3 focusing on personnel in health care delivery systems, "multidisciplinary care" (0.74468) was ranked highest. Lastly, in DCE 4 analyzing features of the organization of health care delivery systems, "travel time" (0.39266), "medical devices and furnishings" (0.41689), and "treatment guidelines" (0.41566) were of almost equal value to patients. **CONCLUSIONS:** The study is intended to close the gap between simplistic representations of patient preferences in today's health care systems and the complexity of actual patient decision-making processes by using the specification and explanatory power of DCEs.

PHP88

SOCIETAL UNMET NEEDS WITHIN SPAIN

Dibonaventura MD[1], Isherwood G[2], Buenestado B[3], Manso M[3]
[1]*Kantar Health, New York, NY, USA,* [2]*Kantar Health, Epsom, Surrey, UK,* [3]*Kantar Health, Madrid, Spain*

OBJECTIVES: The aim of the current study is to examine how unmet needs, defined as prevalence rates, treatment rates, and quality of life, compare between Spain and other countries in the EU. **METHODS:** Data from the EU National Health and Wellness Survey (NHWS) were used (N=57,805), with respondents from France, Germany, Italy, Spain, and UK ("5EU"). NHWS is an internet-based survey which relies on a random stratified sampling framework to ensure demographic representativeness of each country. Among the 10 most prevalent conditions in 5EU, differences in prevalence, treatment rates, and health utilities (using the SF-6D) were compared between 5EU and Spain (N=5,039). **RESULTS:** Prevalence rates were lower in Spain for 7 of the 10 conditions investigated. Despite the lower prevalence rates, treatment rates for these conditions were consistently higher. The single exception was dyslipidemia, which was more prevalent in Spain (24.2% vs. 14.7%) and had a lower treatment rate (50.7% vs. 56.0%) than elsewhere in 5EU. Stronger beliefs in seeing their physician and in prescription medications were also reported by Spanish patients relative to elsewhere in 5EU. The greatest unmet needs in Spain, defined as high prevalence estimates and low treatment rates and health utilities, were reported for patients with insomnia/sleep difficulties (Prevalence=27.6%, Treatment rate=31.4%, Utilities=0.67) and anxiety (Prevalence=23.3%, Treatment rate=41.2%, Utilities=0.62). **CONCLUSIONS:** The results suggest prevalence rates are generally lower in Spain than the rest of 5EU though treatment rates are higher. The latter finding could be due to a greater belief in regular contact with physicians and prescription medications in general. Nevertheless, several unmet needs exist for Spanish patients, particularly for insomnia/sleep difficulties and anxiety.

PHP89

DETECTION OF MEDICATION ERRORS IN THE THAI FDA DATABASE OF ADVERSE DRUG REACTIONS REPORTS

Bunchuailua W[1], Bunthum K[1], Poonpanich N[1], Limpreedeechai P[1], Angkasirikumjorn A[1], Suwankesawong W[2]
[1]*Faculty of Pharmacy Silpakorn University, Muang, Nakhon Pathom, Thailand,* [2]*Food and Drug Administration, Muang, Nonthaburi, Thailand*

OBJECTIVES: Preventable adverse drug reactions (ADRs) are some of the most common consequences of medication errors (MEs). Database of ADR reports can provide information on wide range of different adverse events and other medication related problems including MEs. The aim of this study was to identify MEs from ADR reports in the Thai Food and Drug Administration (Thai FDA) database. **METHODS:** ADR reports of Statin drugs in the Thai FDA database between 1993 and 2009 were retrospectively analyzed. Reports were assessed for identifying MEs regarding type of MEs that caused ADR and the subsequent adverse outcome. **RESULTS:** Of the 1682 reports assessed, 74 reports (4.40%) were identified as MEs that caused ADR. Regarding the type of MEs, most of them were related to failure to adjust for drug-drug interaction (86.5%) following by overdose (13.5%). Among 74 ADRs resulting from MEs, 49 (66%) were serious outcomes and 25 (34%) were considered as non serious outcomes. **CONCLUSIONS:** Analysis of ADR database identified circumstances that are most prone to errors. This capacity can contribute to the detection and prevention of medication related problems, therefore enhance patient safety.

PHP90

THE REFORM OF THE COMMUNITY PHARMACY IN ITALY BETWEEN NEW ROLE AND MANAGERIALISM

Vagnoni E[1], Heidari M[2]
[1]*University of Ferrara, Ferrara, Italy,* [2]*University of Ferrara, Ferrara, Ferrara, Italy*

OBJECTIVES: In Italy the role of community pharmacies is changing. The reform the country is undertaking aims at designing a community pharmacy delivering a number of services and highly involved in the health system. Consequently, new skills and knowledge are required for the pharmacists to be successful regard both the health objectives and the economic ones. The aim of the paper is to analyze a) the perceptions of the pharmacists toward the new context defined by the recent reform, and b) their attitude to play the changing agent role. Thus, the ability of the pharmacists to have a strategic orientation, the nature of its information system, and the his/her knowledge of the context will be investigated. **METHODS:** A survey has been designed, and a questionnaire submitted to a national sample of 500 community pharmacies. The questionnaire was organized in 4 sections: the general profile and training; his/her perception of the role played; the strategic orientation; the pharmacy information system. Answers were graded according to the Likert scale 1-7. The response rate was 32%. **RESULTS:** Data highlight how the pharmacies are already challenging the changing context offering a range of services: prevention campaign (71,8%), booking diagnostic exams and specialists' visits (50,9%), participation to health education programs (49%). However, the strategic attitude of respondents is not very high (m=4.90). Pharmacies deliver a range of services to improve customers fidelity, and their image toward the community. It has not been detected a correlation between range of services delivered and profit targets. Pharmacies have a good control of the global financial results, but a poor ability to monitor partials results. **CONCLUSIONS:** Pharmacies know the new model of pharmacy the government is introducing, however it doesn't seem they have the right background and attitudes to challenge the new context.

PHP91

PATIENT SAFETY ACTIVITIES ASSOCIATED WITH HOSPITAL PHARMACY IN A NATIONWIDE SURVEY ON MANAGEMENT SYSTEM FOR PATIENT SAFETY

Hirose M[1], Imanaka Y[2]
[1]*Shimane University Hospital, Izumo, Shimane, Japan,* [2]*Kyoto University, Kyoto, Japan*

OBJECTIVES: A business hours study by pharmacy practice was examined as a part of patient safety activities associated with hospital pharmacy. **METHODS:** We surveyed nationwide the situation of patient safety activities in hospitals allowed for additional costs on patient safety measures under the social insurance medical fee schedule. Of targeted 2674 hospitals (all hospitals: 8706 as of June 1) in Japan, 669 hospitals responded (response rate: 25.0%). Pharmacy practice includes medication teaching and history administration, brought drugs review on admission, drug adjustment and dispense, question reference from out-of-hospital pharmacy, drug information for safety use. **RESULTS:** We classified 669 hospitals into three classes; additional cost I (85 points) implementing hospitals with more than 401 beds (A group: 173 hospitals), additional cost I (85 points) implementing additional cost I with less than 400 beds (B group: 306 hospitals), and additional cost II (35 points) implementing hospitals (C group: 180 hospitals). The time spent for medication teaching and history administration was 20.6% of all pharmacy practices in A group, 20.4% in B group, and 18.1% in C group. Similarly, the time for brought drugs review was 6.6% in A group, 8.2% in B, and 7.5% in C, and the time for drug adjustment and dispense of anti-neoplastic drugs was 9.4% in A, 5.9% in B, and 1.9% in C. The time for question reference from out-of-hospital pharmacy was 2.9% in A, 4.3% in B, and 4.6% in C. **CONCLUSIONS:** The time for medication teaching and history administration, and drug adjustment and dispense of neo-plastic drug and IVH were spent much more time at large scale hospitals like A group hospitals than at small scale hospitals like C group hospitals.

PHP92

LACK OF CLINICAL EFFICACY AS A MAIN REASON FOR AHTAPOL NEGATIVE RECOMMENDATIONS FOR ORPHAN ONCOLOGY DRUGS

Ofierska-Sujkowska G, Jagodzinska-Kalinowska K, Matusewicz W, Pasierski T
Agency for Health Technology Assessment in Poland, Warsaw, Poland

OBJECTIVES: The objective of this study is to verify if the clinical efficacy is the main reason on which negative recommendations issued by AHTAPol (Agency for

Health Technology Assessment in Poland) for orphan oncology drugs are based. The role of AHTAPol is to prepare for the Minister of Health recommendations on financing all medical technologies from public funds. Orphan oncology drugs undergo pharmacoeconomic evaluations and coverage decision processes similar to other molecules. AHTAPol's reimbursement recommendations are based on evidence of clinical benefit and efficacy/safety ratio, cost-effectiveness, costs and their impact on the payer's budget. **METHODS:** Among recommendations of AHTAPol published until the end of May 2011, we identified all related to orphan oncology drugs. Having categorized into types of recommendations then we analyzed rational for granted decision. **RESULTS:** Among 420 AHTAPol decisions analyzed, 32 (21,7%) applied to non-drugs technologies, 91 (21,7%) to health care programs and 297 (70,7%) to drugs technologies. Among 297 drugs recommendations only 15 (5%) was related to oncology orphan molecules. Granted were 10 (out of 15) positive recommendations. For 3 out of 15 drugs AHTAPol issued conditional recommendations (with restriction related to reducing the cost- effectiveness outcomes). Only two orphan oncology drugs were assessed negatively. In both cases main criteria on which recommendations were based refer to low clinical efficacy and safety. **CONCLUSIONS:** Neither cost-effectiveness nor costs and budget impact were significant arguments in negative recommendations of AHTAPol. As a matter of fact, lack of clinical efficacy and insufficient safety profile were the key issues for orphan oncology drugs negatively assessed by AHTAPol.

PHP93

REGIONAL DIFFERENCES AMONG METHADONE MAINTENANCE PROGRAMS IN SPAIN

Vieta A, Hurtado P
IMS Health, Barcelona, Barcelona, Spain

OBJECTIVES: Methadone maintenance programs (MMP) offer the best treatment for opioid dependence. In Spain, methadone hydrochloride is prepared as a magistral formulation. Despite the organization and the management of the MMP is in hands of the Delegación del Gobierno para el Plan Nacional sobre Drogas, each autonomous region (AR) is responsible for its planning and financing. The aim of this study was to identify planning MMP differences among AR in Spain. **METHODS:** A structured literature review on the IME, SciELO, Doyma, Medline, national and AR official bulletins and health web pages, and general and specialised press, up to July 1, 2010. **RESULTS:** Planning differences were found around four areas. First, in 13 AR the regional health department establishes the health care provision and legal framework for MMP, whereas in 4 AR this is a shared responsibility between health and social security regional departments. Second, three health care networks for the provision of MMP coexist in Spain. Andalusia has drug care centers, 6 AR specialized or mental health centers and 10 AR combine both structures. Third, in 11 AR methadone prescribing and dispensing is performed in one center, in 6 AR in separate centers and in Cantabria coincide both systems. Fourth, in the majority of AR a central laboratory or the hospitals elaborate the greater part of the methadone; however, in 2 AR it is elaborated in pharmacies and in 2 AR in the prescribing center. **CONCLUSIONS:** In Spain, patients are not always normalized into the health care system. Methadone provided in the MMP shows different elaboration, prescribing and dispensing processes across the different AR. This may lead to heterogeneity in the magistral formulation of methadone and patient access to it across the territory.

PHP94

ANALYSIS OF RESULTS OF THE REFERENCE PRICING OF TURKEY

Kockaya G, Uman N, Vural IM, Akbulat A, Ozbek H, Simsek E, Artıran G, Kerman S
General Directorate of Pharmaceuticals and Pharmacy, Ankara, Turkey

OBJECTIVES: IEGM (General Directorate of Pharmaceuticals and Pharmacy) is responsible for setting all human medicinal products prices. Reference pricing system is used for setting prices. Reference countries are reviewed annually and may be subject to certain alterations. The aim of this study is to show the distribution of reference countries which were used for reference pricing. **METHODS:** The price list of pharmaceuticals which was published by IEGM on 15.04.2011 was used for the analysis. Distribution of reference countries and prices were evaluated. **RESULTS:** Prices of 6251 jeneric and 3703 original products were set. 5283 of jenerics and 3306 of originals were in the positive list for reimbursement. Reference pricing was used for 2352 jenerics and 2281 originals. Prices of the remaing were set outside of reference pricing. 32 different countries were used for reference pricing. Italy was the most popular country for reference pricing (24.47%). Italy was followed by Spain (21.96%), Greece (19.69%), France (11.8%) and Portugal (8.7%). Even if Germany was not a reference country, Germany was used in 3.71% of pharmaceuticals. Other 25 countries were used by 13,29%. However the ranking was changed only in pharmaceuticals with prices above 200 Turkish Liras (TL) or original pharmaceuticals; Greece was the most popular country in these rankings by 27.85% and 24.25%, respectively. Italy was the most popular country for reference pricing in sub groups like generics, prices ranging between 0 and 50 TL, 50 and 100 TL, and 100 and 200 TL. **CONCLUSIONS:** It has been shown that Italy has the highest impact on the pricing of all pharmaceuticals in Turkey. Greece has the highest impact on the pricing of originals. Even if Germany was not a reference country, it has been seen that it affects pharmaceuticals more than other countries which were also not used for reference pricing.

PHP95

PAYER PERSPECTIVES ON EVIDENCE FOR FORMULARY DECISION MAKING IN THE UNITED STATES

Wang A, Baerwaldt T, Kuan R, Nordyke R, Halbert R
PriceSpective LLC, El Segundo, CA, USA

OBJECTIVES: The role that payers play in the pharmaceutical market has been increasing in prominence. Much research has focused on public payers and how drug reimbursement policies change in response to data from drug effectiveness studies. However, the commercial payer perspective has not been well researched. This study seeks to describe how U.S. commercial payers use different types of comparative evidence to make reimbursement and formulary placement decisions. **METHODS:** We recruited 20 US commercial payers who currently participate in or lead pharmaceutical and therapeutics committees for their plans. Our participants represent managed care organizations that cover a total of more than 95 million members. We conducted semi-structured qualitative interviews comprised of five representative scenarios and asked payers to rate how they value different study designs for each scenario. The interviews were transcribed, the responses were tabulated, and then analyzed for content. **RESULTS:** The reported value of the study designs differed between national and regional payers as well as between medical and pharmacy directors. National payers have more resources and are more likely to value and conduct retrospective analyses and decision modeling than regional payers. Pharmacy directors tend to favor retrospective analyses and medical directors value RCTs, pragmatic trials, and prospective non-experimental studies. Although RCTs were often the highest ranked study design, payers still found prospective non-experimental studies and retrospective analyses valuable for certain uses. Payers are currently unable to manage most oncology products beyond labeled indications due to political pressure to cover all drugs regardless of price. **CONCLUSIONS:** Payers value and utilize data from a broad range of study designs to inform formulary placement decisions. However, the disease state, market condition, and type of payer will influence what sort of comparative evidence is of the most value.

PHP96

MITIGATING EMERGENCY DEPARTMENT OVER-CROWDING UTILIZING FOCUSED OPERATIONS MANAGEMENT TOOLS

Schwartz D[1], Pliskin JS[2], Goldberg A[3], Ronen B[4]
[1]*Ben-Gurion University of the Negev, Beer- Sheva, Israel,* [2]*Ben Gurion University of the Negev, Beer-Sheva, Israel,* [3]*Ben-Gurion University of the Negev, Beer Sheva, Israel, Israel,* [4]*Tel Aviv University, Tel Aviv, Israel*

OBJECTIVES: Emergency Department (ED) overcrowding (OC) is plaguing EDs worldwide with grave implications on patient and caregiver comfort and quality of care. Alleviating this problem tops agendas of governmental and professional agencies. Many contributing factors have been cited and many approaches have been tried, without widespread success. Focused Operations Management (FM) integrates novel managerial theories and practical tools {such as the theory of constraints (TOC) and the Pareto diagram} into a systematic approach, helping managers to analyze complex operational systems, find bottlenecks and root causes and finally, chart routes to improved throughput and quality. This approach has proved effective in the industry and service sectors, radically improving performance at little additional cost. The FM approach has never been implemented in the ED and could considerably enhance the management of its operations. In this first phase of the research, we use semi-structured interviews with experts, to identify potential high-yield interventions. **METHODS:** A review of the ED operations literature was performed to identify major ED operational challenges, metrics and alleviating measures. Semi-structured interviews with ED head nurses and managers, hospital administrators and Health ministry administrators were conducted. The interviews centered on validation of major challenges identified in the literature search and assessing potential utility of FM tools. **RESULTS:** The major challenges we identified included ED boarding, prolonged length of stay, unjustified ED utilization and slow access to specialist consults, lab tests and imaging studies. Of the FM tools presented to specialists, those assessed to be most promising were "the "complete kit" concept and TOC methods to identify and alleviate bottle necks and to reduce "work in progress". **CONCLUSIONS:** implementation of the novel FM management strategies has enhanced operations and performance in many industries and services. The ED is in dire need and a good candidate for the use of these tools.

PHP97

USE OF PAEDIATRIC "OBSERVATION STATUS" AND EFFECT ON IN-PATIENT ADMISSION RATE IN ACCIDENT AND EMERGENCY (A&E) DEPARTMENTS

Laokri S, Zhang WH, Ben Hamed N, Cohen L, De Wever A, Alexander S
Université Libre de Bruxelles, Brussels, Belgium

OBJECTIVES: To describe the use of paediatric "observation status" in the accident and emergency department (A&E). **METHODS:** A prospective survey was performed in 12 Belgian hospitals during 2 weeks straddling October and November 2010. All patients (<16 years) attending A&E were included. "Observation status" was defined when after the first medical evaluation, instead of hospitalization or home discharge, the situation required further observation of the patient. The clinicians in charge were asked at the start of the "observation" period to prognosticate whether the child would be discharged or admitted. **RESULTS:** Among 3220 children included in the study, the observation rate was 38.6%. The characteristics of these children were as follows. Median age: 5.0 years old (IQR: 1.7-11.3), boys: 53.5%. The median length of stay in A&E was 110 minutes (IQR: 65-175) and 14.3% were admitted as in-patient. The most common observations concerned orthopaedic, medical digestive and respiratory affections. The three main reasons for observation were additional procedures (69.0%), diagnostic determination (10.7%), and treatment testing (8.3%). Most of the observations (86.9%) were performed in a waiting room (not in a bed), 9.7% in an observation unit dedicated to children and

3.4% in an observation unit to adults. Only 4.1% of the observations satisfied the French paediatric short-stay definition (patient in a bed monitored hourly). Compared to the clinicians' prognosticated rate, 1.3% less children were admitted as in-patients. **CONCLUSIONS:** Despite the absence of financial and regulatory frame in Belgium, observation is a frequent modality of care. Observation helped to refine diagnosis and treatments and to reduce in-patient admission rate. However, with regards to the French guidelines less than 5% could be qualified as paediatric A&E short-stay. Flexible observation units should be recommended. **KEYWORDS:** Emergency, paediatrics, short-stay, observation status

PHP98

EXPLORING REGIONAL VARIATION IN TARIFFS/PUBLIC PRICES ACROSS AUTONOMOUS COMMUNITIES IN SPAIN: THE CASE OF DIAGNOSIS RELATED GROUPS AND ICD-9 DIAGNOSTIC CODES

Raluy M[1], De Cock E[2], Rovira J[3], Gimenez E[4], Albarracin MG[5]
[1]*United BioSource Corporation, London, London, UK,* [2]*United BioSource Corporation, Barcelona, Spain,* [3]*Barcelona, Spain,* [4]*Boehringer Ingelheim, Sant Cugat del Valles, Barcelona, Spain,* [5]*QUALIPLUS 77, SL, Barcelona, Barcelona, Spain*

OBJECTIVES: Explore the variability of two sets of tariffs/public prices across Autonomous Communities (ACs) in Spain. **METHODS:** Tariffs/public prices for DRGs and ICD-9 procedure items from all 17 Spanish AC were extracted from official listings. For ICD-9, items appearing in at least 5 ACs were selected. Per item, variability in tariffs/public prices across ACs was measured using the coefficient of variation (CV) where greater CV indicates larger variability. Variability in DRG levels across ACs was assessed for a sub-set of 16 items. We developed a simple relative index whereby a tariff in a region was divided by the average tariff across all regions and then an overall index was computed as the simple mean of all items for each AC. **RESULTS:** Nine out of 17 ACs list DRGs. Navarra had the most complete list (681 items) and Catalonia the least complete (50 items). The lowest CV was for "spinal procedures" (DRG #4, mean: 10,335€, CV: 0.016, N=2) and the greatest for "abdominal interventions to neonates" (DRG 624, mean: 8139€, CV: 1248, N=6). On average, across the sub-set of 16 DRGs, Catalonian tariffs were 63% below and La Rioja tariffs were 31% above the average across 9 ACs. ICD-9 tariffs were identified in 6 out of 17 ACs, and variability for 48 codes that were listed in at least 4 ACs was lowest for "repair of uterine support structures" (ICD-9 #69.2, mean: 1210€, CV: 0.07, N=4) and greatest for "local excision of breast lesion" (ICD-9 #85.21, mean: 710€, CV: 0.83, N=4). **CONCLUSIONS:** Results show great variability amongst AC tariff listings in Spain. Some ACs tend towards consistently higher or lower tariff levels, compared to the average across ACs. Differences are difficult to explain and suggest that tariffs and pubic prices do not reflect actual costs, but may be arbitrary estimates.

PHP99

REIMBURSING TELEMONITORING IN EUROPE: ARE PAYERS READY?

Flostrand S[1], Garde E[2], Toumi M[3]
[1]*Creativ-Ceutical, Paris, France,* [2]*Sanofi, Paris, France,* [3]*University Claude Bernard Lyon 1, Lyon, France*

OBJECTIVES: As evidence and experience of telemonitoring grows, health care payers are confronted with multiple challenges to reimburse these new healthcare solutions. This study evaluated the current reimbursement systems in five European markets (France, Germany, Italy, Spain, and the UK) to determine readiness for telemonitoring and to identify changes required to permit telemonitoring to develop in the future. **METHODS:** To identify current telemonitoring funding, we reviewed the sources and mechanisms used to pay for pilot projects, and then reviewed national and regional health care funding systems to evaluate the readiness to finance telemonitoring. **RESULTS:** There are important differences in financing telemonitoring among European countries. While pilots exist in all countries, these are financed on a project basis from European Union, national or regional funds, outside regular healthcare budgets. Budget silos, disease reference group (DRG) changes and contractual funding are key barriers to payer readiness for telemonitoring. In Germany, only one telemonitoring DRG act is defined, while in France and Italy, defining telemonitoring acts for reimbursement is underway. In these countries, payers are reluctant to pay for the monitoring and alert service component. In Spain, regional authorities are advancing pilots at different speeds but system reforms have not yet been undertaken. Only in the UK, the English NHS has moved from pilots to deployment through financing at the Primary Care Trust level. **CONCLUSIONS:** European reimbursement systems do not yet accommodate telemonitoring, and pilots and device purchases will not sustain this therapeutic solution. To enable telemonitoring, payers need to establish new codes and rules to pay for telemonitoring acts by health care professionals, and decide how to pay for the most complex element: the monitoring and alert service component. Options include: no reimbursement (the current option), a periodic fixed fee or capitation. Any option requires careful framing and the benefits of telemonitoring need further evaluation.

PHP100

DID IQWIG'S DRUG APPRAISALS IN CONNECTION WITH G-BA'S DIRECTIVES CHANGE PRESCRIBING BEHAVIOR OF GERMAN PHYSICIANS?

Valentin M[1], Neises G[2], Salek S[3]
[1]*Fresenius University of Applied Science, Idstein, Germany,* [2]*ABDA, Berlin, Germany,* [3]*Cardiff University, Cardiff, UK*

OBJECTIVES: To assess the impact of different formats of G-BA's (Federal Joint Committee) directives had on the prescription behavior of health care professionals (HCPs) prior to the introduction of the AMNOG legislation (i.e. Directives restructuring the German pharmaceutical market). **METHODS:** A retrospective study of the IQWiG's (Institute for Quality and Efficiency in Healthcare) review of pharmaceutical products covered by a G-BA directive during a 5-year period (2005-2010). An event list reporting the interaction of G-BA, IQWiG and BMG (German Minister of Health) was compiled by systematic searches of official websites. Regression analyses retrieved from IMS data bases (Intercontinental Marketing Services) were conducted defining a 95% confidence interval. Time points where actual sales exceeded or deceeded this confidence interval were reconciled with the list of events concluding if and what kind of events had impacted unit sales. **RESULTS:** G-BA required a mean of 1304 days to generate a directive followed by 567 days required by IQWiG to complete its review. IQWiG achieved a mean output of 15 projects per year, which is half of what NICE achieved in the same period. The format of the final directive had a strong influence on the overall review. These findings indicate that G-BA's directives did not influence the annual number of prescriptions during the five year period. **CONCLUSIONS:** The new set of laws – commonly known as AMNOG is targeting two important weaknesses of the previous systems, which are clearly identified by this study. Thus, clear ambitious timelines should be defined, especially for the most time consuming review stages, namely completion of the report plan and adherence to the principle of evidence based medicine for all reviews.

PHP101

BIOSIMILARS ARE NOT GENERICS FROM PAYER PERSPECTIVE

Shepelev J[1], Rauland M[2], Krattiger C[3]
[1]*GfK HealthCare, London, UK,* [2]*GfK HealthCare, Nürnberg , Germany,* [3]*GfK Research Matters, Basel, Switzerland*

OBJECTIVES: To review the barriers and opportunities in market access for biosimilars. **METHODS:** Both primary & secondary research were used in this study. Primary research was conducted with payers, physicians, pharmaceuticals and biosimilar manufactures. **RESULTS:** The US and EU are currently the largest consumers of biologics in the world; however, other markets are expected to see strong growth in their use of biologics over the next few years. Although many biologics are expected to go off-patent in the next few years, (thereby creating an attractive opportunity for biosimilars); the complex structure of biologics makes the manufacturing process of biosimilars extremely difficult, and with EU legislation currently requiring phase I-III clinical trials to be conducted for all new biosimilars the developmental costs and barriers to entry of biosimilars are high. With respect to the costs per treatment, the price of biologics are significantly higher than for small molecules creating a use-limiting factor in many markets; for this reason biosimilars are recognised by payers and physicians as being cost-effective in the sense of being able to provide the same treatment but at a lower cost (20% cheaper). However, payers confirmed that cost-saving alone will not ensure access for biosimilars and physicians are hesitant to adopt biosimilars due to safety and efficacy concerns. **CONCLUSIONS:** With the use of biologics rapidly increasing, patent expiries expected to occur in the near future and the low numbers of competitors, companies are presented with a new and attractive market with the production of biosimilars. Although there are several challenges to entering the market (including the intense approval process) biosimilars are recognized and are treated differently from generics by payers. With drug costs increasing and concerns over the safety and efficacy of biosimilars, reduced costs of biosimilars together with clinical reassurance will enable broader acceptance and usage of biosimilars in most markets.

PHP102

BIOSIMILARS: PRICING & REIMBURSEMENT IN GERMANY: KEY INSIGHTS FROM SICKNESS FUNDS

Chaudhari SD, Bache B
PAREXEL International, Uxbridge, Middlesex, UK

OBJECTIVES: While the European biosimilars market is still in its infancy, these products are facing tough market access conditions and have yet to match the success of small-molecule generics. With the increasing cost consciousness of the payers and potentially safety concerns, it is imperative to explore the key pricing and reimbursement drivers and barriers for biosimilars from the payer-lens. In addition, the research aims to provide insights into strategies for their successful 'market access' in the German healthcare system. **METHODS:** This research was based on a combination of secondary and primary research to evaluate the key success factors for biosimilars. Secondary research of published data such as G-BA's assessment of biosimilars, current policies, sector-specific research articles contributed towards a framework to understand the key factors affecting payer's attitudes towards biosimilars, which was then validated through a telephone survey of 10 sickness funds in 2011. **RESULTS:** A multitude of factors determine price sustainability for biosimilars in Germany. The attitudes of sickness funds toward biosimilars vary, which affect price dynamics as well as the cost containment measures to encourage/ inhibits its use. While the use and prescribing of biosimilars are subject to quotas and guidelines encouraging its use, some sickness funds' focus on price is moderated by concerns about the safety of biosimilars. Overall, in order to provide access to these products, payers are increasingly raising data requirements. **CONCLUSIONS:** There exits significant inter-payer variability in the extent of inter-changeability and data expectation from future biosimilars. Payer expectations vary, based on the stage of the disease/ indications, the level of unmet need, and the number of available alternatives. In a climate of increasing pricing concerns, securing marketing approval is no longer the end of the road for biosimilars. Hence, unlike generics, biosimilars cannot be merely 'sold' but need to be 'marketed'.

PHP103

GLOBAL HEALTH CARE REFORMS AND PRICING, ACCESS AND HEALTH OUTCOMES STRATEGY

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: During 2009-2011 major healthcare reforms were proposed and implemented in a number of nations, for example, Affordable Care Act in the US, AMNOG in Germany, HSPT in France, KVG in Switzerland and NHS proposed reform in the UK. These reforms have major implications on pricing, market access and HEOR strategy for drug and device products. **METHODS:** To understand the implications of these trends, we analyzed 2009-2011 reform bills and proposed changes worldwide. Additionally, we interviewed public and private payers, key opinion leaders and payer-influencers to understand implications of these reforms on drug and device manufacturers. Stakeholders ranked various data collection methods on a scale of 1-10 (1-least important and 10-most important). **RESULTS:** The global healthcare landscape is expected to undergo significant change during 2012-2016. In the US, government will play increased role as a single payer, especially with–Medicare, Medicaid and CHIP programs– which will cover 114 million Americans, at a cost of $784 billion. In Germany, AMNOG bill marked the end of free drug pricing and would lead to increased insurance premiums (now 15.5% of wages). In the UK, NHS has proposed to replace PCTs with 500-1000 GP-led consortia and use value-based pricing for expensive drugs and devices. Randomized controlled trial, budget impact model and systematic reviews —ranked highest (7.5-9.1) among payers. Overall, payers view that in the future, health economic assessments would play critical role in pricing, coverage and reimbursement of branded products. **CONCLUSIONS:** This analysis shows that global healthcare landscape is expected to undergo significant change during 2012-2016. Discussions with payers, KOLs and payer-influencers highlights increased importance of HEOR data in the future.

PHP104

IDENTIFYING FACTORS INFLUENCING DRUG REIMBURSEMENT IN SCOTLAND

de Raad J[1], Heeg B[2], Charokopou M[2], Corro Ramos I[3], Thuresson PO[2], Heemstra H[2]
[1]*Erasmus University Rotterdam, Utrecht, Utrecht, The Netherlands,* [2]*Pharmerit International, Rotterdam, Zuid-Holland, The Netherlands,* [3]*Erasmus University, Rotterdam, Zuid-Holland, The Netherlands*

OBJECTIVES: Estimate the effect size, by means of odds ratios, of explanatory variables on the reimbursement decision by the Scottish Medicines Consortium (SMC). **METHODS:** SMC submissions between 2008-01-01 until 2011-02-01 were reviewed. From these, 23 a priori defined predictor variables were extracted. Among these were "BI" i.e. high and low net budget impact defined as above £500,000, "certainty-of-ICER" defined as an ICER (base-case or sensitivity analysis) above £30,000, "comparator" defined as active or placebo/uncontrolled trial and "Childhood disease" i.e. the application is for a childhood disease or not, with childhood defined as below or above 18 years of age. The impact of these variables was estimated by means of odds ratios in univariate and multivariate logistic regression analyses. **RESULTS:** Two hundred forty-nine drug applications were reviewed; 151 (61%) received a positive recommendation and 98 (39%) were rejected by SMC. Based on the univariate analyses the following variables were included in the final multivariate model: "BI", "certainty-of-ICER ", "comparator" and "Childhood disease". The other 19 variables such as chronic use, negative risk profile, type of endpoint and societal impact were excluded during the backward selection process for the multivariate model. A positive reimbursement was 47.3:1 more likely for "Childhood disease" versus "no Childhood disease", 25:1 for certain versus uncertain ICER, 3.33:1 for active versus placebo/uncontrolled trial and 2.38:1 for low versus high BI. The corresponding output (OR [95%CI]) from the regression was (47.3[7.1-961.9]) for "Childhood disease", (0.04 [0.01-0.11]) for "certainty-of-ICER ", (0.30 [0.11-0.75]) for "comparator" and (0.42 [0.16-1.10]) for "BI". The R2 statistic for the multivariate model was 0.41 and in-sample prediction was 82%. **CONCLUSIONS:** Most critical predictors for reimbursement were uncertain ICER and Childhood disease. Future research should add granularity by also including reimbursement restrictions as outcome. External validity should be tested by out of sample predictions for new drugs.

PHP105

COST-EFFECTIVENESS IN DRUG REIMBURSEMENT DECISION MAKING: A TOOTHLESS TIGER?

Franken M, Sandmann F, Koopmanschap M
Erasmus University, Rotterdam, The Netherlands

OBJECTIVES: Since 2005, reimbursement requests for outpatient drugs claiming added therapeutic value require pharmacoeconomic evidence to obtain reimbursement in the The Netherlands. This study aims to obtain insight into the role of pharmacoeconomics in actual decision making. **METHODS:** We studied public reimbursement reports from 2005 onwards and investigated in detail the role of pharmacoeconomics next to therapeutic value and budget impact in decision making. **RESULTS:** From 2005 - April 2011, the Dutch reimbursement agency evaluated 304 dossiers, 186 concerned outpatient drugs of which 113 were submitted with a claim of added therapeutic value. In total, 26 out of 113 were denied reimbursement, 60 were classified having added therapeutic value (Annex 1B), 27 were clustered with equivalent drugs (Annex 1A). Only 30% of the submissions (18 out of 60 positive 1B decisions) contained pharmacoeconomic evidence; 37%, 12% and 22% were exempted due to orphan status, being a HIV drug, or other unknown reasons, respectively. Three out of the 18 submissions with pharmacoeconomic evidence only supplied a cost-minimisation analysis, 4 only a cost-effectiveness analysis (1 alongside a cost-minimisation analysis); 11 supplied a cost-utility analysis. Uncertainty was often related to (assumed) treatment utilities and the applied pharmacoeconomic model, only 9 submissions included a cost-effectiveness plane and an acceptability curve. Interestingly, 4 (2) submissions were judged as "insufficiently (moderately) founded" pharmacoeconomic evidence but still received a positive decision, presumably due to their added therapeutic value, treatment modality, expected budget impact, or orphan status. **CONCLUSIONS:** Although cost-effectiveness is a formal reimbursement criterion in the The Netherlands, only 18 out of 60 positively evaluated submissions contained pharmacoeconomic evidence. Only robustness of evidence is evaluated. Even "insufficiently founded" evaluations can yield positive reimbursement decisions. Hence, cost-effectiveness does not seem prominent in actual decision making, resulting in uncertainty about value for money of currently reimbursed drugs.

PHP106

WHEN IS LOWER LEVEL EVIDENCE OF EFFECTIVENESS ACCEPTABLE IN REIMBURSEMENT DECISIONS?: A DECISION ALGORITHM TO GUIDE POLICY MAKERS

de Groot S[1], Rijnsburger A[1], Heymans J[2], Redekop W[1]
[1]*Erasmus University Rotterdam, Rotterdam, The Netherlands,* [2]*Dutch Health Care Insurance Board (CVZ), Diemen, The Netherlands*

OBJECTIVES: Reimbursement decisions require evidence of effectiveness and a randomised controlled trial (RCT) is seen as the best study design to demonstrate effectiveness. However, there may be situations where a (double-blind) RCT will not be considered necessary, appropriate, methodologically feasible, or ethical. The aim of this study was to develop a decision algorithm to determine the appropriate level of evidence when assessing the effectiveness of a medical intervention. **METHODS:** The initial algorithm was based on the literature and interviews with personnel at the Health Care Insurance Board (CVZ), the central reimbursement authority in the The Netherlands. In addition to the results of a previous study of 72 reimbursement dossiers concerning medical specialist care, we also retrospectively studied 20 reimbursement dossiers made by CVZ to identify any arguments why lower level evidence could be accepted. We then interviewed several Dutch and foreign experts. Our algorithm was continuously refined during the study and prospectively validated using new reimbursement dossiers. **RESULTS:** RCT evidence was lacking in most positive reimbursement decisions (8/9), but also in most negative reimbursement decisions. Methodological issues can play a role in accepting lower levels of evidence, e.g. when blinding is impossible. Moreover, an RCT may be unsuitable (e.g. due to time constraints) or viewed as unnecessary (e.g. in testing parachutes). Finally, ethical reasons can play a role in accepting lower level evidence. Our decision algorithm contains a stepwise approach to determine the appropriate evidence level, which includes (double-blind) RCTs, observational comparative effectiveness research or non-comparative effectiveness research. **CONCLUSIONS:** Policy regarding acceptance of lower level evidence in reimbursement decisions needs to be transparent. Our decision algorithm can guide decision makers in reaching a structured and well-founded decision as to whether lower level evidence of effectiveness is appropriate.

Health Care Use & Policy Studies – Health Care Research & Education

PHP107

CLINICAL TRIAL ACTIVITY IN GREECE: OPPORTUNITIES MISSED, SOON TO BE FORGONE?

Athanasakis K[1], Detsis M[1], Baroutsou B[2], Pavi E[1], Kyriopoulos J[1]
[1]*National School of Public Health, Athens, Greece,* [2]*Sanofi-Aventis Greece, Kallithea , Attica, Greece*

OBJECTIVES: Clinical trials (CTs) represent important investments in the clinico-economic setting, as well as in the "human capital" of developed economies. The purpose of the study was to depict CT activity in Greece for 2010. **METHODS:** A questionnaire-based survey was conducted among the members of the Hellenic Association of Pharmaceutical Companies (SFEE). Each company was requested to return via email one questionnaire per interventional CT approved by the Hellenic National Ethics Committee in the year 2010. Items in the questionnaire focused on the following points: phase of the trial, duration, number of patients, CT sites, therapeutic area of the agent under survey and planned budget for the study. The survey lasted for 4 months (December 2010-March 2011). **RESULTS:** Fifty of the 65 SFEE members returned questionnaires (response rate 77%). The majority of CTs was phase-III trials (67%), mainly on oncology (26.5%), endocrine disorders (16.4%) and cardiovascular diseases (13.9%). Most CT sites were affiliated with a university (46%) or an NHS hospital (46%), enrolling 4.5-7.5 patients, on average, depending on CT phase. The average budget per CT was 296,600€ (s.d.: 389,948€). In total, 120 interventional CTs were approved in 2010 in Greece, with the total investment estimated at 35.6 million Euros. **CONCLUSIONS:** Compared to its European peers, the number of CTs conducted in Greece is extremely low. Within a global market context, this constitutes a problem of lost research opportunities and underuse of the country's acknowledged scientific capacity. Major hurdles could be identified in the "bureaucracy" and complexity of the approval process, mainly within NHS, lack of acknowledgement of CT as key priority for research investment and lack of a strong framework for health technology assessment. Quick changes are necessary, in order to cover the distance lost.

PHP108

PUBLIC HEALTH AND PREVENTION IN EUROPE: IS IT COST-EFFECTIVE?

Simoens S
K.U. Leuven, Leuven, Belgium

OBJECTIVES: In the public debate surrounding public health and prevention, it is sometimes assumed that preventive interventions are by definition cost-effective. This study aims to explore whether preventive pharmaceutical interventions are more cost-effective than a curative approach to diseases. **METHODS:** A descriptive study identified European economic evaluations in the Tufts Medical Center Cost-

Effectiveness Analysis Registry between 2000 and 2007. Data were extracted on publication year, target population, intervention, patient sample, disease, prevention stage, and incremental cost-utility ratio of each economic evaluation. Preventive interventions were defined as measures preventing disease onset. Curative interventions related to measures identifying patients with risk factors or preclinical disease or interventions limiting disability after harm has occurred. Results were expressed in terms of costs (valued in 2008 Euro) per quality-adjusted life year. The association between incremental cost-utility ratios and prevention stage was examined by means of the Mann-Whitney U-test. **RESULTS:** The analysis included 231 studies that reported information about 608 incremental cost-effectiveness ratios. Preventive interventions included interventions that were more effective and less expensive than comparators (41% of incremental cost-effectiveness ratios), and interventions that improved outcomes and increased costs (59%). Both preventive and curative interventions covered the full range of cost-effectiveness results. However, preventive interventions had a significantly lower median ratio of 6,255 € per quality-adjusted life year and were thus more cost-effective than curative interventions (12,917 € per quality-adjusted life year) ($p = 0.002$). **CONCLUSIONS:** Although the cost-effectiveness of preventive interventions varies substantially, preventive interventions tended to be more cost-effective than curative interventions.

PHP109
TENDERING OF BIOSIMILARS IN THE UK – DOES LAUNCH PRICE ACTUALLY MATTER?

Viejo Viejo I
PAREXEL INTERNATIONAL, Uxbridge, UK

OBJECTIVES: In the light of the austerity drives and cost containment practices, payers increasingly resort to procurement procedures in order to award contracts for the supply of both conventional drugs and biosimilars. The tough reality of health care economics in conjunction with the commitment of large generic manufacturers, who continue to invest despite the challenges, may mean that tendering of biosimilars may actually be a tool to increase biosimilars' market share by demonstrating price competitiveness.This study aims to evaluate how initial list price, together with other considerations about efficacy and safety, could influence the hospital formulary inclusion of new biosimilar drugs in the UK. **METHODS:** A data framework was developed from secondary research of existing biosimilar list prices, product profiles, clinical data submitted and current landscape. The framework was validated through phone-based interviews across different regions in the UK (n=10) targeting Hospital procurement Pharmacists in 2011. **RESULTS:** Majority of respondents indicated price to be the primary criteria for formulary inclusion although some pharmacists highlighted efficacy and safety parameters as influencing factors **CONCLUSIONS:** The development of clinical commissioning consortia and the expansion of the biosimilar market as major biologicals come off patent mean that more decisions about biosimilar purchasing could be made jointly with primary care. Tendering as a mode of procurement for biosimilars, removes the prescriber's influence which is the acceptance-limiting step for biosimilars currently due to the concerns on efficacy and safety. From a hospital procurement pharmacists' point of view, it is unclear whether a price discount strategy will favour the introduction of new biosimilars in the UK hospitals as other factors might have a more important role in the final purchasing decision.

PHP110
UTILIZATION OF PHYSIOTHERAPY SERVICES IN HUNGARY

Molics B[1], Éliás Z[1], Ágoston I[1], Vas G[1], Endrei D[1], Kriszbacher I[1], Sebestyén A[2], Kránicz J[1], Schmidt B[3], Boncz I[1]
[1]*University of Pécs, Pécs, Hungary,* [2]*South-Trasdanubian Regional Health Insurance Fund Administration, Pécs, Hungary,* [3]*University of Pécs, Zalaegerszeg, Hungary*

OBJECTIVES: Physiotherapy services are reimbursed on a fee for service method in the ambulatory care in Hungary. The aim of this study is to analyze the utilization of physiotherapy services in Hungary. **METHODS:** Data were derived from the financial database of the National Health Insurance Fund Administration, the only health care financing agency in Hungary. We analyzed the year 2008. Medical procedures which can be performed by physiotherapists were included into the study. Medical procedures are listed according to the Hungarian version of the International Classification of Procedures in Medicine of WHO. **RESULTS:** Altogether 151 medical procedures were used by physiotherapists. The following top-11 medical procedure were responsible for more than half (52.5 %) of total activities: ultrasound therapy (8.2 %), iontophorezis (6.5 %), muscle strengthening exercise (4.8 %), individual training (4.4 %), training for circulation improvement (4.1 %), hand massage (4.0 %), passive movement of multiple limb (4.0 %), middle frequency treatment (3.8 %), mobilization of joints (3.3 %), exercises against resistance (3.2 %), education of using medical devices (3.1 %), extension of contracture (3.1 %). Total annual health insurance reimbursement of physiotherapy services was 7.34 billion Hungarian Forint (42.7 million USD; 29.2 million EUR). **CONCLUSIONS:** Physiotherapy care proved to be a highly concentrated health service where 11 medical procedures out of 151 are responsible of more than half of activity and health insurance reimbursement.

PHP111
ISPOR: AWARENESS, DRIVERS AND BARRIERS TO INVOLVEMENT OF UK CANCER NETWORK STAKEHOLDERS

Morton RH[1], Kilby S[2]
[1]*PAREXEL INTERNATIONAL, Uxbridge, UK,* [2]*Surrey, West Sussex and Hampshire Cancer Network, Guildford, UK*

OBJECTIVES: ISPOR's mission is to increase the efficiency, effectiveness, and fairness with which the available health care resources are used to improve health together with a strong vision be recognized globally as the authority for outcomes research and its use in health care decisions towards improved health. Despite modest increases, the membership and conference attendance of health care decision makers still remains low, relative to those involved in academia, industry and consultancy. Assessing if some of those responsible for utilising HEOR data in care provision and care practice are aware of ISPOR and its full resources and the drivers and barriers for involvement could provide an opportunity for increased membership and active involvement. **METHODS:** To elucidate the level of awareness of ISPOR, its publications and other resources, interviews were undertaken with stakeholders within 12 NHS Cancer Networks in the UK. A data framework was developed to support a series of structured telephone interviews according to the British Healthcare Business Intelligence (BHBIA) Legal and Ethical Guidelines for Healthcare Market Research. **RESULTS:** Spontaneous awareness of ISPOR is relatively limited within the NHS Cancer Network stakeholders, with even less awareness to *Value in Health*. Notable areas of interest were Oncology, Patient Adherence and Persistence and Patient Reported Outcomes Measures. The main barriers to membership of ISPOR was its initial awareness and more effective involvement would be limited due to existing NHS commitments, financial resources and levels of individual interest /relevance to existing NHS role. Organisational involvement with NHS stakeholder networks would support increased levels of engagement. **CONCLUSIONS:** To enhance the awareness of ISPOR, its resources, conferences and educational support, ISPOR should consider a more targeted awareness campaign with key NHS clinical networks such as NHS Cancer Networks, British Oncology Pharmacy Association and evolving Clinical Commissioning Groups.

PHP112
INTER-INDIVIDUAL COUNTRY VARIABILITY IN MONOCLONAL ANTIBODIES (MABS) REIMBURSEMENT AND COVERAGE FOLLOWING EMA APPROVAL

Rossi C[1], Miller KL[2]
[1]*PAREXEL INTERNATIONAL, Uxbridge, UK,* [2]*PAREXEL Consulting, Waltham, MA, USA*

OBJECTIVES: Therapeutic monoclonal antibodies (mAbs) are capturing an increasingly larger proportion of the pharmaceutical market. Their specificity for biological targets allows them to effectively treat a variety of indications. Yet, despite their successes, the various stakeholders' viewpoints in European Union (EU) countries are often at odds. We explore mAbs as a drug class, specifically, how they are approved for use by the European Medicines Agency (EMA) and other regulating bodies and how stakeholders' opinions diverge from regulatory decisions. **METHODS:** The following were summarized for mAbs approved for use in EU countries from 2000-2011: regulatory approval decisions; comparing and contrasting payer coverage decisions in selected EU countries; and position statements from patients, advocacy groups, and medical organizations. Discrepancies between initial or post-approval regulatory decisions and the statements of the other stakeholders were highlighted. **RESULTS:** Nineteen mAbs have been approved by the EMA during the past 10 years. The summary data show how stakeholders use clinical data to reinforce their agenda. For instance, bevacizumab has been undergoing battles in both the US and the EU: regulators want to remove specific labeled indications based on safety and effectiveness data and NICE has advised against coverage for treating metastatic colorectal cancer, citing inadequate benefits for the costs, while patients fight for continued access to the therapy to extend their life at all costs. **CONCLUSIONS:** After product approval, physicians have traditionally been the key treatment decision makers; however, the influence of other stakeholders are increasingly affecting the availability and use of drugs. The discordance between decisions made by regulators and payers has forced drug manufacturers to not only show that it is safe and efficacious to regulators, but to demonstrate a product's value to patients and payers. Incorporating the viewpoints of payers as well as patients in the drug development process will narrow the gap between stakeholders.

PHP113
MEASURING THE ORGANIZATIONAL PERFORMANCE IN TENNESSEE: A CASE OF COMMUNITY HOSPITALS

Roh CY, Shirore RM
East Tennessee State University, Johnson City, TN, USA

OBJECTIVES: Recent increase in competition among hospitals, and managed care, and the impact of Medicare Prospective Payment System; properly measured hospital performance has become important to evaluate the impact of policies on the hospital industry. This study assessed the influence of hospital governance on hospital's economic performance and efficiency, and it also attempted to systematically address the issue of 'whether participation by insider and outsider business community stakeholders on the hospital governing board is related to hospital's economic performance'. **METHODS:** The study was focused on 144 community hospitals in Tennessee; those provided general and acute care services from 2000 to 2006. An input-oriented and output-oriented Data Envelopment Analysis (DEA) using multiple input and output variables, which is non-parametric, flexible, and a mathematical programming approach for the performance assessment, was used to measure the efficiency by estimating the optimum level of output, conditional upon the mix of inputs. **RESULTS:** It was found that urban community hospitals were relatively more efficient than rural community hospitals, and smaller community hospitals were relatively more efficient than their larger and medium-sized counterparts. Interestingly, the results revealed that small-sized urban hospitals were relatively more efficient than any other community hospital type. From a management and policy perspective type, the study indicates that both rural and large community hospitals may use urban or small

community hospitals as models in areas such as following: to improve efficiency by downsizing the scale of the hospitals, to adopt new marketing strategies, and to change the cost structure of facility operations. **CONCLUSIONS:** Results of this work can be useful for guidance to hospital CEOs and administrators, creditors and bondholders, health care consultants, public finance and public accounting researchers, public policy analysts, and the government; to gain insights of this issue of hospital's economic performance along the above mentioned variables.

PHP114

PERFORMANCE INDICATORS OF INTENSIVE CARE IN HUNGARY

Varga S[1], Gresz M[2], Boncföldi K[3], Sebestyén A[4], Kriszbacher I[1], Bogár L[1], Boncz I[1]
[1]*University of Pécs, Pécs, Hungary,* [2]*National Health Insurance Fund Administration, Budapest, Hungary,* [3]*Semmelweis University, Budapest, Hungary,* [4]*South-Trasdanubian Regional Health Insurance Fund Administration, Pécs, Hungary*

OBJECTIVES: The aim of the study is to show the change in important parameters of intensive care units in Hungary from the year 2000 to 2010. **METHODS:** Data of the analysis was taken from the financial database of the Hungarian National Health Insurance Fund Administration, the only health care agency in Hungary. We analyzed the number of hospital beds at intensive care units, the number of intensive care units, their average bed numbers, market share. **RESULTS:** The Hungarian health care system has had 150-167 intensive care units all over the country. The teaching and some county hospitals had more then one ICU. That meant 1183-1430 beds during the 10 years. We found the highest number of intensive care beds in 2006 (1430) which was significantly decreased in 2007-2008 below 1300 beds. The median range of beds at a typical ICU was between 5-9. The market share of intensive care hospital beds form the total number of acute care hospital beds increased from 1.8 % in 2000 to 2.9 % in 2011. The proportion of day provided with ventilation also significantly increased from 29 % in 2000 to 68 % in 2010. **CONCLUSIONS:** In Hungary the number of the ICUs and the number of the ICUs' bed did not change significantly in the last 10 years. During this period, the rate of the ventilation increased. The Hungarian intensive care units successfully managed to adapt to the changing hospital environment.

Health Care Use & Policy Studies – Health Technology Assessment Programs

PHP115

PRELIMINARY ANALYSIS OF THE UNWRITTEN DECISION RULES BEHIND THE FRENCH TRANSPARENCY COMMISSION'S ASSESSMENT OF DRUGS

Toumi M[1], Michel M[2], Mraidi M[3], Rahmouni A[3], Duvillard R[3]
[1]*University Claude Bernard Lyon 1, Lyon, France,* [2]*University Paris Descartes, Paris, France,* [3]*Creativ-Ceutical, Paris, France*

OBJECTIVES: Our objective was to analyze the French HTA decision making process of the Transparency Commission (TC) and try to identify unwritten decision rules which influence a drug's SMR and ASMR. **METHODS:** We analyzed the TC database for the years 2005 to 2010, looking at key points of the TC's opinions listed within such as: SMR, ASMR, target population, public health impact, presence of alternatives, orphan drug status, prescription restriction etc. Using a bivariate analysis we compared drugs granted: insufficient SMR versus other SMR; ASMR V versus ASMR IV; ASMR IV versus ASMR I, II and III. **RESULTS:** We found that drugs granted an ASMR V more often had alternatives than drugs with an ASMR IV (89.74% vs. 69.82%, $p<0.005$), while prescription of drugs with an ASMR IV was more often restricted than for drugs with an ASMR V ($p=0.01$ for hospital-only prescription and $p<0.005$ for specialist prescription). The median target population for drugs with an ASMR IV was also smaller than for an ASMR V (15,000 vs. 97,250). On the other hand drugs with an ASMR IV more often had no public health impact than those with an ASMR I-III (55.70% vs. 22.13%, $p<0.005$). Drugs with a high ASMR had smaller median target population (3,400 vs. 15,000) although there was no difference in orphan drug status between the two groups (9.47% for ASMR IV vs. 14.07% for ASMR I-III, $p=0.20$). More drugs with ASMR I-III were paediatric medicines (30.04% vs. 14.79%, $p<0.005$). **CONCLUSIONS:** Further analyses are in progress using additional qualitative criteria extracted from the TC's opinions and using a multivariate analysis. Such information would be critical for the development of TC application dossier.

PHP116

CLINCAL AND ECONOMIC EVIDENCE BASES FOR HEALTH TECHNOLOGY ASSESSMENT: A COMPARISON OF THREE JURISDICTIONS

Walter JW[1], Spinner DS[1], Birt J[2], Bowman L[2], Mauskopf J[1], Drummond M[3], Copley-Merriman C[4]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*Eli Lilly and Company, Indianapolis, IN, USA,* [3]*University of York, Heslington, York, UK,* [4]*RTI Health Solutions, Ann Arbor, MI, USA*

OBJECTIVES: To understand how different evidence bases may contribute to health technology assessment (HTA) across jurisdictions, we reviewed the evidence considered by three HTA agencies supporting reimbursement recommendations for nine drugs. **METHODS:** We selected nine drugs for which the Canadian Common Drug Review (CDR), the Australian Pharmaceutical Benefits Advisory Committee (PBAC), and the National Institute for Health and Clinical Excellence (NICE) had each provided recent reimbursement recommendations. We reviewed the clinical and economic evidence considered for each decision and evaluated whether different evidence bases could have contributed to different HTA decisions. **RESULTS:** The three HTA agencies agreed (recommended to reimburse) for four drugs and reached different recommendations for five drugs. In both categories, somewhat different evidence bases were used by each agency. For a given drug, different comparators were sometimes considered by different agencies. Even when comparators were common across agencies, there was variability regarding which clinical trials were considered. All agencies considered data from direct, randomized trials, but PBAC and NICE accepted indirect comparisons, whereas CDR did not. Regarding economic outcomes, all NICE decisions made use of cost-effectiveness (mostly cost-utility) analyses, but cost-minimization approaches were considered by CDR and PBAC for several drugs. Overall, NICE provided the most transparent reporting on decision making, and CDR was generally the least transparent of the three. **CONCLUSIONS:** HTA drug decisions across the three countries lack good agreement, and considerable variability exists in the clinical and economic bases considered by CDR, PBAC, and NICE. The reluctance of CDR to accept indirect clinical comparisons, and the propensity of NICE to heed expert advice when analyses were inconclusive may contribute to dissimilar decisions being reached for some drugs. Greater transparency and harmonization of HTA methods have the potential to improve efficiency in health care decision-making, and further research analyzing additional HTA drug decisions is warranted.

PHP117

THE COST-EFFECTIVENESS THRESHOLD: THE RESULTS OF A NOVEL LITERATURE REVIEW METHOD

Hinde S[1], Spackman E[1], Claxton K[2], Sculpher MJ[3]
[1]*University of York, York, UK,* [2]*York University, York, UK,* [3]*The University of York, York, UK*

OBJECTIVES: To review the existing literature on; i) the definition of the threshold ii) debate about its use, theory and value and, iii) robust theoretical methods for its calculation. **METHODS:** The traditional approach for literature searching makes use of key terms and Medical Subject Headings (MeSH) that most accurately capture the range of literature relevant to the piece of work while attempting to minimize irrelevant studies. This process requires a degree of expertise (and luck) as to the terms used, with the potential of missing related but differently specified areas of the literature and anything not captured in search engines. The alternative approach is "pearl growing". This approach uses a pool of relevant papers ("initial pearls") to grow the literature both through references and citations until all relevant papers have been discovered. This approach therefore relies on the expertise of the authors of the published literature rather than the searcher's knowledge of applicable terms. **RESULTS:** The traditional method of searching yielded 34 papers, only 17 of which were deemed relevant. In comparison pearl growing resulted in the identification of 76 relevant papers, including all of the 17 papers identified under the traditional strategy. The focus of many of these papers was to debate the use of a threshold, the theory underlying it or its value. A small number focused on methods for estimating its value, with a large majority using the social willingness-to-pay. **CONCLUSIONS:** The "pearl growing" approach offers a range of benefits over traditional methods, including the identification of papers and distinct sections of the literature not discovered otherwise, although it is limited by the existing software. The cost-effectiveness threshold has been heavily debated, but there exists very little literature that attempts to provide a meaningful estimate of its value or even provide a theoretical framework for its calculation.

PHP118

ANALYSIS OF PRICING & REIMBURSEMENT APPROVAL PROCESS FOR NEW DRUGS IN KOREA UNDER NEWLY-INTRODUCED HTA ENVIRONMENT (2007-2010)

Kim HJ, Park JH, Shin HH, Ko SK
Pfizer Pharmaceuticals Korea Limited, Seoul, South Korea

OBJECTIVES: Since 2007, HTA environment has been introduced to evaluate new drug's pricing & reimbursement in Korea, and PE submission became one of mandatory requirements in HIRA (Health Insurance Review Agency). The objective of this study is to understand the overall process and result under the current environment, and to identify factors in the process which might cause a patient access issue. **METHODS:** We reviewed DREC (Drug Reimbursement Evaluation Committee)'s result reports (n=97) of new products from August 2007 to November 2010, which is open to the public. **RESULTS:** Among total 97 cases, the number of reimbursement decision was 58 (59.8%) at HIRA. The majority of reason for reimbursement decision was lower treatment cost (67.2%). DREC accepted only 12 cases' ICER value for reimbursement decision, 85 decisions were made without PE result data. Although clinical usefulness was improved in 33 cases, non-reimbursement decision was made in 6 cases because cost-effectiveness or PE data was uncertain. Among 39 cases of non-reimbursement decisions, 10 cases accepted WAP (Weighted Average Price) that HIRA suggested. Success rate of price negotiation at NHIC was 68.0%, and took 3.7 months including administrative process from DREC decision to MOHW (Ministry of Health and Welfare)'s final announcement. Average duration for final reimbursement decision was 16.9 months. Approximately 7 more months were necessary for applicant with PE data rather than without PE data (22.0 months vs. 15.0 months). **CONCLUSIONS:** The aim for introducing HTA is to list drugs which prove clinical usefulness and cost effectiveness but this analysis shows that it is difficult to expedite patient access to medicine through a HTA environment in Korea. Alternatives beyond PE evidence are needed for timely patients' access to innovative drugs.

PHP119

IS THERE NO OPTIMAL APPROACH FOR ORPHAN DRUGS TO PATIENT ACCESS? RARE DISEASE IS NOT RARE AND NEEDS TO DEVELOP THE NEW PRICING AND REIMBURSEMENT SOLUTION

Kim S, Cho Y, Shim S, Lee J, Kim W, Bae K
Genzyme Korea, Seoul, South Korea

OBJECTIVES: More than 7000 rare diseases have been identified, and mostly have a genetic disorder. In 1983, the Orphan Drug Act was implemented in the United States to encourage the development of drugs for rare diseases. Since then, many orphan drugs have been developed but payers concern about their high prices due to a limited health care budget. In this article we tried to find a solution against lack of methodologies and evidences for pricing and reimbursement of orphan drugs and represent the results graphically. **METHODS:** Cerezyme, Myozyme and Elaprase are reimbursed for rare diseases in Korea. We adopted 3 products to estimate the affordable threshold in cost-effectiveness plane along two properties: 1) reflection of the cost increase in the health care budget, and 2) index of effectiveness including the prevalence, severity and efficacy for each product. Then we modeled a new product by changing its properties and showed results. **RESULTS:** We defined and analyzed the function of affordable threshold based on cost and index of effectiveness in two dimensions. The index of effectiveness was calculated from 0.60 to 0.85 and median cost was distributed between 1.8 and 3.0 hundred million won per year approximately. The affordable threshold for new drug highly depends on weights of prevalence, severity and efficacy. **CONCLUSIONS:** Evidences for rare diseases are often generated from the surrogate outcome, small population and no comparator. Therefore, it is difficult to assess cost-effectiveness of drugs for rare diseases with current approach. We showed that the affordable threshold can be calculated by the products' properties and monitoring periodically. This method needs the social agreement for weights and we discuss further limitations.

PHP120

THE PAST AS PROLOGUE: USE OF COMPARATIVE EFFECTIVENESS REVIEWS (CER) IN NATIONAL COVERAGE DECISION MAKING BY MEDICARE IN THE UNITED STATES AND PREDICTIONS ON FUTURE USE OF CER

Gaffney J[1], Pearson S[2], Jones K[1], Kim H[1], Williams R[1], Hughes KE[1]
[1]*Avalere Health LLC, Washington, DC, USA,* [2]*Institute for Clinical and Economic Review, Boston, MA, USA*

OBJECTIVES: 1) Review all Medicare national coverage determinations (NCDs) from 2007 through 2011 to identify how CER was explicitly an impetus for or considered in the decision, and 2) Make inferences on Medicare's future use of CER from past behavior and recent health reform developments. **METHODS:** We reviewed documentation to identify whether a comparative study or health technology assessment (HTA) was cited in Medicare's decision initiation rationale or referenced in the decision. Specifically, we determined the: 1) Number of NCDs and degree to which CER was used; 2) Types of products and services (e.g., device, procedure); 3) Therapeutic areas; 4) Organizations producing technical CER materials; 5) Inclusion of cost effectiveness; and 6) Frequency and content of a coverage with evidence development (CED) requirement. We characterized Medicare's historical coverage and payment behavior and prognosticated on how aspects of health reform may affect future CER use. **RESULTS:** More than 55% or 36 NCDs considered CER, with radiological procedures and diagnostic/screening tests comprising over half. Sources for the CER technical work were 5 US and 5 international organizations. Eleven of the decisions considered cost effectiveness; 4 reported a cost-effectiveness ratio. While a minority, CED judgments increased over time. Medicare has historically covered and set reimbursement levels that allow for the cost of care plus some profit, only recently and selectively considering evidence of comparative clinical or cost effectiveness. While provisions of the Affordable Care Act and regulatory changes promote the greater use of CER, there are official and practical impediments that serve as a counterbalance. **CONCLUSIONS:** Medicare increasingly will use CER in making NCDs but in ways less straightforward than predicted. While many methods are available to Medicare, perhaps the most promising in the current political environment are evidence threshold "creep", CED, and several novel applications of CER to coverage, coding, and pricing.

PHP121

THE ROLE OF MOLECULAR TESTS IN SHAPING COMPARATIVE EFFECTIVENESS REVIEW (CER)

Hughes KE, Williams R
Avalere Health LLC, Washington, DC, USA

OBJECTIVES: 1) Perform a comprehensive review of the US molecular testing environment; 2) Infer from **RESULTS:** Diagnostic/treatment areas most likely to include comparative effectiveness reviews (CER) involving molecular testing, how CER will be shaped by molecular diagnostics, evidence used in coverage decisions; and 3) Determine global generalizability of US trends. **METHODS:** We reviewed: 1) All non-perinatal molecular tests with actual or potential for CER interface, all Medicare national (NCDs) and selected local coverage decisions (LCDs) involving molecular tests and CER, and US government and related agency high priority disease areas for CER, assessing actual or potential molecular testing inclusion, and 2) We inferred: Clinical areas most likely involving molecular diagnostics and CER,iImpact of molecular testing on CER, evidence required for Medicare/other payer coverage, and universality of US findings. **RESULTS:** 1) Inventory indicates 442 molecular tests/combinations of interest; 259 have potential degrees of CER interface; 2) Medicare database yielded: 2 NCDs (Screening DNA Stool Test for Colorectal Cancer, Pharmacogenetic Testing for Warfarin Response), 9 LCDs and articles: many denials of molecular test coverage, denials cite lack of evidence, including trials, clinical utility, and few cite cost-effectiveness data; 3) Five governmental or health technology assessment organizations point to 14 clinical areas as highest CER priorities: six known to have associated molecular tests; 5 already involved CER activity, and another 7 predicted to have future molecular testing and CER activity per identified priority areas for research. **CONCLUSIONS:** Expect molecular testing: to play an increasing future role in CER, particularly in 7 areas (cancer and hematopathology most prominently, inclusion will necessitate more methodologically sophisticated CER, will make cost-effectiveness part of CER, will require strong clinical utility evidence for payer coverage, and trends will be universal and more pronounced ex-US.

PHP122

A COMPARISON OF HTA RECOMMENDATIONS ISSUED BY AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT IN POLAND (AHTAPOL) AND NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE) IN THE UK – CONSIDERATION OF SOCIAL IMPLICATIONS IN HTA

Cegłowska U, Kolasa K, Hermanowski T
Department of Pharmacoeconomics, Medical University of Warsaw, Warsaw, Poland

OBJECTIVES: Verification whether social implications were considered in HTA process in Poland and the UK. **METHODS:** The comparative analysis included following stages: 1) HTA recommendations issued in the period of January 2010 to May 2011 for AHTAPol and September 2010 to May 2011 for NICE; 2) HTA recommendations were labeled as positive, negative or other (when outcome was neither positive nor negative); 3) Check-list was composed on the basis of INAHTA definition of social issues in HTA and also of a definition which additionally introduced changes in equity and access as a social effect of implementation of a technology. Social issues were grouped in 6 categories; and 4) The impact of consideration of social implications in HTA recommendations was determined. **RESULTS:** Total of 132 AHTAPol Recommendations and 13 NICE Technology Appraisals issued in 2010 were reviewed (in 2 cases, because of the lack of evidence, NICE was unable to make a recommendation). Social implications were found in respectively: 27% and 82% of recommendations. The impact of social implications on HTA recommendations was more common in the UK. In total 59 and 12 were reviewed for AHTAPoL and NICE, social implications were found in respectively: 46% and 83% of recommendations. The impact of social implications on HTA recommendations was more common in the UK. Social implications, frequently raised by AHTAPol during the analyzed period, were: changes in access to health care (48%), influence on patient's functioning in society (15%), patient's ability to work (14%) and others (21% - mainly, avoidable hospitalization). NICE paid more attention to: changes in access to health care (26%), influence on patient's functioning in society (15%), influence on subcultures (15%) and others (35% - mainly, discrimination). **CONCLUSIONS:** During the analyzed period, NICE considered social implications more frequently than AHTAPol. NICE and AHTAPol paid attention to different types of social implications.

PHP123

TO WHAT EXTENT DOES ADVICE FROM THE SCOTTISH MEDICINES CONSORTIUM (SMC) AGREE WITH THAT PUBLISHED BY NICE?

Leonard SA[1], Brooks-Rooney C[2], Kusel J[2], Costello S[1]
[1]*Costello Medical Consulting, Cambridge, UK,* [2]*Costello Medical Consulting Ltd, Cambridge, UK*

OBJECTIVES: In the UK, the National Institute for Health and Clinical Excellence (NICE) assesses the cost-effectiveness of therapies in England and Wales. In Scotland, the Scottish Medicines Consortium (SMC) is responsible for such decisions. There are recognised differences in how these agencies operate, with the SMC adopting an early, rapid approach to health technology appraisal and NICE favouring a more extensive, detailed review. Conflicting decisions between the two agencies can lead to differential drug availability; however, it is generally believed that the recommendations are broadly the same. The purpose of this review is to evaluate the level of agreement over the last year. **METHODS:** The NICE website was searched for single technology appraisals (STAs) published between January and December 2010. The appraisals for the same drugs were identified on the SMC website and the recommendations of NICE and the SMC compared. **RESULTS:** Nineteen STAs were performed by NICE in 2010. These included 11 drugs for cancer indications and an assortment of 8 others. Of the 19 drugs evaluated, NICE recommended 12 and rejected 7. For the same drugs, the SMC recommended 8 and rejected 11. Decisions between the agencies were the same for 13 drugs, equating to agreement in 68.4% of cases. Of the 6 cases where the recommendation differed, 5 were recommended by NICE. In all five cases the SMC found that the economic cases presented by the manufacturers were not sufficiently robust: in one instance weaknesses in the clinical data were also implicated. The one drug recommended by the SMC in contradiction of NICE was also rejected based on cost-effectiveness. **CONCLUSIONS:** In general, there is reasonable agreement between decisions made by NICE and the SMC. Poor evidence regarding cost-effectiveness is the most commonly cited reason for one agency not recommending a drug.

PHP124

PERSONALIZED DECISION MAKING IN CANCER MEDICINE? SYSTEMATIC OVERVIEW OF HTA PROCEDURES AND SPECIFIC APPROACHES IN TEN COUNTRIES ACROSS FOUR CONTINENTS

Schwarzer R[1], Rochau U[1], Mühlberger N[1], Jahn B[1], Sroczynski G[1], Schnell-Inderst P[1], Schall I[1], Kallinger S[1], Lackner M[1], Siebert U[2]
[1]*UMIT - University for Health Sciences, Medical Informatics and Technology; Oncotyrol - Center for Personalized Cancer Medicine, Hall i.T.;Innsbruck, Tyrol, Austria,* [2]*UMIT/ Oncotyrol/ Harvard University, Hall i.T.;Innsbruck, Tyrol, Austria*

OBJECTIVES: Capacity constraints jeopardize health care systems' sustainability all over the world while the number of Health Technology Assessment (HTA) agencies continues to increase. Explicit or implicit use of cost-effectiveness thresholds based on HTA/economic evaluations should indicate whether a technology is worth its costs. Personalized cancer medicine (PCM) promises to be different from established technologies raising the question whether decision making also differs for PCM. Our goal was to identify cost-effectiveness thresholds in general or specific to PCM to finally provide input for decision makers and expert panels. **METHODS:** A conceptual evaluation framework was developed comprising eight

domains including 93 items. We enhanced our previous selection of only European HTA agencies (IQWiG, DAHTA@DIMDI, NICE, HAS, SBU) by AHRQ, MSAC, LBI, BIQG / GOEG, CADTH, DECIT-CGATS, HITAP. Information was collected and compared quantitatively, choosing the item 'cost-effectiveness threshold' as key information. Additionally, HTA agencies' methodological guidelines were extracted for PCM relevant information. Finally, information was entered into the database and compared qualitatively. **RESULTS:** First five agencies differed highly in eight domains (organization scope, processes, methods, dissemination, decision, implementation, and impact). They agreed in only 17-40%. Enhancement by further agencies indicates continued heterogeneity. UK (US$32.000-48,000) and Thailand (US$9,866) indicated explicit but generic (i.e. not specific to disease or type of technologies) thresholds; implicit use was identified in five countries (Australia, Brazil, Canada, Sweden, USA). Germany explicitly uses disease-specific cost-effectiveness ratios. In none of the included countries cost-effectiveness thresholds specific to personalized medicine and/or oncology were identified, even though we found exception rules in UK. **CONCLUSIONS:** Based on a systematic and comprehensive contextual framework displaying HTA in 10 countries of four continents we identified large heterogeneity in the application of HTA. Specific guidance for innovative and costly cancer interventions is lacking.

PHP125

CLINICAL TRIAL LEARNING CURVES MAY IMPACT BOTH CLINICAL AND ECONOMIC OUTCOMES, AND INFLUENCE HEALTH TECHNOLOGY ASSESSMENT AND REIMBURSEMENT DECISION MAKING

Spinner DS[1], Mladsi DM[1], Walter JW[1], Stafford-Smith M[2], Taekman JM[2], Faulkner EC[1]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*Duke University Medical Center, Durham, NC, USA*

OBJECTIVES: We previously presented evidence suggesting that clinical trial learning curves may affect clinical outcomes in patients in drug trials. In the current analysis, we demonstrate the potential effect of learning curves on economic outcomes (specifically, cost-effectiveness). **METHODS:** The PROWESS trial, which evaluated drotrecogin alpha (DrotAA) for severe sepsis, was identified in our previous study and was chosen for further analysis based on several considerations: a published analysis suggested that a clinical trial learning curve may have had a substantial effect on outcomes in a subgroup of patients (APACHE II < 25); and a published cost-effectiveness analysis (which did not account for the learning curve effect) was transparent and easily replicable. Furthermore, a health technology appraisal (HTA) of DrotAA conducted in the UK cited the cost-effectiveness analyses, which suggested that the incremental cost per quality-adjusted life year for patients with APACHE II scores < 25 was $>$ US$400,000. Similarly, an Australian reimbursement decision excluded this patient subpopulation from coverage citing unacceptable cost-effectiveness. We replicated the cost-effectiveness analysis for DrotAA, and used it to model the cost-effectiveness of DrotAA in the subgroup of patients with APACHE II < 25, both with and without the patients enrolled earlier in the trial and thus potentially affected by the learning curve. **RESULTS:** When patients who may have been affected by the trial learning curve were excluded from the analysis, cost-effectiveness of DrotAA improved significantly, from US$411,333 per LYG with all patients with APACHE II score < 25 to US$46,395 per LYG when the first block of patients enrolled at each site was removed from the analysis. **CONCLUSIONS:** Clinical trial learning curves potentially affect both clinical and economic outcomes, and impact reimbursement decisions. Consideration of learning curves may be important in HTAs and reimbursement decisions, particularly when evaluating trial data in which learning curves are more likely to be present.

PHP126

OVERVIEW OF HTA PROCESS AND IMPLEMENTATION AMONG HEALTH STAKEHOLDERS IN BOSNIA AND HERZEGOVINA – SURVEY BASED RESEARCH

Catic T[1], Begovic B[2]
[1]*Society for Pharmacoeconomics and Outcomes Research in Bosnia and Herzegovina, Sarajevo, Bosnia,* [2]*Clinical Centre University of Sarajevo, Sarajevo, Bosnia*

OBJECTIVES: Health Technology Assessment (HTA) is relatively new concept for Bosnia and Herzegovina health care decision-makers. Decision on reimbursement of medicines and other technologies are made on different levels due to decentralised health system and by different stakeholders (Entities/Cantonal Health Insurance Funds-HIF, Hospitals, Ministries of Health-MoH). Objective of this survey was skreening of current situation and understanding of HTA principles, process and implementation in decision making proces among key stakeholders. **METHODS:** A 9-question survey with INAHTA definition of HTA provided has been distibuted to 50 stakeholders with potential influence on reimbursement decisions. Survey include questions on current practices and process of reimbursement decisions, existance of HTA body/commission, criteria for decisions and reasons for de-listing of reimbursed technologies. Deadline for response was two months. **RESULTS:** Overall response rate was 30%; 50% (6/12) of Ministries of Health, 42% (5/12) Health Inusrance Funds and 17% (4/24) Hospitals respond. 73% respondents use criteria for decisions on drug reimbursement, and 67% in case of other technologies. Mostly used criteria are expert opinions (47%) and pharmacoeconomic studies provided by the manufacturer/presentative (40%), while 33% use referal pricing as criteria. Most of respondents use mixed criteria. HTA bodies in form of commission/expert boards are established in 7 institutinons, mostly in MoH and HIFs. This bodies consist of physitians and pharmacists, and only two of respondents include economicst into these bodies. Similar situation is observed in case od medical devices and other technologies reimbursement decisions. De-listing is recorded in 40% respondents but main reason was production discontinuation. **CONCLUSIONS:** Although the response rate is low, it allows conclusions that correlate with the experience and current practices. There is a need for a systematic approach to HTA and adoption of clearer criteria for reimbursement decision-making. Establishing HTA bodies consisted of trained professionals would improve the HTA process and reimbursement decisions.

PHP127

IMPACT OF PATIENT ACCESS SCHEMES ON NICE AND SMC GUIDANCE

Cooke CL
Complete Medical Group, Macclesfield, Cheshire, UK

OBJECTIVES: To determine whether the use of patient access schemes (PAS) in the provision of NICE and SMC guidance could be brought into greater alignment, leading to greater cost savings. **METHODS:** From a survey of technology appraisals published on the SMC and NICE websites, the total number involving a PAS has been assessed. Further, if a PAS is included for a particular drug in one set of guidance, a comparison has been made of the equivalent guidance by the other body. There are differences between NICE and SMC roles: NHS England should fund/resource treatments recommended by NICE; NHS Scotland is expected to consider SMC advice, but it is not binding. SMC issues guidance on all newly licensed medicines, unlike NICE, which prioritizes guidance where it is most needed. **RESULTS:** The list of positive NICE appraisals based on the inclusion of a PAS consists of 15 pharmaceuticals, while the same list for the SMC includes only nine. Most products with a PAS are included in both sets of guidance, with seven of the nine SMC PAS also included in the NICE guidance. The remaining two with SMC PAS have not been assessed by NICE. Of eight NICE PAS not included in SMC guidance, four were accepted/accepted with restricted use, e.g. lenalidomide. The NICE PAS ensures that if a patient receives $>$26 treatment cycles, the manufacturer will cover the cost of further cycles. No PAS is included in SMC guidance; therefore, NHS Scotland has no cost cap. **CONCLUSIONS:** PAS are more frequently included in manufacturers' submissions to NICE than to SMC. SMC has approved a number of therapies for which NICE required a PAS to improve the economic argument. Therefore, for these drugs, NHS Scotland could potentially achieve greater cost savings if SMC demanded similar PAS to those required by NICE.

PHP128

IN DEPTH ANALYSIS OF HEALTH TECHNOLOGY INCORPORATION IN BRAZIL. IS THERE A COST-EFFECTIVENESS MEASURE OF THRESHOLD?

Santos EAV[1], Comparini LB[2], Buschinelli CT[1]
[1]*Roche Brazil, São Paulo, Brazil,* [2]*Bristol-Myers Squibb Brazil, São Paulo, Brazil*

OBJECTIVES: Recently, a study conducted in Brazil (Teich et al, 2010) evaluated the decisions and process submitted to the Brazilian Commission on Health Technology Incorporation (CITEC), classifying them according to therapeutic area, response type and applicant. The study concluded that there is no clear definition of priorities for the incorporation of a new technology; however, it did not analyze a possible cost-effectiveness threshold for decision making. Therefore, the present study aims to evaluate the existence of economic analysis which supports CITEC decisions and map possible trends. **METHODS:** CITEC decisions and technologies for analysis were obtained from the updated list available at the Ministry of Health website. Only economic studies (cost-effectiveness/utility, cost-minimization and budget impact) from the Brazilian perspective were included and the following databases were consulted: "Medline", "SciSearch", "Embase", "Biosis Preview" and "ISPOR Outcomes Research Digest". **RESULTS:** Technologies were classified in 3 categories: incorporated, not-incorporated and in-analysis; and the results from economic evaluations were classified into: dominant /cost-saving; up to $Brz30,000; $Brz30,000-50,000; $Brz50,000-100,000 and above $Brz100,000 per outcome (ideally QALY or LY, but others were considered). Of the technologies that were not-incorporated, only 2 presented economic evaluation from Brazilian perspective: 1 study with incremental cost up to $Brz30,000 and 1 between $Brz50-100,000. From incorporated technologies, only 20% presented economic evaluations with results belonging to all categories (including above $Brz100,000 per outcome). From technologies in analysis, 20% had economic studies, being most of them dominant or cost-saving. **CONCLUSIONS:** Apparently, there is no criterion for health technology assessment and inclusion of new technologies in Brazilian public system (SUS) and also a lack of quality in the economic analysis conducted. Therefore, besides the absence of priorities, the absence of criteria for technology incorporation could potentially lead the system to be inefficient, spending more money than necessary and not adopting cost-saving therapies.

PHP129

SOCIETAL PREFERENCES FOR HEALTH TECHNOLOGY DISINVESTMENT POLICY: VIEWS OF SCOTTISH TAXPAYERS – A QUALITATIVE STUDY

Hislop JM
University of Aberdeen, Aberdeen, UK

OBJECTIVES: Increasingly challenging economic times require challenging decisions to be made regarding health technology disinvestment. Insufficient evidence exists on societal preferences for disinvestment in publicly-funded health care systems. This research sought to explore the acceptability of disinvestment to Scottish taxpayers, their preferences, and whether taxpayer loss aversion is a relevant factor for disinvestment policy development. **METHODS:** Qualitative interviews were conducted with a sample of Scottish taxpayers. Interviews were split into four parts to progress thematic discussion from basic to complex, examine consistency and identify responses potentially indicative of loss aversion. Participants were asked about their general views on the NHS and disinvestment (Part 1), scenario-based questions on disinvestment (Part 2), to freely discuss the disinvestment issues they considered important and who they thought should be involved in making decisions (Part 3), and further scenario-based questions on health technology investment (Part 4). **RESULTS:** Twelve interviews were undertaken. Responses were generally consistent. Scottish taxpayers notionally accepted disin-

vestment, recognising the NHS budget (providing free universal healthcare) was not unlimited. Local organisation of disinvestment policy was preferred, though some national co-ordination was felt necessary to retain equity across geographical jurisdictions. Technologies of unproven or negligible clinical benefit, or obsolete technologies were cited as disinvestment priorities. Respondents preferred disinvestment decisions be clinician-led. Other decision-making groups (e.g. patients) were expected to be biased or not sufficiently knowledgeable about the relevant issues. When existing technologies conferred clinical benefits to (even small numbers of) patients, responses suggested loss aversion, even under circumstances of increased risks alongside these benefits. Biases are uncontrolled when using a qualitative methodology to explore these issues. **CONCLUSIONS:** To maximise acceptability to taxpayers, disinvestment policy-making in Scotland should prioritise technologies of comparatively low or unproven benefit. Decisions should be locally-based and clinician-led. Future research on disinvestment should utilise quantitative, preference-elicitation methods to minimise potential biases.

PHP130

USING ECONOMIC EVIDENCE AND STAKEHOLDER'S PARTICIPATION IN DECISION MAKING ON BENEFIT PACKAGE OF PUBLIC HEALTH INSURANCE IN THAILAND

Pachanee K[1], Mohara A[2], Teerawattananon Y[2], Tantivess S[2], Lertiendumrong J[1], Prakongsai P[1]
[1]*International Health Policy Program, Nonthaburi, Thailand,* [2]*Health Intervention and Technology Assessment Program, Nonthaburi, Thailand*

OBJECTIVES: With the increasing demands for health care from aging society and rapid technological advancement, the National Health Security Office (NHSO) of Thailand demands for the development of systematic, transparent, and participatory processes for selection of new health interventions to be included into the benefit package of universal health coverage (UC) scheme. This study reviews and describes experiences in the development of guidelines for economic evaluation and participatory process of key stakeholders in submission and topic selection of new health interventions into the UC benefit package. Lessons learnt from this initiative are drawn in order to share experiences of Thailand to other developing countries. **METHODS:** Research methods comprise comprehensive literature reviews, focus group discussion, and brainstorming meeting among key stakeholders, working groups, and subcommittee members. **RESULTS:** Research findings indicate that the draft guideline produced by several rounds of stakeholder consultations has been gradually accepted and adjusted by policy makers and key stakeholders. Key features of the guideline comprise a) transparency in topic selection for economic appraisal with full engagement of key stakeholders; b) economic evaluation on selected interventions using incremental cost-effectiveness ratio (ICER); c) budget impact analysis. The ICER threshold of 1 GDP per capita for QALY gained has been applied by the Benefit Package Subcommittee of NHSO. The six criteria for prioritization of topics were adopted in consensus by stakeholder consultations. In Fiscal year 2010 and 2011, this guideline was successfully applied twice a year for topic selection, economic appraisal, and recommendations to the sub-committee and transmitted to NHSO Board for its final decision. **CONCLUSIONS:** This initiative not only produced and applied evidence informed decisions in a transparent manner; it also strengthened and sustained institutional capacities in generating evidence on ICER, budget impact assessment and other ethical social considerations. The NHSO subcommittee is the platform for interchange between evidence and policies.

PHP131

HOW CAN PHARMA INDUSTRY PREPARE ITSELF FOR THE CHANGING PRICING AND REIMBURSEMENT LANDSCAPE OF ORPHAN DRUGS IN EU?

Mukku S[1], Pang F[2], Mcconkey D[3]
[1]*Double Helix Consulting Group, London, UK,* [2]*Shire Human Genetic Therapies, Inc, Basingstoke, UK,* [3]*Double Helix Consulting, London, UK*

OBJECTIVES: Healthc are reforms are inherent in any health care system across the globe in order to take into account changes and developments worldwide on new ways to evaluate innovative medicines. This has impacted drugs being launched in the rare disease space. The research is aimed to understand the dynamics in pricing and reimbursement environment of drugs launched in rare diseases in key European markets. **METHODS:** The research involved desk research as well as interviews with selected stakeholders in EU5, The Netherlands, Sweden, Finland and Romania. **RESULTS:** In the past it was orphan drugs were able to achieve a high price or favourable reimbursement status, largely due to International and National OD legislation. The results inferred that factors such as the level of unmet needs, severity of diseases, prevalence, innovation, clinical effectiveness influence the achievable price and reimbursement. To keep up to speed to the challenges of dynamic healthcare funding environments pharmaceutical companies have to ensure that the value of the product is well demonstrated with a clear value proposition. When products are launched in specific markets, the HTA bodies look for specific criteria to be fulfilled (e.g. the SMC in the UK or HAS in France). **CONCLUSIONS:** Orphan drugs are facing significant challenges in the future. However, opportunities still exist for novel compounds to reach the market place and have an impact on how rare diseases are treated. Low patient numbers, high levels of both disease severity and unmet need and public perception can help boost the economic argument for Orphan Drug Approval and enable strong market access.

Health Care Use & Policy Studies – Patient-Registries & Post-Marketing Studies

PHP132

USE OF A DISEASE SPECIFIC QUALITY OF LIFE TOOL IN A QUALITY ASSURANCE SCHEME FOR DAY CASE HERNIA SURGERY

Koch A[1], Lorenz R[2], Wiese MG[3], Juelicher PW[4]
[1]*Working group , Magdeburg, Germany,* [2]*3 Chirurgen, Berlin, Germany,* [3]*Chirurgie im Gesundheitszentrum, Kelkheim, Germany,* [4]*Johnson & Johnson Medical, Norderstedt, Germany*

OBJECTIVES: Outpatient services in Germany are less controlled by external quality assurance programs. Comprehensive outcome data for benchmarking or health-care decision-making are missing e.g. for day case surgery. A quality-of-life instrument specific to hernia repair with mesh has been recently proposed (Carolinas Comfort Scale, CCS). This study evaluates the integration of CCS as part of a multicentre quality assurance scheme for outpatient surgery. **METHODS:** Sixteen ambulant centres developed a web-based quality assurance scheme for hernia day surgery in Germany. In an evaluation phase, all patients which were intended to treat with 3-dimensional meshes, were registered with consensus into a database through a web-based portal. CCS questionnaires were mailed to patients 4 and 12 weeks after surgery. Patients were requested to send pseudonymized responses to an independent party for inputting answers into the database. Clinical examinations were made 4 and 12 weeks postoperatively. Additional follow-up is planned 52 weeks after surgery. CSS consists of 23 questions in 7 activity- categories and 3 dimensions: sensation of mesh, movement limitations, pain. **RESULTS:** During the first year (Oct 2009 to Sept 2010) 1429 patients were registered (1271 male, 158 female, median age 53 years) and treated for primary (88%) or recurrent (11%) hernia. 1300 (90%)/1246 (87%) patients were clinically reviewed 4/12 weeks after surgery. 1072 (75%) /1002 (70%) questionnaires were retrieved 4/12 weeks after surgery. Patient satisfaction rate was 98%. CCS scores are shown to be decreased from 4 to 12 weeks in all dimensions (Sensation: 0.51 to 0.35, Movement: 0.40 to 0.20, pain: 0.45 to 0.26). **CONCLUSIONS:** CCS, a short, hernia-specific quality-of-life questionnaire, is easy to use and well accepted by patients. It is shown to be a feasible instrument to evaluate patient reported outcome after day-case hernia surgery in a web-based multicentre quality assurance system.

Health Care Use & Policy Studies – Population Health

PHP133

LEVELS OF POPULATION RISK STRATIFICATION BASED ON THE COST OF CARE IN PATIENTS WITH CHRONIC DISEASES

Sicras-Mainar A, Villanueva A, Ibañez J, Frías X, García A, Vila J, Grau J, Reverter M, Bultó C, Martínez S, Llopart J, Vallés M
Badalona Serveis Assistencials, Badalona, Barcelona, Spain

OBJECTIVES: To determine the population risk stratification based on the cost of care (health resource use) in patients with chronic diseases in primary health care (PC). **METHODS:** Multi-center observational design. We included all patients from 6 centers of PC that demanded assistance in 2010 managed by Badalona Serveis Assistencials SA (health organization). The risk population was defined beginning from the complexity (co-morbid chronic [CC]) and fragility (socio-demographic and clinical criteria). Main measures: services (medical, paediatric), chronic co-morbidity (CC) and direct cost model. From a group of experts identified the different chronic conditions and population risk levels: Level 1 (no CC), level 2 (1-2 CC), level 3 (3-4 CC) and level 4 (≥ 5 CC). Fixed (operation) and variable costs were considered. Statistical analysis: linear regression model (coefficient of determination [R2], dependent variable: health care costs) and principal components, $p<0.05$. **RESULTS:** We included 83,090 patients, mean age 40.9 years, women: 53%. The total cost was 56.1 million / EUR. The average / unit cost: 675.3 euros. The cost for drugs was 41%. Stratification levels: level 1 (N = 36,859, 44.4%, €283.9), level 2 (N = 32,644, 39.3%, €694.8), Level 3 (N = 10019, 12.1%, €1461.6, and level 4 (N = 3568, 4.3%, €2331.2). Musculoskeletal diseases (38.1%), mental (31.6%) and cardiovascular (30.4%) were the most frequent, $p<0.001$. Predictive model (R2): age = 23.4%, age-sex = 24.1%, age-sex-CC = 41.8% (medical: 47.9%; Paediatrics: 15.1%, $p<0.001$). It details the complexity and fragility of the patients for each level of stratification and clinical services. **CONCLUSIONS:** The CC is associated with increased healthcare costs. The number of co-morbidities explains much of the costs. Knowledge of the risk / complexity / fragility of the patients should allow preventive intervention strategies.

Health Care Use & Policy Studies – Prescribing Behavior & Treatment Guidelines

PHP134

COMPARISON OF THE KNOWLEDGE IN STANDARD TREATMENT GUIDELINES AMONG MEDICAL PRACTITIONERS AND MEDICAL STUDENTS

Hettihewa LM LM, Wimalasena G, Tharanga D
University of Ruhuna Faculty of Medicine, Galle, south , Sri Lanka

OBJECTIVES: Introduction of module in rational use of medicine (RUM) to pharmacology curriculum needs analysis of existing knowledge among health care workers. The knowledge and attitudes of medical practitioners (MPs) and medical students (MSs) on Standard Treatment Guidelines (STG) were assessed. **METHODS:** Forty-two MPs and 120 MSs were given pretested structured questionnaire on STG and core policies of RUM. **RESULTS:** Results showed that only 78 % of MPs were confident about their knowledge in STG and 7% of them were not attentive. Knowledge of MPs and MSs showed 78% and 84% on contents of STG while the knowledge in core policies was 73% and 34% respectively. More than 99% of MSs and 71% of MPs were attentive on the inclusion of clinical features of the illness in STG. knowledge on updating and significance of STG as guidance for new prescribers of MPs were 84% and 88% respectively while 96 % of MSs had acquainted in those two areas. Both groups had good knowledge on STG is not an accordance with personnel experience (MPs-71%, MSs-74%). 80% of MSs and 75% MPs discerned that common treatment practices is not an inclusion criteria for STG. **CONCLUSIONS:** We found that MSs had good knowledge about the contents of STG and skills in application in RUM are limited. MPs were detailed on core policies & application of STG

but not acquainted on principles of STG. We conclude that MPs need repetitive in-service training programs to ensure the adherence to STG and MSs are in need of skill development programme to pertain STG in clinical practice.

PHP135

EVALUATION OF COST CONTAINMENT INTERVENTIONS INTRODUCED ON THE COMMUNITY DRUG SCHEMES IN IRELAND USING A NATIONAL PRESCRPTION CLAIMS DATABASE

Usher C[1], Tilson L[1], Bennett K[2], Barry M[1]
[1]National Centre for Pharmacoeconomics, Dublin, Ireland, [2]Trinity Centre for Health Sciences, Dublin, Ireland

OBJECTIVES: The aim of this paper was to examine trends in expenditure of pharmaceuticals on the community drug schemes from 2005 to 2010, during which time a range of cost-containment interventions were introduced which affected the pricing mechanism for pharmaceuticals in Ireland. **METHODS:** Data were analysed using a national prescription claims database according to drug class, i.e. generic, patent and off-patent for the two largest schemes; the General Medical Scheme (GMS) and Drug Payment (DP) scheme. Segmented regression was used to analyse the effects of the interventions on expenditure. **RESULTS:** An increase in expenditure was noted across all schemes up to 2009 and declined thereafter to the end of the study period (October 2010). Significant reductions in expenditure were noted following the introduction of a 20% price-cut to patent-expired products (off-patents) ($p<0.001$). In July 2009, pharmacy and wholesale margins were reduced, resulting in significant reductions in expenditure for patented (GMS; $p<0.05$ and DP scheme; $p<0.001$) and generic (DP scheme only; $p<0.01$) products. No significant reductions in expenditure were noted for off-patent products at this time. Furthermore, no significant reductions in expenditure were noted for off-patents following a 15% price reduction in January 2009 and a further 40% price reduction in February 2010. **CONCLUSIONS:** Results from the study indicate that reductions in the wholesale margin and pharmacy mark-up had the largest impact on reducing pharmaceutical expenditure during the study period. This analysis of national expenditure trends over a six-year period provides valuable information for the healthcare payer on the impact of the cost-containment interventions and may provide a benchmark for future negotiations with the pharmaceutical industry.

PHP136

RADIOLOGY DIAGNOSTICS AND INTERVENTIONAL RADIOLOGY SERVICES UTILIZATION PATTERNS AND ECONOMIC CONSEQUENCES ANALYSIS IN A LARGE TERTIARY CARE UNIVERSITY HOSPITAL – THREE YEAR TRENDS

Jakovljevic M[1], Rankovic A[2], Rancic N[1], Jovanovic M[3], Ivanovic M[4], Gajovic O[2], Lazic Z[5]
[1]The Medical Faculty University of Kragujevac, Kragujevac, Serbia and Montenegro, [2]University Clinical Center Kragujevac, Kragujevac, Serbia and Montenegro, [3]University Clinical Center Krgujevac, Kragujevac, Serbia and Montenegro, [4]University of Kragujevac, Kragujevac, Serbia and Montenegro, [5]Clinical Center Kragujevac, Kragujevac, Serbia and Montenegro

OBJECTIVES: Health economic estimates of radioactivity-mediated diagnostic and treatment procedures are seldom in literature. This would be the first one to compare all these examinations and interventions in a large scale trial. Assessment of costs matrix and prescribing patterns of radiology diagnostics and interventional radiographics services and the roots of clinical decision making process contributing to unacceptable allocation of scarce hospital resources. **METHODS:** All inpatients medical dossier files due to wide range of admission causes (approximately 50,000 per year) during three year term and their complete and accurate files on imaging diagnostics and interventional radiographics procedures applied and their consequent costs. An in depth retrospective bottom-up trend analysis of consumption patterns and expenses relative to diagnosis at discharge conducted from perspective of Third party payer, for more than 200.000 inpatients of large tertiary care university hospital (1200 beds) admitted from 2007-2009. **RESULTS:** There were 10.488 patients in 2007, 12.857 in 2008 and 11.893 in 2009 radiologically processed patients with the total expense of provided services of €1,312,123 in 2007, €2,812,460 in 2008 and €1,829,764 in 2009. The patients cost on average 9.887 ± 37.518 RSD (125 ± 475€) in 2007, 17.206 ± 69.552 RSD (218 ± 881€) in 2008 and 14.408 ± 68.297 RSD (154 ± 731€) in 2009. On average, each patient got one lungs graph, each 7th got the ultrasound of the abdomen, each 19th a CT check of the endocranium, whereas each 25th patient got the NMR of the head. **CONCLUSIONS:** The obvious findings confirm irrational prescribing of diagnostic procedures and necessities of cutting costs. These consumption patterns noticed, should gave an important momentum for policy-makers to intervene and provide higher guidelines adherence from clinicians perspective.

PHP137

GUIDELINES FOR PHARMACOECONOMIC EVALUATION FOR SERBIA

Novakovic T[1], Tesic D[2], Stefanovic D[3], Medic G[4], Sovtic D[5]
[1]Galenika a.d., Belgrade, Serbia and Montenegro, [2]Medicines and Medical Devices Agency of Serbia, Belgrade, Serbia and Montenegro, [3]Adoc d.d., 11000 Belgrade, Serbia and Montenegro, [4]Mapi Values, 3995 AX Houten, The Netherlands, [5]Pharmaceutical Chamber of Serbia, 11000 Belgrade, Serbia and Montenegro

OBJECTIVES: To provide methodological and reporting guidelines for pharmacoeconomic evaluation (PE) for Serbia. **METHODS:** A group of researchers specialized in economic evaluation of medicines developed the PE guidelines, following the initiative of other countries in this framework, to provide recommendations for the standardization of methodology applicable to economic evaluation of medicines in Serbia. The guidelines were written in accordance with the best European and international guidelines, with respect to the existing legislation in Serbia. Guidelines are based on a "reference case" (RC) which includes set of preferred methods which analysts should follow when conducting PE for each component of the economic evaluation. **RESULTS:** The literature review should be transparent and reproducible. The RC analysis should only include direct health care costs from the perspective of the health care payer, the governmental payer and the patient. The study question should specify the target population(s) for the intervention. The comparator to be considered in the evaluation is the treatment that most likely will be replaced by the new treatment. Cost-effectiveness and cost-utility analyses are accepted as reference case techniques, under specific conditions. Outcomes in PE in terms of final endpoints instead of intermediary outcomes should be used in the incremental cost-effectiveness ratio (ICER). For the calculation of quality-adjusted life-years (QALYs), a generic quality-of-life measure should be used. Lifetime horizon in principle in PE should be applied, shorter time horizons requires appropriate justification. Uncertainty around the ICER should always be assessed. Costs and outcomes should be discounted at 3% and 1.5%, respectively **CONCLUSIONS:** First Serbian PE guidelines were developed as results of changes in Serbian health system and the need for better and more complete economic information by decision makers. By providing standards for conducting and reporting of economic evaluations, guidelines can address current needs and requests of Serbian health care system.

Health Care Use & Policy Studies – Regulation Of Health Care Sector

PHP138

INTANGIBLE CAPITAL AND RETURN ON ASSETS IN THE PHARMACEUTICAL INDUSTRY

Mahlich J[1], Yurtoglu B[2]
[1]University of Vienna, Vienna, Austria, [2]WHU-Otto Beisheim School of Management, Vallendar, Germany

OBJECTIVES: Price regulation for drugs is often justified by allegedly high profits of the pharmaceutical industry. While older explanations emphasize the importance of market-entry barriers and monopoly power, we argue that high profits are mainly due to measurement errors that arise from the treatment of research and development (R&D) investments and intangible capital by conventional accounting methods. Conventional accounting methods treat R&D as costs and not as an investment that generates (intangible) capital. Applying accounting data for the calculation of companies' return on assets in turn leads to an upward bias of profitability. In this paper we offer a method that corrects for this bias. Based on financial data of 3382 firms worldwide we also estimate a corrected rate of return. **METHODS:** Relying on financial data of 86 publicly listed pharmaceutical firms between 1985 and 2004, we treated R&D expenditures as an investment which has to be activated in the balance sheet. The assumed depreciation rate was 10%. We then calculated the return on assets (i.e. profits after depreciation of intangibles/total assets including intangible capital) and compared the corrected returns with that of 3296 firms of 34 other industries. **RESULTS:** We show that corrected profit rates of the pharmaceutical industry drop by three (average) to five (median) percentage points when assets are calculated to include intangible R&D capital. While the uncorrected profitability of the pharmaceutical industry is indeed among the highest of all industries (only outperformed by the oil and gas industry), the pharmaceutical industry ranks only eleventh when intangible assets are taken into account. **CONCLUSIONS:** Our analysis shows that pharmaceutical profits are biased upwards due to measurement errors of conventional accounting measures. Against this background it is questionable if further price cuts of pharmaceuticals are a good measure of reigning in the exploding health bill.

PHP139

EVOLVING P&R COMPLEXITIES ARE AFFECTING LAUNCH SEQUENCING AND TIME TO MARKET IN 18 DEVELOPED AND EMERGING MARKETS

Marinoni G[1], Bharath A[1], Gennero R[1], Honoré AC[2], Melck B[1], Rodrigues T[1], Uki-Eagleton A[1], Izmirlieva MA[1], Calnan G[1], Krishnan A[1], Ando G[1]
[1]IHS, London, UK, [2]IHS, Zurich, Switzerland

OBJECTIVES: The aim of this study was to evaluate how national pricing and reimbursement processes are affecting medicines' time-to-market (defined as the delay in days between regulatory approval and market launch) and how their evolution over the last 10 years has influenced launch sequences across a sample of 18 developed and emerging markets. **METHODS:** For each market discussed, national pricing and reimbursement processes were studied through primary and secondary research. In each market, these processes were considered from a public versus private sector perspective and from a primary versus secondary-care segment perspective. Meanwhile, to assess evolving launch sequencing trends, time-to-market data were collected in each of the discussed markets for 16 medicines approved for commercialisation between 2000 and 2010. **RESULTS:** Medicine launch occurs within weeks of regulatory approval in free-pricing countries and upon completion of pricing and reimbursement negotiations in countries where either the public or both the public and private markets are price-controlled. Pharmaceutical launch sequences have evolved over the last 10 years, both from a geographic and temporal perspective. Based on our sample of medicines, the time gap between first and second international launch has narrowed from an average of 276 days in 2000 to an average of 57 days in 2010. Primary-care medicines reach the market faster and in a greater number of countries than secondary-care medicines. Secondary-care medicines remain preferentially commercialised in mature, top-tiers markets unless they meet a medical need in emerging markets. **CONCLUSIONS:** A Medicine's time-to-market varies from country to country and broadly reflects the level of complexity and differentiation of national pricing and reimbursement processes. However, additional factors also come into play, including the level of innovation of the medicine, the national medical need for the medicine, the sector (public versus private) and segment (primary versus secondary care) targeted, and the corporate strategy.

PHP140
"TROICA" HEALTH CARE ECONOMICS IN GREECE
Kyriopoulos E[1], Mylona K[2], Tsiantou V[2], Kyriopoulos J[2]
[1]University of Athens, Athens, Greece, [2]National School of Public Health, Athens, Greece
OBJECTIVES: On May 2010 Greece reached an agreement with a joint team of the International Monetary Fund, the European Commission and the European Central Bank, as the country faced severe fiscal problems. According to the Agreement, public pharmaceutical expenditure should be reduced from 1.9% to 1% of GDP, while the reduction on health services and social security expenditure should be accounted for 1.5 billion euros and 1.2 respectively. The aim of the study was to evaluate the progress of the measures taken and to estimate their impact on health expenditure and provision of services. **METHODS:** For the purpose of the study, we used data from the Stand-By Arrangement and its reviews, Hellenic Statistical Authority and Greek System of National Accounts, as well as published data in the literature. **RESULTS:** The cuts of wages in public and private sector (>15%) and the increase of unemployment (from 9% to 15%) resulted in increased demand for public hospital care by 24% as a consequence of reduced demand (>30%) in hospital units of private sector, while a decrease in demand for primary health care in both public and private sector by 10% and 35% respectively was observed. In addition, the cost of time in public hospitals is steadily increased, due to surgical interventions and the use of high technology services, as well as because of reductions on hospital budgets for medical equipment procurements. **CONCLUSIONS:** Although the impact of the implemented reforms and policies in private health expenditures is already visible the significant reduction of health services inputs causes a decrease in quantity and quality of services. The need for balanced development relating both to supply and demand side requires structural reforms in healthcare sector as well as transition from a costly technological model to a health system based on primary care and public health.

PHP141
IN SEARCH OF REFORM FOR THE GREEK HEALTH CARE SYSTEM: DEPICTING THE KEY OPINION LEADERS' VIEWS
Tsiantou V, Athanasakis K, Pavi E, Kyriopoulos J
National School of Public Health, Athens, Greece
OBJECTIVES: Financial crisis in Greece raised the need for more efficient use of resources in the health care sector. A number of policies have been proposed for this purpose. The aim of this study was to investigate the views of healthcare Key Opinion Leaders (KOLs) on the proposed interventions. **METHODS:** Seventy-two KOLs were invited to participate in an expert panel survey. For the purpose of the study a closed questionnaire was developed comprising of six sections based on the proposed policies i.e. audit, economic evaluation, financial management, pricing, health care funding and procurement system. During the meeting KOLs were asked to select the answers that best represented their views on the appropriateness/feasibility of each policy under study and express their opinion in an open discussion that followed. **RESULTS:** Forty experts (55.5%) accepted the invitation. The majority of participants argued that audit is necessary in the health sector but half of them believed that at present it is not feasible. They thought that a certified public institution should be responsible for the audit process. The indicators and targets should be set nationally but can be differentiated locally. Very important was the finding that the audit report should be a criterion for each institution's (hospital) funding and if results are negative then a penalty should be applied. Implementation of economic evaluation in decision-making was considered extremely important. A reform in the hospital's financing was reported as necessary and the most suitable reimbursement technique is a combination of global budget and DRG system. Physicians should be reimbursed based on qualitative criteria. Finally, procurement system should and can be reformed immediately according to the expert panel. **CONCLUSIONS:** All proposed interventions were evaluated positively but experts considered that there is a greater need for an audit mechanism and reform of the procurement system to be implemented first.

Health Care Use & Policy Studies – Risk Sharing/Performance-Based Agreements

PHP142
LANDMARK CER STUDY METHODS REVIEW
Cummins G, Britton K, Doyle J
Quintiles, Hawthorne, NY, USA
OBJECTIVES: Comparative effectiveness research (CER), constitutes a 'real-world' comparison of the risk-benefit profile of a new product with the existing standard of care. In the US, the federal government is supporting the expansion of CER through funding made available in the American Recovery and Reinvestment Act of 2009 (ARRA) and by establishing the Patient-Centered Outcomes Research Institute through the Patient Protection and Affordable Care Act of 2010. Similarly in Europe there is push for relative effectiveness studies. Industry and governments have deployed a variety of experimental research design methods to appraise real-world performance of products vis-à-vis competitors. An evaluation of five recent studies was analyzed to assess CER implications. **METHODS:** We performed a structured review and assessment of five different therapeutic classes (antihyperlipidemics, antipsychotics, antiplatelets, anti-VEGF, and insulin analogues) investigated in CER related studies (AIM-HIGH, CATIE, GeCCO, CATT, and AHRQ CER Premixed Insulin Analogues). CER metrics included study population including comparative agent(s), relevance of conclusions and interpretations outside the study population. **RESULTS:** Study designs varied including head to head, study agent versus placebo, and systematic literature reviews as well as various types of metrics (safety, efficacy, and effectiveness). One study was stopped early due to lack of benefit, three studies determine equivalence of effectiveness (cost, clinical). Another study is still underway (GeCCO) with results expected towards the end of 2011. **CONCLUSIONS:** The number of CER focused studies is increasing with wide variability in study designs, comparators, populations, and endpoints. With the surge of new agencies dedicated to this evolving field of research (e.g., PCORI in the US), it will be important to evaluate the various types of CER studies and resulting information from a multi-stakeholder perspective.

PHP144
MULTI-STAKEHOLDER SURVEY OF COMPARATIVE EFFECTIVENESS RESEARCH PERCEPTIONS
Cummins G, Duong A, Doyle J
Quintiles, Hawthorne, NY, USA
OBJECTIVES: Comparative effectiveness research (CER) is designed to inform health care decision making through evidence generation on relative benefit for treatment options to multiple stakeholders. Payors have experience utilizing self-generated CER information to inform policy decisions including: formulary tier placement, prior authorization requirements, other utilization control techniques, and cost control mechanisms. However, wide acceptance and regular use of CER has yet to be fully realized. The Quintiles New Health Report 2011 survey assessed how and to the extent national payors were receptive to the implementation of CER. **METHODS:** The New Health Report 2011, designed by Quintiles, surveyed multiple stakeholders to better understand each stakeholder's perceptions toward health care, focusing on perceived value. More than 200 biopharmaceutical executives, 153 managed care executives, 500 physicians, and 30 MCOs were sampled in the survey. The focus was payor perspective in relation to value and CER. **RESULTS:** Though the vast majority of payors valued CER and vocalized their desire for more CER data, fewer than half of payors actively promoted CER on their websites or in published literature. Some payors do advocate and sometimes require CER data from manufacturers, 85% of surveyed payors utilized self-generated CER data rather than data provided by manufacturers. Biopharmaceutical executives were overwhelming in agreement to invest more in long-term outcomes data, but only 44% had even access readily available outcomes data to demonstrate value, while 38% admitted that they did not have any access at all to CER information. **CONCLUSIONS:** A large percentage of payors recognize the short/long term value and utility of CER data, but are not accessing the available data and/or are not sure how to access the data. To encourage greater utilization of CER, stakeholders must be more assertive in capturing and evaluating CER information, while partnering together to create more transparent and standardized CER guidelines.

PHP145
THE BURDEN OF EVIDENCE IN THE PHARMACEUTICAL APPRAISAL PROCESS
Brooks-Rooney C, Costello S, Timm B, Leonard SA, Hamer N
Costello Medical Consulting, Cambridge, UK
OBJECTIVES: The emergence of evidence-based medicine (EBM) in the past decade has raised the level of the scientific data required during the drug appraisal process. It is no longer sufficient to prove that a new treatment is better than placebo in one clinical trial; healthcare decision makers additionally require information on how it performs in multiple trials, including against other treatments in the disease area. Systematic reviews, meta-analyses, comparative effectiveness studies and head-to-head trials are becoming essential in the appraisal process as decision makers demand higher levels of evidence from manufacturers. This analysis reviewed PubMed articles for trends in the numbers of such studies from 2001-2010. **METHODS:** The titles of PubMed articles were searched for "systematic review", "meta-analysis", "comparative effectiveness" and "head-to-head" along with the year of publication. **RESULTS:** The mean annual change in the number of articles indexed by PubMed over the period was 6.0%, which represents the background increase in the body of scientific evidence. In contrast, the mean annual change for systematic reviews was 27.4% (from 388 in 2001, to 3406 in 2010), 23.2% for meta-analyses (462 to 2,996), 80.5% for comparative effectiveness studies (5 to 247) and 23.1% for head-to-head trials (11 to 53). These increases are all substantially higher than the background increase in PubMed articles. The increase in comparative effectiveness studies in particular illustrates the strength of interest in this area of research. **CONCLUSIONS:** EBM is now accepted globally as the preferred method of appraising new treatments; as the pharmaceutical industry adapts to this landscape, the number of studies examining the evidence base has increased considerably in the past decade. The next movement in the industry has already arrived, that of direct comparative effectiveness, and whilst the number of head to head studies has already increased we can expect to see further increases over the next decade.

PHP146
CURRENT STATUS AND TRENDS IN PERFORMANCE-BASED SCHEMES BETWEEN HEALTH CARE PAYERS AND MANUFACTURERS
Carlson JJ[1], Gries K[2], Sullivan SD[1], Garrison L[3]
[1]University of Washington, Seattle, WA, USA, [2]University of Washington, Newport Beach, CA, USA, [3]University of Washington Department of Pharmacy, Seattle, WA, USA
OBJECTIVES: To identify and characterize publicly available cases and related trends for performance-based schemes. **METHODS:** We performed a systematic review of performance-based schemes over the past 15 years (1996 – 2011) using publicly available databases and reports from colleagues and health care experts. These were categorized according to a previously published taxonomy of scheme types and assessed in terms of the underlying product and market attributes for each scheme. Macro-level trends were identified related to the timing of scheme adoption, countries involved, types of schemes, and product and market factors. **RESULTS:** Our search yielded in excess of 110 schemes. From this set, we identified:

58 schemes that included a coverage with evidence development component, 25 that included a conditional treatment continuation component, 35 that included a performance-linked reimbursement component, and 37 that included a patient level financial utilization component. Each type of scheme addresses fundamental uncertainties that exist when products enter the market. There has been a continued upward trend in terms of total schemes adopted per year and the number of countries with performance-based schemes in place. Despite the continued enthusiasm, challenges persist including those related to: 1) the cost and burden of implementation; 2) the need for consistent processes for scheme development, data collection, reporting, and evaluation; and 3) negotiating follow-on agreements after scheme initiation. Furthermore, the challenges faced differ by country, health system, and product. **CONCLUSIONS:** There is continued enthusiasm in many countries for using performance-based schemes for new medical products. Given the interest to date and the potential to meet the goals of interested stakeholders, these schemes may become a common element in health care coverage and reimbursement. However, significant challenges persist, and future studies are needed regarding the attitudes and perceptions of various stakeholders as well as evaluating the results and experiences with the schemes implemented thus far.

PHP147

OPINIONS ON MARKET ACCESS NEEDS DIFFER BETWEEN CULTURES AND STAKEHOLDER SECTORS – RESULTS OF A SURVEY OF ISPOR DELEGATES

Kyral A, Johnson KI
Complete Medical Group, Macclesfield, Cheshire, UK

OBJECTIVES: To determine whether stakeholders' opinions on market access issues, in particular the need for QALYs, and risk-sharing, differ by sector and geographical location. **METHODS:** A self-completion questionnaire was presented to a cross section of delegates at the 13th European ISPOR Conference 2010. The questionnaire comprised 7 items, with both ordinal-polytomous Likert scales and open ended responses. Analyses were performed to discriminate between the stakeholder groups including Pearson Chi-squared test of independence, cross-tabulations, and other descriptive statistics for nominal categorical data. The level of agreement between responder groups was obtained from Cohen's Kappa coefficients and radar plots. **RESULTS:** Respondents included representatives of over 60 companies and organisations from over 30 countries. Highly significantly different responses were observed between members from European and non-European countries, with the greatest overall level of agreement being between the industry and academic sectors (87.5%, K=0.75). Fewer respondents from European countries favoured the use of the QALY than those from non-European countries (31.8% vs. 69.2%), whilst significantly more academics favoured the QALY than either industry or agency respondents (62.1% vs 36.6% vs. 21.4% respectively). More academics felt that manufacturers should offer patient access schemes (PAS) routinely (41.4% vs. 19.4% vs. 14.3%). Of non-European respondents, 50.0% felt risk sharing should form part of all health technology assessments compared with only 25% of respondents from European countries. The majority of non-European respondents (53.8%) expressed the need for manufacturers to provide PAS routinely; only 16.3% of European respondents agreed. Only 13.3% of respondents from European countries thought indirect comparisons are a substitute for head-to-head trials, compared with 38.5% of respondents from non-European countries. No other significant differences in opinions on the need for cost-utility analysis or cost-per-QALY thresholds were found. **CONCLUSIONS:** Opinions on market access related issues differ significantly between European and non-European ISPOR members, and between stakeholder groups.

PHP148

GLOBAL PHARMACEUTICAL RISK-SHARING AGREEMENT TRENDS IN 2010 AND 2011

Ando G[1], Reinaud F[2], Bharath A[3]
[1]*IHS, London, UK,* [2]*IHS, Paris, France,* [3]*IHS, London, London, UK*

OBJECTIVES: With payors increasingly looking at ways of cutting pharmaceutical reimbursement costs, pharmaceutical companies need to consider creative solutions to market access for new compounds. The objective of this research was to examine the most recent global trends for 2010 and 2011 in pharmaceutical risk-sharing agreements, which are now a critical part of market access strategies in many countries. **METHODS:** Secondary research was conducted examining reimbursement decisions around the world, with a special focus on Australia, Belgium, Canada, China, France, Germany, Hungary, Italy, The Netherlands, New Zealand, Poland, Spain, UK and United States. This was supplemented by primary research with payors, government agencies and HTA organisations through interviews in native languages to understand the role which risk-sharing agreements have – or have not – played in their respective markets. **RESULTS:** Forty-five new risk-sharing agreements were found under the period of review (January 2010-May 2011), nearly double the total for 2009. Of the new agreements, the majority were finance-based agreements, though there were six new examples of performance-based agreements. 40% of the new agreements were concluded with the UK's NICE, whilst Australia and Italy remain other important markets in this area. However, a significant number of newer countries are beginning to see these agreements, including Belgium, Hungary, Poland and New Zealand, and interest is widening in emerging markets. Around half of the agreements were in the oncology area, but there are signs that risk-sharing is becoming increasingly prominent in other therapeutic areas, including blood disease, mental health, pain treatment, immunology, ophthalmology and cardiovascular care. **CONCLUSIONS:** Risk-sharing agreements are a reality for pharmaceutical companies in many key markets, and need at least to be considered as an alternative market access strategy in certain therapeutic areas.

PHP149

PERCEPTION OF PHARMACEUTICAL COMPANIES ON THE DRUG PRICE-VOLUME NEGOTIATION IN SOUTH KOREA

Kim ES[1], Lee BJ[1], Lee EK[2]
[1]*GlaxoSmithKline Korea, Seoul, South Korea,* [2]*Sookmyung Women's University, Seoul, South Korea*

OBJECTIVES: In Korea, although drug price has continuously decreased due to many price reduction mechanisms, the volume has been increasing. Because this risen volume is considered a main contributor of increasing pharmaceutical expenditure, the government adopted price-volume negotiation in 2006. This study attempted to analyze the status of price-volume (PV) negotiation and identify problems and the solutions to improve the price-volume negotiation. **METHODS:** The comprehensive questionnaire was designed based on Korea price negotiation guideline and validated by three pilot interviewers. It consisted of the status, awareness, satisfaction, problems/solutions. Pharmaceutical company's people involved in market access were interviewed face-to-face. The response rate was 80% (n=34). Multinational and local company accounted for 59% and 41%, respectively. **RESULTS:** Most important factors for PV negotiation were budget impact and price from the Korean PV formula. 69% of 16 PV cases were derived from the price calculated by PV formula and only 42% reached the consensus on budget impact because of different data sources. Most respondents agreed with the objective of the risk-sharing system but the overall satisfaction was significantly low, 1.9 out of 5-point scale. Main reasons are unpredictability of selecting PV product, discreditable NHIC data and non-transparency of the negotiation process. Also, 76.5% of respondents was against PV negotiation because of the government's unnecessary intervention and concerns on weakening the pharmaceutical industry. Especially, respondents worried about profit deterioration due to duplicated price reduction. In response, they suggested the advanced PV model with a more specific PV inclusion criteria and the choice between price reduction and pay-back. Additionally, generic promotion and pay-back system activation to contain the drug expenditure are preferred over price-volume negotiation. **CONCLUSIONS:** The price-volume negotiation in Korea must be improved to motivate the pharmaceutical industry through adopting their opinions on advanced PV model which includes pay-back.

PHP150

PHARMACEUTICAL PRICING UNDER UNCERTAINTY: RISK-SHARING CONTRACTS

Rodriguez-ibeas R[1], Arizti I[2], Antonanzas F[1]
[1]*University of La Rioja, Logrono, La Rioja, Spain,* [2]*Fundación Rioja Salud -CIBIR-, Logrono, La Rioja, Spain*

OBJECTIVES: Pharmaceutical pricing decisions are adopted in a context of uncertainty with regard to the efficacy and safety of the drug as well as to their budgetary implications. Traditionally, pharmaceutical firms have received a fixed price per unit sold regardless of health outcomes and sales volume. This pricing policy tends to increase health budgets and may restrict the access to pharmaceutical innovations for patients. Recently, health authorities have begun to use risk-sharing contracts based on health outcomes to cope with the aforementioned problem. In this paper, we carry out a theoretical modelling of the risk-sharing contracts, emphasizing the variables and parameters that are relevant in the relationship between health authorities and pharmaceutical firms. **METHODS:** We have elaborated a theoretical model that describes the interaction between a pharmaceutical firm and a public health authority using a two-stage game. In the first stage, the health authority chooses the pricing policy, either paying to the firm for treated patient or for cured patient, and in the second stage, the firm, given the pricing policy and the prescribing behaviour of the physicians, selects the price that maximizes its expected profits. We solve the game by backward induction, using the subgame perfect equilibrium as the solution concept. **RESULTS:** Risk-sharing contracts are not always optimal in terms of social welfare. Their optimality depends on the parameters of the problem, being conditioned by the prescribing behaviour of the physicians, the efficacy of the drug and the monitoring costs. We characterize the parametric regions for which each pricing policy is socially optimal. **CONCLUSIONS:** Before using risk-sharing contracts, their convenience must be addressed for each particular case. As a necessary condition, the existence of objective quantitative health indicators is required. Otherwise, it is difficult to implement the pricing policy only based on cured patients.

PHP151

EVIDENCE ON THE IMPACT OF MANAGED ENTRIES ON PAYERS, PATIENTS, MANUFACTURERS, AND HEALTH CARE WORKERS

Ferrario A, Nicod E, Kanavos P
London School of Economics and Political Science, London, England, UK

OBJECTIVES: Managed entries (MEs) are innovative pricing and reimbursement agreements aiming to share the risk related to the introduction of new, high-cost drugs between the payer and the manufacturer. This study aims to review evidence on the impact of MEs on payer, patients, manufacturer, and health care workers and to analyse emerging trends in managed entries at international level. **METHODS:** A systematic literature review (grey and peer-reviewed) was performed complemented by search of health technology assessment agency's websites and selective interviews with decision makers in key European countries. **RESULTS:** Evidence exists of improved cost-effectiveness and lower drug price following the implementation of coverage with evidence development in Sweden. Data from France shows that price-volume agreements led to rebates totalling around 3% of the total drugs bill. Evidence from Italy shows that authorization with a risk-sharing agreement was associated with more rapid patient access in comparison to authorization without such an agreement. It is unclear whether managed entries

constitute a reward for manufacturers, however, various benefits have been reported such as reimbursement for drugs which received an initial negative recommendation (e.g. bortezomib and trabectedin, UK) and competitive advantage in the form of better formulary position (sitagliptin & sitagliptin + metformin, USA); not to mention the possibility of granting discounts while leaving list prices untouched. Considerable administrative burden is placed on health care staff due to the diversity of existing schemes, the complexities linked with retrospective reimbursement, and lack of management capacity at current staffing levels. **CONCLUSIONS:** Although evidence on the impact of MEs is patchy, the systematic literature review showed that there are already lessons to be learnt. Preliminary findings seem to suggest that MEs have indeed the potential of meeting payer, patient, and manufacturer expectations, yet important threats such as implementation difficulties, administrative burden and lack of management capacity need to be addressed.

PHP152

THE ADMINISTRATIVE BURDEN OF PATIENT ACCESS SCHEMES IN THE CHANGING UK HEALTH CARE SYSTEM: A FOLLOW UP STUDY

Haynes S[1], Timm B[1], Hamerslag L[1], Costello S[2]
[1]*Costello Medical Consulting Ltd, Cambridge, UK,* [2]*Costello Medical Consulting, Cambridge, UK*

OBJECTIVES: In the UK, Patient Access Schemes (PAS) have become common in health technology submissions, and have been instrumental in enhancing the availability of otherwise non cost-effective treatments. Despite notable efforts towards recognising and reducing the administrative impact of PAS on frontline staff, evidence suggests that they still result in a significant burden. The study presented here attempted to assess the burden of PAS administration, and how this could change if and when the planned changes to the UK healthcare system are enacted. **METHODS:** A literature search was conducted and freedom-of-information requests were sent to the Patient Access Scheme Liaison Unit (PASLU) for data on PAS administration. A questionnaire developed from our previous pilot study on the administrative burden of PAS was distributed to hospital pharmacists across the UK, and a call for participants was hosted on the Royal Pharmaceutical Society website. **RESULTS:** Value Based Pricing (VBP) is expected to be introduced in the UK once the current Pharmaceutical Price Regulation Scheme comes to an end. PAS approved before this point will continue to be used, although additional PAS may not be introduced under VBP. It is unclear from the available literature how this will affect the role of PASLU and the administration of the remaining PAS. The return-rate for our questionnaire was low; however, responders voiced similar concerns to those recorded in our pilot study, namely the poor recognition of the burden of PAS and the resources required to manage them. Responders were also unclear about how administration of PAS would change with the move to VBP. **CONCLUSIONS:** The role of PAS in the changing NHS, and the burden such schemes could entail, is uncertain. Clear guidelines on the impact of healthcare reform are necessary, alongside additional support to facilitate effective PAS implementation even after VBP is introduced.

Health Care Use & Policy Studies – Conceptual Papers

PHP153

SOME SHORTAGES AND ALTERNATIVES TO THE PATENT SYSTEM FOR PHARMACEUTICALS

Antonanzas F, Juarez-Castello CA, Rodriguez-Ibeas R
University of La Rioja, Logrono, La Rioja, Spain

OBJECTIVES: Pharmaceutical patents have been a useful instrument to promote innovations in some fields. The signature of the TRIP agreement by the World Trade Organization (WTO) in 1994 has implied the generalization of a strong patent system. The objectives of this study is to review some existing alternatives to patents that may both reduce their negative impact in the accessibility to new drugs of patients from less developed countries and promote research in neglected diseases. **METHODS:** We have reviewed the literature on this field and identified different alternatives proposed by international institutions as well as by non governmental organisations. We describe the options and assess their potential impact on public health. **RESULTS:** There are several proposals: i) the intensive use of exceptions and flexibility conditions of Doha´s Declaration, especially, compulsory licensing, ii) the volunteer licensing through the "patent pool", iii) GSPOA initiative that targets the identification and assessment of priorities dealing with R&D referred to diseases prevalent among the developing countries, iv) the approach based on prizes, aiming to incentive innovation through competition by separating the cost of R&D and the price of the drug; v) the Advance Market Commitments to ex-ante obtain the commitment to fund through donations the new agent once it has been developed, and vi) the Priority Review Vouchers that provides incentives to invest in drugs for neglected tropical diseases by offering a transferable voucher to the pharmaceutical firm that allows a priority review process for the authorisation of another agent. **CONCLUSIONS:** Most of the solutions are partial and do not pursue a radical change in the current patent system. In spite of these proposals, there are still many diseases with no treatment as the market does not guarantee a return.

PHP154

IRANIAN HEALTH SYSTEM DECENTRALIZATION REFORM: A QUALITATIVE STUDY OF VARIOUS LEVELS OF AUTONOMY GRANTED TO PUBLIC HOSPITALS AFFILIEATED WITH MINISTRY OF HEALTH IN IRAN

Jafarisirizi M[1], Ibrahimipour H[2], Dehnavieh Tijang R[3]
[1]*Tehran University of Medical Sciences, Tehran, Tehran, Iran,* [2]*Mashhad University of Medical Sciences, Mashhad, Khorasan, Iran,* [3]*Kerman University of Medical Sciences, Kerman, Kerman, Iran*

OBJECTIVES: We aimed to explore the key organizational elements and the degrees of autonomy that is granted to Iranian corportized hospital (trustees hospitals) affiliated to Iranian ministry of health after the Iranian health system decentralization reform. **METHODS:** : All 18 Iranian corportized hospitals (that meet our criteria) involved to the study. In all, 27 Hospital Top Managers were interviewed (82% response rate). The semi-structured interview questions were developed using the Preker and Harding organizational reform Model and in-depth interviews. The "framework" method was used for the analysis. **RESULTS:** Nine themes explain the key organizational elements include: decision right in "strategic", "human resources", "financial" and "physical resources" management, "product" and "procurement" market exposure, "residual claimant" and "social functions". Decision right in "strategic", "human resources" and "physical resources" management was very limited. The hospitals were permitted to generate revenue (fee-for- services) but weren't the residual claimant, completely. The hospital was exposed to product market but limited in procurement market (ceiling payment). Hierarchical and financial accountability were the main accountability mechanism. Several insurance programs and governmental budget were used to protect poor people. **CONCLUSIONS:** We can see a kind of unbalanced and inconsistent autonomy. More decision right in "strategic" and "human resources" management, and procurement market should be granted; and also the hospital needs to be the residual claimant. Government needs a regulatory and accountability mechanism to guarantee hospitals performance and balance the revenue generating and social values objectives.

PHP155

REVIEW OF COST EFFECTIVENESS MODELS OF HIGH BUDGET IMPACT DRUGS

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: The recently made coverage decisions by UK's NICE, Scotland's SMC and the allocation of $1.1 billion for comparative effectiveness research by the United States, are strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top twenty highest selling drugs (~$90-100B worldwide sales). **METHODS:** The Top 20 drugs were selected based on their worldwide sales. For this analysis, we segmented these drugs into categories as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. We analyzed the cost effectiveness studies that were published in peer-reviewed journals. Search was conducted using generic names of the drugs and the phrase "cost effectiveness" in abstract of the published study. **RESULTS:** During 2005-2010, the number of published studies on "cost effectiveness" have increased by more than 30%. There is a large variability in CERs for same drugs for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable CERs than specialty drugs. Variations also exist in methodology used by different groups in modeling cost effectiveness, especially for time horizon and comparator. Majority of primary care drugs were modeled for a time horizon of 35-40 years or lifetime to demonstrate cost effectiveness. **CONCLUSIONS:** This analysis shows the range, variability and methods used for calculation of ICER values for these high budget impact drugs and provides lessons for executives and policy makers.

PHP156

NOVEL DRUG REIMBURSEMENT MODELS: LESSONS AND IMPLICATIONS FROM CANCER DRUG ACCESS SCHEMES

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Cancer drugs are the world's highest selling category of therapeutic products. Due to their premium price and budget impact, several new drug reimbursement models have been implemented worldwide by public and private payers. These models have potential implications for coverage and reimbursement of all branded products. This study reviewed recent cancer drug reimbursement models and developed lessons and implications for future products. **METHODS:** Reviewed cancer drug reimbursement schemes in developed and emerging markets. Interviewed payers and KOLs to develop lessons and implications for future products. **RESULTS:** Public and private payers worldwide have implemented several new models for cancer drug reimbursement to manage budgets and control costs. In the US, private payers are piloting single source compendia and third party protocols (eg. P4 Oncology) to limit off-label use of cancer drugs. In the UK, NICE has successfully negotiated lower price and discounts for first few cycles of therapy. In Italy, AIFA has implemented registry based patient access for cancer drugs. In India, several manufacturers have implemented novel pricing strategy for first few cycles of therapy. In Germany, IQWIG has proposed to use correlations between surrogate endpoints and patient relevant outcomes to determine value of cancer drugs. Due to increased cost pressure on payers, such models are likely to inspire novel reimbursement schemes for other branded products. **CONCLUSIONS:** Cancer drug reimbursement models are setting new benchmark for payers to manage access and control costs. These models have significant implications for other expensive branded products.

PHP157

USING THE CEAC FOR VALUE BASED PRICING: DON'T CHANGE THE GOALPOSTS

Roberts G
Double Helix Consulting, London, UK

ISSUE One approach under consideration for the proposed value based pricing of pharmaceutical is the UK is to have different willingness to pay thresholds. However these are problematic to define, lack transparency and not readily understood by the wider public. **OVERVIEW** Different willingness to pay thresholds have been

suggested as a way to incorporate uncertainty in the measurement of societal value when setting the price of a new pharmaceutical. An alternative approach would be may be to define one WTP threshold and then accept different levels of risk or a different probability of being cost-effective at that threshold. For example innovative products, cancer drugs and drugs for orphan diseases could be assessed with a more flexible approach based on the system already in place. For example we may be willing to accept only a 20% probability that the medicine is cost-effective at £30,000/QALY. In theory, where there is greater uncertainty, the ICER could be any value higher than 30K but at least there is a chance that the treatment is 'cost-effective' for a proportion of patients. Similarly in disease areas where there is low unmet need we could set the barrier higher and these medicines should have a probability greater than 80% of being cost-effective at that threshold. So we have one set of goalposts, if you shoot from the penalty spot you have to score but from the half way line we can accept a few misses. **CONCLUSION** As a society we can remain consistent in what we are willing to pay for a unit of health benefit. For treatments where there is a high unmet need and an added benefit is perceived we can afford to be more risky.

PHP158

DETERMINING THE MONETARY VALUE OF A QUALITY-ADJUSTED LIFE YEAR (QALY): SYSTEMATIC REVIEW OF THE EVIDENCE

Iskedjian M[1], Lelorier J[1], Gafni A[2], Navarro V[3]
[1]*Faculty of Medicine, Montréal, Québec, Canada,* [2]*McMaster University, Hamilton, ON, Canada,* [3]*PharmIdeas Europe SAS, Lyon, France*

OBJECTIVES: There are many thresholds for the value of a Quality-adjusted Life-Year (QALY), varying between countries and jurisdictions, without however clear evidence of the valuation process. The objective of this study was to systematically review the literature for the evidence on the monetary valuation of a QALY. **METHODS:** OVID MEDLINE® was independently searched for 1996-2011 by two reviewers using the keywords [QALY or (Quality and Adjusted and Life and Years)] and [Monetary and (Valuation or Value or (Value estimation) or (Value determination)]. Discrepancies in inclusion and data extraction were handled through agreement. Included articles had to have applied a technique to determine the monetary value of a QALY, either on patients, the public, both, or through other statistical means. **RESULTS:** From 174 articles yielded by the review, 6 met the criteria, 4 were European studies (Denmark, The Netherlands, the UK and Spain), and 1 from each the USA and China. None of them targeted only patients for the valuation, 4 targeted the general public, 2 studies focused on both. Three studies targeted a specific disease while 3 did not limit to any condition. Willingness-to-pay technique was the most common valuation method (5/6) and QALYs were determined with various direct or indirect elicitation measures. The average value for a QALY varied from the equivalent of less than USD$5,000 to more than USD$100,000. While some authors stated that preference valuation can lead to meaningful QALY values, the majority agreed on the large variability of the results depending on many factors such as income level, age, gender or disease condition and method of elicitation. **CONCLUSIONS:** The literature on monetary valuation of a QALY is very limited, and the range of reported values is very wide and can be differently impacted by the survey tools used and by the characteristics of the population of interest.

PHP159

STRUCTURES FOR THE ROLE OF HEALTH TECHNOLOGY ASSESSMENT IN TRANSLATIONAL RESEARCH

Hunger T[1], Schnell-Inderst P[2], Hüsing B[3], Vignola-Gagné E[3], Biegelbauer P[4], Siebert U[5]
[1]*UMIT/ONCOTYROL, Hall i.T./Innsbruck, Austria,* [2]*UMIT - University for Health Sciences, Medical Informatics and Technology; Oncotyrol - Center for Personalized Cancer Medicine, Hall i.T./Innsbruck, Tyrol, Austria,* [3]*Fraunhofer Institute for Systems and Innovation Research ISI, Karlsruhe, Germany,* [4]*Institute for Advanced Studies, Vienna, Austria,* [5]*UMIT/ Oncotyrol/ Harvard University, Hall i.T.;Innsbruck, Tyrol, Austria*

OBJECTIVES: Translational Research (TR) comprises activities aiming at the generation of biomedical knowledge, its transfer into clinical practice, and the take-up of research questions in biomedical research. It is described as a non-unidirectional process with mutual interexchange between different development stages. Health Technology Assessment (HTA) is predominantly located in later phases of the translational process where implementation, diffusion and dissemination of a technology are focused. **METHODS:** Within the ELSA-GEN research collaboration, institutional and social aspects of TR in genomic medicine were investigated (TRi-Gen). We performed literature search and expert interviews to build a concept that captures the potential feed-back loops HTA is involved in, and the characteristics of interactions with actors in TR. **RESULTS:** Traditionally, HTA is applied on a 'societal level' and aims at public and clinical decision-makers. But it can also be performed on a 'project level' to contribute in early phases of development by evaluating premature technologies. In that context, interactions of HTA with manufacturers, clinicians and, to a less extent, (basic) researchers become relevant. Interactions are facilitated and shaped by specific organizational and institutional structures. These 'modes of interaction' include approval and reimbursement regulations, funding structures, stakeholder involvement in the HTA process, and prioritization of assessment topics. Formal prerequisites are not fulfilled between all TR players and phases. Our analysis indicates that where they are not in place, the full potential of HTA for the generation and translation of evidence in TR is not met. Feed-back of HTA results regarding evidence gaps into the research agenda could be strengthened. CONCLUSION: HTA can be regarded not only as a tool to promote successful TR, but also as an additional actor that influences the translation of a technology in different stages. Organizational and institutional structures need to be considered to foster its impact on the translation process.

PHP160

INTRODUCING THE EUROPEAN NETWORK OF CENTRES FOR PHARMACOEPIDEMIOLOGY AND PHARMACOVIGILANCE (ENCEPP): A BRIDGE BETWEEN MEDICINES REGULATION AND HEALTH OUTCOMES RESEARCH

Prieto L, Fitt H, Arlett P
European Medicines Agency, London, UK

Attaining good patient health outcomes (HO) is the underlying purpose of any health care intervention, including drug therapy. The measurement of HO is the basis for evaluating the quality of health services, and a key element in determining the value of health interventions. Along with effectiveness, long term safety is an important component of HO of new authorised human medicines. The explicit assessment of the sustained benefit-risk trade-off of new authorised products must be undertaken to ensure that unintended harmful consequences are not offsetting the intended clinical benefits. Spontaneous reporting schemes provide a means of continuous surveillance of medicines that is important for raising early signals of safety concerns, but ad-hoc post-authorisation safety studies (PASS) may be necessary to evaluate the safety of medicines more accurately. The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) is an initiative led by the European Medicines Agency aimed at further strengthening post- authorisation medicines research in Europe by facilitating the conduct of multi-centre, independent PASS focusing on safety and on benefit/risk. Specifically, ENCePP provides a unique point of access for all involved stakeholders seeking collaboration for the commissioning or the conduct of PASS. This is achieved by offering access to available expertise and research experience in the fields of pharmacoepidemiology and pharmacovigilance across Europe brought together into a functioning network of excellence. It is anticipated that ENCePP will add to knowledge and the EU capacity to conduct PASS studies in the light of shared methodologies and expertise. In doing so, ENCePP can serve as a bridge between medicines regulation and HO research in supporting risk/benefit management planning to minimise adverse events and maximise the benefit of marketed medicines.

PHP161

TOWARDS AN EFFICIENT NATIONAL DRUG POLICY IN THE RUSSIAN FEDERATION

Rudisill C[1], Antoun J[1], Vandoros S[2]
[1]*London School of Economics & Political Science, London, UK,* [2]*London School of Economics & Political Science, London, England, UK*

OBJECTIVES: Russia has a severe access to medicines problem. Of the 142 million people in Russia, only 20 million are eligible for outpatient medicines coverage as part of the Supplementary Medicines Cover (DLO) programme. More than half of the eligible opt-out for cash. The current government's goal is to eventually establish universal outpatient medicines coverage. This study explores pharmaceutical policy options for Russia to improve efficiency and access to medicines. We employ a conceptual framework to explain Russia's priorities and the weighing of each health policy component in developing policy approaches. Based on Russia's particular policy needs, as well as economic environment and market structure, we provide policy options anchored in lessons from the European Union and the United States. Overall, Russia requires more efficient pricing policies to increase coverage and access to medicines. **METHODS:** Our findings suggest that, although generic market shares are high, there is room for lower generic prices. In order to address this inefficiency, we propose the adoption of tenders for high-selling off-patent molecules, and free pricing for molecules with sufficient market competition. The combination of external price referencing and tenders at the wholesaler level for in-patent markets is confusing, and in order to make originator pricing more efficient, we suggest health technology assessment. As universal coverage is a priority, additional funding will be required with potential sources coming from co-payments or abolishing the possibility of opting-out of the DLO for cash. Improving efficiency in the. **RESULTS:** Russian pharmaceutical market will make an additional monetary unit to be invested in medicines rather than somewhere else in the policy environment have a positive effect on social welfare. **CONCLUSIONS:** Russia can achieve greater efficiency and lower prices in its pharmaceutical market, which would contribute to reaching the goal of universal outpatient medicines coverage.

PHP162

IMPACT OF AMNOG ON PHARMACEUTICAL PRICING TRENDS IN GERMANY

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Understand the impact of AMNOG on pharmaceutical pricing trends. **METHODS:** The reforms implemented by AMNOG were reviewed by analysing recent changes in German healthcare system. A basket of five branded products was chosen to analyse pricing trends for past four quarters (Q3 2010, Q4 2010, Q1 2011, Q2 2011). Quarterly increase or decrease in prices were compared for all five drugs. **RESULTS:** AMNOG introduced major changes in German healthcare system. Traditionally Germany was one of the highest priced pharmaceutical markets in Europe, with significant price inflation. However, since the implementation of AMNOG, there has not been any price inflation for the selected five branded products. Our analysis shows that prices have either declined or stayed steady during past four quarters. Some products such as Aranesp saw significant price decreases (5-9% per quarter), driven by AMNOG and by launch of cheaper biosimilar products. Other products show deflation of 0.6-1% per quarter. **CONCLUSIONS:** Pharmaceutical pricing landscape in Germany has significantly altered since the implementation of AMNOG. Newer products would need to demonstrate improvement in comparative efficacy to command premium launch price or increase in price.

PHP163

PHARMACEUTICAL INNOVATION: DEFINITION, AND MECHANISMS FOR REWARD

Hughes D
Bangor University, Bangor, UK

OBJECTIVES: To define the concept of pharmaceutical innovation, examine whether it merits reward, and identify mechanisms for its incentivisation. **METHODS:** Whether or not a medicine is innovative dependents on its novelty and the benefits it generates. Novelty requires something new, original and perhaps ingenious and is a necessary, but not sufficient, requirement for innovation. Novel pharmaceutical attributes include: new target of pharmacological mechanism of action, new chemical structure, improved formulation, improved pharmacokinetics and efficient methods of production. Benefits depend on perspective. Whereas a patient would value health-related quality of life, life expectancy, safety and convenience, payers of healthcare (e.g. UK NHS) may legitimately value population health and cost-effectiveness. A society might additionally value non-health benefits such as attracting pharmaceutical company investment in skilled jobs, and social responsibility (e.g. environment, neglected diseases). **RESULTS:** An effective vaccine developed in the UK against malaria would be considered highly innovative from a societal perspective, but not from an NHS perspective, as malaria does not affect NHS patients. CONCLUSION: Health benefits to NHS patients are already rewarded to (and in some cases beyond) the threshold for cost-effectiveness (£30,000 per QALY). There is no incentive for paying an additional premium. However, where benefits of innovation to society exceed the costs, there is an argument for reward. This should not be through price increases, but through taxation and patent laws. The Patent Box, which will decrease the corporation tax to 10% on profits from UK patents, is one such mechanism. Alternatively, a 'value-based patenting' scheme might vary patent duration according to the benefits achieved, as the clinical evidence matures from the time of licensing. This might benefit patients through the earlier introduction of generics when branded products are mediocre, reward genuinely innovative products, while still allowing the introduction of 'me-toos' to compete on price.

PHP164

A TYPOLOGY OF OUTCOMES FOR HEALTH RESEARCH

Levy A[1], Sobolev B[2], Briggs A[3]
[1]*Dalhousie University, Halifax, NS, Canada,* [2]*University of British Columbia, Vancouver,, BC, Canada,* [3]*Glasgow Universrity, Glasgow, UK*

Measuring "outcomes" is at the heart of this Society's mission and of efforts to improve health and health care delivery. Despite this central role, there is no common agreed-upon definition as to what is meant by outcomes. For example, for some commentators, outcomes refer uniquely to quality-of-life and survival of individual patients; this thinking underlies the US Patient Centered Outcomes Research Institute. For others, including those doing economic evaluation, outcomes may refer to the average health benefit groups of patients. Yet others use "outcomes" to refer to aspects of functioning of the health care system. This lack of consistency does little to illuminate the challenges in equitably delivering timely, high quality, and affordable health care. In this presentation, the authors present a typology of outcomes for health research along with and relevant examples. At the most granular level, endpoints in randomized trials are often clinical outcomes which are characterized as immediately observable - "hard" - such as hospitalization, death or functional status, or latent - "soft" - such as quality-of-life, pain, or satisfaction. At the next level are health outcomes which are the results of care delivered in actual practice and can be subdivided into: treatment outcomes which reflect the intended and unintended medical consequences of undergoing therapy and patient outcomes which reflect the impact on patients of undergoing care in the real world. System outcomes can be thought of as the impact of delivering care to a group of patients and are measures of the degree of functionality of the health care system. At the highest level are societal outcomes, which measure the impact of health on the wellbeing of society. Consensus as to what is meant by "outcomes" would be an important step towards improving the quality of the discourse and critical thinking in this area.

PHP165

A NEW ANTI-REBATE LEGISLATION IN SOUTH KOREA: WILL IT WORK THIS TIME?

Yu SY[1], Yang BM[2]
[1]*Seoul National University, Seoul, South Korea,* [2]*Seoul National University & Institute of Health and Environment, Seoul, South Korea*

OBJECTIVES: The objective of this study is to examine the potential impact of recent reform in anti-rebate law of drugs in South Korea. **METHODS:** It has been an old business practice that some doctors and pharmacists receive financial benefits from pharmaceutical companies and distributors in exchange for business favors in Korea. These kickbacks are considered 'unethical and illegal drug rebates'. The Korea Fair Trade Commission reckoned consumer damage caused by illegal rebates in the medicines market at about US$2.02 billion, accounting for about 20% of total pharmaceutical sales in the year of 2007. There are a couple of reasons why illegal drug rebate is so prevalent in Korea. First, the current drug pricing system guarantees relatively good prices for generic products which local companies focus on producing. Good prices tend to leave rooms for marketing and illegal rebates. On top of that, there are lots of small scale suppliers relative to the pharmaceutical market size of Korea. Fierce competitions among drug suppliers make them concentrate on marketing activities, often coupled with illegal rebates. Third, government has no control over the visits by drug company representatives to doctors' offices. In addition, almost no medical treatment guidelines which could effectively regulate doctor's prescription behavior exist. **RESULTS:** Previously, any illegal marketing practice by drug companies led to criminal punishment of drug companies alone, leaving doctors and pharmacists untouched. Under the new legislation, punishment for illegal rebate is now extended to doctors and pharmacists. By penalizing both rebate givers and receivers, it is hoped that the level of illegal rebate can be disappeared or substantially reduced from the Korean market. However, we need to see what might happen in the real market practices from now on. **CONCLUSIONS:** Remaining issues with this anti-rebate reform will be explored in this study.

PHP166

ON-GOING MARKET ACCESS ADVICE A POSSIBLE SOLUTION TO HELP ENSURE LONG-TERM SUCCESS IN POST-MARKETING CLINICAL STUDIES: CROSS FUNCTIONAL TEAMS OR EXTERNAL CONSULTATION?

Kirpekar S, Mallinson M
Double Helix Consulting, London, UK

OBJECTIVES: Manufacturers are under increasing pressure to conduct shorter clinical trials in order to bring products to market as soon as possible and ensure revenue maximisation before loss of exclusivity. At the same time, authorities from markets across the globe have demonstrated increased interest in post-marketing real-life clinical data in order to help make decisions with regards to reimbursement of drugs as well as their positioning in the treatment pathway. **METHODS:** Manufacturers are spending increasing proportion of their budgets to produce this post-marketing clinical data. It is important to ensure if the data that is being produced is close to the needs of the payers. In majority of instances, it is seen that the data being created is quite far from the expectations of authorities to whose benefit it is being created. The data is typically considered for use in payer discussions only at the end of the clinical study when little flexibility is possible in the end-points and outcomes that will be demonstrated. Also, benefits such as considering early data cuts to present on-going benefit of this long term data is not usually seen. **RESULTS:** ; Market access, outcomes research and medical affairs teams tend to function independently with very little collaboration as a result of differing targets and budgets. This has made it difficult to have early payer-focussed input into clinical studies. This is particularly so if they are post-marketing studies involving teams with lower focus on payer needs compared to peri-launch market access teams. There is an increased need for greater cross-functional effort on producing clinical data to ensure efficient use. **CONCLUSIONS:** Involving an external market access agency that is able to advise on the production, analysis and use of post-marketing clinical data is seen to be the solution to this issue.

PHP167

TELL ME WHO YOUR FRIENDS ARE: "PEERS" IN COMPARING HEALTH CARE SYSTEMS

Carrera P
Ruprecht-Charles University of Heidelberg, Mannheim, Germany

Total health spending and its share in the social product have been staple indicators in assessing and comparing health care systems. Comparison of health care systems based on Euros and cents is limiting, however, since the health care system is not an artifact of the economy. Institutions shape societal values on health care leading to peculiarities even among health care systems that share traditions in terms of health care financing and delivery. This paper presents a framework to compare health care systems in a meaningful way that accounts for systemic differences and similarities using the empirical technique cluster analysis. The analysis will follow a three-step procedure. A review of the literature will be conducted to identify major institutional indicators of any given health care system. Cluster analysis will then be employed using these indicators based on data of OECD member countries. Based on the isolated clusters using the "minimum description length" approach, "peer" health care systems will be identified and described highlighting so-called leaders of the pack. At the heart of the performance of every health care system is the extent to which it is able to respond to the desire for a healthy life by members of society. This implies accounting for both efficiency, which investigates the link between the link between health care resources and health outcomes, and effectiveness, which assesses the achievement of goals rather than choosing one over the other. Assessing health care systems against peers and over time would not only set systems apart given their shared intent of ensuring health by providing health care but may well engender learning and lead to a race to the top.

PHP168

ENDOGENOUS COST-EFFECTIVENESS ANALYSIS IN HEALTH CARE TECHNOLOGY ADOPTION

Jena AB[1], Philipson TJ[2]
[1]*Massachusetts General Hospital, Boston, MA, USA,* [2]*University of Chicago, Chicago, IL, USA*

Increased health care spending across developed nations, including the US, has put pressure on both public and private payers. The current literature has attributed this growth in spending as being largely due to technological change. To prioritize adoption of new technologies, so called cost-effectiveness analysis has been used as the main tool by third-party payers and, as a result, has generated perhaps the largest sub-field within health economics. In this paper we argue utilization of cost-effectiveness analysis is subject to a form of Lucas critique; the stated goals of the policy will not materialize when those affected by it respond to it. In particular, we stress that cost-effectiveness analysis by payers invariably reflects prices set by producers rather than resource costs used to produce treatments. This implies that the "costs" in cost-effectiveness assessments depend on endogenous markups which are, in turn, influenced by demand factors of patients, doctors, and, most importantly, the cost-effectiveness policy used by payers to translate prices to adoption decisions. We argue this has two important implications. First, under

endogenous cost-effectiveness analysis policies aimed at lowering spending may actually raise it. Second, reimbursement policy based on endogenous cost-effectiveness levels may lead to adoption of more inefficient treatments. Under the standard conditions when producer costs are unobservable, we provide a test for these conditions using data on technology appraisals in the UK 1999-2005.

PHP169

THE VALUES OF GENERAL PRACTITIONERS/FAMILY PHYSICIANS SHOULD BE FOSTERED INTO OTHER CLINICIANS: A RESEARCH STUDY

Han-You X

Clinical institute, Workers' hospital of Nanyang textile corporation, Nanyang city , China

OBJECTIVES: The paper is to improve the quality of life and health of the peoples of the world by fostering and maintaining high standards of care in general practice/family medicine and other clinicians. **METHODS:** By comparing the general practitioners/family physicians with the clinicians of specialities, summarizing the shortcomings of present health care services, the proposals for promoting health care services around the world were suggested. **RESULTS:** The article initiates that the values of general practice/family medicine should be fostered into other clinicians when all the clinicians take care of the patients in any conditions, critical or ordinary, by adopting to the values of general practice/family medicine. While the clinicians also take into account of their own specialities. **CONCLUSIONS:** In applying these proposals, a healthy world and high quality of life of the peoples of the world will come soon! So the quality of life and health of the peoples of the world can be promoted and enhanced.

Cardiovascular Disorders – Clinical Outcomes Studies

PCV1

EXPLORATIVE ANALYSIS ABOUT THE APPROPRIATENESS OF A GPS LONGITUDINAL DATABASE ON EVALUATING ATYPICAL ANTIPSYCHOTICS IN TERMS OF DRUGS ADVERSE EVENTS

Heiman F[1], Pegoraro V[1], Katz P[1], Didoni G[2], Calandriello M[2]

[1]*CSD Medical Research S.r.l., Milan, Italy,* [2]*HE OR Unit - Bristol-Myers Squibb S.r.l., Rome, Italy*

OBJECTIVES: The main objective of this study was to understand the appropriateness of a GPs Longitudinal Database on exploring potential causal associations among therapies and adverse events. We've focused on subjects treated with three of the most widespread atypical antipsychotics drugs known as affecting patients' lipidic profile and cardiovascular and diabetes risk. **METHODS:** Data were obtained from CSD LPD, an Italian General Practitioner's longitudinal database. Patients with a first prescriptions of Aripiprazole, Olanzapine or Quetiapine during the period January 2005 to December 2009 have been selected. For each patient, the first prescription has been considered as the Index Date. The final study sample was composed of patients that during the following three months had at least another prescription of the same atypical antipsychotic. Patients have been followed-up for a maximum of 12 months starting from three months after the Index Date. **RESULTS:** Treatment groups were composed of 367 patients for Aripiprazole, 1825 patients for Olanzapine and 3088 patients for Quetiapine. The proportion of patients with an out of range value of Total Cholesterol and LDL was significantly lower in Aripiprazole group. The same trend has been observed for the proportion of patients with at least one recorded diagnosis of cardiovascular events and diabetes. The association between treatment and cardiovascular diagnosis presence was still significant even when performing a multivariate logistic model adjusted for age, gender and presence of a cardiovascular diagnosis during the year before the Index Date (Odds Ratio Olanzapine VS. Aripiprazole: 1.76 [1.08 – 2.85]; Odds Ratio Quetiapine versus Aripiprazole: 1.67 [1.03 – 2.70]). **CONCLUSIONS:** CSD LPD database resulted to be appropriate in exploring potential causal associations among treatments and potential adverse events both in terms of recorded diagnosis and in terms of recorded laboratory exams values even if, in this case, the sample size was reduced.

PCV2

EVALUATION OF THE PROPHYLAXIS PATTERNS AND 90 DAY OUTCOME EVENTS IN HOSPITALIZED MEDICALLY ILL PATIENTS

Baser O[1], Wang L[2]

[1]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA,* [2]*STATinMED Research, Dallas, TX, USA*

OBJECTIVES: To compare the prophylaxis patterns, incidence of venous thromboembolism (VTE), major and minor bleeding and readmission over 90 days in hospitalized medically ill patients. **METHODS:** A retrospective study (January 1, 2005 to December 31, 2007) was conducted using a health insurance claims database. Eligible patients were selected if they were continuously enrolled in their health plan for at least 180 days prior to and 90 days following the index hospital discharge, for which they were hospitalized with a medically ill diagnosis. Prophylaxis use was defined as receiving low molecular weight heparin (LMWH) only, warfarin only, unfractionated heparin (UFH) only, fondaparinux only, LMWH and warfarin, or UFH and warfarin, from the index hospitalization date to 30 days after index hospital discharge and before VTE events. Risk-adjusted venous thromboembolism and major and minor bleeding events among patients with different thromboprophylaxis patterns were compared. **RESULTS:** In patients who were identified as medically ill (n=12,077), 6,464 (53.52%) received anticoagulant therapy during their hospitalization and until 30 days after discharge. Among these patients who received prophylaxis, 2,137 (33.06%) received LMWH only, 693 (10.72%) received warfarin only, 2168 (33.54%) received UFH only, 12 (0.19%) received fondaparinux only, 291 (4.50%) received LMWH and warfarin, and 325 (5.03%) received UFH and warfarin. Among the 6 prophylaxis patterns, patients who received LMWH only were associated with lower VTE (0.39% vs. 1.98%, p=0.0001) and readmission rates (8.38% vs. 13.68%, p=0.0049) than those with LMWH and warfarin combination therapy. In addition, the LMWH only group of patients had lower rates of major and minor bleeding than the UFH and warfarin combination therapy group. **CONCLUSIONS:** Despite existing guidelines, few medically ill patients receive anticoagulant prophylaxis. Appropriate anticoagulant prophylaxis results in lower VTE event rates in hospitalized medically ill patients.

PCV3

THROMBOPROPHYLAXIS USE AND VENOUS THROMBOEMBOLISM, MAJOR AND MINOR BLEEDING EVENT ANALYSIS IN HOSPITALIZED MEDICALLY ILL PATIENTS

Baser O[1], Wang L[2]

[1]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA,* [2]*STATinMED Research, Dallas, TX, USA*

OBJECTIVES: To assess the real-world rate of appropriate prophylaxis use for incidences of venous thromboembolism (VTE), and major and minor bleeding in hospitalized medically ill patients. **METHODS:** A retrospective study (January 01, 2005 to December 31, 2007) was conducted using a health insurance claims database. Eligible patients were selected if they were continuously enrolled in their health plan for at least 180 days prior to and 30 days following the index hospital discharge date, for which they were hospitalized with a medically ill diagnosis. Prophylaxis use was defined as receiving low molecular weight heparin (LMWH) only, warfarin only, unfractionated heparin (UFH) only, fondaparinux only, LMWH and warfarin, or UFH and warfarin, from the index hospitalization admission date to 30 days after index hospital discharge, and before VTE events. Risk-adjusted VTE and major and minor bleeding events among patients with different thromboprophylaxis patterns were compared. **RESULTS:** In patients who were identified as medically ill (n=12,947), 6,949 (53.67%) received anticoagulant therapy during their hospitalization and until 30 days after discharge. Among those patients who received prophylaxis, 2,295 (33.03%) received LMWH only, 752 (10.82%) received warfarin only, 2,313 (33.29%) received UFH only, 12 (0.17%) received fondaparinux only, 309 (4.45%) received LMWH and warfarin, and 353 (5.08%) received UFH and warfarin. Compared with patients who received LMWH only, patients who received the combination therapy of LMWH and warfarin had significantly more VTE events (1.14% vs. 0.32%, p=0.0099) and higher readmission rates (6.11% vs. 3.05%, p=0.0093), while patients who received the combination therapy of UFH and warfarin had significantly higher minor bleeding (11.70% vs. 6.06%, p=0.0002) and readmission rates (7.49% vs. 3.05%, p=0.0001). **CONCLUSIONS:** Appropriate anticoagulant prophylaxis use results in lower VTE event rates as well as lower major and minor bleeding rates in hospitalized medically ill patients. More effort is required to improve the use of appropriate thromboprophylaxis.

PCV4

COMPARATIVE EFFICACY OF MAINTENANCE OF SINUS RHYTHM VERSUS RATE CONTROL STRATEGIES IN THE TREATMENT OF ATRIAL FIBRILLATION – SYSTEMATIC REVIEW AND META-ANALYSES

Wojciechowski P[1], Stozek A[1], Machowska A[1], Gaweska M[1], Lis J[2], Glasek M[2], Rys P[1], Wladysiuk M[1], Plisko R[1]

[1]*HTA Consulting, Krakow, Poland,* [2]*Sanofi Poland, Warszawa, Poland*

OBJECTIVES: The aim of this study was to assess whether restoration and maintenance of sinus rhythm is associated with clinically meaningful improvement in patients with atrial fibrillation (AF) or atrial flutter (AFI). **METHODS:** Assessment was based on randomized controlled trials (RCTs) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines. Studies met the inclusion criteria if they directly compared two treatment strategies, i.e. maintenance of sinus rhythm (MSR) including first generation antiarrhythmic drugs (FGAAD; mainly amiodarone, sotalol, dizopiramide, propafenone, dofetilide, flecainide) vs. rate control (RC) including pharmacologic agents (calcium channel blockers, beta blockers, cardiac glycosides), with regard to clinically meaningful endpoints. The most important medical databases (EMBASE, MEDLINE and CENTRAL) were searched until January 2011. Two reviewers independently selected trials, assessed their quality and extracted data. **RESULTS:** Eight RCTs directly comparing MSR vs RC were identified and included. Meta-analysis of those studies showed that significantly more patients assigned to MSR were in sinus rhythm at the end of study as compared to RC strategy (RB = 4.49 [2.49; 8.09]; NNT13-37months = 2 [2-4]). However, it did not lead to any benefit regarding clinically meaningful endpoints. Comparison between both treatment strategies revealed no statistically significant difference with respect to risk of overall mortality (RR = 1.06 [0.96; 1.17]), cardiovascular mortality (RR = 1.01 [0.88; 1.16]), stroke (RR = 1.02 [0.82; 1.26]), systemic embolism (RR = 0.78 [0.35; 1.71]), heart failure (RR = 0.94 [0.80; 1.09]) or bleeding (RR = 1.10 [0.65; 1.84]). **CONCLUSIONS:** In this analysis, restoration and maintenance of sinus rhythm achieved with FGAAD was not associated with clinically meaningful improvement in patients with AF or AFl. MSR strategy neither improved survival nor decreased morbidity as compared to RC. The reevaluation of current criteria of antiarrhythmic drug assessment should be considered.

PCV5

THROMBOEMBOLISMS WITH THROMBOPOIETIN RECEPTOR AGONISTS: SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

Corrales-Álvarez I[1], Catalá-López F[2], Martín-Serrano G[3], Montero-Corominas D[3], Calvo-rojas G[4]

[1]*Universidad Autónoma de Madrid (UAM), Madrid, Madrid, Spain,* [2]*Centro Superior de Investigación en Salud Pública (CSISP), Valencia, Valencia, Spain,* [3]*Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Madrid, Madrid, Spain,* [4]*Hospital Clínic, Barcelona, Barcelona, Spain*

OBJECTIVES: Romiplostim and eltrombopag are thrombopoietin receptor (TPOr) agonists that promote megakaryocyte differentiation, proliferation and platelet production. Both are orphan drugs mainly indicated for the treatment of adult chronic idiopathic thrombocytopenic splenectomised patients who are refractory to other treatments. Due to increasing platelet counts above the normal range may represent a risk for thromboembolisms, we assessed whether TPOr agonists affect thromboembolisms occurrence by a systematic review and meta-analysis of randomised controlled trials (RCTs). **METHODS:** We searched PubMed, SCOPUS, Cochrane Central Register, regulatory agencies websites and publicly available registries of manufacturers (before January 2011). RCTs using romiplostim or eltrombopag in at least one group were included. Absolute risk ratios (ARR) and number needed to harm (NNH) were calculated to provide the population health impact of the exposure. Relative risks (RR) were also provided. Data were pooled using fixed-effects models. Heterogeneity was analysed using Cochran's Q and I2 tests. **RESULTS:** Of 373 publications identified, 8 studies met the inclusion criteria (n=1,180 patients). In the TPOr agonist group, as compared with the control group (e.g. placebo and/or standard of care), the meta-ARR for thromboembolisms was 1.8% (95% CI, 0.0% to 3.6%), and the meta-RR was 1.5 (95% CI, 0.7 to 3.3). Fifty-five patients would have to be treated using TPOr agonists to produce thromboembolisms in a patient (meta-NNH=55). Non heterogeneity was found (Cochran's Q test, P = 0.9; I2 = 0.0%). **CONCLUSIONS:** Although the small numbers reported, thromboembolisms should be considered as identified risks for these drugs. Healthcare providers should use caution when administering these agents to patients with known risk factors for thromboembolisms.

PCV6

COMPARISON OF BLEEDING RATES BETWEEN STATIN AND STATIN-FREE PATIENTS ON WARFARIN: A CLAIMS DATABASE APPROACH

Guerin A[1], Hylek EM[2], Frois C[1], Ponce de Leon Barido D[1], Marrone C[3], Bae JP[3], Zhao Z[3]
[1]*Analysis Group, Inc., Boston, MA, USA,* [2]*Boston University, School of Medicine, Boston, MA, USA,* [3]*Eli Lilly and Company, Indianapolis, IN, USA*

OBJECTIVES: In a recent study in patients receiving warfarin, the initiation of statins that are cytochrome P450 3A4 inhibitors was associated with an increased risk of hospitalization for gastrointestinal bleeding in a Medicaid-insured population, while the initiation of pravastatin was not. The present research attempted to address some of the study limitations and assess whether similar findings are applicable in a more recent, commercially-insured U.S. population. **METHODS:** A retrospective matched-cohort design was used to compare baseline characteristics and bleeding rates (e.g. gastrointestinal and non-gastrointestinal) between statin and statin-free patients receiving warfarin concomitantly. Patients were matched on a 1:1 ratio to balance patient characteristics, and a cox proportional hazard model was used to control for confounding factors. The analyses were performed for a matched "stabilized" population, i.e., patients who had been on warfarin for ≥6 months, did not have prior bleeding events, and did not use another statin before the index date. For the matched "stabilized" populations, sub-group analyses were performed on patients with atrial fibrillation, patients with venous thrombosis, patients age ≥65 years, patients age ≥75 years, prevalent/persistent warfarin users, and by statin therapy. **RESULTS:** The method produced a small matched sample of 6306 (3.82%) out of 123,328 statin users and 41,734 statin-free patients. There were no statistically significant differences in bleeding rates between statin users and statin-free patients. Results were similar for the sub-group analyses. **CONCLUSIONS:** Using a claims database approach, high degree of heterogeneity between statin users and non-users was found, resulting in a low matching rate. This high degree of heterogeneity suggests that claims databases may be insufficient to detect/conclude as to differences in bleeding rates between statin versus statin-free patients on warfarin. Alternative methods and additional clinical information are needed to more accurately characterize bleeding rates in patients taking warfarin and a statin therapy concomitantly.

PCV7

TOBACCO ADDICTION INFLUENCE IN LATER DEVELOPMENT OF CARDIOVASCULAR EVENTS: 3 YEARS FOLLOW-UP

Sicras-Mainar A[1], Diaz-Cerezo S[2], Sanz de Burgoa V[3], Navarro-Artieda R[4]
[1]*Directorate of Planning, Badalona Serveis Assistencials, Badalona, Barcelona, Spain,* [2]*Pfizer Spain, Madrid, Spain,* [3]*Pfizer Spain, Alcobendas (Madrid), Spain,* [4]*Hospital Universitari Germans Trias i Pujol, Barcelona, Spain*

OBJECTIVES: To determinate tobacco consumption effects on metabolic control (biochemical/anthropometrics parameters), mortality and on CVE relapses incidence during a 3 year follow-up. **METHODS:** Multicentric observational study undertaken through the retrospective review of the medical records of patients at six primary health-care centres and two hospitals. Inclusion criteria: subjects > 30 years, who requested health care after suffering a CVE between 2003 and 2007. Follow-up: 36 months. Groups: smokers, ex-smokers and non-smokers. Main measures: sociodemographics, morbidity, biochemical/anthropometrics parameters (systolic and diastolic arterial pressure (mmHg), baseline glycaemia (mg/dL), body mass index (kg/m2), serum triglycerides (mg/dL), total cholesterol (mg/dL), HDL-cholesterol and LDL-cholesterol (mg/dL)), mortality and later CVE (ischemia, infarction, strokes, ischemic accident, peripheric artheriopathy). Statistical analysis: logistic regression model and Kaplan-Meier curves. **RESULTS:** 2,540 patients fulfilled the inclusion criteria (smokers: 8.4%, exsmokers: 52.9%, non-smokers: 38.7%). Mean age: 68.1 years old; men: 60.7%. By groups: patients showed a similar distributions of comorbidities. 19.1% of smokers still smoked after the first CVE. Smoking addiction was related with COPD (odds ratio, OR=2.4; 95%CI: 1.7-3.5) and depressive syndrome (OR=1.5; 95%CI: 1.1-2.2). The smoking condition mean time was 24.4 (14.5) years for smokers and 4.2 (1.2) years for ex-smokers. Comparing baseline (during hospitalization) and final (3 years follow-up), in the non-smokers group, all parameters showed a significant reduction (8 to (8/8), in exsmokers (6/8) and in smokers group only 4/8. All mortality causes (intrahospital and follow-up included) was 4.2% (N=106; 95%CI: 3.4-5.0%), in smokers: 4.2%; ex-smokers: 5.9% and non-smokers: 1.8%; p<0.001. Incidence rate of new CVE's was 15.2% (95%CI: 13.8-16.6%) in smokers: 18.6%; ex-smokers: 16.5%; non-smokers: 9.6%; p<0.001. CVE's were present in 8.2%, 6.0% and 3.3% respectively, p<0.05. **CONCLUSIONS:** In routine medical practice, smokers compared with ex-smokers and with non-smokers still support a high future risk of suffering CVE and higher mortality rates.

PCV8

EFFECT OF SIADH ON PATIENT OUTCOMES AND HEALTH CARE RESOURCE UTILIZATION IN HOSPITALIZED PATIENTS

Amin A[1], Deitelzweig S[2], Lin J[3], Christian R[4], Baumer D[5], Lowe T[6]
[1]*University of California-Irvine, Orange, CA, USA,* [2]*Oschner Medical Center, Jefferson, LA, USA,* [3]*Novosys health, Flemington, NJ, USA,* [4]*Otsuka America Pharmaceutical, Inc., Rockville, MD, USA,* [5]*Premier Research Incorporated, Charlotte, NC, USA,* [6]*Premier Healthcare Alliance, Charlotte, NC, USA*

OBJECTIVES: Syndrome of inappropriate antidiuretic hormone hypersecretion (SIADH) is a common cause of hyponatremia contributing to 30-50% of hyponatremia cases. Little is known of the influence of SIADH on healthcare resource utilization. This study assessed the effect of SIADH on inpatient total and intensive care unit (ICU) cost and length of stay (LOS), the likelihood of ICU admission, and 30-, 90-, and 180-day readmission. **METHODS:** The Premier hospital database was utilized to identify US hospital inpatients discharged between January 1, 2007 and June 30, 2009. Hyponatremic/SIADH patients were identified using primary or secondary ICD-9 codes (n=430,731) and were matched to a control group (n=430,731) using exact matching on age, gender, provider region and 3M™ APR-DRG assignment. Matching was further refined using propensity scores based on additional patient and hospital covariates. Due to the contribution of congestive heart failure and cirrhosis on hyponatremia development, these patients were excluded from the analysis. The final analytic sample contained 65,973 SIADH patients and 407,874 non-hyponatremia/SIADH patients. Cost was analyzed using gamma regression, LOS with negative binomial regression. ICU admission and hospital readmission were analyzed using multivariate logistic regression. **RESULTS:** In contrast to non-SIADH patients, patients with SIADH had significantly higher total inpatient cost (55.53%,CI=52.53-58.60;p<0.0001), ICU cost (38.07%;CI=33.18-43.15;p<.0001), total LOS (45.11%,CI=43.20-47.03;p<0.0001), and ICU LOS (42.72%,CI=38.36-47.23; p<0.0001). SIADH patients were significantly more likely to be admitted to the ICU (OR=2.131;p<.0001), and readmitted at 30- (OR=1.399;p<0.0001), 90- (OR=1.495; p<0.0001), and 180-days (OR=1.459;p<0.0001) in comparison with non-SIADH patients. **CONCLUSIONS:** The presence of SIADH in hospitalized patients is significantly associated with increased total and ICU cost and LOS, likelihood of ICU admission, and likelihood of readmission. Words = 297

PCV9

OPTIMAL TREATMENT SHORTFALLS AND WORSE 12-MONTH OUTCOMES FOR DIABETIC ACUTE CORONARY SYNDROME PATIENTS AFTER PERCUTANEOUS CORONARY INTERVENTION IN CONTEMPORARY PRACTICE: DATA FROM THE MULTINATIONAL, PROSPECTIVE, ANTIPLATELET TREATMENT OUTCOMES REGISTRY (APTOR)

James S[1], Iniguez A[2], Pavlides G[3], Zeymer U[4], Sartral M[5], Belger M[6], Tomlin ME[7], Norrbacka K[8], Bakhai A[9]
[1]*Uppsala University Hospital, Uppsala, Sweden,* [2]*Hospital de Meixoeiro, Vigo, Spain,* [3]*Onassis Cardiac Surgery Center, Kallithca, Greece,* [4]*Herzzentrum Ludwigshafen, Ludwigshafen, Germany,* [5]*Eli Lilly and Company, Suresnes, France,* [6]*Lilly UK, Windlesham Surrey, UK,* [7]*Eli Lilly & Company, Indianapolis, IN, USA,* [8]*Eli Lilly & Company, Vantaa, Finland,* [9]*Barnet General Hospital, Barnet, UK*

OBJECTIVES: To compare treatment and 12-month outcomes after percutaneous coronary intervention (PCI) of acute coronary syndrome (ACS) patients with and without diabetes mellitus (DM). **METHODS:** Data were from APTOR, robust, prospective, observational registries of 14 European countries from 2007-2009. Kaplan-Meier (KM) estimates 12-months post-PCI were calculated for cardiovascular (CV) event (unstable angina [UA], non-ST-elevation myocardial infarction [NSTEMI], STEMI, urgent target vessel revascularization, acute heart failure, ischemic and hemorrhagic strokes or CV death), bleeding, and mortality. **RESULTS:** A total of 21% (N=942) of patients had DM (median age: 66yrs) and 79% (N=3603) did not have DM (median age: 61 yrs). More patients with DM tended to be women (28% vs. 20%); have hyperlipidaemia (64% vs. 47%) and hypertension (75% vs. 53%); and have prior MI (28% vs. 18%) or PCI (27% vs. 16%) compared to patients without DM. For DM/non-DM patients respectively, ACS presentation was 29%/21% with UA, 35%/30% with NSTEMI, 36%/49% with STEMI; the use of glycoprotein IIb/IIIa inhibitors was 28%/33% and the use of ≥1 drug-eluting stent (DES) was 52%/39%. DM/non-DM patients received similar treatment at hospital discharge and 12-months post-PCI with the exception of ARB/ACE inhibitors at discharge (75% vs. 69%) and 12-months post-PCI (79% vs. 71%). The respective DM/non-DM 12-month outcomes were 17.3% (95% CI: 14.8-19.7%) vs. 13.8% (12.7-15.0%) for CV event, 3.0% (1.9-4.1%) vs. 2.7% (2.2-3.2%) for bleeding, and 4.9% (3.5-6.3%) vs. 1.8% (1.4-2.3%) for mortality. Optimal therapy (≥5 of the following at hospital discharge and at one-year post-PCI: aspirin, clopidogrel, statins, beta-blockers, ARB/ACE-inhibitors, and exercise or diet) was observed with 49%/42% of DM/non-DM patients. **CONCLUSIONS:** Patients with DM more often received DES and ARB/ACE but still incur worse 12 month outcomes compared to non-DM. Evidence-based prescribing post ACS-PCI is still sub-optimal and newer more potent strategies should be considered for diabetic patients to reduce the cardiovascular mortality and morbidity disparity.

PCV10

ANTI-GLYCEMIC MEDICATION TREATMENT PATTERNS AMONG TYPE II DIABETES MELLITUS PATIENTS INITIATING LIPID-ALTERING REGIMENS

Simko RJ[1], Koselleck D[2], Quimbo RA[3], Cziraky MJ[4], Toth PP[5]
[1]Abbott Laboratories, Abbott Park, IL, USA, [2]Abbott Labs, Abbott park, IL, USA, [3]HealthCore, Wilmington, DE, USA, [4]HealthCore, Inc., Wilmington, DE, USA, [5]Sterling Rock Falls Clinic, Ltd.; University of Illinois School of Medicine, Sterling, IL, USA

OBJECTIVES: To evaluate changes in anti-glycemic treatment patterns in patients newly augmenting statin therapy with niacin extended-release (NER+S), relative to patients initiating alternative lipid regimens. **METHODS:** An observational cohort study was conducted using integrated administrative claims and laboratory result data within the HealthCore Integrated Research Database. T2DM patients aged 18 to 64 initiating statin-augmenting therapy (NER+S, ezetimibe (EZE+S), or fenofibrate (FFB+S)) or statin monotherapy (SM) between 1/1/2005-11/30/2008 (index date) were included. Patients with ≥12 months of pre-index eligibility and ≥1 laboratory result for hemoglobin A1c (HbA1c) within the 12-month period were included. The utilization and average daily dose (ADD) of anti-glycemic medications during the 12-month pre-index and follow-up period were compared between cohorts. **RESULTS:** A total of 42,250 patients were identified: 2,041 NER+S, 6,915 EZE+S, 3,095 FFB+S, and 30,199 SM. Compared to each cohort, NER+S patients were more likely to be male (P<0.0001), and have higher prevalence of pre-existing ischemic heart conditions (P<0.0001). NER+S patients had lowest pre-index total cholesterol (174.3 ± 55.2; P<0.0001), HDL-C (37.2 ± 10.1; P<0.0001), second lowest LDL-C (93.7 ± 38.4), and second highest TG (245.3 ± 307.0) prior to the index date. Among oral anti-glycemic therapies, NER+S patients were observed to have the largest decrease in ADD (mg/day) for biguanides (metformin: -155.9 ± 788.0; P<0.0001), sulfonylureas (glimepiride: -0.1 ± 1.9; P = 0.0053; glipizide: -0.8 ± 20.8; P < .0001), TZD's (pioglitizone: -0.8 ± 8.2; P = 0.0210), and incretin mimetic agents (exenatide: -0.1 ± 3.5; P = 0.0012) from pre-index to follow-up. Furthermore, NER+S patients had the smallest increase in ADD of DPP-4's (sitagliptin: 0.3 ± 17.6; P = 0.0067). **CONCLUSIONS:** Despite studies indicating the potential for NER to antagonize glycemic control among T2DM patients, patients initiating NER+S were observed to have decreased utilization and average daily dose of anti-glycemic medications, relative to alternative treatment regimens.

PCV11

TREATMENT AND 12-MONTH OUTCOMES OF ACUTE CORONARY SYNDROMES PATIENTS AGED < 75 AND ≥ 75 YEARS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION: 14-COUNTRY DATA ON 4545 PATIENTS FROM THE PROSPECTIVE ANTIPLATELET TREATMENT OUTCOMES REGISTRY (APTOR)

Berkenboom G[1], Coufal Z[2], Ferrieres J[3], Mohacsi A[4], Sartral M[5], Belger M[6], Tomlin ME[7], Norrbacka K[8], Bakhai A[9]
[1]ULB Erasme University Hospital, Brussels, Belgium, [2]Bata's Regional Hospital, Zlin, Czech Republic, [3]Toulouse University School of Medicine, Toulouse, France, [4]Hungarian Institute of Cardiology, Budapest, Hungary, [5]Eli Lilly and Company, Suresnes, France, [6]Lilly UK, Windlesham Surrey, UK, [7]Eli Lilly & Company, Indianapolis, IN, USA, [8]Eli Lilly & Company, Vantaa, Finland, [9]Barnet General Hospital, Barnet, UK

OBJECTIVES: To compare medication treatment and 12-month outcomes of patients aged <75 and ≥ 75 years who have acute coronary syndromes (ACS) and who have undergone percutaneous coronary intervention (PCI). **METHODS:** Data were from APTOR, robust, prospective, observational registries from 14 European countries from 2007-2009. Kaplan-Meier (KM) estimates at 12-months post-PCI were calculated for cardiovascular (CV) event (unstable angina [UA], non-ST-elevation myocardial infarction [NSTEMI], STEMI, urgent target vessel revascularization, acute heart failure, ischemic and hemorrhagic strokes or CV death), bleeding, and mortality by age. **RESULTS:** 82% were <75 years (N=3742, median age: 59) and 18% were ≥75 years (N=803, median age: 79). Older patients tended to be women (38% vs. 20%); to weigh <60kg (10% vs. 4%); have more hypertension (72% vs. 54%) and diabetes (26% vs. 20%); have prior MI (28% vs. 18%) and PCI (22% vs. 17%). For older/younger patients, respectively, the ACS presentation was 25%/22% for UA, 39%/29% for NSTEMI, and 36%/49% for STEMI; treatment at PCI was 14%/10% for clopidogrel loading doses <300 mg, 24%/33% for GPIIb/IIIa inhibitors, and 5% /11% for thrombolytic/fibrinolytic therapy. KM (95% CI) estimates for older and younger patients, respectively, were: 19.8% (17.0%, 22.6%) vs. 13.4% (12.3%, 14.5%) for CV event, 3.7% (2.4%, 5.1%) vs. 2.6% (2.1%, 3.1%) for bleeding, and 6.8% (5.0%, 8.5%) vs. 1.5% (1.1%, 1.9%) for mortality. **CONCLUSIONS:** Older patients tended to receive GPIIb/IIIa and thrombolytic/fibrinolytic therapy less frequently at PCI, contributing to comparable bleeding rates. However, the higher post-discharge ischemic event rates suggest that the risk/benefit ratios in the elderly may need to be considered more carefully. One strategy might be that, if revascularisation is proposed in older ACS patients, those at lower bleeding risk be treated more aggressively with potent, newer peri/postprocedural, antiplatelet/antithrombotic management to balance the post-PCI outcomes disparity at 12 months.

PCV12

DIFFERENCES IN THE WEIGHTED AVERAGE DAILY DOSES OF STATINS IN EUROPE AND THEIR POTENTIAL IMPACT ON CARDIOVASCULAR OUTCOMES

Liew D, Webb K
The University of Melbourne, Parkville, Victoria, Australia

OBJECTIVES: Market data indicate that simvastatin and atorvastatin, which will soon come off patent, are prescribed at non-equipotent doses across Europe. We sought to estimate the differential effects of this on low-density lipoprotein cholesterol (LDL-C) levels and risk of cardiovascular events. **METHODS:** Weighted average daily doses (WADDs) of prescribed simvastatin and atorvastatin in 16 Western European countries were derived from IMS data for 2010. Dose-specific, LDL-C modifying potencies of the 2 statins were derived from the meta-analysis by Nicholls et al (Am J Cardiol, 2010). The relationship between reduction in LDL-C achieved by statin therapy and impact risk of cardiovascular events was derived from the meta-regression by the Cholesterol Treatment Trialists' Collaboration (Lancet, 2010). This showed that for every 1mmol/L reduction in LDL-C, the relative risk for a major cardiovascular (coronary and/or stroke) event was 0.78 (95%CI 0.76-0.80). **RESULTS:** Across the 16 Western European countries, the WADDs for simvastatin and atorvastatin were 28.2mg and 24.4mg, respectively. The corresponding relative reductions in LDL-C at these doses would be 35.8% and 42.0%. Assuming a pre-treatment LDL-C of 4.0mml/L, these lipid changes would lead to relative reductions in the risk of a major cardiovascular event of 31.5% and 37.0%, respectively. In each of the major markets of France, the The Netherlands, Spain, the UK and Italy, atorvastatin was prescribed at a higher equivalent dose than simvastatin. Hence it is likely to confer greater potential population cardiovascular benefits. **CONCLUSIONS:** In Western Europe, atorvastatin is prescribed at a higher equivalent dose than simvastatin. The significant advantages of atorvastatin over simvastatin in terms of LDL-C and cardiovascular risk reduction will be further enhanced when acquisition prices for atorvastatin fall after its impending loss of exclusivity.

PCV13

COMPARING THE EFFECTIVENESS OF ROSUVASTATIN AND ATORVASTATIN IN PREVENTING CARDIOVASCULAR EVENTS FOR POPULATIONS STRATIFIED BY BASELINE CARDIOVASCULAR RISK: ESTIMATES USING THE ARCHIMEDES MODEL

Schuetz CA[1], Van herick A[1], Alperin PE[1], Peskin BR[1], Hsia J[2], Gandhi SK[2]
[1]Archimedes, Inc., San Francisco, CA, USA, [2]AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA

OBJECTIVES: This study estimated the effectiveness of rosuvastatin 20mg (R20) versus atorvastatin 40mg (A40) and 80mg (A80), and rosuvastatin 40mg (R40) versus A80 in preventing clinical events in several higher cardiovascular-risk patient populations using simulation. **METHODS:** The Archimedes Model was used to simulate head-to-head clinical trials in several populations based on 10-year Framingham risk score (FRS) levels (<10, 10-20, >20) and EURO-SCORE (<5, >5) to estimate the occurrence of MACE (comprising MI, stroke, and cardiovascular death). Simulated patients ages 45–70 with FRS >5% were drawn from the National Health and Nutrition Examination Survey. Treatment models were validated using biomarker/outcomes data from published trials. **RESULTS:** The patient numbers in each FRS and EURO-SCORE level population ranged from 9190 to 38,313. R20 reduced MACE more than A40 or A80 and R40 more than A80 in all scenarios, with higher risk subgroups showing greater absolute benefit. The 5-year number needed to treat (NNT) to prevent a MACE event for R40 versus A80 for EURO-SCORE <5, and >5 were 352 and 154 for 5 years and 154 and 72 for 10 years, respectively. The 5-year relative risk (RR) of MACE for R20 versus A40 was approximately 0.9, irrespective of baseline risk. The 5-year RR of MACE for R20 versus A80 ranged from 0.92 to 0.94, and for R40 versus A80 it was 0.88 to 0.90. RR estimates were similar at 10 and 20 years; however, NNT decreased over time. **CONCLUSIONS:** The Model estimated that R20 lowers the risk of MACE more than A40 or A80, and R40 further lowers risk compared with A80. The estimated absolute risk reduction with rosuvastatin was greater with higher baseline risk and over time. While simulation models cannot replace controlled clinical trials, this study highlights the potential of using rigorous modeling approaches to bridge evidence gaps.

PCV14

MIXED TREATMENT COMPARISON OF DRONEDARONE, AMIODARONE AND SOTALOL FOR THE MANAGEMENT OF ATRIAL FIBRILLATION IN AUSTRALIA

Badcock CA[1], Lee J[2], Gonzalo F[3]
[1]Statistical Revelations Pty Ltd, Black Rock North, Victoria, Australia, [2]Sanofi Australia Pty Ltd, Macquarie Park, NSW, Australia, [3]Sanofi-Aventis Australia Pty Limited, Macquarie Park, Australia

OBJECTIVES: To compare the relative efficacy and tolerability of amiodarone, sotalol and dronedarone for the treatment of atrial fibrillation (AF) in Australia using mixed treatment comparisons (MTC). **METHODS:** There are limited data directly comparing the safety and effectiveness of dronedarone with the alternatively used antiarrhythmic drugs (AADs) in Australia. In the absence of direct comparisons, we have performed an MTC of networks of trials in order to provide best estimates of the relative effectiveness and safety of the alternative AADs. This approach was previously used by Freemantle et al (2011) to compare dronedarone not only with amiodarone and sotalol, but also with flecainide and propafenone. As flecainide and propafenone are not widely used in Australia, we chose to exclude them from the current analysis. Literature in AF involving amiodarone, dronedarone, sotalol or placebo was searched systematically. The 10 selected trials were combined using MTC models to provide direct and indirect comparisons in a single analysis. Randomised trials with at least one month of treatment and at least 3 months follow up were included. **RESULTS:** Results are presented versus placebo. Trends towards increased mortality for sotalol (OR 4.67, 95% CI 1.89 – 11.57) and amiodarone (OR 2.92, 95% CI 1.17 - 7.31) were found. Conversely, a trend towards decreased mortality for dronedarone was found (OR 0.87, 95% CI 0.69 – 1.09). **CONCLUSIONS:** Using an MTC approach of the AADs available in the Australian clinical setting, we have shown that dronedarone is associated with a decrease in the risk of all-cause mortality, and amiodarone and sotalol are associated with an increase in the risk of all-cause mortality.

PCV15

GUIDELINES ADHERENCE AND HYPERTENSION CONTROL IN PATIENTS SUFFERING FROM CARDIOVASCULAR DISEASE

Ahmad N[1], Hassan Y[2], Tangiisuran B[3], Meng OL[4], Aziz NA[2], Saleem F[1], Atif M[5]

[1]*Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia,* [2]*Universiti Teknologi MARA, Puncak Alam, Selongor, Malaysia,* [3]*Universiti Sains Malaysia, Penang, P.Penang, Malaysia,* [4]*Penang Hospital, Penang, P. Penang, Malaysia,* [5]*Universiti Sains Malaysia (USM), Pinang, Malaysia*

OBJECTIVES: To evaluate doctors' adherence to Malaysian Clinical Practice Guidelines on management of hypertension (CPG 2008) in patients with cardiovascular disease, and factors associated with guidelines adherence and hypertension control. **METHODS:** This was a cross sectional study conducted at outpatient cardiology clinic of Penang Hospital. A total of 13 doctors practicing in the clinic were enrolled in the study. Prescriptions written by each doctor to 25 established hypertensive patients with cardiovascular disease (total 325) were noted on visit 1 along with patients' demographic and clinical data. Implicit review of patients' medical record was conducted to find acceptable rationale for nonadherence to guidelines. The prescriptions written were categorized either as adherent or non-adherent to CPG (2008). Two hundred sixty of the enrolled 320 patients (20 out of 25 patients enrolled per doctor) were followed for another one visit. Blood pressure readings noted on visit 2 were related to prescriptions written on visit 1. SPSS 16 was used for data analysis. **RESULTS:** One hundred ninety-one (73.5%) patients received guidelines compliant pharmacotherapy. CPG compliance had statistically significant weak negative association with left ventricular hypertrophy (LVH) (Φ= -0.241, $P<0.01$), and diabetes (Φ= -0.228, $P<0.01$). One hundred fifty-four (59.2 %) patients were on goal BP. Hypertension control had statistically significant weak positive association with guidelines adherence (Φ=0.175, $P<0.01$), and Angiotensin converting enzyme inhibitors (Φ=0.195, $P<0.01$), while weak negative association with diabetes mellitus (Φ=-0.148, P=0.017), left ventricular hypertrophy (LVH) (Φ=-0.153, P=0.017) and monotherapy (Φ=-0.168, $P<0.01$). **CONCLUSIONS:** Adherence to guidelines resulted in better hypertension control. Overall prescribing practices were in fair compliance with guidelines but room for further improvement is still present. Doctors' poor adherence to guidelines in patients with diabetes mellitus and LVH needs further probing and focus in future.

PCV16

GUIDELINES ADHERENT PHARMACOTHERAPY RESULTED IN BETTER HYPERTENSION CONTROL

Ahmad N[1], Hassan Y[2], Tangiisuran B[3], Meng OL[4], Aziz NA[2], Atif M[5], Saleem F[1]
[1]*Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia,* [2]*Universiti Teknologi MARA, Puncak Alam, Selongor, Malaysia,* [3]*Universiti Sains Malaysia, Penang, P.Penang, Malaysia,* [4]*Penang Hospital, Penang, P. Penang, Malaysia,* [5]*Universiti Sains Malaysia (USM), Pinang, Malaysia*

OBJECTIVES: To evaluate impact of guidelines adherence and factors associated with hypertension control **METHODS:** This was a cross sectional study conducted at Penang Hospital. Twenty-six doctors; 13 from cardiology, 5 from nephrology and 4 from hypertension and diabetic clinics each were enrolled in the study. Prescriptions written by each doctor to 25 established hypertensive patients (total of 650) were noted on visit 1 along with patients' demographic and clinical data. Implicit review of patients' medical record was conducted to find acceptable rationale for non adherence to guidelines. The prescriptions written were categorized either as compliant or non-compliant to Malaysian Clinical Practice Guidelines on management of hypertension (CPG 2008). Five hundred and twenty of the enrolled 650 patients (20 out of 25 patients enrolled per doctor) were followed for another one visit. BP readings noted on visit 2 were related to the prescriptions written on visit 1. SPSS 16 was used for data analysis. **RESULTS:** Three hundred forty-nine (67.1%) patients received guidelines compliant pharmacotherapy. Two hundred sixty-five (51%) patients were on goal BP on visit 2. Hypertension control had statistically significant weak positive association with CPG adherence (Φ=0.14, $P<0.01$), greater number of antihypertensive drugs (Effect size =0.11, P=0.01), cardiovascular disease (Φ=0.127, $P<0.01$) and management of hypertension at cardiology clinic (Φ=0.13, $P<0.01$), while moderate positive association with Angiotensin converting enzyme inhibitors (Φ=0.20, $P<0.01$). Statistically significant weak negative association was observed between hypertension control and diabetes mellitus (Φ= -0.17, $P<0.01$), renal disease (Φ= -0.17, $P<0.01$), and management of hypertension at nephrology (Φ= -0.10, P=0.02) and diabetic clinics (Φ= -0.14, $P<0.01$). **CONCLUSIONS:** Guidelines adherent pharmacotherapy resulted in better hypertension control. Suboptimal BP control in patients with diabetes mellitus, renal disease and treated at nephrology and diabetic clinics needs focus and further probing.

PCV17

COST-EFFECTIVENESS ANALYSIS OF BOSENTAN AND SILDENAFIL COMPARED WITH STANDARD THERAPY IN TREATMENT OF PRIMARY PULMONARY ARTERIAL HYPERTENSION IN RUSSIAN FEDERATION

Omelyanovsky V[1], Avxentyeva M[1], Krysanov I[2], Goryaynov S[1], Ivakhnenko O[2], Tsfasman FM[3]
[1]*Research center for clinical and economic evaluation and pharmacoeconomics, Russian State Medical University, Moscow, Russia,* [2]*Research Center for Clinical and Economic Evaluation and Pharmacoeconomics, Moscow, Russia,* [3]*Institute of Clinico-Economic Expertise and Pharmacoeconomics, RSMU, Moscow, Russia*

OBJECTIVES: To conduct cost-effectiveness analysis of bosentan and sildenafil compared with standard therapy (ST, i.e. calcium channel blockers and warfarin) in treatment of primary pulmonary arterial hypertension (PAH) in Russian Federation. **METHODS:** We undertook cost-effectiveness analysis of bosentan (62.5 mg bid during first 4 weeks and 125 mg bid further) and sildenafil (25 mg tid) and estimated incremental cost-effectiveness ratios (ICER) for each drug vs ST. A cohort of 20 patients with PAH, functional class (FC) III was simulated in a model. The patients either received bosentan+ST, or sildenafil+ST, or ST only. The number of patients whose health state improves by one FC was considered a criterion of efficacy. Costs of hospitalization, standard therapy medications, and investigational drugs were calculated in the model. Data on clinical efficacy of bosentan, sildenafil, and ST were extracted from clinical trials. Patient's treatment scheme considered in the model was based on the results of peer interview. **RESULTS:** In our model treatment with bosentan was the most effective: 9 of 20 patients versus 6 and 2 of 20 patients who had improved by one FC with bosentan, sildenafil and ST, respectively. Also, the highest overall costs were in the bosentan group: 1,163,948 USD per 20 patients per year. Overall costs in case of sildenafil and standard therapy were 724,520 and 57,969 USD per group per year, respectively. However, comparison of bosentan with ST yielded lower ICER than comparison of sildenafil with ST: 157,997 and 166,638 USD per one patient with improvement by one FC, respectively. Trend in the results remained the same with bosentan price up to 4400 USD per pack in one-way sensitivity analysis. **CONCLUSIONS:** The results of this study suggest that treatment of FC III PAH with bosentan is more preferable than treatment with sildenafil.

PCV18

RELATIVE EFFICACY OF BIVALIRUDIN VS. HEPARIN ALONE IN STEMI PATIENTS TREATED WITH PRIMARY PCI – AN INDIRECT TREATMENT COMPARISON

Medic G[1], Schwenkglenks M[2], Eijgelshoven I[1], Smith A[3], Day J[3], Plent S[4], Bergman G[1], Toward T[3]
[1]*Mapi Values, Houten, The Netherlands,* [2]*Institute of Pharmaceutical Medicine/ European Center of Pharmaceutical Medicine, University of Basel, Basel, Switzerland,* [3]*The Medicines Company, Abingdon, UK,* [4]*The Medicines Company, Winchester, MA, USA*

OBJECTIVES: The objective of this study was to compare, by means of an indirect treatment comparison (ITC), the efficacy and safety of a bivalirudin-based anticoagulation strategy to heparin monotherapy, in patients with ST-elevation myocardial infarction (STEMI) intended for primary percutaneous coronary intervention (PPCI). **METHODS:** A systematic literature review was performed using Embase, Medline, Medline In-Progress, and the Cochrane Library to identify randomised controlled trials (RCTs) to build a network of bivalirudin and heparin monotherapy strategies in STEMI patients using a common reference strategy (heparin with glycoprotein IIb/IIIa inhibitor (heparin+GPI)). Identified data were analysed using fixed and random effects Bayesian ITC. A base-case analysis was constructed from intention-to-treat populations in the RCTs. Outcomes (mortality, stroke, MI, ischaemic target vessel revascularisation (I-TVR), major adverse cardiovascular events, TIMI major and minor bleeding) were evaluated at 30-days and 1 year. **RESULTS:** Eight RCTs were identified for inclusion in the ITC. At 30-days the bivalirudin-based strategy was expected to result in fewer deaths (odds ratio [OR]:0.55; credible interval [CrL]:0.32,0.95) compared to a heparin monotherapy, which was sustained at 1-year (OR:0.50; CrL:0.31, 0.79). Other outcomes [stroke (OR:0.88; CrL:0.37, 2.13); MI (OR:0.79; CrL:0.40, 1.55); I-TVR (OR:0.75; CrL:0.38, 1.46); TIMI-major (OR:0.85; CrL: 0.47, 1.52) and TIMI-minor (OR:0.70; CrL:0.41, 1.18) bleeding] also tended favourably towards bivalirudin. Consistent with the HORIZONS-AMI trial, when compared to a heparin+GPI-based strategy, a bivalirudin-based strategy resulted in fewer deaths (30-days: OR:0.65; CrL:0.43, 1.00 and 1 year: OR:0.70; CrL:0.49, 0.97) and post-procedural bleeding events (30-day TIMI-Major: OR:0.59; CrL:0.42, 0.83 and TIMI-minor: OR:0.61; CrL:0.42, 0.87)), with comparable ischaemic protection. Scenario analyses of RCT in/exclusion did not influence base-case findings. **CONCLUSIONS:** For STEMI patients intended for PPCI, a bivalirudin-based strategy is expected to result in fewer deaths at 30-days and 1-year, compared to using heparin monotherapy. Other ischaemic and bleeding outcomes also tended towards improvement with bivalirudin.

PCV19

PRESCRIPTION OF ANGIOTENSIN CONVERTING ENZYME INHIBITORS AND HYPERTENSION CONTROL IN DIABETIC HYPERTENSIVE PATIENTS

Ahmad N[1], Hassan Y[2], Tangiisuran B[3], Meng OL[4], Aziz NA[2], Saleem F[1], Atif M[5]
[1]*Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia,* [2]*Universiti Teknologi MARA, Puncak Alam, Selongor, Malaysia,* [3]*Universiti Sains Malaysia, Penang, P.Penang, Malaysia,* [4]*Penang Hospital, Penang, P. Penang, Malaysia,* [5]*Universiti Sains Malaysia (USM), Pinang, Malaysia*

OBJECTIVES: To evaluate prescription of guidelines recommended Angiotensin converting enzyme inhibitors (ACE inhibitors) to established diabetic hypertensive patients, and factors associated with prescription of ACE inhibitors and hypertension control. **METHODS:** This was a cross sectional study conducted at Penang hospital. Prescriptions written to enrolled 250 established diabetic hypertensive patients were noted on visit 1 along with demographic and clinical data. Implicit review of the patients' medical record was conducted to find acceptable rationale for non prescription of ACE inhibitors. The enrolled patients were followed for another one visit and their blood pressure (BP) readings noted on visit 2 were related to prescriptions written on visit 1. Data was analyzed by SPSS 16. **RESULTS:** Two hundred twenty five (86%) patients had multiple comorbidities. The most prevalent comorbidity was cardiovascular disease (55.6%). Two hundred sixteen patients (86.4%) were on polytherapy. ACE inhibitors were the most commonly prescribed antihypertensive agents, prescribed to 158 (63.2%) patients followed by Beta blockers prescribed to 154 (61.6%) patients. Ninety-two (36.8%) patients were not on ACE inhibitors, among whom only 8 (8.6%) had contraindications to its use, and 12 (13%) had diabetic nephropathy and were on guidelines recommended Angiotensin receptor blockers. Chronic kidney disease had statistically significant weak negative association with prescription of ACE inhibitors (Φ=-0.13, P=0.03). One hundred nine (43.6%) patients were on goal BP on visit 2. Hypertension control had statistically significant moderate positive association with the use of ACE inhibitors (Φ=0.26, $P<0.01$), and weak positive association with use of Aldosterone antagonists (Φ=0.13, P=0.04), polytherapy (Φ=0.17, $P<0.01$), cardiovascular disease (Φ=0.13, P=0.03) and male gender (Φ=0.13, P=0.03). **CONCLUSIONS:** Despite of

guidelines recommendations and positive effect of ACE inhibitors on hypertension control, the use of ACE inhibitors in hypertensive patients suffering from diabetes mellitus was suboptimal at Penang Hospital.

PCV20

DURATION OF ACTION OF ALISKIREN IN HYPERTENSIVE PATIENTS WITH DIABETES – IMPLICATIONS FOR CONTROL OF BLOOD PRESSURE IN REAL-WORLD USE IN IMPERFECTLY ADHERENT PATIENTS

Lowy A, Brede Y
Novartis Pharma AG, Basel, Switzerland

OBJECTIVES: Diabetes increases cardiovascular (CV)/renal risk and thus also increases the importance of optimal control of blood pressure (BP), which is generally poor among hypertensive patients with diabetes. Poor adherence to antihypertensives is common. Electronic monitoring has shown that treatment lapses among hypertensives frequently exceed the duration of action of most antihypertensives, allowing the BP to rise, and reducing these drugs' real-world effectiveness by increasing CV risk. Use of long-acting antihypertensives may improve BP control among subjects who, like most, miss doses occasionally. Aliskiren, a direct renin inhibitor, has been shown in the general hypertensive population to suppress BP well beyond its 24-hour dosing interval. Its BP-lowering effect is almost uninfluenced by a single missed dose, and remains strong after treatment interruptions of a week (longer than almost all dosing errors). This study examines the duration of action of aliskiren among hypertensive patients with diabetes. **METHODS:** BP data from one to 28 days post-withdrawal, from diabetic subjects in six clinical trials, were modeled to estimate the extent to which use of aliskiren will ameliorate the effects of imperfect adherence among diabetic subjects, compared to other antihypertensives. **RESULTS:** Thirty-four diabetic subjects had their BP measured 24 hours after treatment withdrawal (48 hours after the last dose). The mean (95% CI) increase in systolic BP from pre-withdrawal baseline was 0.8 (-3.1 to +4.7) mmHg. Seventy-three diabetic subjects had their BP measured either six or seven days after withdrawal. The mean (95% CI) increase in systolic BP from the pre-withdrawal baseline was 3.4 (+0.8 to 6.1) mmHg. **CONCLUSIONS:** Among diabetics, as in the general hypertensive population, aliskiren retains much of its effect for a week after stopping treatment. Its duration of action in diabetic subjects covers the majority of dosing errors. This may confer advantages over other treatments.

PCV21

CLINICAL EFFICACY OF BISOPROLOL COMPARED TO ATENOLOL IN REDUCING THE IN-CLINIC AND AMBULATORY BLOOD PRESSURE IN HYPERTENSIVE PATIENTS

Rai MK, Goyal R
Cardiff Research Consortium, Capita India Pvt. Ltd, Mumbai, Maharashtra, India

OBJECTIVES: The objective was to evaluate the clinical efficacy of bisoprolol compared to atenolol in reducing the in-clinic and ambulatory blood pressure in patients with mild to moderate hypertension. **METHODS:** Studies were retrieved from Embase, Pubmed, and Cochrane databases using relevant search strategies. Randomised controlled trials which compared bisoprolol with atenolol were included according to pre-specified inclusion/exclusion criteria. The outcomes of interest were reduction in in-clinic systolic/diastolic blood pressure, 24-hour ambulatory BP (ABP), and reduction in heart rate. Two reviewers independently extracted data from the included studies. Data was meta-analysed using RevMan (v5). **RESULTS:** Of the 1056 studies identified, 11 studies met the inclusion criteria. In total, 624 patients were randomised to bisoprolol, and 683 were randomised to atenolol. Seven of the included studies were double-blind, three were single-blind and one was open-label study. The Jadad score of eight studies was ≥3 and were of high quality. The study duration of included studies ranged from 8-weeks to 52-weeks. Results of meta-analysis showed a significantly better reduction of clinical systolic BP with bisoprolol compared to atenolol (WMD: 3.07 (1.79, 4.35, $p<0.00001$). The reduction in clinical diastolic BP was significantly better with bisoprolol compared to atenolol (2.68 (1.88, 3.48, $p<0.00001$). The systolic ABP was significantly reduced with bisoprolol compared to atenolol ($p<0.001$). The reduction in diastolic ABP was more with bisoprolol but was not significantly better. A significantly better reduction in heart rate was achieved with bisoprolol compared to atenolol (1.81 (0.97, 2.65, $p<0.0001$). **CONCLUSIONS:** This review has included the evidence to date with regards to reduction of clinical and ambulatory blood pressure with bisoprolol compared to atenolol. This review concludes that bisoprolol is significantly better than atenolol in effectively reducing the in-clinic BP, ambulatory BP and heart rate in patients with mild to moderate essential hypertension.

PCV22

GEOGRAPHIC VARIATION TRENDS IN CRITICAL LIMB ISCHEMIA PREVALENCE IN THE UNITED STATES

Baser O[1], Wang L[2]
[1]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA,* [2]*STATinMED Research, Dallas, TX, USA*

OBJECTIVES: To examine the geographic variation trends in the annual prevalence of critical limb ischemia (CLI) in the US elderly population. **METHODS:** Using national medical claims data from 2006 through 2008, all patients who were aged 65 years or older and diagnosed with CLI were identified. The direct standardization method was used to assess year, age, gender, race and diabetes-adjusted prevalence of CLI. The change in prevalence of CLI over the 3 years was assessed and the variation in the prevalence of CLI was tested by state. **RESULTS:** Geographic variation in the prevalence of CLI was obtained for patients over the age of 65 when adjusted by age, gender, race and diabetes status. Although approximately constant prevalence of CLI was reported in Utah (less than 0.15%) and Maryland (greater than 0.30%), a progressively increasing prevalence of CLI was observed in Montana (2006: 0.149%; 2007: 0.163.%; 2008: 0.277%) and Delaware (2006: 0.245%; 2007:0.247%; 2008: 0.330%) while progressively decreasing prevalence of CLI was observed in Arkansas, Colorado, Georgia, Ohio, Virginia, West Virginia, and Washington. The total trend over 3 years followed the pattern of higher rates in eastern states and lower rates in western states. **CONCLUSIONS:** The spatial distribution of CLI prevalence is uneven and strongly suggests a geographic variation of CLI risk areas. Targeted prevention and treatment could help gain better control of CLI in the United States.

PCV23

CLOPIDODGREL AND STATIN PRESCRIBING PATTERNS IN ACS PATIENTS – AN OBSERVATIONAL STUDY USING LINKED SECONDARY AND PRIMARY CARE DATA IN A UK POPULATION 2003-2009

Boggon R[1], Fox KA[2], Begg A[3], Ray K[4], Timmis A[5], Hemingway H[6], Emmas CE[7], Van staa T[1]
[1]*GPRD, London, UK,* [2]*University of Edinburgh, Edinburgh, UK,* [3]*University of Dundee, Dundee, UK,* [4]*St George's University of London,, London , UK,* [5]*Barts and the London School of Medicine and Dentistry,, London, UK,* [6]*University College London, London , UK,* [7]*AstraZeneca UK Ltd, Luton, UK*

OBJECTIVES: To use a novel linkage database to describe prescribing patterns in patients discharged from hospital with acute coronary syndrome (ACS) over a period of changing national guidelines. **METHODS:** Unique identifiers were used to link patients in a hospital registry (Myocardial Ischaemia National Audit Project), with longitudinal primary care data (General Practice Research Database). This retrospective observational study examined post-discharge prescribing patterns for unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI) and ST elevation MI (STEMI). The population comprised patients ≥40 years, hospitalised for ACS from 2003-2009, discharged home, with ≥3 months follow-up. Patients were followed from discharge until death, or censoring. A patient was classified as discontinued if they had no further prescription within the duration of a prescription plus a grace period of 90 days. **RESULTS:** Of the 7,888 linked patients with at least 3 months of follow-up, 865 had a discharge diagnosis of UA, 4108 NSTEMI and 2915 STEMI. Overall 412(48%) UA, 2820(69%) NSTEMI and 1830(63%) STEMI patients were treated with clopidogrel in primary care within 3 months of discharge. The proportion of UA patients treated remained relatively stable over the study period (2003:47%, 2009:38%), in contrast prescribing increased in NSTEMI (2003:41%, 2009: 78%) and STEMI patients (2003:24%, 2009:87%). Statin use was high in all three groups (734(85%) UA, 3609(88%) NSTEMI, 2784(96%) STEMI) and remained so throughout the study period. The median time until discontinuation of medicine was 12 months for clopidogrel and >24 months for statin across all three ACS types. Patterns of discontinuation remained constant across all study years. **CONCLUSIONS:** The proportion of patients with STEMI and NSTEMI treated with clopidogrel increased from 2003 to 2009, in line with national guideline recommendations. However there was no evidence that clinicians differentiated length of therapy by type of ACS.

PCV24

PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMIC ASPECTS OF USE OF ACE INHIBITORS IN SERBIA COMPARED WITH MONTENEGRO IN 2009

Tomic Z[1], Mikov M[1], Sabo A[1], Milijasevic B[1], Sahman M[2], Andric V[3]
[1]*School of Medicine, Novi Sad, Vojvodina, Serbia and Montenegro,* [2]*ALMS, Podgorica, Montenegro, Podgorica, Serbia and Montenegro,* [3]*Republic Institute for Health Insurance of Serbia, Belgrade, Serbia and Montenegro*

OBJECTIVES: The aim of the study was to analyze use of ACE inhibitors in Serbia compared with Montenegro in year 2009. **METHODS:** Data about use of ACE inhibitors in Serbia and in Montenegro in 2009 taken from Republic Institute for Health Insurance from Serbia and from Health Service Fund of Montenegero. **RESULTS:** Use of ACE inhibitors in Serbia in 2009 was 179,26 DDD/1000 inh/day and in Montenegro was 83,32 DDD/1000 inh/day. In Serbia 5.977.289,00€ has been spent for ACE inhibitors and in Montenegro 2.488.464,95€ in the same year. In Serbia on the first place is enalapril with 78,32 DDD/1000 inh/day or 44,43%, on the second place fosinopril with 20,09 DDD/1000 inh/day or 11,40%, while on the third place is ramipril with 19,11 DDD/1000 inh/day or 10,84% of total drug utilization in this subgroup. Amount spent on enalapril was 1.717.416,00€ or 28,73%, on fosinopril 1.116.972,00€ or 18,69%, and on ramipril 470.937,00€ or 7,88% of total finances spent on this subgroup C09 in year 2009. In Montenegro on the first place are lisinopril and hydrochlorothiazide with 19,62 DDD/1000 inh/day or 23,55%, on the second place are fosinopril and hydrochlorothiazide with 12,77 DDD/1000 inh/day or 15,33%, while on the third place is fosinopril with 11,92 DDD/1000 inh/day or 14,31% of total drug utilization inside this subgroup. Money spent on lisinopril and hydrochlorothiazide are 425.547,30€ or 17,10%, on fosinopril and hydrochlorothiazide 762.333,74€ or 30,63%, and on fosinopril 533.307,43€ or 21,43% of total finances spent on this subgroup C09 in the year 2009. **CONCLUSIONS:** Comparing the consumption of ACE inhibitors in Serbia and Montenegro in the year 2009, it becomes clear that the combination of ACE inhibitors with diuretics is most frequently used in Montenegro, while in Serbia the use of this combination is on the the fifth place in this group of drugs.

PCV25

CHARACTERISING PATIENTS WITH A FIRST-TIME ADMISSION FOR ATRIAL FIBRILLATION IN THE UNITED KINGDOM

Jones J[1], Townsend R[2], Jameson K[3], Amber V[4], Evans LM[5]
[1]*Cardiff Research Consortium, Cardiff, UK,* [2]*CRC, Cardiff, UK,* [3]*MSD Ltd, Hoddesdon, UK,* [4]*MSD Ltd, Hertfordshire, UK,* [5]*University Hospital Llandough, Cardiff, UK*

OBJECTIVES: To characterise patients with atrial fibrillation (AF) in a UK secondary care centre. **METHODS:** Eligible patients admitted to Llandough Hospital (Cardiff, UK) as an emergency with AF (ICD10 code: I48X), and discharged between 1/10/2009

and 31/03/2010, were identified through examination of electronic patient records. Exclusion criteria included patients with atrial flutter (AFl), or an ICD10 code indicating prior inpatient attendance for AF since 1995. Patient notes were reviewed manually and an anonymised data collection template completed by the clinician for analysis. **RESULTS:** Of the 126 patients meeting the inclusion criteria, the notes of 7 patients were unobtainable and 8 with a diagnosis of AFl were excluded. The majority of patients were symptomatic at presentation (56%) and less than half were male (41%). Within the study population, the frequency of patients with AF increased with age, peaking at 80-89 years (45% of the study sample). Method of admission was primarily through A&E or GP referral (48% each); with 50% of A&E admissions being for symptomatic AF, compared with 60% of those referred via a GP. Almost half the study population were recorded with "first detected AF" (47%); 67% of whom were symptomatic, compared to 47% being symptomatic in patients recorded as "not first detected AF". The majority of patients were reported to have 1 or 2 of the pre-defined co-morbidities of interest (29% each); one fifth had no co-morbidities. The most common co-morbidities were hypertension (51%), ischaemic heart disease (20%), heart failure (18%), diabetes (16%) and pulmonary disease (15%). **CONCLUSIONS:** Results from this study demonstrate the majority of patients presenting to secondary care with AF have multiple associated co-morbidities, which are known to influence the management and treatment strategy, and long-term complications. Further up-to-date epidemiological studies, which describe the history, management and prognosis of patients with AF, are required.

PCV26

REAL WORLD ADD-ON AND SWITCH PATTERNS FOR PLATELET AGGREGATION INHIBITORS

Löfroth E, Bruce S, Myrén KJ
IMS Health, Stockholm, Sweden

OBJECTIVES: To analyze the add-on and switch patterns for patients who dispensed platelet aggregation inhibitors, excluding heparin (acetylsalicylic acid, clopidogrel, and dipyridamole) in the South-West region of Sweden. **METHODS:** This was a retrospective database study of medication utilization amongst patients from the South-West region of Sweden (1.5 million inhabitants). All patients who dispensed platelet aggregation inhibitors (B01AC), excluding heparin, from 2006 to 2009 were included in the study. A dispatch was classified as new, switch, add-on, or continuation. All dispatches were annotated, at the ATC level, as either new (no other anticoagulant within 105 days), add-on (another anticoagulant dispatched both before and after), switch (another anticoagulant dispatched before, but not after), or continuation (dispatched same ATC-code within 105 days). **RESULTS:** 163 330 patients had at least one B01AC filled prescription. The total number of dispatches for these patients were 3 327 499. 96% of all patients had been dispatched acetylsalicylic acid (ASA), 11% clopidogrel and 6% dipyridamole. ASA was dispatched as a new prescription in 17% of all dispatches, in <0.5% as add-on, <0.5% as switch, and in 83% as continuation. For clopidogrel the distribution was 17% (new), 4% (add-on), 3% (switch), and 77% (continuation). For dipyridamole the distribution was 7%, 18%, 8%, and 68%. **CONCLUSIONS:** Not surprisingly ASA was by far the most common treatment. ASA and Clopidogrel both had first line treatment profiles, of which it was most pronounced for ASA (<1% add-on or switch). Dipyridamole is used more as an add-on or switch therapy with 18% as add-on, 8% as switch, and only 7% as new dispatches.

PCV27

FREQUENCY OF ADVERSE DRUGS EVENTS (ADES) AS POSSIBLE CAUSES OF REQUEST OF DRUGS NOT INCLUDED IN ESSENTIAL MEDICINES LIST IN COLOMBIA

Buendia Rodriguez JA
Universidad de Buenos Aires, Buenos Aires, Argentina

OBJECTIVES: To describe the frequency of adverse drugs events (ADEs) as possible causes of request of drugs not included in essential Medicines list in Colombia **METHODS:** This was a retrospective, descriptive study developed in a private medical insurance company in Bogota, Colombia. Data were obtained from drug request form of drugs not included in a national essential Medicines list. We analyzed the content of the notes to identify the records related to the occurrence of ADEs in the period 2005 to 2008. Information concerning the adverse event and the drug involved was recorded in a data collection instrument developed by the researchers. The pharmacological classification of drugs was performed according to the Anatomical Therapeutic Chemical Classification System (ATC). Univariate descriptive statistical analysis was performed **RESULTS:** A total of 116 cases of ADEs were detected. The level 1 groups of the ATC of drugs with greater frequency of ADEs were the cardiovascular agents (66; 47.15%), nervous system agents (34; 23.7 %) and antineoplastic and immunomodulating agents (21; 14.7 %). The great majority was cases of light severity (89; 62.7 %) and classified as possible (66; 48.4 %). **CONCLUSIONS:** We conclude that our study encourages the private medical insurance companies in developing countries to design pharmacosurveillance programs; recognizing the importance of looking for new sources of report of adverse reactions to diminish the under-notification of ADEs.

PCV28

CONTROL OF HYPERTENSION IN SPAIN: A SYSTEMATIC REVIEW AND META-ANALYSIS OF 76 EPIDEMIOLOGICAL STUDIES ON 341,632 PARTICIPANTS

Catalá-López F[1], Sanfélix-Gimeno G[1], García-Torres C[2], Ridao M[3], Peiró S[1]
[1]*Centro Superior de Investigación en Salud Pública (CSISP), Valencia, Spain,* [2]*Oxford Radcliffe Hospitals NHS Trust, Oxford, UK,* [3]*Instituto Aragonés de Ciencias de la Salud (I+CS), Zaragoza and Centro Superior de Investigación en Salud Pública (CSISP), Valencia, Spain*

OBJECTIVES: Hypertension is a leading global risk factor for the burden of cardiovascular disease. Data about changes in hypertension control are important to set intervention priorities. We conducted a systematic review and meta-analysis of epidemiological studies to determine the control of hypertension in Spain over the last decade. **METHODS:** A search of PubMed/MEDLINE, SCOPUS and IME was performed for epidemiological studies conducted in Spain (since 2000) with data on control rates for hypertension. The primary outcome was the prevalence of uncontrolled hypertension defined as the percentage of patients having systolic blood pressure (SBP) ≥ 140 mmHg and/or diastolic blood pressure (DBP) ≥ 90 mmHg. For populations at risk (e.g. patients with diabetes), the definition was SBP ≥ 130 mmHg and/or DBP ≥ 80-85 mmHg. Pooled-prevalence estimates and 95% confidence intervals (95% CI) were determined by random-effects models using the inverse variance method. Heterogeneity was assessed using Cochran's Q and I2 statistics. **RESULTS:** Seventy-six studies evaluating 341,632 patients (79% with hypertension) met the inclusion criteria. Among hypertensive patients, the overall pooled-prevalence of uncontrolled hypertension (≥ 140/90 mmHg) was 67.0% (95% CI: 64.1% to 69.9%), but was 87.6% (95% CI: 86.2 to 89.0%) when the most restricted definition (≥ 130/80-85 mmHg) was used for patients at risk. The test for heterogeneity was significant (P<0.001). Using metaregression analyses, we showed that the prevalence of uncontrolled hypertension did not change significantly over time, but the percentage of patients receiving at least two antihypertensive drugs increased (P=0.032, and 0.001). **CONCLUSIONS:** In Spain, the control of hypertension is far from optimum and does not appear to have improved in recent years despite the increased intensity of therapy. Patients at risk with comorbidities appear to be controlled worse.

PCV29

RECENT IN-HOSPITAL MORTALITY TRENDS AMONG PATIENTS WITH HEART FAILURE IN THE NETHERLANDS

Overbeek JA[1], Penning-Van Beest FJA[1], Herings RMC[2], Agodoa I[3]
[1]*PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands,* [2]*Erasmus Medical Centre, Rotterdam, The Netherlands,* [3]*Amgen Inc., Thousand Oaks, CA, USA*

OBJECTIVES: Recent in-hospital mortality data among heart failure (HF) patients in the The Netherlands are lacking. This study described in-hospital mortality rates among HF patients in the The Netherlands from 2005 to 2009. **METHODS:** The PHARMO database network includes, among other things, hospitalization records of approximately 3.2 million residents in the The Netherlands. From this database, all patients with a hospitalization for HF between 2005 and 2008 were selected. The date of the first HF admission was defined as the index date. Patients hospitalized for HF in the 12 months prior to index date were excluded. Patients were followed from index date until end of data collection, death, or a maximum of 12 months, whichever occurred first. Crude mortality rates over time were determined during index HF admission, any HF readmission, and during any all-cause readmission . **RESULTS:** The study included 9786 patients with an index HF admission. Mean (± SD) age was 77 (± 11) years and 52% were female. During index HF admission (mean (±SD) length of stay (LOS):11 (±10) days) 10% of patients died. Hence, 8,850 patients were at risk for readmission. During follow-up, 1,563 (18%) patients were readmitted for HF and 4,542 (51%) patients had an all-cause readmission. In-hospital mortality during HF readmission (mean (±SD) LOS: 11 (±9) days) was also 10%. In-hospital mortality during all-cause readmission (mean (±SD) LOS: 7 (±11) days), was 5%. Mortality rates over time from 2005 to 2009 were stable. Mean (±SD) number of days between hospital (re)admission and death was 10 (±13) days for the index HF admission and 12 (±12) days for both HF readmission and all-cause readmission (12 (±15) days). **CONCLUSIONS:** In most recent years, in-hospital mortality remains unchanged with 10% of HF patients dying during HF admission.

PCV30

HEART FAILURE (RE)ADMISSIONS IN THE NETHERLANDS: RATES, LENGTH OF STAY AND COSTS

Overbeek JA[1], Penning-van Beest FJA[1], Herings RMC[2], Agodoa I[3]
[1]*PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands,* [2]*Erasmus Medical Centre, Rotterdam, The Netherlands,* [3]*Amgen Inc., Thousand Oaks, CA, USA*

OBJECTIVES: Hospital admissions are common among heart failure (HF) patients and contribute to the significant clinical and economic burden of HF. This study determined rates, length of stay (LOS) and costs of HF (re)admissions. **METHODS:** The PHARMO database network includes, among other things, hospitalization records of approximately 3.2 million residents in the The Netherlands. From this database, all patients with a primary hospital discharge code for HF between 2005 and 2008 were selected. Date of first HF admission was defined as index date. Patients hospitalized for HF in the 12 months prior to index date were excluded. Patients were followed from index date to end of data collection, death, or a maximum of 12 months, whichever occurred first, in order to assess primary hospitalizations for HF within one year, i.e. HF readmissions . Main outcomes for each identified HF (re)admission were LOS (in days) and costs per (re)admission (amount paid in €). **RESULTS:** The study included 9,786 patients with an index HF admission. Mean (± SD) age was 77 (± 11) years and 52% were female. Mean (± SD) LOS was 11 ± 10 days and mean (± SD) hospitalization costs of index HF admission were €8,650 (± €9,100). During the index HF admission 936 patients died, therefore 8,850 patients were at risk for a HF readmission. Of those patients, 1,563 patients were readmitted for HF within one year. Overall, one-year HF readmission rate was 21.8 per 100 person years. Mean (± SD) LOS of first HF readmission was 10 ± 10 days and mean (± SD) hospitalization costs of first HF readmission were €8,850 (± €8,450). **CONCLUSIONS:** One fifth of patients hospitalized for HF in the The Netherlands have a subsequent HF admission within one year. Overall, costs of index HF admission and first HF readmission are similar.

PCV31

CEREBRAL HEMORRHAGE AND TRANSIENT ISCHEMIC ATTACK AFFECTED BY METEOROLOGICAL FACTORS

Kriszbacher I[1], Boncz I[1], Szalai M[1], Sebestyén A[2], Szili R[1], Kornya L[1], Radnai Z[1], Csoboth I[1]
[1]University of Pécs, Pécs, Hungary, [2]South-Trasdanubian Regional Health Insurance Fund Administration, Pécs, Hungary

OBJECTIVES: The purpose of our study is to investigate whether the time of onset of an acute cerebrovascular event demonstrates a seasonal variation, and we also examined the influence of certain meteorological factors on the occurrence of this event. **METHODS:** Patients admitted to the Departments of Neurology in Hungary between 2005 and 2007 with the diagnosis of a cerebral hemorrhage (n=11,604) or a transient ischemic attack (n=12,513) were examined. For data collection we used the database of the Hungarian National Health Insurance Fund Administration (OEP) on the basis of International Classification of Diseases (ICD). Meteorological data (temperature, atmospheric pressure, relative humidity) was retrieved from the National Meteorology Service. Statistical analysis was carried out with SPSS 14.0 for Windows. **RESULTS:** The analysis of meteorological data showed that an increase in average temperature on the previous day resulted in a notable drop of cerebral hemorrhage incidence during all seasons ($p<0.05$), while in case of transient ischemic attack such a decrease only occurred during Summer ($p<0.05$). We have not found demonstrable influence while examining atmospheric pressure and relative humidity. **CONCLUSIONS:** To summarize, we can say that our results indicate that the incidence of cerebral infarction, cerebral hemorrhage, and a transient ischemic attack show a typical variation depending on the season of the year. We can also say that the values of temperature may influence the development of different cerebrovascular events.

PCV32

POPULATION ATTRIBUTABLE RISK (PAR) OF MACROVASCULAR EVENTS ASSOCIATED WITH HBA1C, BLOOD PRESSURE OR WEIGHT IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: EVIDENCE FROM A DUTCH COHORT

Heintjes E[1], Penning-van Beest FJA[2], Parasuraman SV[3], Grandy S[3], Pollack M[3], Herings RMC[1]
[1]PHARMO Institute, Utrecht, The Netherlands, [2]PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands, [3]AstraZeneca, Wilmington, DE, USA

OBJECTIVES: To determine the population attributable risk (PAR) of macrovascular events associated with HbA1c, systolic blood pressure (SBP), or weight (BMI) in patients with type 2 diabetes mellitus (T2DM). **METHODS:** The population-based PHARMO database contains T2DM patients regularly monitored in primary care for cardiovascular risk factors HbA1c, SBP and BMI. In the period 2000-2008 patients without baseline macrovascular events and on antidiabetic treatment for ≥6 months were followed from start of monitoring until monitoring ended. Multivariate survival modeling of the composite outcome of macrovascular events was used to estimate the expected number of events after 5 years, either with unchanged risk factors (base-case) or with reductions in risk factors. The PAR was calculated as the number of averted events divided by the number of expected events in the base-case analysis. **RESULTS:** Mean age of 5841 included patients was 66 years (55% male), 45% had HbA1c levels ≥7%, 66% had a SBP ≥140 mmHg and 85% had a BMI >25 kg/m2. The base case expected number of macrovascular events at 5 years was 796, and 687 after reduction to target of all 3 risk factors. The combined PAR of elevated HbA1c, SBP and BMI was 14%, ranging from 5% among those with one elevated risk factor to 21% among those with three risk factors elevated. Incremental reductions of 0.5% HbA1c, 10mmHg SBP and 10% BMI led to 4% fewer events, ranging from 2-10%. The PAR of reducing HbA1c to target (7%) was 5%, ranging from 2-10%. The PAR of reducing SBP to target (135 mmHg) was 9%, ranging from 3-12%. There was no effect of reduction in BMI alone. **CONCLUSIONS:** Reducing elevated HbA1c and blood pressure levels was associated with improvements in cardiovascular risk. Even modest reductions in risk factors lead to significant reductions in macrovascular events in T2DM patients.

PCV34

IMPROVING GLOBAL VASCULAR RISK MANAGEMENT (GVRM) USING THE COSEHC CARDIOVASCULAR RISK ASSESSMENT TOOL

Ferrario C[1], Moore M[2], Simmons D[3], Colby C[4], Exuzides A[4], Panjabi S[5]
[1]Wake Forest University School of Medicine, Winston Salem, NC, USA, [2]Wake Forest University School of Medicine, Winston Salem, NC, USA, [3]COSEHC, Winston-Salem, NC, USA, [4]ICON, San Francisco, CA, USA, [5]Daiichi Sankyo, Inc, Parsippany, NJ, USA

OBJECTIVES: To report on the goal rates for SBP, plasma lipid variables, and body mass index (BMI), based on published guidelines, from data available in the 2nd quarter (Q2) post-baseline of the GVRM initiative; a 5-year project focusing on validating the COSEHC risk score through cardiovascular risk factor management. **METHODS:** The Consortium for Southeastern Hypertension Control (COSEHC) developed a risk score tool to predict cardiovascular disease (CVD) mortality in the southeastern (SE) US. This global approach to SE CVD calculates the absolute risk for 5-year CVD mortality based on: age, sex, total, HDL and LDL-cholesterol, triglycerides (TG), SBP, and evidence of smoking, diabetes, family history of CHD, and ECG-confirmed cardiac hypertrophy. Baseline data were obtained from 78,540 patients (42,707 females) across ten medical facilities. **RESULTS:** From 39,080 females and 33,144 males with Q2 data at goal for SBP (63 vs. 70%), LDL-cholesterol (41 vs. 55 %), TG (59 vs. 57%), and % of non-smokers were similar between the two sexes. Female subjects, however, achieved higher at goal targets for HDL-cholesterol (63 vs. 36% in males, $p < 0.05$) and BMI (22 vs. 16 in males, $p < 0.003$). In addition, at goal rates for SBP control correlated with improved HDL-cholesterol ($r=0.64$, $p< 0.05$) and weight values in females ($r= -0.69$, $p < 0.05$) and only weight in males ($r= -0.76$, $p < 0.05$). COSEHC 5-year absolute risk scores for CVD mortality in the entire population were higher in males [(Mean ± SD) 36.43 ± 2.26] compared to females (30.57 ± 3.38, $p < 0.0005$). **CONCLUSIONS:** The GVRM initiative provides an effective way of benchmarking risk factors in a population at high risk for cardiovascular events. The initiative is assisting health care providers to monitor risk factors at regular intervals and proactively manage the cardiovascular risk of their patient population.

PCV35

SAFETY AND TOLERABILITY OF BISOPROLOL COMPARED TO ATENOLOL IN PATIENTS WITH MILD TO MODERATE HYPERTENSION

Goyal R, Rai MK
Cardiff Research Consortium, Capita India Pvt. Ltd, Mumbai, Maharashtra, India

OBJECTIVES: The objective was to evaluate the safety and tolerability of bisoprolol compared to atenolol in patients with essential mild to moderate hypertension. **METHODS:** Studies were retrieved from Embase, Pubmed, and Cochrane databases using relevant search strategies. Randomised controlled trials which compared bisoprolol with atenolol were included according to pre-specified inclusion/exclusion criteria. The outcomes of interest were total withdrawals from study, withdrawals due to adverse events (AE), withdrawals due to lack of efficacy, any adverse events, bradycardia, fatigue, oedema and vertigo. Two reviewers independently extracted data from the included studies. Data was meta-analysed using RevMan (5). **RESULTS:** Of the 1056 studies identified, 11 studies met the inclusion criteria. In total, 624 patients were randomised to bisoprolol, and 683 were randomised to atenolol. Seven of the included studies were double-blind, three were single-blind and one was open-label study. The Jadad score of eight studies was ≥3 and were of good quality. The study duration of included studies ranged from 8-weeks to 52-weeks. Results of meta-analysis showed that with bisoprolol there was lower risk of study withdrawals [RR: 0.95 (0.79, 1.16)] and withdrawals due to lack of efficacy [RR: 0.58 (0.14, 2.37)] as compared to atenolol. Withdrawals due to AE were more in the bisoprolol group compared to atenolol. The risk of AE (any) was lower with atenolol compared to atenolol [RR: 0.94 (0.73, 1.21)]. The risk of bradycardia was higher with bisoprolol compared to atenolol ($p=0.3$). Lower risk of oedema ($p=0.3$) and vertigo ($p=0.6$) was reported with bisoprolol as compared to atenolol. **CONCLUSIONS:** This review has included the evidence to date with regards to safety and tolerability of bisoprolol compared to atenolol. This review concludes that availability of bisoprolol provides the patients with a safe and efficacious first-line therapy option in hypertension.

PCV36

HIGH DOSE AND LONG-TERM SAFETY OF SYSTEMIC CORTICOSTEROIDS IN THE TREATMENT OF POLYMYLAGIA RHEUMATICA AND VASCULITIS: A SYSTEMATIC REVIEW

Nyssen OP[1], Gauthier A[1], Schmitt C[2], Levy V[2], Cognet M[1], Aguiar-ibanez R[1]
[1]Amaris Consulting UK, London, UK, [2]GlaxoSmithKline, London, UK

OBJECTIVES: To review the evidence base for the safety of high dose and long-term usage of systemic corticosteroids (CSs). **METHODS:** Selection of studies: population-based studies involving patients with polymyalgia rheumatica or vasculitis treated with systemic CSs and reporting the incidence of diabetes, hypertension, cataract, osteoporosis or cardiovascular events. Search strategy: A systematic literature review was conducted in Medline, Medline-in-process, Embase, and the Cochrane Library up to January 2011, with very broad search terms in order to limit the risk of missing relevant studies. Data synthesis: "Key studies" were identified as assessing comparisons relevant to our study question (CSs vs. no use of CSs and/or assessment of CSs at different doses) and reporting at least one outcome of interest by treatment group. Results were summarized separately for key studies and other studies. **RESULTS:** Out of 3671 citations initially identified for screening 76 publications were selected. Few studies were identified as key: only 3 reported the incidence of diabetes, hypertension or cardio-vascular events, four studies documented the development of cataract and seven reported outcomes related to osteoporosis. Based on these studies, outcomes such as cataract and osteoporosis presented a higher rate of incidence for both indications within the CSs treatment groups, and tended to be less common when the treatment arm combined intravenous or intramuscular CSs with oral CSs than with oral CSs alone. No significant association was found for the other outcomes of interest. The magnitude of the CSs effect on the outcomes of interest varied greatly between studies. **CONCLUSIONS:** Although CSs are a cornerstone of treating polymyalgia rheumatica and vasculitis, the evidence base for their safety profile is poor, subject to a high level of heterogeneity, and the findings for the different outcomes were not always consistent across studies, demonstrating the need for further research in this area.

PCV37

PARAMETRIC CONDITIONAL NON-FRAILTY MODEL FOR RECURRENT EVENTS IN PERSONS WITH TYPE 2 DIABETES IN SWEDEN: THE EXAMPLE OF MYOCARDIAL INFARCTION

Ahmad Kiadaliri A[1], Clarke PM[2], Gerdtham UG[1], Nilsson P[1], Eliasson B[3], Gudbjörnsdottir S[3], Steen carlsson K[1]
[1]Lund University, Malmö, Skane, Sweden, [2]University of Sydney, Sydney, Sydney, Australia, [3]University of Gothenburg, Göteborg, Göteborg, Sweden

OBJECTIVES: The risk of subsequent events after a first cardiovascular event in persons with type 2 diabetes has received less attention to date. Simulation models, including risk engines and health-economic cost-effectiveness models, have thus relied primarily on estimations of the risk of first events and assumed constant transition probabilities for subsequent events. The aim of the current study is to analyze the differences in risk of having a first and a second myocardial infarction (MI) for persons with type 2 diabetes. **METHODS:** Observational data from the

Swedish National Diabetes Register (NDR) for 35,238 persons with type 2 diabetes aged 30-74 years at diagnosis from January 1, 2004 to December 31, 2008 were analyzed using the conditional non-frailty Weibull model. To not underestimate the effect of BMI, two specifications of the model were estimated. Age at diagnosis, sex, hypoglycaemic treatment, diabetes duration, microalbuminuria and smoking were common covariates in both models. **RESULTS:** A total of 1409 patients had one MI event and 200 experienced two events. The results showed that the risk of a second MI differ from the risk of having a first MI. In addition, the effects of covariates were not constant between multiple events. Women had a lower risk for developing a first event compared to men, but a higher risk for a second event conditional on the first MI. Preliminary results indicate four times higher hazard of developing a MI conditional on a first MI during the follow up. **CONCLUSIONS:** The findings show the need for an update of simulation models including health-economic models and risk engines to include separate transition probabilities for first and subsequent events for correct predictions of costs and quality of life gains. Using recurrent event risk equations may reduce the bias from the previous assumption of constant transition probabilities for consecutive events in health economic models.

Cardiovascular Disorders – Cost Studies

PCV38

BUDGET IMPACT OF CHANGING FUTURE STATIN USE PATTERNS IN SWEDEN

Sternhufvud C[1], Jacob J[2], Costa-Scharplatz M[3], Gandhi SK[4]
[1]*AstraZeneca R&D, Mölndal, Sweden,* [2]*AstraZeneca Nordic MC, Södertälje, Sweden,*
[3]*AstraZeneca R&D, Södertälje, Sweden,* [4]*AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA*

OBJECTIVES: To assess the health and budget impact of increasing use of rosuvastatin in patients with high cardiovascular risk, while maintaining the overall level of use, upon the entry of generic atorvastatin in Sweden. **METHODS:** A model was developed to estimate the budget impact associated with changed statin utilization pattern in different risk groups. The Framingham Risk equation was used to estimate cardiovascular events, and the relative risk reduction for statins was modeled using the JUPITER (Justification for the Use of statins in Primary prevention: an Intervention Trial Evaluating Rosuvastatin) trial. A similar relative risk reduction was used for primary and secondary prevention settings based on available literature. Baseline risk distribution was derived from the Malmö Primary Prevention Study. The use of rosuvastatin was assumed to increase from 4% (2011) to 7% (2014) in the high-risk group (27% baseline 10-year Framingham risk), but the overall use was kept unchanged (4%). A gradual atorvastatin use increase was assumed with a corresponding decrease in simvastatin use over 3 years. Cost calculations were from Swedish public health sources. Generic price for atorvastatin was assumed to be 5% of branded price. **RESULTS:** For the Swedish population on statin treatment (810,304 patients, 25% with a previous history of CVD) the estimated budget impact decreased by SEK 359 millions in 2012 (compared with 2011) and by SEK 441 millions in 2014 with changed statin utilization. The estimated number of CVD events avoided ranged from 98 in 2012 to 197 in 2014 compared with current year (0.81% decrease over the 3-year period). **CONCLUSIONS:** A shift to generic atorvastatin in 2012, accompanied by increased use of rosuvastatin in high-risk patients whilst maintaining rosuvastatin overall use at current levels, was estimated to prevent more cardiovascular events and resulted in overall healthcare budget savings for the 3-year period in Sweden.

PCV39

HEPARIN-INDUCED THROMBOCYTOPENIA TYPE II IN TIMES OF DEMOGRAPHIC CHANGES – EPIDEMIOLOGICAL AND ECONOMIC ASPECTS IN GERMANY

Schopohl D, Berger K, Schramm W
University Hospital of Munich, Muenchen, Germany

OBJECTIVES: The antibody-mediated, prothrombotic heparin-induced thrombocytopenia type II (HIT-II) is a life-threatening disease with high thrombosis risk of 38-76% and up to 20% mortality. Pulmonary embolism occurs in up to 40% of patients, and amputations are necessary in up to 15%. The objective was to evaluate frequency and cost of HIT-II in Germany. **METHODS:** Systematic literature searches regarding epidemiology and cost of HIT-II were conducted until end of 2000 with Medical Subject Heading terms “incidence”, “epidemiology”, “risk”, and “cost” each in combination with “heparin-induced thrombocytopenia”. German secondary data were obtained by desktop research from the German Federal Statistical Office and a German university hospital. **RESULTS:** Literature search yielded eleven relevant publications selected by successive title, abstract and whole publication screening from a total of 1225 hits. Published incidence for HIT-II in Germany was 0.039% for in-hospital patients, and average additional costs per patient amounted to €9004 (Wilke et al., J Thromb Haemost, 2009). Data from the German Federal Statistical Office for 2009 show an incidence of 0.05% for patients with secondary diagnosis HIT-II, ICD-10 Code D69.53, corresponding to 8,585 cases (age peak 65-85 years) with an average prolongation of hospital stay by 18 days. The frequency of documented HIT-II as secondary diagnosis increased since 2005 by 60.4% (2005: 5353; 2006: 6263; 2007: 7177; 2008: 7454 cases). Estimated additional costs generated by HIT-II in Germany in 2005 amount to 48 million euro, and in 2009 to a minimum of 77 million euro. **CONCLUSIONS:** Cost and burden of HIT-II are considerable. Due to the demographic development to be expected in Germany during the next decades in combination with the age peak of the disease a further increase in HIT-II cases has to be anticipated. Data are limited. Further epidemiological research and analysis of burden of disease from several perspectives are needed.

PCV40

BUDGET IMPACT MODEL AFTER THE INTRODUCTION OF VERNAKALANT IN SPAIN

Nocea Pulfer G[1], Caloto Gonzalez MT[1], Martín Martinez A[2]
[1]*MSD Spain, Madrid, Spain,* [2]*Hospital Universitario Severo Ochoa, Leganés, Madrid, Spain*

OBJECTIVES: To estimate the hospital impact with the introduction of vernakalant in hospital emergency departments (EDs) in Spain. **METHODS:** Patients with recent onset atrial fibrillation (AF) (<48H) or non-permanent AF without thromboembolic risk (anticoagulation or negative transesophageal echocardiography) were included in the ED setting. Scenario: Data derived from the RHYTHM-AF-Spain study or determined by the hospital. Budget impact model with the following variables: percentage of use of anti-arrhythmic drugs (AAD) before and after the entry of vernakalant, time to cardioversion with AAD and number of patients per year that could be treated with vernakalant. Outcome variables: impact on pharmacy budget, length of stay in ED (cost offset, additional patients treated in ED). Time to achieve sinus rhythm for vernakalant, drug cost, and hospital stay were obtained from published data. **RESULTS:** According to Spanish RHYTHM-AF study data, in 67% of these patients cardioversion (CV) is attempted with the following AAD (proportion; mean time to normal sinus rhythm): amiodarone iv (55%; 7 hours), flecainide iv/oral (12%/28%; 1.5/4.2 hours), propafenone iv/oral (1%/4%; 2/6.1 hours). It is estimated that in a hospital like those enrolled in RHYTHM-AF, approximately 150 patients per year would be admitted into the ED and pharma-cardioversion would be attempted in 101. Assuming that AADs were partially substituted for vernakalant (30% for amiodarone, 15% flecainide oral, 5% flecainide iv, and 5% propafenone oral), 22 patients would receive vernakalant per year. The annual incremental cost is €7,772.13, but offset in 63.4% due to a reduction of 123.16 hours of stay in the ED that would also allow for the assistance of 15 additional patients. **CONCLUSIONS:** The reduction of hospital stay associated with the use of vernakalant carries a high percentage of compensation costs associated with reduction of stay in the ED and frees up resources to attend to more patients.

PCV41

THE BUDGETARY IMPACT OF IMPLEMENTING A TELEHEALTH HOME MONITORING SYSTEM FOR CHRONIC HEART FAILURE PATIENTS IN A TYPICAL UK PRIMARY CARE TRUST

Almond C[1], Latimer J[1], Brereton NJ[1], Chapman AM[2]
[1]*BresMed Health Solutions, Sheffield, South Yorkshire, UK,* [2]*GE Healthcare, Chalfont St Giles, Buckinghamshire, UK*

OBJECTIVES: There has been enormous interest in the potential benefit, primarily around decreased medical resource use, of the introduction of telehealth home monitoring systems (THMS) for chronic disease management. Widespread adoption has nevertheless been slow due to a lack of information on the financial implications of implementation. THMS requires a substantial initial investment which in a time of budget cuts needs economic justification. The objective of this study was to provide an estimate of the potential short-term financial implications of introducing the Care Innovations™ Guide THMS for patients with chronic heart failure (CHF) in a typical PCT within the UK. **METHODS:** A one-year budget impact model was developed looking at key financial drivers of CHF care including GP visits, unplanned hospitalisation, ambulance time, etc. The model assessed the impact on these costs after the introduction a THMS package for a PCT with a population of 500,000, assuming the initial THMS uptake would be 30% of CHF patients. Population and disease incidence and prevalence data for England were taken from the Quality and Outcomes Framework 2009-10. Average costs per unit of medical resource use, amount of resource use per year for a typical chronic CHF patient receiving standard care and estimates of the impact of the THMS on resource use were estimated from published literature. **RESULTS:** The model estimated that the introduction of THMS required an initial investment of £9,440,567 but yielded a return of 2% (£158,812) within one year. **CONCLUSIONS:** The introduction of THMS requires considerable initial investment; however this model suggests that this is offset within a very short time-frame due to reductions in medical resource usage and is expected to lead to substantial savings over the medium-term. This should encourage decision-makers to seriously consider moving from small pilot studies to more widespread implementation of THMS.

PCV42

A BUDGET IMPACT ANALYSIS TO ESTIMATE THE ECONOMIC IMPACT OF SEVIKARHCT® FOR THE TREATMENT OF ARTERIAL HYPERTENSION IN SPAIN

Darba J[1], Kaskens L[2], Nilsson J[3], Oberdiek A[4]
[1]*Universitat de Barcelona, Barcelona, Spain,* [2]*BCN Health, Barcelona, Spain,* [3]*OptumInsight, Stockholm, Sweden,* [4]*Daiichi Sankyo Europe GmbH, Munich, Germany*

OBJECTIVES: To assess the economic impact of adding SevikarHCT® to the Spanish market for the treatment of arterial hypertension in the adult population aged over 35. SevikarHCT® concerns a new three-in-one combination tablet containing olmesartan medoxomil, amlodipine and hydrochlorothiazide. **METHODS:** To estimate the economic impact a budget impact was developed using the Spanish national healthcare system (NHS) perspective and a 3-year time horizon. The patient population was estimated based on disease prevalence, population growth and data on the currently treated population with combinations of receptor blockers of the antagonists of the angiotensin II (ARBII) with calcium channel blockers (CCB) alone or together with diuretics (DIU) in fixed doses. Costs considered in this model included drugs actually marketed or over the next three years consisting of Balzak®, Balzak plus®, Capenon®, CapenonHCT®, Copalia®, CopaliaHCT®, Dafiro®, DafiroHCT®, Exforge®, ExforgeHCT®, Imprida®, ImpridaHCT®, Twynsta®, Sevikar® and SevikarHCT® expressed in EUR 2010. Based on the annual drug costs per patient and market shares for each treatment the economic burden before and after the introduction of SevikarHCT® was estimated. A drop of 28% in drug prices

was assumed when generic alternatives became available. **RESULTS:** The Spanish population with arterial hypertension over 35 years treated with combinations of ARBII and CCB with or without DIU was estimated at 990,000 patients in 2010, expecting to rise to 1.17 million patients in 2013. Total treatment costs for hypertension treatment over the next 3 years were estimated at €1.638 million before the introduction of SevikarHCT® and at €1.649 million after introduction. **CONCLUSIONS:** Although the introduction of SevikarHCT® adds incremental costs for the Spanish NHS, a decrease in the overall economic burden with or without the introduction of SevikarHCT® was observed from 2010. These budget savings can be explained by the effect in price drop caused by the availability of generics.

PCV43

BUDGET IMPACT OF THE IMPLEMENTATION OF A TREATMENT PROTOCOL FOR PULMONARY ARTERIAL HYPERTENSION IN A REFERRAL HOSPITAL

Vega-Coca MD[1], Flores S[2], Bautista J[3]
[1]*Andalusian Agency for Health Technology Assessment, Seville, Seville, Spain,* [2]*Andalusian Agency for Health and Technology Assessment, Seville, Andalucia, Spain,* [3]*Hospital Virgen del Rocio, Sevilla, Sevilla, Spain*

OBJECTIVES: To examine evidence on efficacy and safety of oral drugs for pulmonary arterial hypertension (PAH). Analyze their utilization and their cost. To propose a treatment protocol based on efficacy, safety and efficiency. Calculate the estimated budget impact after its implementation. **METHODS:** A search was conducted in MEDLINE, EMBASE and Cochrane Database. Systematic reviews and meta-analysis of bosentan, ambrisentan, sildenafil or tadalafil in PAH (functional class II/III) were included. Their utilization was analyzed retrospectively in patients with primary or associated with connective tissue diseases pulmonary hypertension that started treatment during 2008 to 2010. The annual cost per patient for each alternative was calculated (standard dosage). A treatment protocol was developed, based on efficacy, safety, and efficiency. The incremental cost for each drug, and the potential savings if all patients start their treatment with the most cost-effective were calculated. **RESULTS:** No evidence was found to support the superiority of any treatment over another, in terms of efficacy and/or safety. Seventeen patients started treatment during the study period (47% bosentan, 41.2% sildenafil, 11.8% ambrisentan). Estimated annual cost per patient: 30,987.07, 26,861.93, 7,807.74 and 6,865.65 €, for bosentan, ambrisentan, sildenafil and tadalafil, respectively. In absence of significant differences in efficacy or safety, the treatment protocol was based on efficiency (sildenafil> tadalafil> ambrisentan> bosentan). Incremental cost (compared to sildenafil): 24,121.42, 19,996.28 and €942.09 for bosentan, ambrisentan and tadalafil, respectively. Estimated potential savings with implementation of protocol: 77,654.64 €/ year. **CONCLUSIONS:** No evidence supports the superiority of any treatment over another, so they could be considered equivalent therapeutic alternatives. Bosentan is most widely used drug in naïve patients. The cost associated with bosentan/ambrisentan is markedly greater to sildenafil/tadalafil. Establishing a protocol that prioritizes sildenafil/tadalafil use would help to more efficient management of resources.

PCV44

COST-UTILITY ASSOCIATED WITH DIFFERENT MONITORING STRATEGIES AMONG PATIENTS RECEIVING LONG-TERM ORAL ANTICOAGULATION THERAPY IN AUSTRIA

Schmidt LJ, Habacher W, Koenig C, Beck P
Joanneum Research, Graz, Austria

OBJECTIVES: To ascertain the cost-utility of patient self-management (PSM) compared to standard monitoring among long-term oral anticoagulation therapy patients in Austria. **METHODS:** A Markov model was used to combine international effectiveness data and local cost and mortality data in a life-long simulation (closed cohort with a mean baseline age of 67 years). Costs were calculated using information on healthcare contacts from healthcare professionals and associated tariffs. Costs for standard monitoring were based on monthly visits to primary/outpatient settings and determination of PTZ levels. PSM costs included costs of the handheld device, materials, training and regular healthcare check-ups. Costs associated with complications (thrombotic and haemorrhagic events) in primary-care, acute care and rehabilitation settings were also considered, since complications occur at different rates between monitoring strategies. Sensitivity analyses were performed. **RESULTS:** PSM was associated with 15.9 life years or 10.7 QALYs compared to 14.6 life years or 9.4 QALYs with standard monitoring. Costs per patient for the entire period were €7,873 for PSM, €8,170 for monitoring by GPs, €8,354 for monitoring by community-based consultants and € 8,810 for monitoring at a hospital out-patient clinic. PSM was the dominant strategy for both the cost per life-year gained and cost per QALY analysis. Although PSM led to higher initial costs (between €908 and €916 per patient in the first year), follow-up costs were lower (between €228 and €235 per patient per year thereafter) due to lower frequency of health care visits. Standard monitoring was associated with monitoring costs of between €273 and €391 per patient per year. **CONCLUSIONS:** Encouraging suitable patients to self-manage leads to better health outcomes and lower costs. In Austria, initial costs are compensated by lower complication rates and associated costs and lower monitoring expenses. Cost-savings to the health sector could be accrued as soon as 3 years after patients switch strategies.

PCV45

HEALTH ECONOMIC EVALUATION OF TICAGRELOR IN PATIENTS WITH ACUTE CORONARY PATIENTS (ACS) BASED ON THE PLATO STUDY FROM A SPANISH HEALTH CARE PERSPECTIVE

Delgado-Ortega L[1], López-Sendón JL[2], Heras Fortuny M[3], Alvarez Sanz C[1], Nikolic E[4], Mellström C[5], Wallentin L[6]
[1]*Astrazeneca Spain, Madrid, Spain,* [2]*Hospital de la Paz, Madrid, Madrid, Spain,* [3]*Hospital Clinic, Barcelona, Spain,* [4]*Linköping University, Linköping, Linköping, Sweden,* [5]*Astrazeneca R&D, Lomma, Sweden,* [6]*Uppsala University, Uppsala, Sweden*

OBJECTIVES: PLATO was a multi centered, double blind, randomized study that included 18,624 ACS patients from 43 countries, comparing ticagrelor + aspirin versus clopidogrel + aspirin. The PLATO demonstrated that ticagrelor was superior on the primary composite endpoint: myocardial infarction, stroke, cardiovascular death (HR 0.84, 95% CI: 0.77 to 0.92) without an increase in major bleedings compared to clopidogrel, and whether the strategy of choice was invasive or conservative. The aim of this analysis is to estimate direct health care costs from a Spanish health care perspective (excluding drug costs because ticagrelor price has not yet been established). **METHODS:** Resource utilization was pre specified in the PLATO trial and included hospitalization bed days, investigations, interventions and blood products. Direct health care costs per patient at 12 months were estimated by multiplying the resource use with Spanish unit costs derived from the Spanish database e-salud, the GRDs of the Ministry of Health, published literature, and the CMBD 2008. **RESULTS:** Ticagrelor resulted in numerically fewer bed days (mean difference per patient 0.21, 95% CI -0.16 to 0.59), PCIs (mean difference per patient 0.01, 95% CI -0.01 to 0.03) and CABGs (mean difference per patient 0.01, 95% CI: 0.00 to 0.01). Ticagrelor is associated with €341 reduction per patient (95% CI: 31 to 652) in healthcare costs at 12 months compared to clopidogrel. The reduction in healthcare costs was mainly due to fewer hospital days and cardiovascular interventions in the ticagrelor group. The reduction in cost increased over the 12-month treatment period consistent with the rate of clinical events over time in the PLATO study. **CONCLUSIONS:** Treatment with ticagrelor is associated with cost savings in patients with ACS at 12 months compared with clopidogrel (excluding drug costs) from a Spanish health care perspective. However, the total cost savings will depend on drug price, data not available yet.

PCV46

CLINICAL AND ECONOMIC BURDEN OF MAJOR BLEEDING IN ABDOMINAL SURGERY PATIENTS

Baser O[1], Wang L[2]
[1]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA,* [2]*STATinMED Research, Dallas, TX, USA*

OBJECTIVES: To assess the clinical and economic burden of major bleeding in abdominal surgery patients. **METHODS:** A retrospective study (January 1, 2005 to December 31, 2007) was conducted using a medical claims database. Patients included in the study were admitted to the hospital with abdominal surgery as their primary procedure. Patients' demographic, clinical and discharge statuses were compared using Chi-square testing and standardized differences. Risk-adjusted health care visits and costs were estimated using the General Linear Model (GLM). Potential risk factors for venous thromboembolism (VTE) events were selected using the Cox Proportional Hazard Regression Model. **RESULTS:** In patients identified with abdominal surgery (n=49,355), 773 (1.57%) suffered major bleeding in the 6-month follow-up period. Compared with patients who did not suffer major bleeding, patients who did were more likely to be older, have higher Charlson Comorbidity Index (CCI) scores and have other comorbid conditions such as cancer. The percentage of patients who had baseline emergency room (ER) visits was also higher in the major bleeding group. After risk-adjustment for pre-specified covariates, inpatient ($21,573 vs. $10,954), outpatient ($12,891 vs. $7,852) and pharmacy costs ($2,025 vs. $1,901) were higher for patients who suffered major bleeding. In addition, patients with major bleeding events had higher readmission rates (0.11% vs. 0.03%) during the follow-up period. **CONCLUSIONS:** Since the health care costs of patients with major bleeding events were significantly higher than those of patients without, it is important for individual hospitals to improve major bleeding prophylaxis therapy.

PCV47

ANALYSIS OF TRANSIENT ISCHEMIC ATTACK-RELATED CLINICAL OUTCOMES, HEALTH CARE UTILIZATION AND COST BURDEN OF PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

Baser O[1], Wang L[2]
[1]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA,* [2]*STATinMED Research, Dallas, TX, USA*

OBJECTIVES: To estimate clinical outcomes, health care utilization and cost burden of patients who suffered a transient ischemic attack (TIA) during the 180 days after a diagnosis of non-valvular atrial fibrillation (NVAF) and compare it with patients who did not. **METHODS:** Based on 2005-2007 US insurance claim files, patients aged 65 years and older who have had two or more primary diagnoses of NVAF, occurring within 30 days of one another, were selected. The 180 days follow-up event rates, health care facility use and costs for patients with and without a TIA were compared. Risk adjustment was performed using the propensity score matching (PSM) method with the ProbChoice™ algorithm. **RESULTS:** A total of 18,575 patients were identified with NVAF, of which 163 (0.88%) suffered a TIA during the 180 days after the NVAF diagnosis. Patients were not significantly different in terms of gender, region, and baseline comorbid conditions. After PSM risk-adjustment for pre-specified covariates, outpatient emergency room (ER) visits (85.89% vs. 48.47% $p<0.0001$), cardiovascular-related length of stay (6.59 days vs. 5.57 days, $p<0.0001$) and ischemic stroke events (89.57 vs. 8 /100 person years, $p<0.0001$) were higher for patients who suffered a TIA compared to those who did not. Although risk-adjusted outpatient office visit, international normalized ratio (INR) testing, Coumadin outpatient visit, drug and other costs did not differ significantly between the two groups, patients who suffered a TIA had significantly higher inpatient ($21,740 vs. $22,663, $p<0.0001$) and total ($31,675 vs. $18,045, $p<0.0001$) expenditures. **CONCLUSIONS:** After adjusting for patient clinical and

demographic characteristics, total health care utilization and cost burden were higher for patients who suffered a TIA after an NVAF diagnosis, relative to patients who did not.

PCV48

CLINICAL OUTCOMES AND COSTS ASSOCIATED WITH STROKE IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION

Baser O[1], Wang L[2]
[1]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA,* [2]*STATinMED Research, Dallas, TX, USA*

OBJECTIVES: To compare clinical outcomes and cost burden of patients who suffered a stroke during the 180 days after diagnosis of non-valvular atrial fibrillation (NVAF) with patients who did not. **METHODS:** Based on 2005-2007 US Medical insurance claim files, patients aged 65 years and older who have had two or more primary diagnoses of NVAF, occurring within 30 days of one another, were selected. The 180-day follow-up mortality rate, health care facility use and costs for patients with and without incidences of stroke were compared. Risk adjustment was performed using the propensity score matching (PSM) method with the ProbChoice™ algorithm. **RESULTS:** Out of patients who were identified with and without NVAF pre-stroke (n=18,195), 541 (2.97%) suffered a stroke during the 180 days after the NVAF diagnosis. After PSM risk-adjustment for pre-specified covariates, mortality (7.39% vs. 1.07% $p<0.0001$), outpatient emergency room (ER) visits (80.59% vs. 48.11% $p<0.0001$), readmission rates (1.85% vs. 0.40%, $p<0.0001$), transient ischemic attacks (44 vs. 8 /100 person years), and intracranial hemorrhage rates (71 vs. 7/100 person years) were all higher for patients who suffered a stroke compared to those who did not. Although risk-adjusted outpatient ER costs and office visit costs did not differ significantly between the two groups, patients who suffered a stroke had significantly higher inpatient ($24,231 vs. $15,137, $p<0.0001$) and total ($33,439 vs. $13,782, $p<0.0001$) expenditures. **CONCLUSIONS:** Most of the adverse events analyzed were higher for patients who suffered a stroke after an NVAF diagnosis relative to patients who did not. Total health care utilizations and health care costs were also significantly increased.

PCV49

EVALUATING THE MANAGEMENT OF THE REHABILITATION UNIT IN A TERTIARY REFERRAL HOSPITAL IN SPAIN: A COST-ANALYSIS STUDY

Cuervo J[1], Llavona R[2], Fernández L[1], Rebollo P[1], Castejón N[1]
[1]*BAP Health Outcomes Research, Oviedo, Spain,* [2]*Hospital Valle del Nalón, Langreo, Spain*

OBJECTIVES: To ascertain the direct costs related to hospitalization in the Physical Medicine Service and Rehabilitation of a tertiary referral hospital during the year 2009. **METHODS:** An epidemiological, observational retrospective study was carried out in the Central University Hospital of Asturias –HUCA-, Spain. All patients admitted to the Rehabilitation Unit (RU) and suffering from a cerebrovascular disease (CVD), brain injury (BI), spinal cord injury (SCI) or amputations were included. RU services was acting as secondary referral level -SRL- in case of BI and CVD. In contrast, SCI and amputations were attended in the same RU as tertiary referral level-TRL-. A cost-analysis following hospital perspective was performed recording all health resources at patient level. Next, direct costs were calculated attaching a published cost to each resource. Socio-demographic and clinical variables were registered to describe the sample and to facilitate external comparisons. Mean costs per patient were calculated considering each of the pathologies and comparing SRL and TRL. Costs were defined in 2009 Euros. Chi2 test was used to compare socio-demographic and clinical variables between groups. Next, parametric (Student's t test and ANCOVA analysis) and non parametric analysis (bootstrapping) were applied to estimate economic differences between groups. **RESULTS:** A total of 243 patients admitted to RU were assessed. Mean age (SD) was 59.62 years (1.41) and 71.2% males. Mean cost per patient (SD): BI(n= 15) 28,837.87(23,998.80); CVD(n= 116), 31,751.05(19,151.26); SCI(n= 105), 27,635.39(24,856.55); amputations(n= 7), 24,342.86(5,426.48). Mean SRL cost was significantly higher than TRL: 31,417.48(19,681.03) and 27,429.61(24,106.37), respectively (p= 0.013). Total anual SRL cost was 4,115,751.43 and 3,072,167.39 TRL. **CONCLUSIONS:** Forty-six percent of total activity in the RU is related to TRL requiring 43% of total expenditure. Further research comparing this policy with early discharge and home rehabilitation should be implemented to promote the efficiency of this service.

PCV50

HOSPITAL COSTS ASSOCIATED WITH ATRIAL FIBRILLATION IN CANADA

O'Reilly D[1], Hopkins R[2], Burke N[3], Dorian P[4], Healey JS[2], Sauriol L[5], Tarride JE[2], Goeree R[2]
[1]*PATH Research Institute, McMaster University, Hamilton, ON, Canada,* [2]*McMaster University, Hamilton, ON, Canada,* [3]*PATH Research Institute, Hamilton, ON, Canada,* [4]*University of Toronto, Toronto, ON, Canada,* [5]*Sanofi-Aventis Canada, London, ON, Canada*

OBJECTIVES: Atrial fibrillation (AF) is a prevalent disease that often requires costly hospital care, but the cost of hospital utilization has not been reported in Canada. The purpose of this study was to estimate the cost of hospital utilization for AF in Canada. **METHODS:** Three national administrative databases (Discharge Abstract Database, Same Day Surgery and National Ambulatory Care Reporting System) for the year 2007/08 were used to capture admissions, same day surgeries and emergency department (ED) visits. Provincial/territorial data were extrapolated to the national level using age-gender census information where necessary. Records with a most responsible diagnosis (MRD) of AF, atrial flutter or a secondary diagnosis of AF were included in the analysis. Hospital costs were estimated by applying an average cost per weighted case to the resource intensity weight that was provided for each admission/visit, and then adding the physician fees for admissions, surgeries and interventions. All cost estimates are expressed in 2010 Canadian dollars. **RESULTS:** In 2007/08, the number of hospital admissions with MRD of AF was 10,924 for men and 11,899 for women, same day surgeries was 3,910 for men and 1,797 for women and ED visits were 29,754 for men and 28,312 for women. The average cost per admission was $6,718 with an average length of stay of 5.7 days. The average cost of same day surgery was $3,524 and an ED visit was $849. The total hospital cost for patients with AF was $815M; $710M for hospital admissions, $72.9M for ED visits, and $31.8M for same day surgery. Most of the costs were for hospital admissions when AF was listed as a comorbidity ($558.2M, 69%) **CONCLUSIONS:** The substantial cost burden of AF in the acute care sector is driven by the consequences of AF, while the costs for specific treatments for AF are relatively low.

PCV51

COST OF ACUTE CORONARY SYNDROME IN SWITZERLAND

Wieser S[1], Rüthemann I[1], De boni S[1], Eichler K[1], Pletscher M[1], Radovanovic D[2], Auerbach H[1]
[1]*Winterthur Institute of Health Economics, Zurich University of Applied Sciences, Winterthur, Switzerland,* [2]*Institute of Social and Preventive Medicine, University of Zurich, Zurich, Switzerland*

OBJECTIVES: Acute coronary syndrome (ACS) is the most important clinical consequence of coronary artery disease and a leading cause of death worldwide. This study aims to assess the costs of ACS from a social and health insurance perspective evaluating direct costs, production losses and intangible costs in terms of quality adjusted life years (QALYs) lost. **METHODS:** A bottom-up incidence approach was used. ACS-Patients with one or more ACS events were extracted from a national hospital database and from mortality statistics. Remaining life years of surviving patients were modelled on age, gender and life expectancy statistics. Inpatient costs include acute care and rehabilitation in 2008. Outpatient costs include costs for ambulance, visits to GP and cardiologist, outpatient diagnostics, medication and rehabilitation. Production losses were calculated according to the human capital approach, including absenteeism, permanent disability and premature death. Intangible costs were calculated based on literature data. Cost data are derived from official price lists, literature and experts. Validation of clinical data was conducted using the AMIS-PLUS registry. **RESULTS:** A total of 14,955 patients experienced a total of 16,815 ACS events in 2008; 2,752 died as a consequence of these. This resulted in 19,064 hospital stays with an average length of stay in acute care of 8.9 days per patient. Total direct costs amounted to 690 Mio Swiss Francs (CHF) for the society and 523 Mio CHF for health insurers. Forty-four percent belong to inpatient and 56% to outpatient services. Production losses were 515 Mio. CHF and intangible costs resulted in 37,457 QALYs lost. Average total direct costs and production losses per patient were 80,873 CHF. Results appear robust in sensitivity analysis. **CONCLUSIONS:** ACS causes considerable costs in terms of direct medical expenditures, lost production and premature death, even without taking into account costs for its chronic consequences such as congestive heart failure.

PCV52

TEMPORAL TRENDS IN THE HOSPITAL BURDEN OF ATRIAL FIBRILLATION AND STROKE ON SECONDARY CARE COSTS IN ENGLAND BETWEEN 2006 AND 2009

Bakhai A[1], Righetti C[2], Punekar Y[2], Majeed A[3]
[1]*AMORE Health Ltd, London, UK,* [2]*Sanofi-aventis, Surrey, UK,* [3]*Imperial College, London, UK*

OBJECTIVES: Atrial fibrillation (AF) is the commonest cardiac arrhythmia found in clinical practice with an increasing prevalence in the aging population. Local estimates vary from 1.2 to 2.5%. The objective of our study was to evaluate the burden of AF on secondary care costs in England, which is responsible for substantial cardiovascular morbidity and mortality. **METHODS:** AF and stroke event and cost data captured in Hospital Episode Statistics(HES), between 2006 and 2009, was analysed to estimate the trends in hospital episodes in England. **RESULTS:** A total of 193,742 patients with a primary or secondary diagnosis of AF were hospitalised in 2009, representing a 19% increase in AF patients on the previous 3 years. During this period there were 239,746 hospital spells with a diagnosis of AF; a 22% increase from 2006-2009. The total inpatient cost attributable to AF increased from £353 million in 2006 to a total of £361 million in 2009. As a proportion of all admissions, AF admissions were 1.1% in 2006 to 1.2% in 2009 and represented 1,162,213 bed days occupied in 2006 versus 1,108,283 in 2009. In 2009, of the 193,742 patients with a diagnosis of AF, 5,391 subsequently had a stroke. This gives a conversion rate from AF to stroke of 3.1% of patients – up from 2.5% in 2006. During this same period, the average length of stay for the stroke patient with AF has increased from 38 days to 43 days (higher than those patients who have only had a stroke). **CONCLUSIONS:** Despite advances in both AF and stroke management, AF presents a significant and increasing burden on hospital care in England. New initiatives are needed to detect AF early and prevent hospital admissions or to manage AF in rapid access arrhythmia clinics where appropriate therapies to manage the rate, rhythm and cardiovascular risks can be dispensed without needing admission.

PCV53

COST STUDY OF CAREGIVING FOR PATIENTS WITH CHRONIC SYMPTOMATIC HEART FAILURE IN SPAIN, INSIGHTS FROM THE INOESCARO STUDY

Marti B[1], Delgado J[2], Oliva J[3], Llano M[4], Pascual P[5], Comin J[6], Grillo JJ[7], Diaz molina B[8], Culebras J[9], Martínez de la Concha L[10], Manito N[11]
[1]*Medtronic Iberia, Madrid, Spain,* [2]*Hospital□ de Octubre, Madrid, Spain,* [3]*Universidad de Castilla La Mancha, Toledo, Spain,* [4]*Hospital Universitario Marqués de Valdecilla, Santander, Spain,* [5]*Hospital Universitario Virgen de la Arrixaca, Murcia, Spain,* [6]*Hospital del Mar (IMIM), Barcelona, Spain,* [7]*Hospital Universitario Nuestra Señora de la Candelaria, Santa Cruz de Tenerife, Spain,* [8]*Hospital Universitario Central de Asturias, Oviedo, Spain,* [9]*Hospital Universitario Insular, Las Palmas De Gran Canariaý, Spain,* [10]*Hospital Universitario Infanta Cristina, Badajoz, Spain,* [11]*Hospital de Bellvitge, Barcelona, Spain*

OBJECTIVES: The objective of this study was to quantify, for the first time in a Spanish population, the time and cost burden of informal care for pts with heart failure. **METHODS:** A descriptive analysis of a multicenter, prospective observa-

tional study was performed. Pts who met inclusion criteria were followed-up for 12 months, with 3 visits programmed at baseline, 6 and 12 months. Baseline characteristics and caregiver's information were registered for every pt. Once identified total hours, the replacement cost method was used. **RESULTS:** A total of 330 pt were included, 74.2% men, mean age was 62.9 years. 82.4% were in NYHA class II, 16.4% NYHA class III and 1.2% NYHA class IV. A 28.5% needed support for daily living. Ninety four informal caregivers were identified, mean age of 58yo, mostly women (85.1%). Main relationship with caregiver was spouse/couple (77.7%), followed by son/daughter (14.9%). Number of weekly hours of main caregiver was estimated at 44.3 hours (40.6 hours for patients NYHA class II and 53.3 hours for patients NYHA class III-IV) and shadow prices values from 8-13€/hour. Total costs associated to informal caregiving increased between €21,298-€34,609 per pt of which between €18,892-€30,049 are informal costs associated with the main caregivers. Likewise, focusing on main caregivers, using the proxy-good method and the shadow prices shown, the cost of replacing services by care giving a Class II patient (2,115 yearly hours) were between €16,919-€27,494 for pts in NYHA class II; and between €22,230-€36,123 for caregiving a Class III or IV pt (2,779 yearly hours). **CONCLUSIONS:** Almost a 30% of pts with chronic symptomatic HF in Spain required support from an informal caregiver, which represents a significant burden for society and often has not been accounted for in economic evaluations of treatments for heart failure. Costs for informal care are associated with disease severity as measured by NYHA class.

PCV54

FIRST-YEAR DIRECT MEDICAL COST OF NEWLY DIAGNOSED STABLE ANGINA IN HONG KONG

Lee V[1], Cheung SY[1], Yuen A[1], Yan B[2]
[1]*The Chinese University of Hong Kong, Shatin, N.T Hong Kong, Hong Kong,* [2]*The Chinese University of Hong Kong, Shatin, Hong Kong*

OBJECTIVES: To evaluate the first-year direct medical cost for diagnosis and management of newly diagnosed SA, to identify SA-related resource consumption pattern in public hospitals in the New Territories East Cluster in Hong Kong and in patients with and without procedures, and with comorbidities of hypertension (HTN), diabetes mellitus (DM) and hyperlipidemia. **METHODS:** A retrospective non-randomized study was conducted including patients documented with new diagnosis of SA in the Clinical Management System during January 2007 to December 2009. Subjects were followed for 1 year after diagnosis. Cost items studied consisted of hospitalization, clinic visits, diagnostic tests, radiological examinations, laboratory tests, therapeutic operations and medications. For statistical analyses, Mann-Whitney Tests were performed to compare medians of costs in patients with and without procedures, and with different comorbidities of HTN, DM and hyperlipidemia. P-value <0.05 was regarded significant. **RESULTS:** 89 patients were recruited. The mean first-year total direct medical cost of SA per patient was HKD$89,518, with the cost for hospitalization being the most dominant, accounting for 29.2%. Increase in complexity of disease would increase the total from HKD$47,744 for patients without procedures to HKD$115,342 for patients with procedures ($p<0.001$). For the three comorbidities interested, SA patients co-morbid with hyperlipidemia required more resources for the management, HK$98,295 ($p<0.001$). **CONCLUSIONS:** This study revealed the huge expenses incurred by SA in the first year of initial diagnosis on local public healthcare system, which has a significant implication on future resources allocation. Strategies for cost saving and preventive measures should be implemented.

PCV55

CLINICAL AND ECONOMICAL BURDEN OF OROPHARYNGEAL DYSPHAGIA AMONG STROKE SURVIVORS IN EUROPE AND NORTH AMERICA

Takizawa C
Nestle Health Science, VEVEY, Switzerland

OBJECTIVES: Dysphagia commonly occurs following stroke and contributes to subsequent morbidity and mortality in stroke survivors with related substantial economical implications. Literature on the burden of this medical condition is scarce. This study aimed to identify the reported burden of dysphagia among stroke patients. **METHODS:** Epidemiological data were collected from publications in stroke and/or dysphagic patients and included prevalence of dysphagia and pneumonia, as its main complication. Economical data mainly included hospital length of stay, and pneumonia treatment costs. **RESULTS:** The data demonstrate stroke mostly occurs in people older than 65 years age (>75%). Prevalence and epidemiological figures varied widely from one publication to another. Indeed, up to 81% of stroke patients were diagnosed as dysphagic, depending on the method and time after stroke episode in which dysphagia is identified. Thus reportedly, up to 19.6 million stroke patients suffer dysphagia in North America and Europe. Studies identified that 40% to 50% of dysphagic stroke patients aspirate. In addition, pneumonia occurs in up to 51% of dysphagic stroke patients. Of course, dysphagic stroke patients who aspirate are at higher risk of pneumonia: up to 11-fold more than non aspirators. In Europe and North America, up to more than 10 million dysphagic stroke patients develop pneumonia. Furthermore hospital length of stay ranges from 5.07 to 10.55 days for stroke patients with dysphagia versus 3.26 to 4.74 days without dysphagia. The average hospital cost for pneumonia is $919 per day, totaling up to $96.5 billion in Europe and North America. **CONCLUSIONS:** The overall dysphagia burden is substantial worldwide, especially in Europe and North America. It is probably underestimated since only direct medical costs were included. However, it will most probably increase given the growing elderly population, which is at higher risk of having stroke.

PCV56

THE ECONOMIC BURDEN OF ATHEROTHROMBOSIS IN GREECE: RESULTS FROM THE THESIS STUDY

Maniadakis N[1], Kourlaba G[1], Angeli A[2], Kyriopoulos J[1]
[1]*National School of Public Health, Athens, Greece,* [2]*Sanofi Aventis, Athens, Greece*

OBJECTIVES: The aim of the present study is to estimate the annual direct and indirect costs in patients with a history of or at risk for atherothrombosis in Greece, using a bottom-up approach. **METHODS:** A multicentre, prospective, cost-of-illness study was conducted between January 2007 and December 2009. In this study, 800 patients with coronary artery disease (CAD) or cerebrovascular disease (CD) or peripheral artery disease (PAD) or multiple cardiovascular risk factors (MRF) were recruited from 11 major hospitals in Greece. All patients were followed up for 12 months. Resources used for the care of patients within the healthcare system and productivity losses during the follow-up period were recorded. The annual direct and indirect costs were calculated by combining these data with unit costs. **RESULTS:** The mean annual total cost was €5,940/patient (€5,416–€6,522). This cost ranges from €9,963/patient (€8,515–€11,868) for PAD group to €1,761/patient (€1,462–€2,232) for MRF group. The mean annual direct healthcare cost was €5,056 /patient (€4,653–€5,507). This cost escalates from €1,623 /patient (€1,319– €2,073) for MRF group to € 8,697 /patient (€7,648– €9,695) for PAD group. The annual direct healthcare costs was mainly driven by vascular intervention costs among CAD and PAD patients, (50.6% and 46.5%, respectively) and by the simple hospitalization cost among CD and MRF patients (67.7% and 35.7%, respectively). The mean annual indirect cost was €979 (€386– €1,395), €441 (€142- €835), €525 (€148 – €1,137) and €29 (€1- €87) per patient in the CD, CAD, PAD and MRF groups, respectively. The total annual expenditures related to atherothrombosis, in Greece, are estimated to be 7.5 billion € at a national level. **CONCLUSIONS:** The findings of the THESIS study indicate, for the first time, the high economic burden of atherothrombosis in Greece, since the direct healthcare cost related to atherothrombosis management accounts for almost 25% of annual healthcare expenditures.

PCV57

EPIDEMIOLOGICAL STRUCTURE, SOCIOECONOMIC EFFECTS AND BURDEN OF DISEASE IN PATIENTS WITH ORAL ANTICOAGULATION AND ATRIAL FIBRILLATION IN AUSTRIA

Schöllbauer V[1], Walter E[2], Brennig C[1]
[1]*Institute for Pharmaeconomic Research, Vienna, Austria,* [2]*Institut fuer Pharmacoekonomische Forschung, Vienna, Austria*

OBJECTIVES: Atrial fibrillation (AF) is the most common arrhythmia in clinical practice and associated with a high risk of stroke. In Austria, about 130,000 people are affected by AF. The first aim was to create a patient flow with epidemiological data to close the research gap for Austria and further to estimate the total cost of patients (direct and indirect costs) with AF and recommended oral anticoagulation. **METHODS:** The model is based on these detected AF patients. The approach used is prevalence-based, which is usually forgone within the time horizon of one year. For 68% of these patients oral anticoagulation is recommended, but only 54% of patients in the high-risk group received an OAC therapy. The remaining patients get Aspirin (31%), other medication (5%) or no therapy (10%). Clinical-data and costs of the adverse events stroke and major bleeding were considered. Direct costs comprise all direct medical costs like consultation, lab test, inpatient costs, medication and treatment costs. Indirect costs represents costs for AF patients after stroke like care allowance and costs of nursing homes. The resource use was determined by literature and experts. All costs represent data from 2011. The burden of disease study is conducted from a societal perspective. **RESULTS:** The direct costs of AF patients amount to 51,972,668€ and the total costs inclusive indirect costs are 93,915,299€ for the time horizon of one year. **CONCLUSIONS:** With rising life expectancy the number of patients with AF and the prevalence of strokes will increase. Therefore the time has come to give greater attention to the epidemiological and socioeconomic burden of AF.

PCV58

THE IMPACT OF COMORBID MENTAL ILLNESS ON COSTS OF HEALTH CARE FOR INPATIENTS WITH HEART FAILURE

Shimizu S[1], Ishikawa KB[2], Ito H[3], Fushimi K[1]
[1]*Tokyo Medical and Dental University, Tokyo, Japan,* [2]*National Cancer Center, Tokyo, Japan,* [3]*National Institute of Mental Health, Tokyo, Japan*

OBJECTIVES: Interactions of mental illnesses and heart failure have been indicated. Mental illness has been shown to be a risk factor of heart failure. In addition, it may worsen the symptoms as well as compliance to the therapy of patients with heart failure. A recent study has showed that comorbid depression may be associated with higher medical costs. The purpose of this study was to assess the impact of comorbid mental illness on costs of health care for inpatients with heart failure. **METHODS:** A retrospective cohort study of inpatients with heart failure. Data were collected between July 1, 2008, and December 31, 2008 from 855 acute care hospitals in Japan. In total, 38,446 admissions of patients with heart failure in 855 hospitals were included in the analysis. We compared health care costs of 5 groups: 1) no mental illness; 2) antidepressant prescription only; 3) co-prescription of antidepressant and other psychotropic drugs; 4) antidepressant prescription and depression diagnosis recorded; and 5) anxiolytic or hypnotic prescription only. Statistical analyses were performed using JMP 8.0. **RESULTS:** Psychotropic drugs were used in 19,839 (51.6%) patients with heart failure. The average number of psychotropic drugs was 3.69 per hospitalization in heart failure inpatients. After adjustment for covariates, patients prescribed with psychotropic drugs had significantly higher costs than patients not prescribed. **CONCLUSIONS:** This study suggested that comorbid mental illness is associated with higher medical costs.

PCV59

ANNUAL MEDICAL EXPENDITURE AND MORTALITY RELATED TO ACUTE CORONARY SYNDROME (ACS) IN THE UNITED KINGDOM – A SYSTEMATIC REVIEW

Zhang Q[1], Jameson K[2], Bolinder B[3], Angeletti F[4], Liczencziás E[5], Neumann M[5], Oberle-ofenheusle M[5], Stern L[4], Yousaf M[4]
[1]Merck & Co, Inc, Whitehouse Station, NJ, USA, [2]Merck Sharp & Dohme Ltd., Hoddesdon, Hertfordshire, UK, [3]Merck & Co, Inc, KENILWORTH, NJ, USA, [4]Analytica International, New York, NY, USA, [5]Analytica International, Lörrach, Lörrach, Germany

OBJECTIVES: Overall expenditure for the treatment of ACS imposes a heavy burden on global health care systems. As new treatments and procedures have become available in the past decade, the cost to healthcare systems has increased, yet mortality rates have remained relatively high. A recent research effort was undertaken to benchmark expenditures and outcomes in patients with ACS. The aim of this study was to understand the efficiency of resource use, in relation to mortality for patients with ACS in the UK. **METHODS:** A systematic literature search of 11 databases and secondary desk research were performed to identify ACS related expenditure and outcomes. Data were retrieved for UK patients with MI (STEMI, NSTEMI) and unstable angina. The reported cost data were extracted for hospitalizations, procedures, pharmaceutical treatment, and monitoring; mean annual expenditure per patient was estimated based on of these cost components. Outcomes focused on ACS mortality rate over the entire UK population. **RESULTS:** In the UK, the overall annual mortality rate for ACS was found to be 0.0473%. Total annual expenditure for all patients with ACS was £392,245,277 (£3,733 per patient). Results showed hospitalizations to be the main cost driver, accounting for 65.7% of the total annual cost. Procedure costs represented 24.5% of the total cost, whereas pharmaceutical treatment and monitoring costs accounted for 5.3% and 4.5%, respectively. **CONCLUSIONS:** The findings of this systematic review demonstrate that hospitalization cost accounts for almost two thirds of the total direct cost associated with ACS in the UK. More research and cross-country comparison are needed to determine treatment strategies which provide greater efficiency in resource use for the management of ACS.

PCV60

COST-EFFECTIVENESS OF DABIGATRAN FOR THE PREVENTION OF STROKE IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION IN AUSTRALIA

Tilden D[1], Germanos P[2], Gordon J[2], Tocchini L[1], Monz B[3]
[1]THEMA Consulting Pty Ltd, Pyrmont, NSW, Australia, [2]Boehringer Ingelheim Pty Limited, North Ryde, NSW, Australia, [3]Boehringer Ingelheim GmbH, Ingelheim am Rhein, Germany

OBJECTIVES: The objective of this cost-utility analysis was to compare the costs and effectiveness of dabigatran (DAB) with adjusted dose warfarin (WAR), aspirin (ASP) or no treatment (UNT) in patients with Non-Valvular Atrial Fibrillation (NVAF), from the perspective of the third party payer in the Australian public healthcare system. **METHODS:** A Markov cohort model was constructed based on the pivotal RE-LY clinical trial and indirect comparisons with aspirin and no treatment. The model calculated the incremental cost per QALY of different dabigatran doses (150 mg BID or 110 mg BID) relative to adjusted-dose warfarin, aspirin or no treatment. The model estimated the number of ischaemic strokes (IS), haemorrhagic strokes (HS), systemic embolic events (SEE), intracranial haemorrhages (ICH), transient ischaemic attacks (TIA), extra-cranial haemorrhages (ECH), minor bleeds (MB) and myocardial infarctions (AMI) associated with the respective treatments. The key consequences of the clinical events were costs, disability and/or reduction in quality of life, and death. The costs, morbidity and mortality of IS and HS in Australia were estimated from a patient audit of 3,307 strokes in Australia. **RESULTS:** The dabigatran treatment groups were associated with greater life years and QALYs compared with all the other treatment groups. These gains were primarily driven by a lower incidence of IS, SEE, TIA, ICH and HS in most comparisons. Incremental cost per QALY ratios were calculated by comparing the expected utilisation of the dabigatran doses (50% of patients using each dose) with current utilisation of adjusted-dose warfarin (40%), aspirin (40%) and no treatment (20%). The incremental cost per QALY of dabigatran was $10,028. Sensitivity and subgroup analyses consistently demonstrated the cost-effectiveness of dabigatran. **CONCLUSIONS:** Treating patients with dabigatran represents a cost-effective treatment for preventing strokes in patients with NVAF in Australia.

PCV61

ARE HOSPITAL COSTS FOR STROKE UNDERESTIMATED IN SPAIN?

Alvarez sabin J[1], Masjuan J[2], Yebenes M[3], Mar J[4], Oliva J[5], Gonzalez Rojas N[6], Becerra V[6], Casado MA[7]
[1]Hospital Vall DHebron, Barcelona, Barcelona, Spain, [2]Hospital Ramon y Cajal, Madrid, Madrid, Spain, [3]Pharmacoeconomics & Outcomes Research Iberia, Pozuelo de Alarcón, Madrid , Spain, [4]Hospital Alto Deba, Mondragon, Guipuzcoa, Spain, [5]Universidad de Castilla La Mancha, Toledo, Spain, [6]Boehringer Ingelheim, Sant Cugat del Valles, Barcelona, Spain, [7]Pharmacoeconomics & Outcomes Research Iberia, Pozuelo de Alarcón , Madrid, Spain

OBJECTIVES: To estimate the costs for the first clinically diagnosed stroke, in Spain. **METHODS:** Observational prospective study conducted in 16 Spanish centers (CONOCES study; Costes Socioeconómicos del Ictus en España). Patients will be followed during a 1 year period; 3 visits will be performed (inpatient hospitalization due to stroke, 3 and 12 months after stroke). Patient inclusion was controlled by the presence of Atrial Fibrilation (AF). Currently, hospitalization data from the first visit has been collected including patients' demographics, stroke severity, patient status and QoL at discharge, and direct resource consumption: length of stay, imaging and laboratory tests, specific therapeutic interventions (thrombolysis, decompressive craniectomy, angioplasty. . .), supporting therapies, and medication. Unitary costs were obtained from national healthcare databases and the Spanish Catalogue of Medicinal Products (€, year 2011 values). **RESULTS:** A total of 322 patients were recruited from November 2010 to May 2011. Preliminary results from the first visit showed the following characteristics: 50.3% had AF, mean age of 71.95+11.57, 44.6% female, 28.6% with intravenous thrombolysis, NIH 6.72+8.11, modified Rankin Score 3.04+1.85, Barthel index 56.71+38.68. Mortality rate during stay was 6.2%. Only 257 patients were evaluable for economic purposes. Mean length of hospital stay was 9.65 days (95%CI, 8.71-10.60). Mean inpatient cost per patient was €6428 (95% confidence interval [CI], €5912-€6943). The most relevant categories of costs were inpatient hospitalization (€3960, 95%CI, €3574-€4347, 61.6% of direct hospitalization costs), specific therapeutic interventions (€984, 95%CI, €783-€1185, 15.3%), imaging tests (€951, 95%CI, €878-€1024, 14.8%), medication (€302, 95%CI, €209-€394, 4.7%), laboratory tests (€145, 95%CI, €126-€164, 2.3%), and supporting therapies (€86, 95%CI, €45-€127, 1.3%). **CONCLUSIONS:** The inpatient economic burden of stroke in Spain is substantial because of long hospital stays and other health resource utilization. Results from this study show higher costs than previously published data.

PCV62

INFLUENCE OF SMOKING ON THE USE OF HEALTH-CARE RESOURCES AND COSTS IN PATIENTS WITH CARDIOVASCULAR DISEASE

Sicras-Mainar A[1], Diaz-Cerezo S[2], Sanz de Burgoa V[2], Navarro-Artieda R[3]
[1]Directorate of Planning, Badalona Serveis Assistencials, Badalona, Barcelona, Spain, [2]Pfizer Spain, Alcobendas (Madrid), Spain, [3]Hospital Universitari Germans Trias i Pujol, Barcelona, Spain

OBJECTIVES: To determine the effect of the use of tobacco in the consumption of health care resources and their associated costs in patients who have suffered some kind of cardiovascular event (CVE) in a populational scope. **METHODS:** Multicentric observational study undertaken through the retrospective review of the medical records of patients at six primary health-care centres and two hospitals. Inclusion criteria: subjects > 30 years, who requested health care after suffering a CVE between 2003 and 2007. Follow-up: 36 months. Groups: smokers, ex-smokers and non-smokers. Variables: Main measures: sociodemographics, comorbidities, resources used and total costs (health related, [primary care settings and hospitals] and productivity losses [absenteeism days]). Statistical analysis: logistic regression model and ANCOVA (procedure: marginal means; adjustment: Bonferroni); $p < 0.05$. **RESULTS:** A total of 2540 patients fulfilled the inclusion criteria (smokers: 8.4%, ex-smokers: 52.9%, non-smokers: 38.7%). Mean age: 68.1 years old; men: 60.7%. Smoking addiction was related with COPD (OR=2.4; 95%CI: 1.7-3.5) and depressive syndrome (OR=1.5; 95%CI: 1.1-2.2). Smokers patients, compared to ex-smokers and non-smokers, needed more hospitalization days (2.4 vs. 1.7 and 1.1; $p<0.001$), more specialized health care visits (2.2 vs. 1.5 and 1.3; $p<0.001$) and incurred more absenteeism days (36.7 vs. 30.7 and 10.5; $p<0.001$) respectively. Total costs: €16.8 millions (health related: 78.4%; productivity losses related: 21.6%; mean annual cost/patient: €6,309.8). Annual costs were higher among smokers in comparison with ex-smokers and non-smokers (€ 7,980.70 versus € 7,322.10 and € 5,618.90; $p < 0.001$); in terms of both health-care costs (€ 6,272.90 versus € 5,672.50 and € 4,822.90; $p < 0.001$) and losses of productivity at work (€ 1,707.70 versus € 1,649.60 and € 796.00; $p < 0.001$), respectively. **CONCLUSIONS:** In routine clinical practice, smokers patients compared to ex-smokers and non-smokers, show a higher cost from a societal perspective, both in health care related costs and in labour productivity losses.

PCV63

DIRECT HEALTH CARE COSTS OF ORAL ANTICOAGULANT TREATMENT IN PATIENTS WITH NON VALVULAR ATRIAL FIBRILLATION

Askari E[1], Hidalgo A[2], Villoro R[2], Vidal R[1], Miranda C[1], Ene GS[1], Ivanova A[2], González A[2], Llamas P[1]
[1]Fundación Jiménez Díaz, Madrid, Madrid, Spain, [2]Instituto Max Weber, Majadahonda, Madrid, Spain

OBJECTIVES: To quantify direct health care costs of oral vitamin K antagonist anticoagulant treatment in patients diagnosed with non valvular atrial fibrillation (NVAF). We examine whether a correlation exists between poor INR control and direct health care costs. **METHODS:** We designed an observational study. We revised the clinical histories of patients diagnosed with NVAF and treated with OATs at the Fundación Jiménez Díaz (FJD) between 01/10/2009 and 30/09/2010 (N=1,257). We collected INR value, number of visits due to INR control, type of anticoagulant (warfarin or acenocoumarol), hospital admissions due to complications and other current medication. The cost of all drugs was assumed to be the official price. Expenditure in INR control was calculated using the costs of all health care resources involved in the procedure. We used DRGs for the cost of each hospitalisation. The cost of a hospital visit was calculated using four scenarios, using actual invoices or using analytical accountancy methods. All costs are expressed in 2010 euros. **RESULTS:** The monthly average number of visits per patient was 1.17. Direct health care costs are in the range of 423,695€ and 1,436,038€. The average cost per patient varies between 392€ and 1,341€. The average cost of those patients with an INR within therapeutic range in 25% of the visits was 441.70€-1,592€. When INR was within therapeutic range in 25%-50% of the visits the average cost was 512.37€-1,703.91€. INR within therapeutic range in 50%-75% of the visits represented an average cost of 400.80€-1,375.74€. When INR was within therapeutic range in over 75% of the visits the average cost decreased to 305.23€-1,049.84€. **CONCLUSIONS:** The main part of direct health care costs of treating NVAF patients with OAT are due to hospital control in a specialised area and the high frequency of the visits. There is an inverse relationship between good INR control and direct health care costs.

PCV64

THE POTENTIAL CLINICAL AND ECONOMIC OUTCOMES OF PHARMACOGENETIC-ORIENTED WARFARIN THERAPY IN RUSSIA

Gerasimova KV
The First Moscow State Medical University named after I.M. Sechenov, Moscow, Russia, Moscow, Moscow, Russia

OBJECTIVES: To evaluate the potential clinical and economic outcomes of using genotype data to guide the management of warfarin anticoagulation therapy. **METHODS:** A decision tree was designed to simulate two groups – group of standard care and genotyped group. Both groups were separated by CYP2C9 genotypes in patients with alleles CYP2C9*2 and CYP2C9*3 and patients with genotype CYP2C9*1*1. CYP2C9*1*1 patients were subdivided further into VKORCBB and VKORCAA/AB types. Outcomes in each group were: major bleeding (gastrointestinal and intracranial), minor bleeding (hemorrhoid, hemarthrosis, hemophtalmos and others) and no bleeding. Direct medical costs from the Russian healthcare system point of view were estimated. Rate of bleedings in patients with different genotypes and relative risks of bleedings in pharmacogenetic-oriented approach were obtained from the literature. Sensitivity analysis to key parameters was performed. **RESULTS:** In the basic scenario costs of the standard treatment were higher than in pharmacogenetics-oriented group: 8545 rubles (USD305) and 6806 rubles (USD243) for 1 patient per year respectively. Sensitivity analysis showed that the model is sensitive to the price of pharmacogenetic test only: the pharmacogenetic approach remains cost-saving until the test costs less than 2600 rubles (USD93). **CONCLUSIONS:** In the Russian health care system, pharmacogenetic-oriented warfarin therapy is cost saving if the price of pharmacogenetic test does not exceed 2600 rubles (USD93).

PCV65

CLINICO-ECONOMIC EVALUATION OF COMPLEX CARDIOVASCULAR THERAPY WITH MAGNESIUM OROTATE IN PATIENTS WITH CHRONIC HEART FAILURE VERSUS STANDARD THERAPY IN UKRAINE

Iakovlieva L, Kyrychenko O, Mishchenko O
National University of Pharmacy, Kharkiv, Ukraine

OBJECTIVES: To evaluate the profitability of the complex cardiovascular therapy with magnesium orotate in patients with chronic heart failure (CHF) IV functional class (NYHA IV). **METHODS:** Cost-effectiveness evaluation of 2 treatment strategies was performed using the modeling "decision tree". Data from various sources: the results of two clinical trials (Stepura O.B., Martynow A.I., 2009; Libis R.A. et al, 1999) and National standard of treatment of patients with CHF FC IV were used in the modeling. Cost-effectiveness ratio was evaluated in accordance with the threshold willingness to pay for improving health achievement. The analysis of the impact of the investigated treatment strategies on the budget, taking into account the lost productivity was conducted. **RESULTS:** The inclusion of magnesium orotate in the CHF standard therapy improves the health (NNT was 1 / 0, 24 ≈ 4), it gives an additional 0,14 QALYs and requires additional costs. Only direct medical costs were included in the cost value. Incremental cost-effectiveness ratio was 1517,82 $ / add. QALY. It is less than GDP per capita (current threshold willingness to pay), i.e. cardiovascular therapy with magnesium orotate is cost effective. However, taking into account the financial capacity of the health system in Ukraine, in real practice such costs for achieve better health are less acceptable than the costs of standard therapy. Indirect costs (lost productivity) during 2 years in the application of standard therapy with magnesium orotate were less than indirect costs in application only standard therapy. Saving money - 606,7 $ per patient. **CONCLUSIONS:** Thus the inclusion of magnesium orotate in the standard therapy in patients with CHF is cost effective. High direct costs are compensated due in indirect costs savings.

PCV67

HEALTH-ECONOMIC IMPACT OF THE HUNGARIAN SALT INTAKE REDUCTION PROGRAM

Nagyjanosi L[1], Martos É[2], Bödönyi D[3], Vokó Z[3]
[1]*Syreon Research Institute, Budapest, Hungary,* [2]*National Institute for Food and Nutrition Science, Budapest, Hungary,* [3]*Eötvös Loránd University, Budapest, Hungary*

OBJECTIVES: Salt consumption in Hungary is high in international comparison, the average salt intake is 17,28g per day in men and 12,05g in women. Our aim was to study the cost-effectiveness of the salt intake reduction program run by the Hungarian National Institute for Food and Nutrition Science. **METHODS:** We built a cohort simulation Markov-model. The health benefit achieved by reduced salt intake was calculated for the 40-60 year old Hungarian population in 7 health states: healthy, hypertension, acute- and post AMI and stroke, death The transitional probabilities were calculated from national and international publications. We used the data of National Health Found and expert estimations to define the costs of interventions and health states. The efficacy was modeled with the use of data from the literature. It was assumed that 3g salt reduction results in 5Hgmm decline in systolic blood pressure (SBP) and 1Hgmm SBP lowering will reduce the prevalence of the hypertension with 1%. A discount rate of 5% was applied. **RESULTS:** If a public health program could reduce the salt intake to 10g/day/capita at in 5 years by 31 USD PPP/capita/year investment, then the ICER would be 4090.5 USD PPP (1USD PPP=128.92 HUF). In this scenario the lifelong risk of AMI and stroke would decrease with 0.0034The incremental cost of the intervention is 27.15 USD PPP, and the QALY win is 0.0066. **CONCLUSIONS:** An effective public health program to reduce salt intake would be cost-effective in Hungary.

PCV68

PHARMACOGENOMIC TESTING FOR WARFARIN USE IN TYPICAL OUTPATIENT SETTINGS LOWERS HEALTH CARE COSTS: THE MEDCO-MAYO WARFARIN EFFECTIVENESS STUDY

Aubert RE[1], Epstein RS[1], Yao J[1], O'Kane DJ[2], Tinnirello J[1], Teagarden JR[1], Moyer TP[2]
[1]*Medco Health Solutions, Inc., Franklin Lakes, NJ, USA,* [2]*Mayo Clinic, Rochester, MN, USA*

OBJECTIVES: To measure the comparative direct medical care costs between incident warfarin patients who did or did not experience genotyping to guide dosing. **METHODS:** We reanalyzed the previously published MM-WES in which we demonstrated that genotyping reduces the risk of hospitalization for bleeding and thromboembolism in patients who initiate warfarin treatment in typical outpatient practice settings. We used a cost consequence analysis to estimate the 6-month costs and consequences of warfarin genotyping. The intervention group (IG) comprised 896 patients and a comparison group was constructed from 2688 historical controls (HC). The direct medical care costs were estimated for inpatient, office visits and laboratory utilization (including cost of genotyping) and summed to a total cost per patient. A boot-strapping method was performed to estimate confidence limits around the difference in mean cost per patient to assess statistical significance. **RESULTS:** Over the 6-month monitoring period, the all cause–related per patient costs for the genotyped IG patient was $4127 compared to $5040 for HC. The all-cause difference of -$913 per patient reached statistical significance, 95% CI (-$895, -$930). Various subgroup analyses including warfarin-related costs will be presented. **CONCLUSIONS:** Our analysis suggests that providing results of warfarin genotyping to treating physicians in typical outpatient settings produces cost-savings within six months of initiating warfarin therapy. These estimates are likely conservative as they do not include ancillary costs such as rehabilitation or indirect costs, nor do they estimate costs beyond six months.

PCV69

ECONOMIC EVALUATION OF PRIMARY PREVENTION OF CARDIOVASCULAR DISEASES IN MILD HYPERTENSION: A SCENARIO ANALYSIS FOR THE NETHERLANDS

Stevanovic J[1], O'Prinsen AC[2], Postma MJ[1], Pechlivanoglou P[1]
[1]*University of Groningen, Groningen, The Netherlands,* [2]*Sanofi-Aventis, Gouda, The Netherlands*

OBJECTIVES: According to current Dutch guidelines, antihypertensive treatment for patients with mild hypertension is recommended if the 10-year fatal cardiovascular disease (CVD) risk exceeds 10% or if accompanying risk factors are present. Recent evidence suggests that lifelong CVD risk estimates might be more informative than 10-year risk estimates. The aim of this study was to estimate the economic impact and influence on CVD risk of blood pressure (BP) reduction, in patients ineligible for treatment according to guidelines. **METHODS:** A Markov model was developed to assess the lifetime costs and health benefits of BP reduction with hydrochlorothiazide (HCT) or HCT plus losartan. Patients had mild hypertension and low 10-year CVD risk. The SCORE risk estimates were modified to predict fatal and non-fatal events over a lifelong time horizon. We analysed scenarios for different age groups, gender and reductions in BP. Costs and health effects were discounted at 4.0% and 1.5%, respectively; a Dutch healthcare perspective was used. **RESULTS:** A total of 48 different scenarios were modeled. Minor BP reductions were potentially not cost-effective in young women treated with HCT (€59,000 per life-year gained (LYG)), whereas potential cost-effectiveness was observed in a comparable male population (€12,000 per LYG). BP reduction was, generally, found to be more cost-effective in men, in older subjects and for larger BP reductions (up to cost-saving results). Results for HCT plus losartan were comparable. **CONCLUSIONS:** In patients ineligible for antihypertensive treatment according to current Dutch guidelines, reducing BP, nonetheless, resulted in clinical benefits for several patient populations. BP reduction was found to be potentially cost-effective in males for all age groups and even cost-saving in older ages, whereas for females it was less favorable. This, together with recent decreases in drug prices, should trigger further discussion on antihypertensive treatment in patients with low 10-year fatal CVD risk.

PCV70

COST EFFECTIVENESS OF TICAGRELOR IN THE TREATMENT OF ACUTE CORONARY SYNDROME IN GERMANY

Theidel U[1], Asseburg C[2], Giannitsis E[3], Katus H[3]
[1]*Herescon Gmbh, Hannover, Germany,* [2]*ESiOR Ltd, Kuopio, Finland,* [3]*Department of Medicine III, University of Heidelberg, Heidelberg, Germany*

OBJECTIVES: The PLATO trial showed that in patients with acute coronary syndromes (ACS) treatment with ticagrelor plus acetylsalicylic acid (ASA) compared with clopidogrel/ASA significantly reduced the rate of myocardial infarction (MI), stroke, or death from vascular causes without a significant increase in the rate of overall major bleedings. The present study evaluates the long-term cost-effectiveness of treating patients with ticagrelor in Germany from the perspective of the Statutory Health Insurance (SHI). **METHODS:** : A two-part decision-analytic model, comprising a decision tree approach for the first year followed by a long-term Markov model, was constructed to estimate lifetime costs and life year gained (LYG) of treating ACS patients for one year with ticagrelor/ASA compared with clopidogrel/ASA. Data for the first year were derived from the PLATO trial. For the long-term model the German lifetable from the cause-of-death-statistics and selected conservative assumptions were utilized to extrapolate survival conditional on whether a non-fatal MI, a non-fatal stroke or no event occurred during the first year. Costs were based on official tariffs (e.g. DRGs) and published literature. For the base case daily cost of €2.99 was applied for ticagrelor. Daily cost for clopidogrel was applied in a range from €0.38 (lowest generic) to €2.44 (Plavix) with an average generic cost of €0.68 (base case). Extensive probabilistic, uni- and multivariate sensitivity analyses were performed. **RESULTS:** : Treatment with ticagrelor was associated with 0.16 LYG versus clopidogrel. The cost per LYG in the base case was €3,361. Overall the cost per LYG ranged from €-430 (dominant situation) to €4,077 compared with clopidogrel (Plavix vs. lowest generic). Results were consistent

throughout the sensitivity analyses. **CONCLUSIONS:** Based on evidence from the PLATO study, treating a broad spectrum of ACS patients with ticagrelor for one year seems to offer a cost-effective option in the German health care setting compared with clopidogrel.

PCV71

SPONSORSHIP AND PHARMACOECONOMIC CONCLUSIONS OF STUDIES ON STATIN USE FOR CARDIOVASCULAR PREVENTION: A SYSTEMATIC ANALYSIS

Catalá-López F[1], Ridao M[2], Sanfélix-Gimeno G[1], Garcia-Altés A[3], Peiró S[1]
[1]*Centro Superior de Investigación en Salud Pública (CSISP), Valencia, Spain,* [2]*Instituto Aragonés de Ciencias de la Salud (I+CS), Zaragoza; Centro Superior de Investigación en Salud Pública (CSISP), Valencia, Spain,* [3]*Catalan Agency for Health Information, Assessment and Quality (CAHIAQ), Barcelona, Spain*

OBJECTIVES: We examined sponsorship of published economic evaluations of statin use for cardiovascular (CDV) prevention and evaluated whether funding is associated with study conclusions. **METHODS:** A systematic review was conducted in PubMed/MEDLINE (up to June 2011) to identify cost-effectiveness analyses of statin use for CDV prevention reporting outcomes as cost per life years gained and/or quality-adjusted life years. The review was restricted to 6 licensed statins: simvastatin, pravastatin, fluvastatin, lovastatin, atorvastatin and rosuvastatin. We classified study intervention data as follows: 1) comparators: statin-statin or statin-non active drug comparisons, and 2) primary or secondary CDV prevention. We established relationships between funding source (industry- vs. non-industry-sponsored studies) and qualitative conclusions (favorable, unfavorable or neutral) by means tests of differences between proportions. **RESULTS:** Overall, 72 studies were included. Thirty-six studies (50%) were carried out in Europe and 31 (43%) in North America. Fourty-seven (65%) articles compared statins versus non-active drugs. The category of CDV prevention was distributed as follows: 46% secondary, 39% primary and 15% both. Considering funding source, 64% were industry-sponsored studies. For studies evaluating primary CDV prevention, industry-sponsorship was much less likely to have unfavorable or neutral conclusions (0% vs. 59%; $p<0.001$). Conversely, these differences were not detected for studies evaluating secondary CDV prevention (0% versus 13%; $p=0.212$). **CONCLUSIONS:** Our results suggest that sponsorship of economic evaluation of statins is associated with their qualitative conclusions in primary CDV prevention.

PCV72

LONG-TERM COST EFFECTIVENESS ANALYSIS OF TICAGRELOR IN PATIENTS WITH ACUTE CORONARY SYNDROME FROM A POLISH HEALTH CARE PERSPECTIVE

Macioch T[1], Niewada M[1], Perkowski P[2], Mellström C[3], Budaj A[4]
[1]*HealthQuest Sp.z o.o., Warsaw, Poland,* [2]*AstraZeneca Pharma Poland Sp. z o.o., Warsaw, Poland,* [3]*Astrazeneca R&D, Lomma, Sweden,* [4]*Postgraduate Medical School, Grochowski Hospital, Warsaw, Poland*

OBJECTIVES: The PLATO trial showed that in patients with acute coronary syndromes (ACS) treatment with ticagrelor compared with clopidogrel significantly reduced the rate of myocardial infarction, stroke, or death from vascular causes without a significant increase in the rate of overall major bleeding. The aim of this analysis is to estimate long-term cost-effectiveness of treating ACS patients with ticagrelor from a Polish health care perspective. **METHODS:** The model used is a two-part decision-analytic model, comprising a one-year decision tree and a long-term Markov model. Model estimates lifetime costs, LYGs and QALYs of treating ACS patients for one year with ticagrelor plus ASA compared with clopidogrel plus ASA. The model is based on the results observed in the PLATO study and populated with the overall clinical, resource use and quality of life results from PLATO trial. Unit costs were derived from the National Health Fund in Poland. A generic clopidogrel price of 0,92 PLN per day, and a ticagrelor price of 10,85 PLN per day were applied. Standard mortality rates for the Polish population were used. Data are presented in PLN with exchange rate: 1,00 PLN= € 0,25. **RESULTS:** Treatment with ticagrelor was associated with a QALY gain of 0,11 and a LYG gain of 0,12 compared with clopidogrel. The incremental cost of ticagrelor treatment was 2814 PLN. The ICER per QALY gained with ticagrelor compared with clopidogrel was 25 675 PLN, while the ICER per LYG with ticagrelor was 22 257 PLN. Probabilistic sensitivity analysis indicates that ticagrelor treatment has a 90% probability of being cost effective given a willingness of pay threshold of 40 000 PLN. The results are consistent in all ACS subgroups. **CONCLUSIONS:** Based on clinical and health economic evidence from the PLATO study, treating ACS patients with ticagrelor for one year is cost-effective compared with clopidogrel in Polish settings.

PCV73

COST EFFECTIVENESS OF SPEECH AND LANGUAGE THERAPY FOLLOWING STROKE

Davies (on behalf of the ACT NoW study team) LM
University of Manchester, Manchester, UK

OBJECTIVES: Communication impairment after stroke affects everyday activities and social participation. Speech and Language therapy (SLT) has waiting lists of 6 months plus in the National Health Service (NHS), implying a high opportunity cost. The aim was to evaluate the cost effectiveness of SLT versus attention control (AC), at six months, for people with communication difficulties due to aphasia/dysarthria following stroke. **METHODS:** The economic analysis was an integral component of a randomised, controlled, pragmatic trial comparing SLT (n= 85) and AC (n=85). The perspective was the NHS and social care, patients and families. The time horizon was 6 months (baseline to end of scheduled follow up). Resource use and health status (EQ-5D) were collected on all participants recruited into the trial. Utility values were estimated from the EQ-5D and associated population tariffs. The setting was inpatient and community/primary care in North West England; data were collected between 2006 and 2010. Unit cost data are for 2008-2009. Regression models estimated incremental or costs and outcomes for the ICER, adjusted for predefined covariates. Incremental costs and outcomes were bootstrapped to derive cost effectiveness acceptability curves, net benefit statistics and probability that SLT was cost effective. **RESULTS:** The net cost of SLT was £110 (95% percentiles: -£640 to +£861). The net utility was 0.01 (95% percentiles: -0.03 to +0.04). SLT is only likely to be cost effective if decision makers are willing to pay £25,000 or more to gain a 1 point increase in utility ($p=0.50$). The cost effectiveness of SLT depends on the outcome measure used and the baseline severity of stroke. **CONCLUSIONS:** The primary and sensitivity analyses indicated a high level of uncertainty suggesting it is not possible to conclude whether therapy is more or less cost effective than attention control.

PCV74

IS TREATMENT OF DEPRESSION COST EFFECTIVE IN THE MANAGEMENT OF PEOPLE WITH CHD AND DIABETES: A SYSTEMATIC REVIEW OF THE ECONOMIC EVIDENCE

Jeeva F, Davies LM
University of Manchester, Manchester, UK

OBJECTIVES: About 33% of patients develop depression after myocardial infarction, while 25% of patients with diabetes have depression. Patients with co-morbid depression have lower treatment compliance and health status, increased healthcare use, social isolation and mortality. This study aimed to systematically review current economic evidence of non-pharmacological treatment interventions for patients with CHD or diabetes and co-morbid clinically-relevant depression. **METHODS:** The electronic search strategies (conducted in MEDLINE, EMBASE, PsycINFO, CINAHL, NHS EED) combined clinical search terms with terms used by the UK National Health Service Economic Evaluation Database (NHSEED), to identify full economic evaluations of the relevant interventions. Pre-specified screening and inclusion criteria were used. Standardised data extraction and critical appraisal (using NHSEED criteria) were conducted. **RESULTS:** Excluding duplicates, 1336 studies for CHD and 1281 for diabetes were screened. Four economic evaluations were identified (two for diabetes and two for CHD). The studies found that the interventions improved health status, reduced depression and were cost-effective compared to usual care. Both CHD studies were UK-based and used home-based cognitive behavioural programmes. The net costs were -£42 to £2, the net QALY gains were 0.006 to 0.009. The diabetes studies were based on US-based and used stepped collaborative care programmes delivered by specialised nurses. The net costs were -$1378 to $216, the net gains in depression free days were 53 to 115. **CONCLUSIONS:** The review highlighted the paucity of evidence in this area and associated uncertainty. Four small studies indicated the potential of psychological interventions to improve the quality of life, reduce depression and be cost-effective compared to usual care. Robust and well-designed economic evaluations of non-pharmacological treatment interventions for patients with co-morbid depression are needed. An economic model is being developed to synthesise data from various sources to explore this further.

PCV75

COST-EFFECTIVENESS OF OPTIMIZING USE OF STATINS IN AUSTRALIA: USING OUTPATIENT DATA FROM THE REACH REGISTRY

Ademi Z[1], Reid C[2], Hollingsworth B[3], Stoelwinder J[3], Steg G[4], Bhatt D[5], Liew D[6]
[1]*Melbourne University, Melbourne , Australia,* [2]*Monash University, Melbourne, Australia,* [3]*Monash University, Melbourne , Australia,* [4]*Université Paris, Paris, France,* [5]*Harvard Medical School, Boston , MA, USA,* [6]*The University of Melbourne, Parkville, Victoria, Australia*

OBJECTIVES: To estimate the cost-effectiveness of closing the statin 'treatment gap' in the secondary prevention of coronary artery disease (CAD) in Australia. **METHODS:** We developed a decision-analysis Markov model with yearly cycles and the following health states: 'Alive' and 'Dead'. Using data from the Australian Reduction of Atherothrombosis for Continued Health (REACH) registry, the model compared current statin coverage (82%) in the secondary prevention of CAD ('Current' group) with a hypothetical situation of 100% coverage ('Improved' group). The 18% gap was filled with use of generic statins. Data from a recent meta-analysis were used to estimate the benefits of statin use in terms of reducing recurrent cardiovascular events and death. Government-reimbursement data from 2011 was used to calculate direct healthcare costs. The cost of the intervention to improve statin coverage was assumed to be $250 per person. Years of life lived and costs were discounted at 5% annually. **RESULTS:** Among the 2058 subjects in the 'Current' group, the model estimated that there would be 106 non-fatal myocardial infractions, 68 non-fatal strokes and 275 deaths over five years. In the 'Improved' group, within which all subjects took statins, the corresponding numbers were 101, 65, and 259, equating to numbers needed to treat of 426, 639, and 127, respectively. Over the five years, there would be 0.018 life years gained (discounted) at a net cost of AUD $546 (discounted) per person. These equated to an incremental cost-effectiveness ratio (ICER) of AUD $29,717 per life year gained. **CONCLUSIONS:** The results suggest that for patients with CAD, maximizing coverage with statins, in line with evidence-based recommendations, represents a cost-effective means of secondary prevention.

PCV76

A COST-EFFECTIVENESS ANALYSIS OF CLOPIDOGREL IN PATIENTS WITH NON STABLE ACUTE CORONARY SYNDROME IN GREECE

Kourlaba G, Fragoulakis V, Maniadakis N
National School of Public Health, Athens, Greece

OBJECTIVES: To evaluate the cost-effectiveness of one-year treatment with clopidogrel plus aspirin compared to aspirin alone in patients without ST-segment elevation (NSTEMI) from the Greek third-party-payer perspective. **METHODS:** A

Markov model for evaluating the long-term cost-effectiveness of clopidogrel in patients with NSTEMI was adapted and extended by using local utility and economic values. The effect of clopidogrel was applied during the first year in the model and was estimated by the CURE trial. Costs assigned to each health state included antiplatelet treatment cost, cost for the management of adverse events and the costs for concomitant medication, hospitalization, outpatient visits, rehabilitation and nursing. The incremental cost-effectiveness ratio (ICER) was calculated. A probabilistic sensitivity analysis was conducted in order to assess the impact of all uncertain model parameters varying simultaneously. The results are presented as mean (95% Uncertainty Interval (UI)). **RESULTS:** The analysis showed a discounted survival of 8.27 (8.25-8.30) years in the aspirin treatment group and 8.42 (8.39-8.44) years in the aspirin+clopidogrel treatment group; a difference of 0.14 (0.11-0.18, p<0.001) years. Adjusting the survival for the quality of life, the model predicts 7.52 (7.15–7.79) and 7.66 (7.27–7.94) discounted QALYs in the aspirin and clopidogrel+aspirin arm, respectively, resulting in a difference of 0.14 QALYs (0.10-0.17, p<0.001). The cumulative lifetime costs per patient were € 15,976 (€14,848–€17.156) and € 15,392 (€14,301- €16,535), for aspirin and clopidogrel+aspirin treatment arm, respectively, a difference of € 584 (€525-€647). The ICER was €4111 (€3342–€5169) for each life-year saved and €4385 (€3487–€5647) for each QALY saved. For a decision threshold of €5500 per discounted QALY, clopidogrel+aspirin is cost-effective in more than 95% of randomly sampled analyses. **CONCLUSIONS:** Treatment with clopidogrel in addition to aspirin is a cost-effective treatment option in patients with NSTEMI from the perspective of a third-party payer in Greece.

PCV77

ECONOMIC EVALUATION OF DABIGATRAN ETEXILATE 150DIB FOR THE STROKE PREVENTION IN ATRIAL FIBRILLATION IN GREECE: A COST –EFFECTIVENESS ANALYSIS UNDER THE GREEK NHS SETTING

Fragoulakis V[1], Theodoratou T[2], Maniadakis N[1]
[1]*National School of Public Health, Athens, Greece,* [2]*Boehringer Ingelheim, Athens, Greece*

OBJECTIVES: To estimate the cost-effectiveness of Dabigatran etexilate 150dib relative to Sintrom, Aspirin, Aspitin-Clopidogrel, Best Supportive Care and no treatment, in the management of patients with Atrial Fibrillation in the Greek health care setting. **METHODS:** A Markov model was adopted to estimate long term outcomes of patients moving during their lifetime in between the following health states: primary and recurrent ischemic stroke, hemorrhagic stroke, transient ischemic attack, systemic embolism, acute myocardial infarction, intracranial hemorrhage, extracranial hemorrhage and death. Data on event rates and patent quality of life associated with different health states and patient survival times were based on a multinational clinical trial (RE-LY) and the related literature. Furthermore, data on resource use associated with the management of patients and of different events were collected from a survey of local hospitals. Unit prices were collected from official resources and relate to 2011. A 3.5% discount rate was used for all outcomes. Sensitivity analysis and probabilistic analysis was used to test the robustness of the analysis **RESULTS:** The mean total life-time cost of patients on Dabigatran etexilate was estimated at €20,103, relative to €11,639 in the case of Sintrom, while mean Quality Adjusted Life Years (QALYs) were 9.86 and 9.83 for the two treatments, respectively. The incremental cost-effectiveness ratio of Dabigatran etexilate relative to Sintrom was estimated at €25,952. Similarly it was estimated at €8,223, €10,392 and €7,536 against Asprin-Clopidogrel, Aspirin alone and No-Tretament, respectively. Sensitivity analyses indicated that the cost-effectiveness of Dabigatran etexilate remained below acceptable thresholds (€50,000 per QALY gained) in significant variations of baseline parameters. Probabilistic analysis indicated that in about 85% of cases its cost-effectiveness ratios, relative to the above comparators were below the aforementioned threshold. **CONCLUSIONS:** Dabigatran etexilate may represent a cost-effective choice for the management of patients with atrial fibrillation in Greece.

PCV78

A COST-EFFECTIVENESS ANALYSIS OF CLOPIDOGREL VERSUS ASPIRIN IN PATIENTS WITH ATHEROTHROMBOSIS IN GREECE

Kourlaba G, Fragoulakis V, Maniadakis N
National School of Public Health, Athens, Greece

OBJECTIVES: To conduct an economic analysis comparing treatment with clopidogrel against aspirin in patients with peripheral artery disease, a recent stroke, or a recent myocardial infarction from the Greek third-party-payer perspective. **METHODS:** A Markov model with a 6-month cycle length was developed to evaluate the lifetime cost-effectiveness of clopidogrel versus aspirin. The effect of clopidogrel was applied only during the first 2 years of the model and this was retrieved from CAPRIE trial. Local utility data were used to estimate quality-adjusted life years (QALY). The state-specific costs consists of the costs that reflect and encapsulate all resource used for the care of patients within the health care system during a 6-month period in the acute and follow-up phase, separately. The cost-effectiveness of clopidogrel over aspirin was evaluated by calculating the incremental cost per life year saved (LYS) and incremental cost per QALY saved (ICER). A probabilistic sensitivity analysis was conducted and the results are presented as mean (95% Uncertainty Interval (UI)). **RESULTS:** The analysis showed that the discounted survival was 11.83 (11.41-12.22) years and 12.17 (11.75-12.55) years in aspirin and clopidogrel treatment group, respectively, a difference of 0.27 (0.10-0.45) life-years. The corresponding discounted QALYs were 8.63 (8.34 – 8.91) and 8.84 (8.54–9.10), respectively. The cumulative lifetime costs per patient were €19,880 (€18,863–€20,939) and €21,039 (€20,006–€22,089), for aspirin and clopidogrel treatment arm, respectively. The ICER was calculated to be € 4,921 (€ 3,079–€ 9,969) for each LYS and €6,326 (€ 3,737–€ 16,699) for each QALY saved. For a "willigness-to-pay" threshold of € 9,500 per discounted QALY, clopidogrel was found to be cost-effective in more than 90% of randomly sampled analyses. **CONCLUSIONS:** This economic analysis indicates that treatment with clopidogrel for secondary prevention of cardiovascular events in atherothrombotic patients is a cost-effective antiplatelet treatment over aspirin in a Greek third-party payer perspective.

PCV79

ECONOMIC EVALUATION OF ROSUVASTATIN VERSUS ATORVASTATIN, SIMVASTATIN AND PRAVASTATIN IN HIGH RISK PATIENTS TREATED FOR PRIMARY AND SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE IN GREECE

Fragoulakis V, Kourlaba G, Maniadakis N
National School of Public Health, Athens, Greece

OBJECTIVES: To evaluate common therapeutic alternatives (rosuvastatin, atorvastatin, simvastatin, pravastatin) for the prevention of primary and secondary cardiovascular events in Greece. **METHODS:** A Markov model with distinct health states (no event, fatal/non fatal acute myocardial infarction (MI), fatal/non fatal stroke, post-MI, post-stroke & all cause death) was developed, to reflect within a 20-year time span health and economic outcomes of non-smoking patients assumed to be at base line at mean age of 70 years, with no prior treatment of hypertension, systolic blood pressure at 140mmHg and total cholesterol at 260mg/Dl. The HellenicSCORE risk score equation was used to transform systolic blood pressure reductions in different medications into long-term reductions in cardiovascular events. Transition probabilities from acute myocardial infarction or stroke to death were obtained from the Framingham study. Treatment cost was estimated from a payer perspective and includes the cost of medication and all resources used in the management of events. Health states were associated with local quality of life data to estimate Quality Adjusted Life Years (QALYs). A probabilistic sensitivity analysis was conducted to deal with uncertainty. Prices reflect 2011 and outcomes were discounted at 3.5%. **RESULTS:** For males, discounted QALYs were: 10.18 (95%CI:10.11-10.23), 10.04 (95%CI:9.96-10.10), 9.94 (95%CI: 9.84-10.02) and 9.88 (95%CI: 9.76-9.97) for rosuvastatin, atorvastatin, simvastatin and pravastatin, respectively. The mean total cost was: 15,646 (95%CI:15,173-16,130), 16,678 (95%CI:16,184-17,187), 17,242 (95%CI:16,732-17,766) and 17,585 (95%CI: 17,060-18,119) respectively. For females, QALYs were: 10.33 (95%CI:10.28-10.37), 10.26 (95%CI:10.20-10.30), 10.20 (95%CI:10.13-10.25) and 10.16 (95%CI: 10.08-10.22), respectively. Similarly, mean total cost was: 15,030 (95%CI:14,632-15,430), 15,608 (95%CI:15,192-16,023), 15,951 (95%CI:15,521-16,379) and 16,153 (95%CI:15,714-16,591) respectively. Hence rosuvastatin was a dominant therapy option. **CONCLUSIONS:** Rosuvastatin may represent an attractive option relative to alternative therapies, from an economic and clinical point of view, in the primary and secondary prevention of cardiovascular events in the National Health Service of Greece.

PCV80

ECONOMIC EVALUATION OF PRAVASTATIN FOR THE PREVENTION OF CORONARY ARTERY DISEASE IN JAPAN

Onishi Y, Hinotsu S, Nakao YM, Urushihara H, Kawakami K
Kyoto University, Kyoto, Japan

OBJECTIVES: The cost-effectiveness study of pravastatin for primary prevention of coronary artery disease (CAD) was assessed applying epidemiologic data and risk predictions of CAD in Japan. **METHODS:** A Markov transition model was used for evaluating the cost-effectiveness of 20mg/day of pravastatin treatment with diet therapy. The incidence of acute myocardial infarction (AMI) was estimated using newly developed risk predictions of CAD in Japan. Hypothetical population of men and women from 45 to 75 years old were assumed according to the cardiac risk factors from Japan Atherosclerosis Society Guideline for Prevention of Atherosclerotic Cardiovascular Disease. Quality-adjusted life-years (QALYs) and incremental cost-effectiveness ratios (ICERs) over a lifetime horizon were estimated from the perspective of payers. One way sensitivity analysis and probabilistic sensitivity analysis were conducted to see the robustness of the model. **RESULTS:** The predicted incidence of AMI was 4.4/10,000 person-years for men and 1.4/10,000 person-years for women aged 55 years with initial total cholesterol level (TC) of 240 mg/dl without other cardiac risk factors (i.e. low cardiac risk) and 20.1/10,000 person-years for men and 6.6/10,000 person-years for women with initial TC level of 240 mg/dl, and risks of smoking, hypertension and diabetes (i.e. high cardiac risk). Over a lifetime horizon, the ICERs were depended on the level of cardiac risk factors. The ICERs were decreased proportionally with increased age and number of cardiac risk factors. Considering the willingness to pay threshold per QALYs, pravastatin treatment was not cost-effective in all subgroups evaluated in this study. **CONCLUSIONS:** Due to the predicted low incidence of CAD in Japan, pravastatin treatment was not cost-effective for primary prevention of CAD in population not only at low cardiac risk but also at high cardiac risk. Further evaluations of cost-effectiveness on CAD treatment in Japan using available epidemiological data and risk predictions are needed.

PCV81

COST-EFFECTIVENESS OF TICAGRELOR VERSUS CLOPIDOGREL IN PATIENTS WITH ACUTE CORONARY SYNDROME: RESULTS FROM THE PLATO STUDY: A CANADIAN ANALYSIS

Mittmann N[1], Chan B[2], Seung SJ[3], Liovas A[4], Cohen E[1]
[1]*Sunnybrook Health Sciences Centre, Toronto, ON, Canada,* [2]*University of Toronto, Toronto, ON, Canada,* [3]*HOPE Research Centre, Toronto, ON, Canada,* [4]*AstraZeneca Canada Inc., Mississauga, ON, Canada*

OBJECTIVES: Ticagrelor, co-administered with acetylsalicylic acid, is a new antiplatelet therapy for patients with acute coronary syndrome (ACS) aimed at preventing thrombotic events [i.e., cardiovascular mortality, myocardial infarction (MI) and stroke]. The goal was to determine the cost per life year gained (LYG) for ticagrelor compared to current standard therapy (clopidogrel) using a cost-effectiveness analysis framework based on the published results from the Platelet Inhibition and Patient Outcomes (PLATO). **METHODS:** A Markov model framework was developed in order to evaluate the costs and benefits of ticagrelor over a lifetime time horizon. The clinical outcomes consisted of four health states: "MI", "Stroke", "All Cause Mortality" and "Recovered", with frequencies derived from the pivotal PLATO study at one year. These health states were extrapolated into the future via "Live" and "Die" scenarios. Resources and costs (2010 Canadian $) were obtained from the literature or public domain. A 5% discount rate was applied to all the cost and clinical inputs after the first year. **RESULTS:** An incremental cost effectiveness ratio (ICER) of $1125/LYG was determined. Probabilistic sensitivity analysis presented greater than 99% of all iterations resulting in an ICER less than $50,000/LYG. The economic model was most sensitive to the probability of death within one year of ticagrelor or clopidogrel treatment. **CONCLUSIONS:** Based on outcomes in the PLATO trial, the use of ticagrelor instead of clopidogrel for treatment of ACS in Canada is associated with an ICER of $1,125/LYG.

PCV82

SIMULATION OF LONG-TERM CLINICAL BENEFITS AND COSTS OF ADD-ON THERAPY WITH ALISKIREN IN HYPERTENSIVE PATIENTS WITH DIABETIC NEPHROPATHY: A GERMAN STATUTORY HEALTH INSURANCE PERSPECTIVE

Graf von der Schulenburg JM[1], Weycker D[2], Kaiser E[3], Neidhardt K[3], Brede Y[4]
[1]*Leibniz-Universität Hannover, Hannover, Germany,* [2]*PAI, Brookline, MA, USA,* [3]*Novartis Pharma GmbH, Nürnberg, Germany,* [4]*Novartis Pharma AG, Basel, Switzerland*

OBJECTIVES: Diabetic nephropathy significantly increases the risk of cardiovascular disease (CVD) and end-stage renal disease (ESRD) in hypertensive patients. According to the AVOID study, the direct renin-inhibitor aliskiren, when added to losartan and optimal antihypertensive therapy in patients with hypertension, type 2 diabetes (T2DM) and diabetic nephropathy, significantly (p=0.001) reduced albuminuria by 20% over 6 months, as assessed by urinary albumin-creatinine ratio (UACR). This simulation examines the potential long-term clinical benefits and costs of add-on therapy with aliskiren in hypertensive patients with T2DM and diabetic nephropathy in Germany. **METHODS:** We developed a micro-simulation model to depict the progression to ESRD, measured by UACR levels over time. Patients at model entry were on maximal recommended doses of losartan and optimal antihypertensive therapy, and either continued this regimen or received aliskiren as an add-on therapy. In scenario analyses, different assumptions on the maintenance of the 20% UACR-reduction were made. Expected costs of pharmacotherapy and medical care were calculated based on German-specific sources over 10 years applying an annual discount rate of five percent. Sensitivity analyses were conducted to analyze the impact of different input parameters. **RESULTS:** Add-on therapy with aliskiren was projected to reduce the risk of ESRD by 1.8% and delay the onset of ESRD by 0.15 years assuming that the effects of aliskiren on UACR-reduction are maintained over 5 years. While discounted costs of pharmacotherapy were estimated to increase by 1762€ per patient with aliskiren, costs of ESRD-related care were estimated to decrease by 3804€ over this same period, yielding total cost savings. Findings were sensitive to the duration over which the benefits of add-on therapy with aliskiren were assumed to be maintained. **CONCLUSIONS:** In hypertensive patients with T2DM and diabetic nephropathy receiving losartan and optimal antihypertensive therapy, add-on therapy with aliskiren is projected to yield clinical benefits and cost savings.

PCV83

A COST-EFFECTIVENESS ANALYSIS OF TICAGRELOR IN PATIENTS WITH ACUTE CORONARY SYNDROME IN GREECE

Kritikou P, Yfantopoulos J
University of Athens, Athens, Greece

OBJECTIVES: To evaluate the cost-effectiveness of a one-year treatment period with 90 mg twice daily Ticagrelor compared to 75 mg/day Clopidogrel in acute coronary syndrome (ACS) patients with or without ST-segment elevation from the third-party-payer perspective in Greece. **METHODS:** An existing model consisting of a one-year decision tree based on the PLATO trial data and a long-term extrapolation Markov model was adapted to the Greek health-care setting. Utility values obtained from the PLATO trial were used to estimate quality-adjusted life years (QALY) for both the decision tree and the Markov model. Local unit costs in combination with resource use data collected within the PLATO trial were used to estimate the costs incorporated in the analysis. These costs included treatment and medication costs, cost for the management of adverse events, hospitalization, outpatient visits, rehabilitation and nursing costs. Cost-effectiveness and cost-utility was expressed as the incremental cost per life year gained (LYG) and QALY gained (ICER), respectively. **RESULTS:** Implementing a lifetime horizon, the analysis predicts a discounted survival of 11.63 years in the Ticagrelor treatment group and 11.48 years in the Clopidogrel treatment group. The corresponding discounted QALYs were 9.78 and 9.65, respectively. The cumulative lifetime costs per patient were €24,967 and €24,170, for Ticagrelor and Clopidogrel treatment arm, respectively. The ICER was €5239 for each LYG and €6079 for each QALY saved. Implementing a 5-year horizon analysis, results in a discounted survival of 4.36 and 4.31 years for Ticagrelor and Clopidogrel treatment respectively. The QALYs and costs per patient were 3.77 and €15,239 for Ticagrelor and 3.73 and €14,604 for Clopidogrel. The ICER in this case was €12,631 for each LYG and €14,176 for each QALY saved. **CONCLUSIONS:** One-year treatment with Ticagrelor in addition to aspirin is a cost-effective treatment option vs Clopidogrel plus aspirin in patients with ACS in Greece.

PCV84

RESOURCE UTILIZATION AND COSTS FOR CANDESARTAN IN HEART FAILURE: ASSESSMENT OF REDUCTION IN MORTALITY AND MORBIDITY (CHARM) PROGRAMME FOR THE AUSTRIAN SETTING

Fruhwald FM[1], Vavrovsky AD[2]
[1]*Medical University Graz, Austria, Graz, Steiermark, Austria,* [2]*Academy for Value in Health GmbH, Vienna, Vienna, Austria*

OBJECTIVES: Chronic heart failure (HF) is a major cause of morbidity and mortality and a growing burden to the healthcare system. The objective was to assess the cost-effectiveness of candesartan cilexetil, an angiotensin II type 1 receptor blocker (ARB) for the treatment of HF in the Austrian setting. **METHODS:** A pre-specified economic evaluation was conducted on resource utilization prospectively collected alongside the CHARM programme. We examined the effect of adding candesartan in all 7599 patients randomized. All patients were considered to have been managed in Austria. Our analysis takes the perspective of a third party payer. CHARM consisted of a series of parallel randomized clinical trials comparing candesartan with placebo (standard therapy) in patients with NYHA Class II-IV HF: - CHARM-Alternative (LVEF≤ 40% patients not receiving ACE inhibitors because of previous intolerance); - CHARM-Added (LVEF≤ 40% patients currently receiving ACE inhibitors); - or CHARM-Preserved (LVEF ≥ 40% patients). Primary outcome of the overall programme: all-cause mortality; for the component trials: composite of cardiovascular death and hospital admission for HF. Resource use was collected prospectively on drug treatment, patients admitted to hospital, admissions for cardiovascular reasons, and procedures/operations. These data were used to determine the additional direct costs incurred, and potential savings made with candesartan. Unit costs were elicited from published Austrian sources in accordance with local guidelines. 2008 was chosen as the price year. **RESULTS:** Adjunctive treatment with candesartan in CHARMAlternative and CHARM-Added led to clinical benefits and, depending on the trial, to either cost savings or low additional costs. **CONCLUSIONS:** Not only does candesartan improve all important clinical outcomes in HF but also offers these benefits at little or no additional cost to the health care system; indeed, its use in patients with HF and reduced LV systolic function may lead to an actual reduction in the direct costs of healthcare in Austria.

PCV85

COST-EFFECTIVENESS OF INCREASING STATIN ADHERENCE FOR SECONDARY PREVENTION IN COMMUNITY PHARMACIES

Oosterhof P[1], Van Boven JFM[1], Visser ST[1], Hiddink EG[2], Stuurman-bieze AGG[2], Postma MJ[3], Vegter S[1]
[1]*University of Groningen, Groningen, The Netherlands,* [2]*Health Base Foundation, Houten, The Netherlands,* [3]*University of Groningen, Groningen, The Netherlands, The Netherlands*

OBJECTIVES: Increasing real-life adherence to statin therapy is important to achieve the clinical benefits of reducing cardiovascular events (CVEs) reported in randomized clinical trials (RCTs). The aim of this pilot study was to determine the cost-effectiveness of a pharmaceutical care intervention program in community pharmacies, aimed to increase statin adherence for the secondary prevention of CVEs. **METHODS:** Meta-analyses of five RCTs were performed to determine the clinical efficacy of statins for secondary prevention, adjusted for different levels of therapy adherence. A Markov model with a lifelong time horizon was developed to estimate the influence of statin adherence on CVEs: stroke, myocardial infarction (MI), revascularization and mortality. Baseline adherence was calculated in a large Dutch prescription database, using the proportion of days covered (PDC) method. The effect of pharmacists' interventions on statin adherence was derived from literature. A Dutch health care provider's perspective was adopted; costs and effects were discounted at 4.0% and 1.5% per annum, respectively. **RESULTS:** Adherence to statin therapy for secondary prevention in The Netherlands was 73.0%. In a cohort of 1000 patients, a 7% increase in adherence resulted in a reduction of 1.9 non-fatal strokes, 0.5 fatal strokes, 7.9 non-fatal MIs, 3.7 fatal MIs and 9.1 revascularizations. Additional medication and intervention costs in the intervention group were €56,000; the cost-savings due to reduced CVEs were €109,000. Overall, the pharmaceutical care program resulted in 53 quality-adjusted life years (QALYs) gained and cost-savings of €53,000. **CONCLUSIONS:** Pharmaceutical care programs in community pharmacies can improve statin adherence for secondary prevention of CVEs. At a reasonable level of intervention effectiveness, the programs resulted in both clinical benefits and cost-savings. The model developed in this pilot study will be used to estimate the cost-effectiveness of a pharmaceutical care program (the MeMO intervention) in the The Netherlands that is currently under clinical evaluation.

PCV86

LONG-TERM COST-EFFECTIVENESS ANALYSIS OF TICAGRELOR IN PATIENTS WITH ACUTE CORONARY SYNDROME (ACS) FROM A MEXICAN PUBLIC AND PRIVATE HEALTH CARE PERSPECTIVE BASED ON DATA FROM THE PLATO TRIAL

Garcia-Castillo A[1], De-los-Rios M[2], Polanco AC[3], Ramirez MA[4], Nikolic E[5], Mellström C[6]
[1]*Hospital de Cardiologia, UMAE 34 IMSS, Monterrey, Nuevo Leon, Mexico,* [2]*Centro para el Desarrollo de la Medicina y de Asistencia Médica Especializada, Culiacan, Sinaloa, Mexico,* [3]*AstraZeneca, México, D. F., México, D. F., Mexico,* [4]*AstraZeneca, Ciudad del Mexico, Mexico DF, Mexico,* [5]*Linköping University, Linköping, Sweden,* [6]*AstraZeneca R&D, Mölndal, Sweden*

OBJECTIVES: The multicentre, double-blind, randomized PLATO trial showed that treatment with ticagrelor + aspirin reduced the risk of myocardial infarction, stroke or death from vascular causes without a significant increase in major bleeding compared to clopidogrel + aspirin treatment in patients with ACS. The long-

term cost-effectiveness is evaluated using a 12-month treatment period with ticagrelor versus clopidogrel in patients with ACS based on PLATO trial data from the Mexican public and private perspective. **METHODS:** The cost-effectiveness model is divided into two parts: a short-term decision tree based on data from the PLATO trial to estimate rates of cardiovascular events, healthcare costs, and health-related quality of life for the 12 months of therapy and a long-term Markov model to estimate quality-adjusted survival and costs conditional on whether a non-fatal MI, a non-fatal stroke or no MI or stroke occurred during the 12 months of therapy. Costs were calculated by applying 2010 Mexican unit costs. The daily drug price used was $2.05 and $4.91 for clopidogrel and ticagrelor, respectively. The estimated mean costs and QALYs are calculated over a lifetime time horizon and presented as incremental cost per QALY. Probabilistic sensitivity analyses were performed. **RESULTS:** Ticagrelor was associated with a QALY gain of 0.10; this was primarily driven by lower mortality and fewer non fatal MI's resulting in an incremental cost per QALY gained of $7670 and $7073 for the public and private healthcare sector, respectively. Probabilistic sensitivity analysis indicated that ticagrelor has more than 99% probability of being more cost-effective than clopidogrel at a willingness to pay of $30,000 per QALY. The results were consistent in all ACS subgroups. **CONCLUSIONS:** Ticagrelor + aspirin is a cost effective treatment compared to clopidogrel + aspirin for one year treatment in ACS patients based on the PLATO trial and Mexican unit costs.

PCV87

TICAGRELOR FOR THE TREATMENT OF ACUTE CORONARY SYNDROMES (ACS): A DUTCH ANALYSIS BASED ON THE PLATO TRIAL

Thurston S[1], Heeg B[2], Hofsté C[3]
[1]*Pharmerit Ltd, York, UK,* [2]*Pharmerit International, Rotterdam, The Netherlands,* [3]*Astrazeneca, zoetermeer, The Netherlands*

Recently, ticagrelor showed a statistically significant absolute reduction (1.1%/year) in cardiovascular (CV) mortality and in myocardial infarction (MI) (1.1%/year) compared to clopidogrel in acute coronary syndrome (ACS) patients (from published results of the PLATO trial). The majority of earlier ACS trials (including CURE - placebo vs. clopidogrel and TRITON - clopidogrel vs. prasugrel) have not shown this significant reduction in CV mortality. **OBJECTIVES:** To estimate the cost-effectiveness of 1-year add-on therapy to aspirin with ticagrelor versus clopidogrel in patients with ACS in the Dutch setting, based on the published results from PLATO. **METHODS:** A published Markov cost-effectiveness model with MI, stroke, death and subsequent events as health states is used to assess the cost-effectiveness of ticagrelor in comparison to clopidogrel. In the model relevant utilities and costs are linked to the health states. Short-term probabilities are based on the published PLATO trial, while probabilities for subsequent events are assumed to change with time and occurring events. Several sources were used for these extrapolations. The cost-effectiveness was tested over daily acquisition cost of ticagrelor varying between €1 and €7 higher than clopidogrel. Relevant discount rates were applied and probabilistic sensitivity analyses were conducted. **RESULTS:** Considering direct medical costs only, the incremental cost-effectiveness ratios (ICERS) when the cost of ticagrelor is assumed to be €1, €3, €5, and €7 higher than clopidogrel per day are estimated at €3,742/QALY, €12,058/QALY, €20,374/QALY, and €28,691/QALY respectively. Probabilistic sensitivity analyses show that ticagrelor is expected to be cost-effective at a willingness to pay of €30,000 in 100.0%, 98.2%, 89.4%, and 58.0% of cases when the price is assumed to be €1, €3, €5, or €7 higher than clopidogrel per day, respectively. **CONCLUSIONS:** The reduction in mortality seen in the PLATO trial translates to favorable cost-effectiveness results for ticagrelor, assuming the price difference over clopidogrel does not exceed €7.50 per day.

PCV88

LONG TERM COST-EFFECTIVENESS ANALYSIS OF TICAGRELOR IN PATIENTS WITH ACUTE CORONARY SYNDROMES FROM A BRAZILIAN PUBLIC HEALTHCARE PERSPECTIVE BASED ON DATA FROM THE PLATO TRIAL

Nicolau JC[1], Piha T[2], Nikolic E[3], Rikner K[4], Mellström C[4]
[1]*University of São Paulo Medical School, São Paulo , Brazil,* [2]*AstraZeneca, Cotia, São Paulo, Brazil,* [3]*Linköping University, Linköping, Sweden,* [4]*AstraZeneca R&D, Mölndal, Sweden*

OBJECTIVES: The PLATO trial was a multicentre, double-blind, randomized trial comparing clopidogrel + aspirin and ticagrelor + aspirin for treatment of patients with ST-elevation and non-ST-elevation acute coronary syndromes (ACS). The results showed a significant reduction for ticagrelor in the primary composite endpoint – cardiovascular deaths, myocardial infarction, or stroke - without a significant increase in major bleeding. Based on PLATO trial data long-term cost-effectiveness was evaluated for 12-month treatment with ticagrelor versus clopidogrel in patients with ACS, from the Brazilian public health care perspective. **METHODS:** For the analysis of cost-effectiveness a two-part cost-effectiveness model was used. The first part was a 12-month decision tree using PLATO trial data to estimate rates of cardiovascular events, healthcare costs, and health-related quality of life for the 12 months of therapy. The second part was a long-term Markov model estimating quality-adjusted survival and costs conditional on whether a non-fatal MI, a non-fatal stroke, or no MI or stroke occurred during the 12 months treatment. The model applied a lifetime horizon to calculate mean costs and QALYs. The results are presented as incremental cost-effectiveness ratios (ICER's). Daily costs of $1.62 for generic clopidogrel and $4.58 for ticagrelor were applied. Other costs were calculated by applying Brazilian year 2010 unit costs. Probabilistic sensitivity analysis was performed. **RESULTS:** Ticagrelor was associated with a QALY gain of 0.10, primarily driven by lower cardiovascular mortality. The resulting incremental cost per QALY gained was $8966 in the public sector. Probabilistic sensitivity analysis indicated that ticagrelor had more than 99% probability of being cost-effective at a willingness to pay of $30,000 per QALY. The results were consistent in all analyzed subgroups. **CONCLUSIONS:** Based on the PLATO trial data one year treatment with ticagrelor + aspirin versus clopidogrel + aspirin in ACS patients is cost-effective from a Brazilian public health care perspective.

PCV89

COST-EFFECTIVENESS ANALYSIS OF ROSUVASTATIN VERSUS GENERIC ATORVASTATIN IN PATIENTS AT HIGH CARDIOVASCULAR RISK IN SPAIN

Brosa M[1], Barrios V[2], Lobos JM[3], Serrano A[4], Capel M[5], Alvarez C[5]
[1]*Oblikue Consulting, Barcelona, Spain,* [2]*Hospital Ramón y Cajal, Madrid, Spain,* [3]*Centro de Salud Jazmin, Madrid, Spain,* [4]*Centro de Salud Repelega, Portugalete, Vizcaya, Spain,* [5]*AstraZeneca, Madrid, Spain*

OBJECTIVES: To evaluate the long term cost-effectiveness of rosuvastatin versus generic atorvastatin in the treatment of patients at high cardiovascular risk (CVR) ≥ 5% SCORE or patients with established cardiovascular disease in Spain. **METHODS:** The efficacy data from STELLAR trial (Statin Therapies for Elevated Lipid Levels compared Across doses to Rosuvastatin) was used to simulate cLDL goal attainment at different doses of rosuvastatin and generic atorvastatin during an initial period of one year. These results were combined in the long term through a Markov model which estimated the number of cardiovascular events and their impact on quality of life in patients at high CVR using the Framingham risk equations. The model estimated quality adjusted life years (QALY) and costs (drug and events costs) up to 20 years. The analysis was conducted from the Spanish National Health System perspective. 3% annual discount rate was applied to costs (€ 2010) and outcomes. Cost-effectiveness was estimated in several subgroups of patients at high CVR according to blood pressure, smoking status, age, cholesterol levels and established cardiovascular disease. **RESULTS:** In primary prevention of cardiovascular events in patients at high risk, rosuvastatin was a cost-effective option (cost/QALY less than €30,000) versus generic atorvastatin in most of the subgroups analyzed. In patients with established cardiovascular disease, rosuvastatin was a cost-effective option in all males subgroups (ICERs between €4,000 and €18,000 per QALY) and in most of the females subgroups. **CONCLUSIONS:** The treatment of patients at high cardiovascular risk with rosuvastatin was more effective than generic atorvastatin in terms of survival and quality adjusted survival. Incremental cost-effectiveness ratios were below the commonly accepted efficiency threshold in Spain (€30,000) in most of the defined subpopulations by different combination of risk factors.

PCV90

DEVELOPMENT OF AN INSTITUTIONAL COST OF CARE MODEL FOR ANTICOAGULATION MANAGEMENT OF PATIENTS WITH WARFARIN VERSUS NOVEL ORAL AGENTS

Pizzi LT[1], Thomson L[2], Jutkowitz E[1], Vogenberg FR[3], Swift B[2], Merli G[2]
[1]*Thomas Jefferson University, Philadelphia, PA, USA,* [2]*Thomas Jefferson University Hospitals, Philadelphia, PA, USA,* [3]*Institute for Integrated Healthcare, Sharon, MA, USA*

OBJECTIVES: 1) To estimate the time and cost of discharge for patients receiving the current antithrombotic standard of care, warfarin +/− a heparin product at a large US academic medical center, and 2) to estimate the system-level impact of a hypothetical new oral antithrombotic in terms of improved discharge efficiency. **METHODS:** Data were obtained from 2010 institutional metrics: patient volume, major diagnoses (e.g., orthopedic surgery, atrial fibrillation), and resource requirements (time and cost of personnel providing antithrombotic discharge counseling; time and cost of INR-related discharge delays). Metrics were coded as inputs in a MS Excel model to estimate the potential time and cost impact of changes in patient volume, personnel providing counseling, or addition of novel oral agents to the formulary. It was assumed that 80% of warfarin patients would receive the novel antithrombotic, that these drugs would reduce discharge counseling time by 70%, and would not require INR testing. The cost per day of the new agent was assumed to be $7 versus $0.82 for warfarin, and the bed of discharged patients was assumed to be refilled with a new patient 100% of the time at a reimbursement rate of $1500/day. **RESULTS:** Based on 1000 patients with a LOS of 4 days, efficiency impacts of the new agent were estimated as follows: 4000 hours through avoidance of INR-related delays, 400 hours through elimination of delayed discharge counseling, 284 hours in reduced time to administer discharge counseling. Total patient days saved by the new drug were 142 per year, translating to $213,000 in revenue opportunity by improving the efficiency of the discharge process. Additional drug costs to the facility were estimated to be $19,776 assuming drug prices and patient volume are consistent with model inputs. **CONCLUSIONS:** The model quantifies the system-level impact of new oral antithrombotics and informs formulary decision making.

PCV91

COST-EFFECTIVENESS OF ENDOVASCULAR TREATMENT VERSUS OPEN SURGERY IN PATIENTS WITH STENO-OCCLUSIVE DISEASE OF THE FEMORAL ARTERY

Ramos-Goñi JM[1], Mar-Medina J[2], Valcárcel-Nazco C[1], Castilla-Rodríguez I[1]
[1]*Servicio de Evaluación del Servicio Canario de Salud, Santa Cruz de Tenerife, Tenerife, Spain,* [2]*Hospital Alto Deba, Gipuzkoa, Gipuzkoa, Spain*

OBJECTIVES: To compare the efficiency of three strategies for the stenosis of the femoropopliteal sector treatment: bypass surgery (BP), percutaneous transluminal angioplasty with selective stent insertion (PTA/S), and percutaneous transluminal angioplasty with selective stent insertion followed by possible bypass surgical re-intervention (PTA/S/BP). **METHODS:** An economic evaluation was developed by implementing a Markov model with three main branches representing each of the strategies studied. We used a time horizon of 30 years, discounting 3% to costs and effects. The measure of effectiveness was years of quality-adjusted life (QALYs). Probabilistic and multivariate sensitivity analysis was performed by using Monte Carlo (MC) methods. Acceptability curves and the expected value of perfect infor-

mation were calculated. **RESULTS:** Taking into account the results from MC simulations, the PTA/S alternative is the most expensive and less effective (€ 24,581 and 6.857 QALYs), but attending to small differences and the large variability on results between alternatives, these results are not conclusive. The least costly alternative is PTA/S/BP (€ 18,351), with an effectiveness of 7.049 QALYs. PTA/S/BP shows higher effectiveness than PTA/S, but lower effectiveness than BP (7.281 QALYs). The cost of the BP alternative is € 24,056. PTA/S/BP and BP alternatives show higher probabilities of being efficient alternatives. If the willingness to pay is € 30,000/QALY, opportunity cost of implementing PTA/S/BP would exceed € 15,000 per patient treated. **CONCLUSIONS:** Although the results of effectiveness identified PTA/S/BP as the most efficient alternative for a willingness to pay less than € 40,000/QALY, the probability of making a proper decision is only about 50%. This situation, together with the high opportunity costs, encourages the development of new clinical trials or observational studies in our environment in order to remove uncertainty over the results.

PCV92

COST UTILITY OF RANOLAZINE IN THE SYMPTOMATIC TREATMENT OF PATIENTS WITH CHRONIC ANGINA PECTORIS IN SPAIN

Ramos-Goñi JM[1], Hidalgo A[2], Villoro R[2]
[1]*Servicio de Evaluación del Servicio Canario de Salud, Santa Cruz de Tenerife, Tenerife, Spain,* [2]*Instituto Max Weber, Majadahonda, Madrid, Spain*

OBJECTIVES: Ranolazine is an antianginal agent that was approved for use in the EU in 2008 as an add-on therapy for the symptomatic treatment of chronic angina pectoris in patients who are inadequately controlled by or intolerant to first-line antianginal therapies, such as beta blockers and calcium antagonists. The objective of this study is to assess the cost utility of ranolazine relative to placebo as an add-on therapy for the symptomatic treatment of patients with chronic angina pectoris in Spain, from the payer's perspective. **METHODS:** We use a decision tree model with a time horizon of one year, under the Spanish health service perspective. Transition probabilities and utility levels for different angina frequencies were obtained from published clinical trials. Costs were obtained from Spanish official DRGs for patients with chronic angina pectoris. We calculate the incremental cost utility ratio of using ranolazine compared with placebo as an add-on treatment. Sensitivity analyses include Monte Carlo simulations and ANCOVA models. **RESULTS:** The incremental cost utility ratio is 8455 € per QALY per patient in Spain. Sensitivity analyses show that if the decision makers' willingness to pay is set at half the usual threshold (15.000 € per QALY), the treatment with ranolazine will be cost effective at a 95% level of confidence. The incremental cost utility ratio is particularly sensitive to changes in the level of utility of those non hospitalized patients with mild or moderate angina frequency. The cost of ranolazine explains 6.44% of the variation in our results. **CONCLUSIONS:** Ranolazine is a very cost effective add-on therapy for the symptomatic treatment of chronic angina pectoris in patients who are inadequately controlled by or intolerant to first-line antianginal therapies in Spain.

PCV93

THE POLYPILL IN THE PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE: COST-EFFECTIVENESS IN THE DUTCH POPULATION

Van Gils PF, Hamberg-van Reenen HH, Over E, de Wit GA, van den Berg M, Schuit AJ, Engelfriet PM
National Institute for Public Health and the Environment, Bilthoven, The Netherlands

OBJECTIVES: Cardiovascular disease is a major cause of illness and death. The polypill seems to offer a promising strategy in the prevention of cardiovascular diseases. The aim of the present study was to estimate the cost-effectiveness of the polypill in the primary prevention of cardiovascular diseases in people at a 10 years risk of cardiovascular death of 5%, 7,5% and 10% or above in the The Netherlands. **METHODS:** A computer simulation study was conducted, in which people eligible for prescription were identified by opportunistic screening. The polypill was offered in different compositions: scenario 1: the polypill as used in the Indian polycap study, with three different types of blood pressure lowering drugs, a lipid lowering drug, and an antiplatelet agent, scenario 2: as 1) but without aspirin, scenario 3: as 2) but with a double statin dose (which is the standard in The Netherlands), and scenario 4: separate antihypertensive and/or statin medication. Outcome measures were cases of acute myocardial infarction and stroke prevented, QALYs gained, and the costs per QALY gained. **RESULTS:** All scenarios are cost-effective with an incremental cost-effectiveness ratio between €8,700-12,000 per QALY compared with usual care. The most preferable is scenario 3, because for all risk thresholds most health gain was reached. At a 10-years risk of 7.5% scenario 3 would prevent approximately 3%-5% of all cardiovascular events. **CONCLUSIONS:** Depending on the cardiovascular risk, opportunistic screening in combination with the polypill or separate medication offers a cost-effective strategy. Most health gain is achieved by the polypill without aspirin and a double statin dose. The major advantage of a polypill without aspirin is avoiding aspirin's adverse effects.

PCV94

DRONEDARONE IS COST-EFFECTIVE FOR THE PREVENTION OF DOWNSTREAM CARDIOVASCULAR MORBIDITY AND MORTALITY IN AUSTRALIAN PATIENTS WITH ATRIAL FIBRILLATION

Liew D[1], Lee J[2], Gonzalo F[3]
[1]*The University of Melbourne, Parkville, Victoria, Australia,* [2]*Sanofi-Aventis Australia Pty Ltd, Macquarie Park, NSW, Australia,* [3]*Sanofi-Aventis Australia Pty Limited, Macquarie Park, Australia*

OBJECTIVES: To assess the cost-effectiveness of the anti-arrhythmic agent dronedarone for the prevention of cardiovascular disease (CVD, comprising myocardial infarction and stroke) and death among Australian patients with atrial fibrillation (AF). **METHODS:** A Markov model was developed with one-year cycles and three health states: 'Alive without CVD', 'Alive post CVD' and 'Dead'. Model subjects' cardiovascular and mortality risks were derived from a cohort study of 313 AF patients from the Geelong Hospital, a tertiary hospital in Victoria, Australia. Decision analysis quantified the health and economic effects of giving all patients dronedarone versus usual care. Data regarding the efficacy of dronedarone were derived from the two-year 'ATHENA' randomized controlled trial (Hohnlosser, New Engl J Med, 2009). This showed that compared to placebo, dronedarone 400mg bd reduced the risk of hospitalized cardiovascular events and death by 24% (hazard ratio 0.76, 95%CI 0.69-0.84). Relevant costs and utilities were drawn from published sources. The annual cost of dronedarone was AUD $1668. Follow-up was simulated for ten years, with application of a 5% annual discount rate to costs and years lived. **RESULTS:** In the usual care arm, 26.3% and 12.0% of the cohort were predicted to suffer myocardial infarctions and strokes, respectively. The equivalent figures in the dronedarone arm were 21.4% and 9.7%, equating to numbers needed to treat of 20.3 for myocardial infarction and 44.6 for stroke. Compared to usual care, each dronedarone subject lived an extra 0.44 years and 0.35 QALYs (discounted). Net costs of dronedarone amounted to AUD $4495 per subject (discounted). Incremental cost-effectiveness ratios were therefore AUD $10,187 per life year gained and AUD $12,966 per QALY gained. Sensitivity analyses indicated the results to be robust. **CONCLUSIONS:** Dronedarone represents a cost-effective means to prevent downstream cardiovascular morbidity and mortality among Australian patients with AF.

PCV95

ECONOMIC ANALYSIS OF INTERVENTIONS TO IMPROVE CONTROL OF BLOOD PRESSURE IN NIGERIAN HOSPITALS

Ekwunife OI[1], Aguwa CN[2], Ezenduka CC[3]
[1]*University of Nigeria, Nsuukka, Enugu, Nigeria,* [2]*University of Nigeria, Nsukka, Enugu State, Nigeria,* [3]*University of Nigeria, Enugu, Enugu, Nigeria*

OBJECTIVES: Emerging evidence shows that the prevalence of hypertension is on the rise in most African countries while control remains poor. There are effective interventions which could be implemented in hospitals of low resource setting to improve control of blood pressure amongst hypertensive patients. This study aimed to evaluate the cost-effectiveness of interventions that could be implemented in Nigerian hospitals in order to ensure better control of high blood pressure in patients with hypertension. **METHODS:** The study employed decision analytic modeling. Interventions were obtained from a meta-analysis. The Markov process model calculated clinical outcomes and costs during a life cycle of 30 years of 1000 hypertensives stratified by 3 cardiovascular risk groups, under the alternative intervention scenarios. Quality adjusted life year (QALY) was used to quantify clinical outcome. The average cost of treatment for the 1000 patient was tracked over the Markov cycle model of the alternative interventions and results were presented in Nigerian Naira. Probabilistic cost-effectiveness analysis was performed using Monte Carlo simulation, and results presented as cost-effectiveness acceptability curves and frontiers. Population expected value of perfect information analysis was also conducted. **RESULTS:** Patient education intervention was the most cost-effective option across the 3 cardiovascular risk groups except in high cardiovascular risk scenario where a trade-off has to be made in terms of commitment of extra fund (approximately N10,000 per QALY). Professional led care was the second best consistent option across the 3 cardiovascular risk groups although it will require extra financial investment to the tune of N30,000 per QALY. **CONCLUSIONS:** The result of this study shows that patient education programme followed by professional led care intervention could be a feasible strategy in order to ensure that patients with high blood pressure are better controlled.

PCV96

COST-UTILITY ANALYSIS OF THE LONG-TERM CARDIOVASCULAR PREVENTION PROGRAM IN RUSSIAN FEDERATION AS AN ARGUMENT FOR THE WIDESPREAD INTRODUCTION OF PREVENTIVE TECHNOLOGIES INTO CLINICAL PRACTICE

Kontsevaya A, Kalinina A, Deev A
National reseacrh center for preventive medicine, Moscow, Russia

OBJECTIVES: To evaluate the economic efficiency of 10-years cardiovascular prevention program in primary care of Russian Federation. **METHODS:** In 1977-1990 in Moscow a large prevention project was realized. The project was realized in two primary care areas of Moscow and included men with baseline age 40-59. One primary care area was intervention area where cardiovascular prevention program was realized during the 5 years, other area was control. Participants of intervention (n=3488) and control primary care areas (n=3168) had the similar age, education and cardiovascular morbidity. The cardiovascular prevention program included preventive counseling for participants with CVD risk factors. All cardiovascular endpoints were registered during 10 years. In this study we calculated the gain of life years saved (LYS) and quality adjusted life years (QALY) in intervention group compared with control group (on 1000 participants) during the 5 years on the intervention and during 10 years of total follow up period. Also we calculate the total cost of the program in the prices of 2008 years. The cost utility analysis was conducted with calculation of cost per gained QALY during 5 years and during 10 year. **RESULTS:** The number of gained LYS in the intervention group was 45.7 on 1000 participants in 5 years and 139.4 – in 10 years. The number of QALY was 46.2 and 132.7 on 1000 participants in 5 and 10 years accordingly. The total costs were 174,124$ on 1000 participant in 5 years and 237,928$ in 10 years. Cost per QALY gained was 3769$ during the 5 years and 1793$ during the 5 years. The gross domestic product per capita in 2008 was 11,806$. **CONCLUSIONS:** Cardiovascular prevention program for men aged 40-59 is highly cost-effective and economic arguments can be used for policy-makers.

PCV97

COST-EFFECTIVENESS ANALYSIS OF PUBLIC HEALTH INTERVENTIONS TO PREVENT OBESITY IN NEW ZEALAND

Mernagh P[1], Coleman K[1], Cumming J[2], Green T[3], Harris J[4], Paech D[1], Weston A[1]
[1]Health Technology Analysts, Sydney, NSW, Australia, [2]University of Victoria, Wellington, Wellington, New Zealand, [3]University of Canterbury, Christchurch, New Zealand, [4]Ministry of Health, New Zealand, Wellington, New Zealand

OBJECTIVES: To provide evidence to assist decision making and cost-effective investment in population-based public health interventions designed to prevent obesity and obesity-related health problems in New Zealand. The findings will inform policy makers about the relative merits of different investments, with a view to reducing the prevalence of a range of chronic health problems. **METHODS:** Following a systematic review of literature, a cost-utility analysis was conducted using a lifetime model to rank the cost-effectiveness of selected intervention scenarios in the New Zealand setting. In all, 1- scenarios across six interventions were considered; six interventions considered the whole New Zealand population, two of which considered separate estimates of the cost-effectiveness relevant to the Mâori and the Pacific populations individually. For each intervention, a simulation model estimated the increase in BMI for individuals exposed to the intervention and for those not exposed. The model then calculated the likelihood of individuals in each group contracting any of fourteen BMI-related chronic illnesses, and the consequential survival and quality of life. From this, the quality adjusted years of life gained from the intervention were estimated. Similarly the additional cost of the intervention group was estimated by considering the cost of the intervention itself, and the lifetime costs of healthcare in relation to the fourteen chronic conditions for both the intervention and control groups. Increases in expenditure due to increased life expectancy were also considered. **RESULTS:** The ten scenarios ranged from highly cost-effective to not offering good value. Four of the interventions appeared highly cost-effective at less than NZ$10,000 per QALY gained. **CONCLUSIONS:** The most cost-effective interventions for obesity prevention would appear to be a school-based programme for children and general health screening and advice for adults in a primary care setting, though all were highly sensitive to duration of benefit and discounting.

PCV98

ESTIMATING WILLINGNESS TO PAY FOR HYPERTENSION OUTPATIENT BENEFIT PACKAGES

Valera MT[1], de Rosas-Valera M[2]
[1]University of the Philippines, Quezon City, Metro Manila, Philippines, [2]World Health Organization, Manila, Metro Manila, Philippines

OBJECTIVES: Hypertension is ranked as the 4th leading cause of morbidity in the Philippines, and as such, it greatly contributes to the increasing health expenditures of the country. The Philippine Health Insurance Corporation (PhilHealth), the mandated provider of social health insurance in the country, currently only has an inpatient benefits package system for hypertension, causing many members and beneficiaries to avail of this rather than more cost-effective outpatient maintenance treatments. This study explores the possibility of contributing to the formulation of an outpatient benefits package for PhilHealth by probing into the willingness to pay of patients for anti-hypertensive healthcare. **METHODS:** An Ordinary Least Squares regression model with a log-transformed outcome variable to measure WTP was specified using various socio-economic, demographic, and health status data from PhilHealth Member Surveys. A contingent valuation approach was elicited to measure the level of WTP among respondents. An asset valuation method also complements the WTP analysis to assess ability to pay. **RESULTS:** Mean WTP was significantly ($p = 0.01$) associated with asset ownership, which was used as a proxy variable for long-term wealth. The adjusted mean WTP amounted to $3.3 per month for anti-hypertensive medicines. WTP was also observed to be significantly higher for non-paying retirees and indigent members, which are the two most vulnerable groups in the population. **CONCLUSIONS:** Based on the results of the study, it is deemed necessary for PhilHealth to enhance safety nets for vulnerable groups and employ cost-effective measures through an outpatient benefit package for hypertension. WTP analysis, as a preference measure, is a helpful tool in determining the economic value of medical treatments to PhilHealth beneficiaries and provide basis for costing the rate of premiums for outpatient benefit packages.

PCV99

UTILISATION OF RENIN –ANGIOTENSIN SYSTEM AGENTS INVOLVED IN TREATMENT OF CARDIOVASCULAR DISEASES IN SLOVAK REPUBLIC

Bellova K[1], Gatialova K[2], Urban M[3], Foltan V[4], Binder R[2]
[1]Comenius University in Bratislava, Bratislava, Slovak Republic, Slovak Republic, [2]Comenius University, Bratislava, Slovak Republic, [3]Slovak University of Technology, Bratislava, Slovak Republic, [4]Faculty of Pharmacy, Comenius University, Bratislava, Slovak Republic

OBJECTIVES: The number of patients suffering cardiovascular diseases increase annually worldwide. The main objective of this study was to evaluate the utilisation of renin- angiotensin system agents (C09), as the group of medicines with highest consumption in terms of expenditures units, number of packages and DDD in Slovak Republic within the years 2006 -2010. **METHODS:** Analysed data were abstracted from two databases – PharmaData and IMS. Data were studied in accordance with Daily Defined Dosage (DDD), financial units (€) and number of packages prescribed every year. **RESULTS:** The consumption of Renin –Angiotensin system agents increased within the years 2006-2010 as in number of packages as well as in terms of financial units and DDD. The most prescribed were plain ACE Inhibitors (C09A) and they raised in number of packages from 3,528,618 (2006) to 483,4360 (2008), and slightly decreased until 2010 (4,409,095). In accordance with financial expenditures, the highest consumption was in the group Angiotensin II receptor blockers plain (C09C). The expenses increased sharply from 58,4540€ in 2006 to 1,397,097€ in 2010. The financial expenses on Angiotensin II receptor blockers combined (C09D) raised from 440,299€ (2006) to 107,2043€ (2010). According to DDD the highest consumption can be seen in C09A – ACEI plain, followed by C09B – ACEI combined, C09C Angiotensin II receptor blockers plain and the lowest in group C09D Angiotensin II receptor blockers combined. **CONCLUSIONS:** This study concluded that ACEI plays an important role in treatment of cardiovascular diseases, they are preferred, most prescribed and not so expensive as Angiotensin II receptor blockers.

PCV100

RESOURCE USE IN PATIENTS WITH ACUTE CORONARY SYNDROME - AN OBSERVATIONAL STUDY ACROSS SECONDARY AND PRIMARY CARE IN A UK POPULATION

Boggon R[1], Fox KA[2], Begg A[3], Ray K[4], Timmis A[5], Hemingway H[6], Emmas CE[7], Van staa T[1]
[1]GPRD, London, UK, [2]University of Edinburgh, Edinburgh, UK, [3]University of Dundee, Dundee, UK, [4]St George's University of London,, London , UK, [5]Barts and the London School of Medicine and Dentistry,, London, UK, [6]University College London, London , UK, [7]AstraZeneca UK Ltd, Luton, UK

OBJECTIVES: Acute coronary syndrome (ACS) treatment guidelines recommend a range of interventions to prevent recurrence. The objective of this analysis was to assess patterns of resource use prior to and following hospitalisation for unstable angina (UA), ST elevation myocardial infarction (STEMI) and non-ST elevation myocardial infarction (NSTEMI). **METHODS:** Unique identifiers were used to link patients in a comprehensive hospital registry (Myocardial Ischaemia National Audit Project), with longitudinal primary care data (General Practice Research Database) and outcomes (Hospital Episode Statistics). The study population comprised patients ≥40 years, hospitalised for ACS from 2003-2009, discharged home. Resource utilisation was estimated at: 1) 1-2 year(s) prior to the hospitalisation; 2) one year prior to the hospitalisation to the hospitalisation itself; 3) discharge to one year after discharge; and 4) 1-2 years after discharge. Prescribed medications, consultations, laboratory tests and referrals to specialist care were assessed from GPRD. Hospital admissions and days spent in hospital, by cause, were assessed from HES. Analyses were repeated by discharge diagnosis and for patients prescribed clopidogrel in primary care within three months of discharge. **RESULTS:** Utilisation of all primary and secondary care resources assessed increased in the first three time periods, peaked in the year following discharge, and decreased in the second year. The average number of medications prescribed (mean (s.d.)) rose from (1)8.5(6.9) to (2)9.6(7.3) to (3)14.2(6.7), followed by a decrease to (4)12.7(6.5). The average number of days spent in hospital rose from (1)2.7(11.1) to (2)4.5(12.8) to (3)8.5(20.3), followed by a decrease to (4)4.4(15.1). Resource utilisation was lower in patients with STEMI compared to UA and NSTEMI, but no difference in resource use was observed for patients treated with clopidogrel. **CONCLUSIONS:** Primary and secondary care resource utilisation increases prior to an ACS hospitalisation, with a peak in the year following discharge, and a slight decrease in the second year.

Cardiovascular Disorders – Patient-Reported Outcomes & Preference-Based Studies

PCV101

POPULATION BASED STUDY : IMPACT OF ADHERENCE TO ANTIHYPERTENSIVE AGENTS ON CARDIOVASCULAR ISSUES

Perreault S[1], Yu AYX[2], Côté R[2], Dragomir A[3], White-guay B[3], Dumas S[3]
[1]Université de Montréal, Montréal, QC, Canada, [2]McGill University, Montreal, QC, Canada, [3]University of Montreal, Montreal, QC, Canada

OBJECTIVES: Antihypertensive agents have been shown to reduce the risk of major cardiovascular events. However, there are no large effectiveness studies which have assessed adherence to antihypertensive medications and major cardiovascular outcomes in high risk individuals who have recently suffered an ischemic stroke. Our primary aim was to evaluate the relationship between antihypertensive drug adherence and non-fatal vascular events in a cohort of older patients hospitalized for an ischemic stroke and discharged in the community. **METHODS:** A cohort of 14, 227 patients with an ischemic stroke was reconstructed from individuals 65 years and older who were treated with antihypertensive agents between 1999 and 2007. A nested case-control design was conducted to evaluate the occurrence of non-fatal major cardiovascular outcomes including stroke or myocardial infarction. Every case was matched by age and duration of follow-up with up to 15 randomly selected controls. The adherence to antihypertensive drugs was measured with the medication possession ratio. Conditional logistic regression models were performed to estimate the rate ratio of non-fatal vascular events associated with adherence to antihypertensive agents, adjusting for various potential confounders. **RESULTS:** Mean patient age was 75 years, 54% were male, 23% had diabetes, 47% dyslipidemia, 38% coronary artery disease, and 14% atrial fibrillation or flutter. Adherence to antihypertensive therapy of ≥80% decreased the risk of non-fatal vascular events RR: 0.74 (0.67-0.83), compared to an adherence of <80%. A reduction in all cause mortality RR: 0.52 (0.47-0.58) was also associated with higher adherence. Male gender and cardiovascular disease were also risk factors for non-fatal vascular events. **CONCLUSIONS:** Our study suggests that higher adherence to antihypertensive medication is associated with a risk reduction of non-fatal vascular events and all-cause mortality among patients with a recent ischemic stroke.

PCV102

EVALUATION OF THE MEASUREMENT PROPERTIES OF THE ANTIHYPERTENSIVE ADHERENCE SURVEY

Hudgens S[1], Lynch J[2], Pasquale K[2], Zacker C[3]
[1]Mapi Values, Boston, MA, USA, [2]Connecticut Center for Primary Care, Farmington, CT, USA, [3]Novartis Pharmaceuticals, Emmaus, PA, USA

OBJECTIVES: Patient adherence with hypertension therapy is a leading cause for uncontrolled blood pressure in the United States. The Anti-hypertensive Adherence Survey (aHA Survey) was developed as a patient self-reported assessment of therapy adherence. This study reports the psychometric properties and construct validity of the tool. **METHODS:** The aHA Survey was administered to hypertensive patients in a cross-sectional, non-interventional multisite study. The aHA Survey comprises 25 items organized within six domains: Knowledge (9 items), Medical Acceptance (3 items), Compliance (6 items), Finance (1 item), Willingness to Change (4 items) and Depression (2 items). The aHA scoring algorithm assigns points and designates intervention prompts based on patient's responses to individual items across each domain. Construct validity of the aHA Survey was evaluated using an extension of the 1-parameter Rasch model for polytomous response data when the items within a domain have unique rating domains and recall periods, the Partial Credit Model. Unidimensionality was evaluated for the full instrument and related scoring using goodness-of–fit statistics with an expected range between 0.60-1.40. Reliability of the scores was assessed using the Rasch person reliability estimate and the internal structure evaluated using Principal Components Analysis. **RESULTS:** A total of 273 patients ere included in the study (50.9% male, 89.7% Caucasian). Item fit was acceptable for all items on the aHA Survey. The overall reliability for aHA Survey was moderate to high (alpha = 0.84) and 33.3% of the underlying variance in adherence was measured by the items on the instrument. **CONCLUSIONS:** This study demonstrates the utility of measuring a multi-dimensional phenomenon such as adherence in patient's hypertensive therapy using a brief 25-item assessment. The current items and related scoring algorithm indicate good construct validity and reliability; which is imperative for clinical utility. Validation against real-world data will be considered in the next phase of research.

PCV103

ESTIMATING THE IMPACT OF ADHERENCE TO ALLOPURINOL THERAPY ON CARDIOVASCULAR OUTCOMES IN GOUT PATIENTS USING THE HEALTH IMPROVEMENT NETWORK (THIN) GENERAL PRACTICE DATABASE

Rabi R[1], Elliott R[1], Quinn C[2]
[1]University of Nottingham, School of Pharmacy, Nottingham, UK, [2]University of Nottingham, School of Community Health Sciences, Nottingham, UK

OBJECTIVES: Gout is one of the most common inflammatory arthritides; it is commonly managed in primary care in the UK and has been associated with poor cardiovascular (CV) outcomes. Allopurinol use has been associated with improved outcomes, particularly at a higher dose (>600mg/day); however, published studies have shown that prescribed doses in the UK are 300mg or less. Adherence to allopurinol has not been well evaluated in the UK; we estimate the impact of adherence to allopurinol on CV in gout patients in the UK. **METHODS:** The Health Improvement Network (THIN) database from 1990 to 2009 was examined; patients aged 18+ were identified using Read and drug codes. The CV-related outcomes were myocardial infarction (MI), heart failure, stroke, peripheral thrombosis, angina and coronary artery bypass. Adherence was measured using proportion of days covered (PDC). Descriptive statistics were calculated and Kaplan-Meir survival curves were constructed for different levels of adherence (PDC in quartiles). Analyses were performed in a subset of patients that experienced a particular CV event during the observation period. **RESULTS:** A total of 91,665 gout patients were identified, 39,747 of which were prescribed allopurinol; of these, 9% had MI, 18% had heart failure, 15% had stroke, 4% had thrombosis, 16% had angina and 5% had coronary artery bypass. Mean PDC in patients prescribed with allopurinol was 0.72 (SD±0.28). Higher PDC was associated with increased survival time in all CV events except for angina. PDC > 0.75 resulted in substantially greater survival time. High adherence has the greatest impact in MI and coronary artery bypass. **CONCLUSIONS:** Greater adherence to allopurinol appears to be associated with better CV outcome in all conditions except angina. A more profound effect in PDC higher than 0.75 suggests that high adherence is needed to achieve clinical benefit.

PCV104

PERSISTENCE IN HYPERTENSION TREATMENT WITH OLMESARTAN MEDOXOMIL VERSUS VALSARTAN - ANALYSIS OF REAL-LIFE PRESCRIPTION DATA IN GERMANY

Ehlken B[1], Kostev K[2], Breitscheidel L[1], Sandberg A[3], Holz B[2], Oberdiek AM[3]
[1]IMS Health, Munich, Germany, [2]IMS Health, Frankfurt, Germany, [3]Daiichi Sankyo Europe, Munich, Germany

OBJECTIVES: To evaluate treatment persistence in patients receiving fixed-dose combinations or unfixed combinations with olmesartan medoxomil (OLM) or valsartan (VAL) for hypertension treatment in Germany. **METHODS:** This retrospective study analyzed prescription data collected by general practitioners, using a longitudinal database, the German IMS Disease Analyzer (DA). The DA database was searched for patients with hypertension (ICD-10 code I10) who were initiated on OLM or VAL in double combinations with hydrochlorothiazide (HCT) or amlodipine (AML) in the period 09/2008 to 08/2009 with a follow-up of at least 12 months. Persistence was defined as proportion of patients who remained on their initially prescribed therapy at 1 year. **RESULTS:** In total, 2882 patients were eligible for analysis (1079 patients receiving OLM, thereof 75.2% with fixed-dose combinations; 1803 patients receiving VAL, thereof 88.5% with fixed combinations). 12 months after the first prescription, more patients receiving OLM stayed on their initial therapy compared to VAL: unfixed combination with AML 27.4% vs. 25.2%; fixed-dose combination with AML 47.3% vs. 44.6%; unfixed combination with HCT 25.0% vs. 13.7%; fixed-dose combination with HCT 44.6% vs. 39.6%. Mean duration of persistence in patients receiving OLM compared to VAL group was: 183.6 [SD 163.5] days vs. 181.2 [SD 159.8] days in unfixed combinations with AML; 235.7 [SD 167.8] days vs. 234.6 [SD 165.0] days in fixed-dose combinations with AML; 184.0 [SD 155.4] days vs. 123.4 [SD 138.9] days in unfixed combinations with HCT; 228.5 [SD 167.8] days vs. 222.9 [SD 165.6] days in fixed-dose combinations with HCT. **CONCLUSIONS:** Overall, findings based on real-life prescription data suggest better patient persistence with unfixed and fixed-dose OLM combinations compared to respective VAL combinations. In terms of persistance not all angiotensin receptor blockers perform equal rather hint at patient-individual treatment. Further research is needed to confirm these first results.

PCV105

USING THEORY OF REASONED ACTION VARIABLES TO PREDICT AND IMPROVE STATIN ADHERENCE

Schwartz JS, Bleakley A, Kydd S, Fishbein M
University of Pennsylvania, Philadelphia, PA, USA

OBJECTIVES: Patient adherence with prevention and treatment of chronic disease is challenging. Communication theory has potential to improve effectiveness of interventions to improve adherence. This study used Theory of Reasoned Action (TRA) variables to examine behavioral, normative injunctive and control beliefs associated with statin adherence; association of beliefs with intentions and adherence; and variation among subgroups (sex, race, treatment duration, primary vs. secondary prevention). **METHODS:** Cardiology and primary care academic health system patients prescribed statins January 2007 to December 2009 (n=101,492). Elicitation Study: Semi-structured telephone interviews (n=40). Mail Survey: Random sample stratified by race and prior CVD events (N=1829). Causal path regression coefficients were compared using multi-group structural equation modeling, stratified by race, gender and age. **RESULTS:** Elicitation Study: Respondents perceived statin therapy as beneficial and reported supportive social norms and good self-efficacy. Adherence failure was associated primarily with inability to act on intentions rather than lack of intention. Mail Survey: Response=50.2%; (53% male, 61% CVD event; 39% AA; mean age 65). AAs & women had lower intentions; AA lower self-efficacy and normative pressure; older respondents higher self-efficacy; secondary prevention higher normative pressure and behavioral beliefs. Males were higher and those with perceived side effects lower for all three reasoned action intention predictors. Non-event group: R2 intentions=0.41. Adherence was associated most strongly with attitudes. AAs were lower on all reasoned action intention predictors. CVD event group: R2 Intentions=0.20. Adherence was most strongly associated with attitudes and self-efficacy. No socio-demographic variable differentiated among intention predictors. **CONCLUSIONS:** Intentions and adherence were associated most strongly with behavioral, normative and self-efficacy beliefs and differed across demographic and prior event subgroups, suggesting potential to improve adherence using targeted messages based on reasoned action variables addressing subgroup specific beliefs. Intentions and adherence were predicted better for primary than secondary prevention, suggesting greater potential for TRA-based targeted messages for those without a previous CVD event.

PCV106

PREDICTORS OF MEDICATION ADHERENCE IN A HYPERTENSIVE POPULATION

Saleemx F[1], Hassali MA[2], Shafie AA[3], Bashir S[4]
[1]Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia, [2]Universiti Sains Malaysia, Minden, Penang, Malaysia, [3]Universiti Sains Malaysia (USM), Penang, Penang, Malaysia, [4]University of Sargodha, Sargodha, Punjab, Pakistan

OBJECTIVES: The study aimed to assess predictors of medication adherence in a hypertensive population of Pakistan. **METHODS:** This descriptive study was shaped as a questionnaire-based cross sectional analysis. A prevalence based sample of 385 hypertensive patients was selected from 2 tertiary care hospitals. Hypertension Fact Questionnaire (HFQ), Drug Attitude Inventory (DAI-10) and European Quality of Life scale (EQ-5D) were used for data collection. Demographic and disease related information was also taken into account. SPSS versus 16.0 was used to compute descriptive analysis of patients' demographic and disease related information. The factors that were significantly associated with adherence were further assessed by binary logistic regression analysis. The analysis included only those parameters with p value ≤0.25 in Chi-square analysis. The power of independently related parameters and predictive models were expressed as odds ratio (OR) with 95% confidence intervals (CI). The statistical significance was set at 0.05. **RESULTS:** The mean age (SD) of the patients was 39.02 (6.596), with 68.8% males. The mean ± SD duration of hypertension was 3.01±0.939 years. Forty percent (n=154) had bachelor level of education with 34.8% (n=134) were working in private sector. The mean EQ-5D descriptive score was calculated 0.4674±0.28444 and EQ-Vas score 63.97±6.621. Mean knowledge and adherence scores were 8.03 ± 0.42 and -1.74 ±2.154 respectively. The created model showed a significant goodness of fit as the Omnibus Test of Model Coefficient was highly significant (Chi square = 10.983, p = 0.027, df = 4). Knowledge score had significant association (adjusted OR= 1.159, 95% CI = 1.004 – 1.339, P < 0.001) with medication adherence. **CONCLUSIONS:** From the results of our study, it is concluded that improved knowledge towards hypertension can result in better medication adherence. Patient education must be formalized and acknowledged as an official part of the health care system.

PCV107

CORRELATION OF PHYSICIAN-RATED ADHERENCE WITH THERAPEUTICAL OUTCOMES IN ANTIHYPERTENSIVE TREATMENT: POOLED ANALYSIS FINDINGS FROM SIX VALSARTAN STUDIES INCLUDING 15,583 AVAILABLE PATIENTS

Villa L[1], Abraham I[2], Macdonald K[3], Denhaerynck K[4]

[1]University of Arizona, Tucson, AZ, USA, [2]University of Arizona College of Pharmacy Center for Health Outcomes and PharmacoEconomic Research/ Matrix45 LLC, Earlysville, VA, USA, [3]Matrix45 LLC, Earlysville, VA, USA, [4]Matrix45, Basel, Switzerland

OBJECTIVES: In this study, we seek to measure the association between physician-rated adherence to antihypertensive treatment and blood pressure outcomes. Prior to the study, we hypothesized that systolic and diastolic blood pressure outcomes were also related with patient and physician variables. Therefore, we also seek to determine the impact of these variables on the outcome. **METHODS:** Unlike prior adherence studies, which have consulted small sample sizes by means of time-consuming and complex questionnaires, our research pools the findings from six Valsartan studies, thereby evaluating 15,583 patients, while utilizing a simple and cost-effective survey method. Adherence was measured using a four-item yes/no Basel Assessment for Adherence Scale (BAAS), in which a "yes" answer on any item classified a patient as non-adherent. The measurements were performed at baseline and at 90 days. Hierarchical logistic regression was used to identify patient- and physician-related determinants. **RESULTS:** Our results indicate that inadequate blood pressure control correlates with poor adherence at baseline and 90 days. The mean absolute difference in blood pressure between those who were adherent (70% of the patient population) and those who were not was 5 to 19 mmHg ($p<0.001$). Every adherent patient was likely to decrease his systolic and diastolic blood pressure by 2.3 and 1.3 mmHg, respectively ($p<0.001$). The majority of the variability in blood pressure values, however, was due to patient variables, many of which can be managed with medical care, or identified in patients with higher risks, poor adherence, or poly-pharmacy. **CONCLUSIONS:** Physician-reported adherence by means of a short patient BAAS questionnaire is a direct, simple and especially inexpensive method to assess adherence status. This method can be easily integrated into routine clinical practice and provides evidence that adherence is positively correlated with blood pressure reduction in hypertensive patients. However, patient-related variables also correlate strongly with the outcome and demand further investigation.

PCV108

DERIVING UTILITY VALUES FROM THE GENERAL POPULATION FOR DRONEDARONE IN THE TREATMENT OF ATRIAL FIBRILLATION

Adams J[1], Lee J[2], Gonzalo F[3]
[1]Pretium, Sydney, NSW, Australia, [2]Sanofi Australia Pty Ltd, Macquarie Park, NSW, Australia, [3]Sanofi-Aventis Australia Pty Limited, Macquarie Park, Australia

OBJECTIVES: To derive Australian utility values for different health states associated with a new antiarrhythmic drug, dronedarone, for the treatment of patients with atrial fibrillation (AF). **METHODS:** ○One hundred nineteen participants were recruited by an independent research company. They ranged from 18–69 years (mean age 44 years). Participants were presented information about AF, as well as treatment for their disease. Participants were then presented with 8 health states describing AF and its treatment and were asked to value these using a standard gamble technique. **RESULTS:** The results demonstrated that participants had a strong understanding of the condition and its treatment, and successfully valued the health states, applying values derived for the 8 health states (AF, mild stroke, moderate stroke, severe stroke, myocardial infarction, mild stroke and myocardial infarction, moderate stroke and myocardial infarction, and severe stroke and myocardial infarction) and their varying severity levels in a logical sequence. Values ranged from 0.41 (SD = 0.25) for the health state describing a patient with severe stroke and myocardial infarction, to 0.78 (SD = 0.22) describing a patient experiencing a mild stroke. **CONCLUSIONS:** Overall, the results of this study show that a sample of the general Australian population is able to use the standard gamble successfully to derive utility values for atrial fibrillation health states.

PCV109

MEASURING HEALTH UTILITY IN THAI STROKE PATIENTS

Wannasiri Y[1], Kapol N[2]
[1]Ratchaburi Hospital, A.Muang, Ratchaburi, Thailand, [2]Silpakorn University, Nakhon Pathom , Thailand

Stroke is the common cause of death and disability worldwide. Survived stroke patients have impairment and pass to long term disability. A little is known what the health utility of Thai stroke patients is.

OBJECTIVES: To measure health utility of stroke patients and to compare those using 4 measurement methods, i.e., visual analogue scale (VAS), standard gamble (SG), time trade off (TTO) and European Quality of Life–5 Dimensions (EQ-5D). **METHODS:** All 284 stroke patients at Ratchaburi Hospital were recruited between August to October 2009 with the following criteria; aged over 20 years, contained the Barthel ADL Index scores of over 25 and be able to communicate. The patients were invited to participate in the study and respond to the questionnaire. Six parts of the questionnaire included general information, the Barthel ADL index, VAS, SG, TTO and Thai EQ-5D. Difficulty of each assessment method was ranked. Data were then analyzed by ANOVA. **RESULTS:** The mean health utility of stroke patients measured by VAS, SG, and EQ-5D were 0.70, 0.72, and 0.55, respectively. However, the score evaluated by TTO could not be measured since the questionnaires were too difficult for patients to understand. In addition, there was no significant difference between health utility measured by VAS and SG. However, a significant difference between VAS and EQ-5D, and between SG and EQ-5D were found. **CONCLUSIONS:** Thai stroke patients' health utility was moderate level. However, there was a significant difference in utilities obtained from different methods.

PCV110

HEALTH-RELATED QUALITY OF LIFE AFTER VENOUS THROMBOEMBOLISM

Sullivan P[1], Fraessdorf M[2], Feuring M[2], Schulman S[3], Hass B[2]
[1]Regis University, Rueckert-Hartman College for Health Professions, Denver, CO, USA, [2]Boehringer Ingelheim, Ingelheim, Germany, [3]HHS - General Hospital, Hamilton, ON, Canada

BACKGROUND: Venous thrombembolism (VTE) is a frequent event in the developed world and is associated with serious long-term complications, including post-thrombotic syndrome, recurrent VTE, poor health-related quality of life (HRQL) and death. VTE can manifest as deep venous leg thrombosis or lung embolism. **OBJECTIVES:** To examine factors associated with HRQL in a randomized, double-blind phase III trial comparing dabigatran etexilate to dose-adjusted warfarin in acute VTE (RE-COVER). **METHODS:** Following parenteral treatment of acute VTE, patients were randomized to oral dabigatran etexilate or warfarin for six months. Patients completed the EQ-5D questionnaire at baseline, three and six months. EQ-5D index scores (UK weights) were regressed on treatment, time since index VTE, age, gender, race, ethnicity, smoking status, body weight, and various clinical characteristics/conditions. Multivariate Censored Least Absolute Deviations (CLAD), Tobit and Ordinary Least Squares (OLS) regression methods were compared. EQ-5D questionnaire responses were also examined to identify the most affected domains. **RESULTS:** There were 1245 patients on warfarin and 1264 on dabigatran with valid EQ-5D scores at baseline; 1149 and 1150, respectively, at trial end. After controlling for covariates, the following factors were statistically significant ($p<0.05$; CLAD) and exhibited the largest magnitude changes in EQ-5D index scores (from largest to smallest): 6 months post VTE (+0.21), 3 months post VTE (+0.192), recurrent DVT (-0.17), underweight (-0.09), female (-0.08), morbidly obese (-0.07), recurrent pulmonary embolism (-0.06), heart failure (-0.05), age >65 (-0.04) and clinically relevant bleeding (-0.03). There were no statistically significant differences between treatment groups. All regression methods yielded comparable results. Domains most affected by VTE were mobility, usual activities and pain/discomfort. **CONCLUSIONS:** Results of the RE-COVER trial demonstrate that HRQL after VTE is largely dependent on the time from event rather than choice of treatment. Further, significant differences in HRQL were associated with certain clinical and patient characteristics.

PCV111

ECONOMIC BURDEN AND HEALTH- RELATED QUALITY OF LIFE IN EUROPEAN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE

Marrett E[1], Dibonaventura MD[2], Zhang Q[3]
[1]Merck, Sharp & Dohme, Whitehouse Station, NJ, USA, [2]Kantar Health, New York, NY, USA, [3]Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA

OBJECTIVES: Assess the burden of peripheral arterial disease (PAD) on patient health-related quality of life (HRQoL), work productivity, health care resource use, and to estimate the related direct and indirect costs in patients with PAD in five EU countries. **METHODS:** Cross-sectional data were obtained from the 2010 EU National Health and Wellness Survey, an internet-based survey in adults. Patients with PAD were identified based on a self-reported PAD diagnosis. We assessed HRQoL (SF-12v2 and estimated health utility), healthcare resource use in previous 6 months and work productivity in previous 7 days (Work Productivity and Activity Impairment questionnaire) reported by respondents with and without self-reported PAD diagnosis. Resource use and work productivity loss were monetized on an annual basis to provide per-person cost estimates (2010 Euros). **RESULTS:** We identified 743 respondents with (France 278, Germany 151, UK 69, Italy 159, Spain 86) and 57,062 without PAD. Compared to non-PAD respondents, those self-reporting PAD were older (mean age 58.1 vs. 46.3 years), had more comorbidities, reported lower mean (SD) HRQoL scores [mental summary: 43.4 (11.4) versus 46.6 (10.6); physical summary: 37.6 (11.2) versus 48.8 (9.7); health utilities: 0.63 (0.12) versus 0.73 (0.13)], greater mean (SD) percentage of absenteeism [12.1 (27.7) versus 5.4 (19.2)], higher mean (SD) health care utilization over 6 months [physician office visits 11.9 (13.7) versus 5.3 (7.4), emergency room visits 0.40 (1.6) versus 0.19 (1.1), hospitalizations 0.39 (1.5) versus 0.13 (1.2)], and higher total median (SD) direct [1,329 (3,198) versus 544 (2,630) €] and indirect [8,850 (10,244) versus 4,015 (7,135) €] yearly costs. **CONCLUSIONS:** Respondents with self-reported PAD reported lower HRQoL scores and generated greater direct and indirect costs suggesting that PAD poses a significant health burden to patients and society in Europe. Better management of PAD may improve patient quality of life and reduce societal costs associated with the disease.

PCV112

A COMPARISON OF EUROPEAN HEALTH CARE SYSTEMS ON STROKE PREVENTION IN ATRIAL FIBRILLATION – INTERIM RESULTS OF A PATIENT SATISFACTION SURVEY

Oberdiek A[1], Sandberg A[1], Franczok E[2]
[1]Daiichi Sankyo Europe GmbH, Munich, Germany, [2]Harris Interactive AG, Munich, Germany

OBJECTIVES: To evaluate and compare patient satisfaction in stroke prevention in atrial fibrillation (SPAF) in Europe. Interim results are presented to initiate discussions and guide analysis for the main survey. **METHODS:** A survey based on the Commonwealth Fund Survey (2008) for chronically ill adults is applied to patients with SPAF, with few disease-specific adjustments made. The survey is carried out with structured randomized anonymous telephone interviews in France, Germany, Italy, Spain and UK, screening for respondents with AF aged over 18. Total pilot sample size is 152 respondents, evenly divided per country. **RESULTS:** The pilot results indicate differences to other chronically ill patients and country variations. Mean age of respondents is 67, 50% female. Overall, 43% of the respondents are totally satisfied with their health care system (highest in the UK: 57%). Most frequent co-morbidities are hypertension (66%) and heart disease, including heart attack (53%) beside arthritis, depression, chronic lung problems, diabetes, cancer – with an average of 2,2 co-morbidities per respondent, regularly on 5,4 different prescriptions. Ten percent had a period when they were uninsured (highest with 20% in the UK) and 11% had problems with unpaid medication (highest in Germany with 33%) or refusal of payment by the insurance 9% (highest in France with 27%).

Fifty-two percent were hospitalized during the last 2 years. Due to cost, 9% had a specific medical problem but did not visit a doctor and 9% skipped or did not get a medical test, treatment, or follow-up, recommended by a doctor. The respondent with family spent on average 667;- € (highest in UK: 1.357,- €) on medical treatment not covered by insurance. **CONCLUSIONS:** These interim survey results point to a patient population (SPAF) under challenging conditions requiring numerous resources. Future research with extended respondent numbers needs to be analyzed to allow robust and clear recommendations.

PCV113

PATIENT SATISFACTION WITH STROKE PREVENTION IN ATRIAL FIBRILLATION – MEDICAL-DRIVEN INTERIM RESULTS OF A EUROPEAN SURVEY

Sandberg A[1], Franczok E[2], Oberdiek A[1]
[1]*Daiichi Sankyo Europe GmbH, Munich, Germany,* [2]*Harris Interactive AG, Munich, Germany*

OBJECTIVES: To evaluate and compare patient satisfaction with stroke prevention in atrial fibrillation (SPAF) in Europe. Secondary objective is to investigate and compare the influence of health care systems on patient satisfaction. Interim results are presented to initiate discussions and guide analysis for the main survey. **METHODS:** A survey based on the Commonwealth Fund Survey (2008) for chronically ill adults is applied to patients with SPAF, with few disease-specific adjustments made. The survey is carried out with structured randomized anonymous telephone interviews in France, Germany, Italy, Spain and UK, screening for respondents with AF aged over 18. Total pilot sample size is 152 respondents, evenly divided per country. **RESULTS:** The pilot results indicate differences to other chronically ill patients as well as country variations. Mean age of respondents was 67, 50% were female. For 12%, test results, medical records, or reasons for referrals, were not available at the time of their scheduled doctor's appointment. Twenty percent had doctors recommending treatment that the respondents thought had little or no health benefit. 30% felt often or sometimes during the past 2 years that their time was wasted because of poorly organized medical care. 35% had a doctor who sometimes, rarely or never encouraged them to ask questions. 29% had a doctor who sometimes, rarely or never gave them clear instructions about symptoms and when to seek further care or treatment. 39% of the respondents had sometimes, rarely or never (21%) a regular doctor or someone in their doctor's practice to help coordinating or arrange the care they received from other doctors and places. **CONCLUSIONS:** The interim survey results implicates that there is room for improvement of the health care systems, the organization of medical care and for communication. Future research with extended respondent numbers needs to be analyzed to allow robust and clearer recommendations.

PCV114

PREFERENCES FOR COMMUNICATION OUTCOMES FOLLOWING A STROKE

Davies (on behalf of the ACT NoW study team) LM
University of Manchester, Manchester, UK

OBJECTIVES: Communication impairment after stroke has wide-ranging impacts on everyday activities and social participation. Following stroke, there are waiting lists of upto 6 months for National Health Service (NHS) speech and language therapy (SLT). Objectives were to estimate the willingness of participants to wait for SLT for communication impairment. **METHODS:** A binary, forced choice, discrete choice experiment (DCE) measured preferences. Attributes, levels and descriptions were derived from COAST, a validated communication impairment specific measure developed with service users. Factor analysis and expert review identified four (5-level) items for the DCE (impact of communication impairment on: social/family life; involvement in interests/hobbies; daily activities; worry and unhappiness; waiting time). A fractional factorial design and modulo arithmetic identified 25 choice sets. A random sample of 4000 members of the general public was invited to participate by post. The design had 89% efficiency for a linear additive, main effects model, with all five attributes. **RESULTS:** A total of 278/4000 people participated. All the attributes were important contributors to the preferences of participants ($p<0.01$). Ability to communicate with family and friends was the most important attribute. Participants were willing to wait longer than 6 months for improvements (8-37 months) in each attribute. Participant characteristics did not affect the results. **CONCLUSIONS:** Participants may be willing to wait longer than one year for treatment that improves their ability to communicate and the impact that this has on their lives. This is longer than the maximum waiting time included in the survey, and questions government policy to target waiting times to improve health care. Younger people are willing to wait for longer for therapy than older people. A number of assumptions were made in the design and conduct of the DCE survey. Combined with the low response rate (7%), the results are only indicative of preferences. Further surveys are merited.

PCV115

THE SENSITIVITY OF PRO'S IN EVALUATING ADVERSE EVENTS IN PEOPLE RECEIVING "STATIN" THERAPY

Pumford N, Wade A, Crawford G
Patients Direct, Glasgow, UK

OBJECTIVES: To investigate whether patient reported outcomes could detect adverse event differences between cholesterol lowering agents "statins" and patients could recall enough information to assess the differences. **METHODS:** In this evaluation, PROBE (patient reported outcomes based evaluation) methodology consisting of a web-based system supplemented by telephone reporting was used to collect naturalistic data from people who were taking or about to start "statin" therapy. People were recruited through internet pay per click advertising, social networking sites and search engine optimisation. Data collection was a one off questionnaire. Data included baseline demographics, therapy name, dose, cholesterol level before and after treatment, any side effects and action taken in response to side effect. **RESULTS:** A total of 679 recipients participated in the evaluation. 49% of participants were male with 43% aged between 41-60 and 52% between 61 -80. Overall, 336 (52%) of respondents felt they had experienced a side effect since commencing "statin" therapy with an average of 5 side effects per person. 121 (18%) people reported that they required treatment with respect to the side effect, the commonest report being muscle pain in the arms or legs (28% of patients accounting for 39% of all side effects). Interestingly, 24% of people on atorvastatin (mean dose 26mg) required treatment in relation to their side effect(s) as compared to 19% on simvastatin (mean dose 29mg). 64% of people could recall their cholesterol before starting therapy and 94% supplied a meaningful figure. **CONCLUSIONS:** This evaluation shows that the PROBE methodology quickly and simply captured patient reported outcome information on adverse events and patient actions in a population taking cholesterol lowering therapy. Half the population receiving "statins" reported a side effect and 18% required a medical intervention in relation to their side effect(s).

PCV116

THE IMPACT OF HIGH RISK OF STROKE PATIENTS DIAGNOSED WITH ATRIAL FIBRILLATION ON HEALTH-RELATED QUALITY OF LIFE, AND HEALTH CARE USE IN 5EU

Gupta S[1], Gross H[1], Isherwood G[2]
[1]*Kantar Health, Princeton, NJ, USA,* [2]*Kantar Health, Epsom, Surrey, UK*

OBJECTIVES: This study investigates stroke risk and the association with health-related quality of life (HRQoL), and resource use among diagnosed atrial fibrillation (AF) patients. **METHODS:** The study included data from the EU 2010 (N=57,805) National Health and Wellness Survey, a self-administered, internet-based questionnaire from a demographically representative sample of adults (aged ≥18) in 5EU. Stroke risk was assessed with CHA2DS2-VASc, an index summing the presence of congestive heart failure, hypertension, age ≥ 75 (2 points), diabetes mellitus, previous stroke/transient ischemic attack (2 points), vascular disease, age 65-74, and female gender. Low- (CHA2DS2-VASc = 0), moderate- (1), and high- (2+) risk patients reported on measures of HRQoL (mental (MCS), physical component summary (PCS) and SF-6D (health utility) scores from the SF-12v2), and health care resource use. **RESULTS:** Among 479 diagnosed AF respondents (prevalence of 0.93%), 15.1% were low, 27.9% moderate, and 57.0% high risk for stroke. Significant differences exist in the use of anticoagulant medication for stroke prevention among low- (38.9%) vs. moderate- (54.9%), and high- (59.8%) risk patients, $p<0.05$. High-risk patients reported significantly lower levels of HRQoL relative to low-risk patients (PCS: 37.1 vs. 41.3; Utilities: 0.65 vs. 0.70, $p<.05$). The number of hospitalizations and physician visits in the past 6 months were also significantly higher for high-risk patients compared with both low-risk and moderate-risk patients (hospitalization: high- (0.43) vs. moderate- (0.26) and low-risk (0.14), $p<0.05$) **CONCLUSIONS:** In 5EU, 40% of AF patients at high-risk of stroke are not taking anticoagulant medication. Being high-risk for stroke can be a substantial burden on AF patients, reducing their HRQoL, after accounting for demographics, patient characteristics, and comorbidities. Increased number of hospitalizations and physician visits suggests that these AF patients can place a substantial burden on the healthcare system. There remains an unmet need for enhanced treatment of high-risk AF patients.

PCV117

CLINICAL AND PATIENT-REPORTED OUTCOMES OF TRIPLE COMBINATION OF OLMESARTAN MEDOXOMIL (OM), AMLODIPINE BESYLATE (AML) AND HYDROCHLOROTHIAZIDE (HCT) IN HYPERTENSIVE PATIENTS

Ehlken B[1], Claus V[1], Shlaen R[1], Oberdiek AMS[2]
[1]*IMS Health, Munich, Germany,* [2]*Daiichi Sankyo Europe, Munich, Germany*

OBJECTIVES: To compare clinical and patient-reported outcomes of OM/AML/HCT triple combination of different dose strengths with that of respective double combination in hypertensive patients. **METHODS:** The study (CS8635-A-E302) was a randomised, double-blind, parallel-group study, multi-centre, European, phase III clinical trial evaluating the efficacy and safety of co-administration of triple combinations OM/AML/HCT directly compared with the corresponding double combination of OM/AML in subjects with hypertension. The following five pairwise treatment group comparisons were considered after 10 weeks: A) OM20/AML5/HCT12.5mg vs. OM20/AML5; B) OM40/AML5/HCT12.5mg vs. OM40/AML5; C) OM40/AML5/HCT25mg vs. OM40/AML5; D) OM40/AML10/HCT12.5mg vs. OM40/AML10; E) OM40/AML10/HCT25mg vs. OM40/AML10. Primary clinical outcome was the responder rate defined as percentage of subjects achieving blood pressure goal (<140/90 mmHg; <130/80 mmHg for subjects with diabetes, chronic renal disease, or chronic cardiovascular disease). The number-needed-to-treat (NNT) was calculated. Patient reported outcomes (PRO) were recorded on two quality-of-life (QoL) instruments, EQ-5D and MINICHAL. **RESULTS:** Overall, 2690 patients (mean age: 56.5±10.5 years; 53.6% female) were followed over 10 weeks, balanced in each treatment group. Responder rate was higher in triple treatment groups compared to respective dual combination: A) 53.0% versus 42.7%, $p<0.05$, NNT 10 patients; B) 52.4% versus 46.4%, NNT 17 patients; C) 58.8% versus 46.4%, $p<0.05$, NNT 9 patients; D) 56.5% versus 49.6%, NNT 15 patients; E) 53.9% versus 49.6%, NNT 23 patients. Whereas patients reported statistically significant intra-individual improvements for most of the treatment regimens (mean improvement ranged from 0.007 to 0.026 (EQ-5D utility score) and from -1.2 to -1.7 (MINICHAL), the 10-week change in QoL was not significantly different between treatment groups of triple and the respective dual combination. **CONCLUSIONS:** Overall, responder rates are superior in patients receiving triple combination OM/AML/HCT in comparison to the respective dual combination OM/AML. Although the triple combination contains a further agent this had no negative impact on QoL.

PCV118

OBSERVATIONAL STUDY ON THE TREATMENT, COST AND QUALITY OF LIFE OF SUBJECTS WITH HEREDITARY ANGIOEDEMA

Bouillet L[1], Montauban V[2], Finck K[2], Jeanbat V[3], Bouee S[3]
[1]CHU Grenoble, La Tronche, France, [2]Shire France, Boulogne Billancourt, France, [3]CEMKA, Bourg la Reine, France

OBJECTIVES: Hereditary angioedema (HAE) is a rare and potentially serious disease. Due to its rarity, there are very few epidemiological and therapeutic data on this disease. The objectives of this study were to generate new information describing HAE patients and their symptoms, costs of therapeutic management, and impact on health-related quality of life (HRQoL). **METHODS:** A one-year retrospective observational study was conducted involving 306 HAE patients across 19 French medical centres. Data were collected on disease pathology, management,, resources and health-related quality of life based on the SF-36. **RESULTS:** 64.1% of patients had type I and/or II HAE, whilst 35.9% of patients had type III. The initial symptoms appeared in adolescents for type I/II HAE and in young adults for type III HAE. Across all HAE types, 87.4% of patients had already experienced at least one severe (life threatening) event related to the pathology and had an average of 8.5 episodes in the prior year. Out of 883 episodes, hospitalisation was necessary in 11.4% of episodes. An ICU stay was needed in 13.8% of the hospitalised episodes, and 3 of these stays necessitated intubation. 55.2% of the patients had ongoing long-term prophylactic treatment. The annual per-patient cost of HAE episodes (treatment, hospitalisation) was €4892 for type I/II and €3313 for type III. As compared with a population of patients with allergies, patients suffering from HAE have a decrease in their SF-36 scores in the areas of mental health and social well-being, as well as in most domains of physical health. Notably, there is a significant degradation in the SF-36 scores of patients when the number of episodes increases. **CONCLUSIONS:** HAE is a disease which reduces the QoL and has a high cost of treatment

PCV119

RELATIONSHIP BETWEEN QUALITY OF LIFE AND LEVEL OF CARDIOVASCULAR RISK AND COMORBIDITIES IN SPANISH HIPERTENSIVE PATIENTS-ALHAMBRA STUDY

Font B[1], Lahoz R[1], Salazar J[1], Roca-cusachs A[2], Abellán A[3]
[1]Novartis Farmacéutica, S.A., Barcelona, Spain, [2]Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, [3]Universidad Católica de Murcia, Guadalupe (Murcia), Spain

OBJECTIVES: To establish the relationship between cardiovascular risk (CVR) and health-related quality of life (HRQoL), as well as the presence or absence of comorbidities, in a Spanish hypertensive population. **METHODS:** Epidemiological, cross-sectional, multicenter study conducted in adult patients with essential hypertension of ≥1 year of evolution. Patients were stratified in 5 categories according to the CVR within 10 years (ESH/ESC, 2007): average, low added, moderate added, high added and very high added CVR. HRQoL was measured by MINICHAL questionnaire. It comprises 2 domains (mental status and somatic manifestations) referred to the past week. Overall scores range from 0 to 48, with higher scores representing worse HRQoL. Presence of kidney and cardiovascular disease was evaluated. **RESULTS:** A total of 6,654 patients (55.2% male) were assessed; median age (Q1, Q3) 63.0 (55.0, 72.0) years and time since hypertension diagnosis 6.5 (2.9, 10.7) years. Average CVR was presented in 3.5%, low added in 13.6%, moderate added in 12.8%, high added in 39.0% and very high added in 31.0% of patients. Overall MINICHAL scores ranged from 4.0 (2.0, 8.0) in patients with average CVR to 11.0 (5.0, 18.0) in patients with very high added CVR ($p<0.0001$). Mental status and somatic manifestations domains scores ranged from 4.0 (1.0, 6.0) for average CVR to 8.0 (4.0, 13.0) for very high added CVR, and from 0.0 (0.0, 2.0) for average CVR to 3.0 (1.0, 6.0) for very high added CVR, respectively ($p<0.0001$, in both cases). Overall MINICHAL scores related to comorbidities (presence vs. absence) were: kidney disease 13.0 (7.0, 20.0) vs. 7.0 (3.0, 12.0) and cardiovascular disease 10.0 (5.0, 17.0) vs. 6.0 (3.0, 12.0), [$p<0.0001$, in both cases]. **CONCLUSIONS:** Hypertensive patients with increased CVR show significant worse HRQoL, in both mental status and somatic manifestations domains. The presence of comorbidities is associated with a worse HRQoL.

PCV120

QUALITY OF LIFE IN CHRONIC SYMPTOMATIC HEART FAILURE PATIENTS IN SPAIN, INSIGHT FROM THE INOESCARO STUDY

Marti B[1], Delgado J[2], Oliva J[3], Llano M[4], Pascual P[5], Comin J[6], Grillo JJ[7], Diaz molina B[8], Culebras J[9], Martínez de la Concha L[10], Manito N[11]
[1]Medtronic Iberia, Madrid, Spain, [2]Hospital 12 de Octubre, Madrid, Spain, [3]Universidad de Castilla La Mancha, Toledo, Spain, [4]Hospital Universitario Marqués de Valdecilla, Santander, Spain, [5]Hospital Universitario Virgen de la Arrixaca, Murcia, Spain, [6]Hospital del Mar (IMIM), Barcelona, Spain, [7]Hospital Universitario Nuestra Señora de la Candelaria, Santa Cruz de Tenerife, Spain, [8]Hospital Universitario Central de Asturias, Oviedo, Spain, [9]Hospital Universitario Insular, Las Palmas De Gran Canariaý, Spain, [10]Hospital Universitario Infanta Cristina, Badajoz, Spain, [11]Hospital de Bellvitge, Barcelona, Spain

OBJECTIVES: To analyze, for the first time in a large Spanish population of heart failure pts, quality of life according to NYHA class II, III or IV using generic and specific quality of life questionnaires. **METHODS:** A descriptive analysis of a multicenter, prospective observational study was performed. Pts who met inclusion criteria were followed-up for a period of 12 months, with 3 visits programmed at baseline, 6 months and 12 months. A total of 9 Spanish hospitals were involved in the study. Questionnaires used to measure quality of life were: EQ-5D (generic questionnaire), Minessotta living with heart failure- MLWHF (specific questionnaire) and Barthel Index (index of independence). **RESULTS:** A total of 330 pts completed the study, 74.2% men, mean age was 62.9 years. 82.4% were in NYHA class II, 16.4% NYHA class III and 1.2% NYHA class IV. A total of 20 pts died along the period of study and 25 pts did not complete follow up. Significant differences were observed in Barthel Index's scores depending on class: class II 97.2 ± 7.3 vs. Class III-IV 91.4 ± 14.3. Related to EQ-5D scores, individuals in class II had a mean value of 0.8058 ± 0.2048 (out of 1), and mean VAS value of 56.75 ± 17.39 (out of 100). Individuals in NYHA class III-IV had a mean value of 0.6135 ± 0.3032 (out of 1) and mean VAS value of 50.45 ± 20.24 (out of 100). In a MLWHF questionnaire analyses, pts in NYHA class II showed a mean score of 29.81 ± 18.57 while pts in NYHA class III-IV showed a mean score of 48.53 ± 17.97. **CONCLUSIONS:** Chronic heart failure patients in NYHA III and IV seemed to have a higher grade for physical disability and worse health-related quality of life compared to patients in NYHA II and population of similar age.

PCV121

THE ECONOMIC AND HUMANISTIC BURDEN OF ACUTE CORONARY SYNDROME (ACS): A SYSTEMATIC REVIEW

Weir S[1], Ratcliffe M[1], Mollon P[2], Langham S[1], Ossa D[2]
[1]PHMR Associates, London, UK, [2]Novartis Pharma AG, Basel, Switzerland

OBJECTIVES: ACS encompasses a spectrum of clinical presentations arising from the progression of coronary artery disease including: unstable angina, non-ST segment elevation myocardial infarction (NSTEMI) and ST segment elevation myocardial infarction (STEMI). The epidemiology of ACS varies internationally with shifting incidence related to changes in lifestyle over time with broad implications for health care systems. This review focuses on the economic and humanistic burden of ACS. **METHODS:** A systematic electronic literature search was conducted to identify published reports from 1965 through 2009 for ACS. Abstracts from the initial search were reviewed to identify relevant papers. A full review was conducted on articles that met general inclusion criteria. Reference lists were hand searched to identify additional data. Studies not available in English were excluded. **RESULTS:** ACS has been associated with large reductions in health-related quality of life (HRQOL). Statistically significant declines in both the physical and social functioning domains of the SF-36 have been reported for individuals with MI, in particular, even years after the clinical event. However, such research is limited to specific populations and particular clinical events with variable findings across studies. Economic models have used utility values for ACS ranging from 0.61-0.93 (scale:0-1), depending upon age group and the clinical presentation of interest. A study of five European countries shows that economic costs also vary. Annual cost per patient ranged from €7,009 (UK) to €12,086 (Italy), with hospitalizations accounting for 50% of the total, on average, and pharmaceutical expenditures comprising between 14% (Spain) to 23% (Germany) of ACS total cost. **CONCLUSIONS:** ACS is a major source of morbidity and is associated with significant economic burden on health care systems, though the estimated impact on HRQOL varies by country, clinical presentation and metric. Future therapies for ACS may offer opportunities to reduce some of the economic and humanistic burden of ACS.

PCV122

HOW PATIENTS WITH CHRONIC STABLE ANGINA PERCEIVE AND LIVE WITH THEIR DISEASE ON AN EVERYDAY BASIS?

Benmedjahed K[1], Arnould B[2], Guillemin I[3], Alegre P[4]
[1]Mapi Values, Lyon, Rhône, France, [2]MAPI Values, Lyon, France, [3]Mapi Values, Lyon, France, [4]Science Union et cie (Servier), Suresnes Cedex, France

OBJECTIVES: Data seldom report the experience of chronic stable angina (CSA) directly perceived by patients. This qualitative work aimed to explore how patients perceive CSA and its impact on their life in order to optimise communication between the doctor and their patient in the decision-making process. **METHODS:** CSA patients with and without professional activity and treated with the most frequent anti-anginal therapeutic strategies were recruited. They were interviewed face-to face, based on a guide specifically designed for the purpose of the study including questions on knowledge and beliefs, as well as on impact and management of CSA. Recruitment was completed when no additional information was obtained with the last interview, thus reaching saturation of the themes investigated and allowing building the comprehensive picture of patients' perception. **RESULTS:** Symptoms perceived by CSA patients are cardiac pain, fatigue, breathlessness and increased heart rate. The disease impairs patients' daily life such as physical activities (in particular walking/running, climbing stairs/hill, and holding/carrying heavy things), work, family, sexual and social life and leisure activities, in addition to psychological/emotional status. In order to avoid symptoms, treated patients adopt coping strategies such as anticipating, avoiding or segmenting efforts, limiting/taking things easy, getting help, initiating healthy lifestyle. For those who live with partners they mainly delegate treatment management to them. Saturation was reached with the sample size population (n=25). **CONCLUSIONS:** CSA has detrimental impact on patients' lives. Treated patients adopt various coping strategies to help them live with their disease and lessen their symptoms. This exploratory work will help to better understand the disease and assess benefits of anti-anginal treatment from a patient's perspective. This is likely to facilitate patient-doctor communication in the decision-making process.

PCV123

THE PARTICIPATION DECISION FOR LIFESTYLE DISEASE SCREENING

Søgaard R[1], Lindholt J[2], Gyrd-Hansen D[3]
[1]University of Southern Denmark, Odense, Denmark, [2]Viborg Hospital, Viborg, Denmark, [3]University of Queensland, Brisbane, Australia

OBJECTIVES: The objective of this study was to compare attenders' and non-attenders' preferences in relation to participation in lifestyle disease screening. **METHODS:** During a screening trial of about 25,000 male citizens between the age of 65 and 75, 2,119 invitees were sampled. The screening programme comprised a test for abdominal aortic aneurysm, hypertension and peripheral artery disease,

with relevant follow up for positive tests. Prior to the test, attenders were given a questionnaire about their doubt and arguments in relation to the participation decision, including different willingness-to-pay (WTP) questions. Non-attenders were mailed a similar questionnaire. **RESULTS:** 70% responded to the questionnaire, which lead to a study sample of 1,053 attenders and 435 non-attenders. Among attenders, 5% had doubt about participation and the most frequent argument was that they did not want to know about the test result. Among non-attenders, 46% would reconsider attendance after further information, the main argument for doubt being the same as for attenders. Further arguments were self-perceived low risk and the trouble and costs associated with attending. Attenders valued the programme significantly higher than non-attenders but this was sensitive to exclusion of bidders who did not pass a simple test for internal consistency of the reported WTP. Doubt about participation was associated with significantly lower WTP among attenders whereas the opposite was the case for non-attenders. Amongst those in doubt, the WTP was the same for attenders and non-attenders. **CONCLUSIONS:** Up to half of the non-attenders appeared to have doubt about their decision, which presents a potential for increasing the participation rate. Non-attenders in doubt about their participation decision value the programme at a similar level as attenders in doubt, suggesting that non-attenders in doubt do not differ significantly in their base-line valuations from those of the individuals in doubt who choose to attend.

Cardiovascular Disorders – Health Care Use & Policy Studies

PCV124

REFERENCE PRICING, ORIGINATOR DRUGS AND CONSUMERXS CHOICE

Haula T[1], Koskinen H[2], Valtonen H[3]
[1]*National Institute for Health and Welfare, Helsinki, Finland,* [2]*The Social Insurance Institution, Helsinki, Finland,* [3]*University of Eastern Finland, Kuopio, Finland*

OBJECTIVES: Generic reference pricing of medicines was introduced in Finland in April 2009. The system restricts the amount of reimbursement paid to a consumer, thus creating a financial incentive for the consumer to accept the switch to a reference priced product. The aim of this study was to assess the impact of reference pricing on consumer's choice, and to analyze the factors associated with the choice of an originator drug priced higher than the reference price. **METHODS:** The data used in this study was collected from the Social Insurance Institute's prescription register. Data covers the records of the purchases in five active ingredient groups (atorvastatin, simvastatin, risperidone, olanzapine, quetiapine) by a sample population from January 2008 to August 2010. Data includes information of the consumer's socio-demographic characteristics and income, and of the prescribed and purchased product. Logistic regression analysis and logistic multilevel regression analysis were used to examine the factors associated with a consumer's originator drug choice. **RESULTS:** After the introduction of reference pricing the use of originator drugs declined but some of the consumers chose originator drugs even when priced higher than reference price. An important factor explaining the probability of choosing over reference priced originator drugs is habit, the choice history of the patient. In some active ingredient groups' higher age, higher income and female sex increased the probability of originator drug choice. The right to special reimbursement mainly lowered the probability. **CONCLUSIONS:** In earlier studies it has been shown that some of the consumers have prejudices on generic products and they want to stick with doctor's choice of medicine. The results of our study also indicate that doctor's primary decision of the prescribed medicine probably has an influence on some consumers choices and that decision has an important role in promoting the use of cheaper, generic products.

PCV125

THE INCREASING BURDEN OF ATRIAL FIBRILLATION ON HEALTH CARE IN SCOTLAND

Choy AM[1], Punekar YS[2], Keech M[3]
[1]*Ninewells Hospital and Medical School, Dundee, UK,* [2]*Sanofi-Aventis, Guildford, UK,* [3]*Pharmakos Ltd., St. Albans, UK*

OBJECTIVES: Atrial fibrillation (AF) is the most common cardiac arrhythmia in clinical practice with increasing prevalence in the aging population. The objective of our study was to evaluate the impact of AF on secondary care costs in Scotland. **METHODS:** Patient hospitalisation data collected by the Information and Statistics Division (ISD) of the Scottish National Health Service (NHS) from 2004 to 2008 were analysed to estimate the trends in hospital episodes in the 5.2 million population of Scotland. The associated costs were estimated using the tariff prices in Scotland for the respective years. **RESULTS:** Over the 5 year period, the number of patients hospitalised for AF increased by 21.0% to 26,510 patients in 2008 from 21,907 in 2004, with a total of 162,449 hospital admissions for AF over this period and accounting for 20.8% of total cardiovascular (CV) hospitalisations in 2008. The total inpatient bed days in 2008 were 394,128; a 14.5% increase during this time, with mean length of inpatient stay for AF higher than the mean for all cardiovascular conditions (10.9 vs 8.7). The total cost (inpatient and day cases) attributable to AF increased from £138.9 million in 2004 to £162.5 million in 2008, accounting for a quarter (23.8%) of all CV hospital costs in Scotland. Overall, the burden of AF was higher among women and increased progressively with age. **CONCLUSIONS:** AF presents a significant and increasing burden on hospital care in Scotland. As a proportion of total CV burden, AF accounts for nearly a quarter and is increasing at a relatively higher rate.

PCV126

MULTIDIMENSIONAL NON-INTERVENTIONAL STUDY TO ASSESS CURRENT PRACTICE, UTILIZATION OF RESOURCES AND COSTS RELATED TO ANTICOAGULATION TREATMENT IN POLAND – "ECONOMEDICA"

Wilczynska J[1], Haldas M[2], Bolisega D[2], Rutkowski J[2], Smaga A[1], Wladysiuk M[2]
[1]*Sequence HC Partners, Warszawa, Poland,* [2]*HTA Consulting, Krakow, Poland*

OBJECTIVES: To evaluate current practice, characteristics of treated population, utilization of resources and direct medical costs related to anticoagulation treatment in 6 indications in Poland. **METHODS:** The study consisted of 3 parts: cross-sectional study (performed in hospitals and open care), retrospective chart review and experts opinion-based study. The study was carried out between December 20, 2010 and March 15, 2011. Patients data on anticoagulation therapy or with atrial fibrillation or immobilized were included in cross-sectional part (2021 hospitalized patients and 4175 monitored in outpatient treatment). Documentation of 1752 patients treated for stroke, myocardial infraction, coronary artery disease, deep vein thrombosis, pulmonary embolism or atrial fibrillation or undergoing surgery (e.g. hip or knee replacement) was included in retrospective chart review. A total of 546 face-to-face interviews with physicians of different specializations (orthopedists, general and vascular surgeons, cardiologists, neurologists, general practitioners and rehabilitation therapists) were conducted in opinion-based study. Projection of treated population was made in order to generalize the results to the whole country. **RESULTS:** About 150,000 prescriptions for anticoagulants were made within 2 weeks of study. Approximately 36,000 patients daily were treated with anticoagulants in hospitals. The main reason for administrating anticoagulants in outpatient treatment was primary stroke prevention in patients with atrial fibrillation (28%), secondary prevention of venous thromboembolism (18%) and secondary stroke prevention in atrial fibrillation (14%). During hospitalization anticoagulants were administered mainly as a prevention of venous thromboembolism in patients who underwent a surgery (33%), or were immobilized due to other reasons (17%). Vitamin K antagonists accounted for 65% of market in outpatient practice, while low-molecular-weight heparins (LMWH) constituted 77% in inpatient treatment. **CONCLUSIONS:** Administration of anticoagulants in inpatient treatment is usually surgery-related, while in outpatient treatment the most common reason is stroke prevention. Oral anticoagulants are usually administrated in outpatient treatment, while LMWHs are most commonly used in hospitals.

PCV127

TIME TO INITIATION OF ORAL ANTIHYPERGLYCAEMIC AND STATIN THERAPY IN PATIENTS WITH NEWLY DIAGNOSED TYPE 2 DIABETES MELLITUS

Tunceli K[1], Sun P[2], Seck T[1], Ambegaonkar B[1], Lento K[1], Davies MJ[1], Zhang Q[1], Radican L[1]
[1]*Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA,* [2]*Kailo Research Group, Fishers, IN, USA*

OBJECTIVES: To assess the time to initiation of therapy with an oral antihyperglycaemic agent (OAHA) or statin in patients with newly diagnosed type 2 diabetes mellitus (T2DM). **METHODS:** In a retrospective US cohort study using the General Electric electronic medical record database, patients ≥18 years were included if they were newly diagnosed with T2DM between January 1, 2004 and December 31, 2005 (index period), with last pre-index A1C ≥7%, and had not received any antihyperglycaemic agents within the 2 years prior to diagnosis (index date). In addition, patients were required to be eligible for statin therapy per 2008 American Diabetes Association recommendations but not on a statin within 1 year prior to index date. Patients had to have medical records 1 year prior to (baseline) and at least 2 years after (follow up) the index date. Initiation of OAHA and statin was determined based on the first prescription record for each therapeutic class. **RESULTS:** Of the 2254 patients with newly diagnosed T2DM (58% male), mean age at index date was 58 years. The most recent mean HbA1c before diagnosis was 8.5% and mean LDL-cholesterol was 106 mg/dL. Further, 21% of patients had pre-existing overt CV disease, 40% had dyslipidaemia, 37% were obese, and 11% were smokers. After 2 years of follow up, 48% and 53% of patients initiated an OAHA and statin, respectively, with 18% initiating both agents on the same day. The median time from diabetes diagnosis to initiation of OAHA was 119 days and 325 days for statin initiation. Median time from initiation of OAHA to initiation of statin was 69 days. **CONCLUSIONS:** Treatment with OAHA and/or statin was suboptimal after years years in patients with newly diagnosed T2DM who were also eligible for statin therapy. Of those treated, patients initiated treatment earlier with OAHA than with statin.

PCV128

A REAL WORLD EVALUATION TO DESCRIBE THE CHARACTERISTICS, OUTCOMES AND RESOURCE USE ASSOCIATED WITH PATIENTS BEING MANAGED BY A SECONDARY CARE BASED ANTICOAGULATION SERVICE

Rose P[1], James R[2], Chapman O[3], Marshall S[4]
[1]*University Hospitals Coventry & Warwickshire, Warwick, UK,* [2]*University Hospitals Coventry & Warwickshire, Coventry, UK,* [3]*University Hospitals of Coventry & Warwickshire, Coventry, UK,* [4]*pH Associates, Marlow, UK*

OBJECTIVES: To describe the resource use and level of anticoagulation control associated with different patient characteristics within a secondary care anticoagulation service. **METHODS:** An observational research study was conducted in one secondary-care anticoagulation service between March and June 2010. Retrospective data were collected on patient characteristics (age, diagnosis, co-morbidities, concomitant medications), number of INR (International Normalised Ratio, prothrombin time) visits and time in target range (TTR) from all patients registered with the service after January 1, 2008 and >3 months before data collection. Data were analysed by initiation (0-12 weeks after initiation of warfarin) and maintenance (> week 12) phases and correlations run to explore relationships. **RESULTS:** Data were collected from 288 patients; mean age 67 years, 54% male. 45% had atrial fibrillation (AF), 37% were receiving warfarin for venous thromboembolism treatment or prevention (VTE), 18% other reasons (e.g cardiac valves). Mean number of INR visits was 8.4 during initiation and 1.6 per month during maintenance for patients with AF and 10.2 and 1.9 respectively for VTE. Mean TTR was 45% during

initiation and 65% thereafter for AF and 53% and 59% respectively for VTE. There was a positive relationship between number of visits during initiation and the number of subsequent visits (correlation coefficient (r)=0.29) and a negative relationship between number of visits and TTR during both initiation (r=-0.3) and maintenance (r=-0.35). **CONCLUSIONS:** Increasing number of anticoagulation visits was associated with reduced time in range suggesting that despite increased monitoring some patients fail to stay in range. In addition, patients who require frequent visits during the initiation phase continue to do so during maintenance, suggesting that this may be a useful predictor for patients who are likely to be poorly controlled despite high resource use in the longer term and may hence be candidates for alternative means of anticoagulation.

PCV129

DISCREPANCIES BETWEEN DEFINED DAILY DOSES AND ACTUAL PRESCRIPTION PATTERNS IN THE POLISH SETTING: THE ACE INHIBITORS EXAMPLE

Borowiec L[1], Szeligowski M[2], Zmigrodzki B[1]
[1]*Servier Poland, Warsaw, Poland,* [2]*Polish Mother's Memorial Hospital - Research Institute, Lodz, Poland*

OBJECTIVES: While WHO guidance considers a "misuse" to base national pricing and reimbursement regulations on ATC/DDD system, in Poland, drugs are reimbursed based on costs associated to their corresponding Defined Daily Doses (DDD). We analysed the group of ACE inhibitors to check whether the observed Prescribed Daily Doses (PDD) in the Polish setting correspond to DDDs. ACE inhibitors constitute an important therapeutic group in Poland (45 million packs yearly). According to a recent National Health Fund report, ramipril ranked fifth in terms of total reimbursement expenditure in 2010 (205 million PLN; 2.4% of the total budget). **METHODS:** We used IMS Medical Index report to derive average PDDs for ACE inhibitors available in Poland. Both monotherapies and fixed-dose combinations were analysed, irrespective of their prescribed indication. Average Daily Doses reported for specific preparations were weighted using the actual sales, so that the results can be interpreted as average PDDs, adjusted to drug use structure. Analysis is based on year 2010 data. **RESULTS:** For 10 molecules (benazepril, captopril, cilazapril, fosinopril, imidapril, lisinopril, moexipril, perindopril, quinapril, trandolapril) the PDDs did not differ more than ± 0.5 times vs the respective DDDs. On the contrary, PDD for enalapril and ramipril was significantly higher than DDD (1.8 and 2.9 times the DDD, respectively). This finding is consistent with the prescription patterns reported in the German setting – 1.9 and 3.5 times the DDD, respectively (Grimmsmann, Himmel 2010). **CONCLUSIONS:** New reimbursement law due to come into force in 2012 may apply a PDD instead of DDD as reference for reimbursement, in case DDD is lower than the most frequent dosage. In view of the above findings, ACE inhibitors should be revised in this aspect. The current practice of basing limits on DDDs may lead to suboptimal allocation of public funds and have ultimately negative impact on patients' access to therapy.

PCV131

CARDIOVASCULAR DRUG UTILIZATION IN RELATION TO AGE IN NIS REGION

Kodela B[1], Aleksić G[2], Milićević G[2], Veličković-Radovanović R[3]
[1]*Pharmaceutical Institution of Nis, Nis, Serbia and Montenegro,* [2]*Pharmaceutical Institution of Nis, Niš, Serbia and Montenegro,* [3]*University Clinical Center Faculty of Medicine Nis Serbia, Niš, Serbia and Montenegro*

OBJECTIVES: Evaluation of cardiovascular (CVS) medication prescription in 2010 as compared to 2005, in relation to age, in the field of primary health care, of Nis region **METHODS:** A retrospective study on cardiovascular drugs utilization according to ATC classification, was conducted on the basis of data received from Central City Pharmacy Nis, and results were presented in DDD/1000 inhabitants/day **RESULTS:** Data analysis confirmed a total increase of CVS medication prescription of 58% during the research period (251,76:399 DDD/1000inh/d). Thereby, a significantly higher percentage of prescription was notified among population older than 60 as compared to younger population (67%: 40%). Except for diuretics, there was an increasing tendency in all groups of CVS medication prescription in both age ranges. The highest percentage of prescription was marked in the group of Calcium antagonist drugs: 95% in patients older than 60 and 84% in younger population. Beta blockers were prescribed to elderly CVS patients for 29% more than to younger ones in 2010. The CVS medications prescribed most in the research period were drugs affecting the renin-angiotensin-aldosterone system (101,5:226,7DDD/1000inh/d), whereby the increase of usage prevailed among elderly patients (67%:41%). **CONCLUSIONS:** The obtained results show a significan increase of CVS medication prescription, predominantly among elderly patients. The highest percentage of prescription was manifested in the group of calcium antagonist drugs as compared to other medications, in patients of all age groups, whereas no significant change in diuretics usage was reflected during the research period.

PCV132

DO ATRIAL FIBRILLATION (AF) PATIENTS GET ORAL ANTICOAGULATION (OAC) AS GUIDELINES RECOM-MEND? AN ANALYSIS OF GERMAN HEALTH INSURANCE CLAIMS DATA

Wilke T[1], Mueller S[1], Groth A[2], Verheyen F[3], Linder R[4], Pfannkuche M[5], Breithardt G[6], Bauersachs R[7], Maywald U[8]
[1]*University of Wismar, Wismar, Germany,* [2]*Institute for Pharmacoeconomics and Drug Logistics, University of Wismar, Wismar, Germany,* [3]*WINEG, Hamburg, Germany,* [4]*Scientific Institute of Techniker Krankenkasse for Benefit and Efficiency in Health Care, Hamburg, Germany,* [5]*Boeringer Ingelheim Pharma GmbH & Co.KG, Ingelheim, Germany,* [6]*University Clinic Muenster, Muenster, Germany,* [7]*Klinikum Darmstadt GmbH, Darmstadt, Germany,* [8]*AOK Plus, Dresden, Germany*

OBJECTIVES: AF is the most frequent, clinically significant form of arrhythmia leading to stroke in a substantial proportion of patients. This paper investigates a possible OAC underuse based on a large German health insurance data set. **METHODS:** Based on data from 2 German statutory medical aid funds (2007-2008), a patient was considered to be in need of OAC if a CHADS2-Score≥2 without any OAC contraindication (CI) had been recorded. We used two CI scenarios; 1) a more extensive CI list based on the German Summary of product characteristics, and 2) a more limited list based on latest publications. In our day-specific analysis covering 2008, we classified each observed day into one of the following 3 categories: OAC use: day covered by OAC prescription (daily required dose defined by daily defined dose (DDD) or within a 180-days grace-period after consumption of last prescription); and Uncertain OAC use: OAC prescription in 2008, but the day was outside the grace-period, or it was covered by other anticoagulants/antiplatelets (DDD+90 days' grace-period). OAC underuse: no OAC prescription in 2008, or other anticoagulants/antiplatelets did not cover the day (DDD-based+90 days grace-period). **RESULTS:** Data of 183,448 AF patients were included, mean age 73.2 years (SD: 10.97 years), 55.6% male. Their average CHADS2 was 2.8 (SD 1.58). Considering CI, OAC was recommendable for 54251 (29.6%; scenario 1)/83653 (45.6%; scenario 2) of all patients. Between 28.1% and 31.8% of all days were OAC use days whereas 43.0%-48.7% were OAC underuse days. Relative underuse rates did not differ between the two CI scenarios. Older female patients with a high number of co-morbidities had a greater OAC underuse probability. **CONCLUSIONS:** Our analysis shows that the OAC underuse problem in AF patients in the German health care system is possibly more widespread than previous observational studies have shown.

PCV133

BASELINE CHARACTERISTICS, INTERVENTION MODALITIES AND UTILIZATION OF EVIDENCE BASED MEDICATIONS AMONG ACS PATIENTS: DOES PRESENCE OF DIABETES AFFECT THE PRESENTATION AS WELL AS MANAGEMENT SCENARIO FOR ACS? – RESULTS FROM SINGLE CENTRIC CROSS-SECTIONAL STUDY FROM INDIA

Shah B[1], Mahajan S[2], Patel B[3], Parikh K[4]
[1]*KSV University, Gandhinagar, Gujarat, India,* [2]*H. H. University, Duesseldorf, Germany,* [3]*Institute of Science & Technology for Advanced Studies & Research (ISTAR), Vallabh Vidyanagar (Anand), Gujarat, India,* [4]*Care Institute of Medical Sciences (CIMS), Ahmedabad, Gujarat, India*

OBJECTIVES: Assessment and comparison of baseline clinical characteristics, current trend of utilization of key evidence-based-medications (EBM) and interventional strategies for ACS patients presented with and without diabetes. **METHODS:** This observational cohort study was conducted at The Heart Care Clinic, Ahmedabad among patients presented with ACS. In this cross-sectional study, data base from the clinic was accessed to collect the data. This includes demographic information, vital signs, personal particulars and details of other risk factors for ACS such as diabetes, smoking and family history of coronary artery disease. Also information pertaining intervention procedure (medical management or percutaneous transluminal coronary angioplasty [PTCA] or coronary artery bypass grafting [CABG]) and medications prescribed at discharge were collected. **RESULTS:** Among 370 ACS patients, about 30% patients were diabetic. Typically, percentage of hypertensive patients was significantly higher among diabetics compared to non-diabetics (59.29% vs. 38.91%, p=0.0004). The difference in proportion of patients on medical management among diabetic and non-diabetic patient population was found to be highly significant (47.79% vs. 39.30%, p=0.0002). Key medications (ACEIs/ARBs, BBs, statins, and aspirin) were prescribed in 98.2, 85.0%, 87.6%, and 95.6% diabetic (113); while 97.3%, 82.1%, 93.8%, and 96.5% non-diabetic (257) patients, respectively on discharge. **CONCLUSIONS:** Diabetes is highly prevalent among ACS patient population and the worse prognosis in ACS patients from India may be attributed to clustering of several cardiovascular risk factors at presentation. The diabetics are being managed more frequently with cardiovascular medications rather than revascularization therapy (PTCA or CABG) compared to non-diabetics. Utilization of evidence-based-medication for both diabetic and non-diabetic ACS is consistent with the guidelines and recommendations and is not differing among the diabetic and non-diabetic population; except for the lipid lowering therapy. This observational study might serve as a maneuver to the current practice and highlights awareness on the adherence to the recommendations from the guidelines.

PCV134

CONCOMITANT MEDCIATION USE IN US ADULTS ON STATIN THERAPY: FINDINGS FROM A MULTI-EMPLOYER CLAIMS DATABASE

Molife C[1], Zhu Y[1], Yu C[1], Mccracken R[2], Zhao Z[1]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*i3 Statprobe, Ann Arbor, MI, USA*

OBJECTIVES: To assess the prevalence and pattern of concomitant medication (CM) use in US adults on statin therapy. **METHODS:** A retrospective analysis was conducted using a large, US employer-based claims database. The study cohort included adults ≥18 years old with ≥1 statin prescription between January 1, 2009 and December 31, 2009 with at least 6 months pre- and 3 months post-index (90-day study period) continuous enrollment. CM use was defined as a drug, excluding statins, recorded as prescribed to a patient. Data on the prevalence and pattern of use of CMs, including CMs that potentially interact with statins, were analyzed. Chi-square analyses were performed to examine relations between prevalence of CM use (≥5 CM use vs. <5 CM use) and demographic variables (age groups and gender). **RESULTS:** The study included 403,182 statin users, mean age 58 (SD ±12) years, 75% <65 years, and 52% male. Patients were prescribed an average of approximately 6 CMs during the study period. A total of 334,033 (83%) and 231,508 (57%) patients were prescribed ≥3 and ≥5 CMs. The proportion of patients prescribed ≥5 CMs was significantly higher in females (63% vs. 52%, P<0.0001) and patients >65 years old (72% vs. 52%, P<0.0001) compared to males and those <65 years old. Commonly prescribed CMs that potentially interact with statins included

fenofibrates (4%), diltiazem hydrochloride (3%), niacin (2%), verapamil hydrochloride (1%), fluconazole (1%), gemfibrozil glucuronide (1%), amiodarone (1%), ketoconazole (1%), and clarithromycin (1%). The proportion of patients prescribed with CMs that potentially interact with statins was generally higher in patients with ≥5 CMs. **CONCLUSIONS:** The majority of statin users in this study were taking ≥5 CMs. Statin users with ≥5 CMs were more likely to be female and ≥65 years old. Use of CMs that potentially interact with statins is not uncommon and more prevalent in those using ≥5 CMs.

PCV135

LOW LIPOPROTEIN CHOLESTEROL GOAL ATTAINMENT IN DYSLIPIDEMIC PATIENTS WITH EXISTING STATIN THERAPY: A CHART EXTRACTION-BASED APPROACH

Ivanova J[1], Frois C[2], Bae JP[3], Boykin SD[3], Mccracken R[4], Molife C[3], Waldman T[2], Zhao Z[3]
[1]*Analysis Group, Inc., New York, NY, USA,* [2]*Analysis Group, Inc., Boston, MA, USA,* [3]*Eli Lilly and Company, Indianapolis, IN, USA,* [4]*i3 Statprobe, Ann Arbor, MI, USA*

OBJECTIVES: To evaluate the proportion of patients initiating statins achieving NCEP ATP III low-density lipoprotein cholesterol (LDL-C) goals. **METHODS:** Adults ≥18 years of age, initiating statins (atorvastatin, rosuvastatin, simvastatin, pravastatin, fluvastatin, or lovastatin) between January 1, 2009 through September 30, 2009 with no use of the index statin 3 months prior to initiation were identified via retrospective physician survey/chart extraction. LDL-C goal attainment was evaluated based on: 1) LDL-C lab values extracted from patients' medical charts at 6 weeks, 12 weeks, 6 months, and 12 months after statin initiation, and 2) physician's assessment. Secondary endpoints included the proportion of patients with HDL-C >40 mg/dL (male) and >50 mg/dL (female), and non-HDL-C goal within 12 months. Subgroup analyses were conducted among 4 different populations: patients with 1) prior CHD; 2) diabetes without CHD; 3) other CHD risk equivalents excluding diabetes or CHD; and 4) multiple (≥3) concomitant medications. **RESULTS:** A cohort of 869 patients was identified with mean age of 52 years, mean baseline LDL-C of 162 mg/dL, HDL-C of 40mg/dL, and non-HDL-C of 206 mg/dL. The proportions of patients achieving LDL-C goal based on lab values were 38%, 59%, 66% and 74% at 6 weeks, 12 weeks, 6 months, and 12 months, and were similar based on physician assessment. The proportion of patients with HDL-C >40 mg/dL (male) was 68%, >50 mg/dL (female) was 44%, and 68% of patients reached non-HDL-C goal. The proportions of patients achieving LDL-C goal in subgroup populations were 22%, 41%, 52%, 63% in patients with CHD; 17%, 39%, 45%, 55% in patients with diabetes; 20%, 34%, 52%, 60% in patients with other CHD risk equivalents; and 26%, 48%, 60%, 70% in patients with multiple concomitant therapies. **CONCLUSIONS:** A low percentage of patients achieved LDL-C goal after 1 year; particularly in patients with diabetes and other CHD risk equivalents.

PCV136

FACTORS ASSOCIATED WITH FAILING TO ACHIEVE LOW DENSITY LIPOPROTEIN CHOLESTEROL GOAL WITH EXISTING STATIN THERAPY: A CHART EXTRACTION-BASED APPROACH

Zhao Z[1], Ivanova J[2], Bae JP[1], Boykin SD[1], Mccracken R[3], Molife C[1], Waldman T[4], Frois C[4]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*Analysis Group, Inc., New York, NY, USA,* [3]*i3 Statprobe, Ann Arbor, MI, USA,* [4]*Analysis Group, Inc., Boston, MA, USA*

OBJECTIVES: Understand the factors associated with failing to achieve NCEP ATP III low-density-lipoprotein cholesterol (LDL-C) goals. **METHODS:** Adults ≥18 years of age, initiating statins (atorvastatin, rosuvastatin, simvastatin, pravastatin, fluvastatin, or lovastatin) between 1/1/2009 through 9/30/2009 with no use of the index statin 3 months prior to initiation were identified via retrospective physician survey/chart extraction. Risk factors associated with failing to achieve LDL-C goal were identified using 1) direct physician assessment and 2) logistic regression analysis. Physician assessment was reported for all patients as well as 4 subgroups (patients with CHD, type 2 diabetes without CHD, other CHD risk equivalents excluding diabetes, and multiple [≥3] concomitant therapies). **RESULTS:** A cohort of 869 patients was identified (mean age 52 years). Twenty-four percent of patients were unable to achieve LDL-C goal within 1 year after statin initiation. Based on physician assessment, 45% did not achieve LDL-C goal due to poor adherence to statin therapy, 35% for lifestyle changes, 26% for no/slow improvement on statin therapy, and 14% for adverse events (e.g., myalgia) with statin therapy. Reasons (poor adherence to statin therapy, lifestyle changes, no/slow improvement, and adverse events) for not achieving LDL-C goal differed among subgroups: CHD subgroup 36%, 38%, 26%, 14%; diabetes subgroup 32%, 24%, 32%, 21%; other CHD risk equivalents subgroup 39%, 29%, 50%, 18%; multiple concomitant therapies subgroup 36%, 30%, 39%, 15%. The logistic regression model indicated index statin, older age, non-adherence to statin, having diabetes or other CHD risk equivalents, smoking, high baseline LDL-C, and low baseline HDL-C were significantly ($P<0.05$) associated with failing to achieve LDL-C goals. **CONCLUSIONS:** This retrospective chart review identified poor adherence to statin therapy, underlying clinical conditions (diabetes or other CHD risk equivalents), adverse events such as myalgia, smoking, baseline high LDL-C, and low HDL-C as factors associated with failure to achieve LDL-C goals.

PCV137

THE IMPACT OF DEMENTIA ON CARE PATTERNS AFTER DISCHARGE FOR ACUTE CORONARY SYNDROMES UNDER NATIONAL HEALTH INSURANCE SYSTEM

Lin CF[1], Hsiao FY[2], Bai CH[3], Gau CS[2], Shen LJ[2]
[1]*National Taiwan University, Taipei , Taiwan,* [2]*National Taiwan University, Taipei, Taiwan,* [3]*Taipei Medical University, Taipei, Taiwan*

OBJECTIVES: The prevalence of dementia is growing considerately in the recent years. Little is known about how dementia affects care patterns after discharge for acute coronary syndromes. This study was designed to assess differences between care patterns for ACS patients with and without dementia. **METHODS:** We conducted a retrospective cohort study of 87298 patients hospitalized for ACS (1835 with dementia) from January 1, 2006 to December 31, 2007, based on a nationwide population-based data under national health insurance system. Primary outcomes were use of aspirin, beta-blocker, angiotensin-converting enzyme inhibitors (ACEI) or angiotensin receptor blocker (ARB), statin, and clopidogrel within 365 days after the first ACS event. Secondary outcomes were implementations of invasive procedures. Age-matched cohort at 1:2 ratio (N=5005) was identified to control for confounding variable age. Multivariate logistic regression was performed to examine the relationships between the diagnosis of dementia in ACS patients and their care patterns. **RESULTS:** ACS patients with dementia were less likely to receive aspirin (adjusted odds ratio (OR), 0.71; 95% CI, 0.64-0.78, $p<0.001$), beta-blocker (adjusted OR, 0.68; 95% CI, 0.61-0.75, $p<0.001$), ACEI or ARB (adjusted OR, 0.70; 95% CI, 0.64-0.78, $p<0.001$), statin (adjusted OR, 0.57; 95% CI, 0.50-0.64, $p<0.001$), and clopidogrel (adjusted OR, 0.84; 95% CI, 0.74-0.95, $p=0.007$) after the first ACS event compared with ACS patients without dementia. They were also less likely to underwent invasive procedures such as percutaneous transluminal coronary angioplasty (PTCA) (adjusted OR, 0.57; 95% CI, 0.51-0.64, $p<0.001$), coronary artery bypass graft (CABG) (adjusted OR, 0.31; 95% CI, 0.20-0.48, $p<0.001$), and revascularization (adjusted OR, 0.52; 95% CI, 0.47-0.59, $p<0.001$) during the first ACS event. Similar results were found in the age-matched cohort. **CONCLUSIONS:** The presence of dementia was associated with underutilization of evidence-based therapies in ACS patients. Influence of suboptimal treatments in ACS patients with dementia should be further evaluated.

PCV138

USING A POPULATION- BASED, BUDGET- CONSTRAINED, COST-EFFECTIVENESS MODEL TO ASSESS THE HEALTH AND ECONOMIC IMPACTS OF USING STATINS FOR PRIMARY PREVENTION BASED ON THE JUPITER TRIAL INTENDED USE POPULATION

Arbel R, Greenberg D
Ben-Gurion University of the Negev, Beer-Sheva, Israel

OBJECTIVES: New treatment modalities may improve health outcomes but are usually associated with substantial cost and budget impact, thus limiting the number of patients that may benefit from them. An alternative is implementing a substantially lower cost intervention to a much wider population, accepting inferior per-patient outcomes. We examined whether this approach can provide better outcomes under a pre-specified budget constraint. **METHODS:** We used the results from the JUPITER trial (Justification for the Use of Statins in Prevention: An Intervention Trial Evaluating Rosuvastatin) and the United-States target population as a case study. The target population is estimated at 6,700,000 patients: women >60; men >50, with normal LDL but elevated high sensitive C Reactive Protein levels. We built a model that can compare the outcomes on the entire intended-use population, and compared three treatment alternatives: 1) Rosuvastatin for a limited patient population, with the clinical effect reported in JUPITER; and 2) Lowest cost statin for most patients, with 75% of the JUPITER effect per patient; and 3) Usual care (do-nothing) as a baseline for cost and effectiveness. We used a budget constraint of $200M per year, which covers the lowest cost statin for 75% of the target population, and used a 5-year horizon, during which a potential of 268,000 Cardiovascular adverse events could be prevented. **RESULTS:** The budget allows for 3% of the target patient population to be treated with Rosuvastatin, which resulted in prevention of 7229 cardiovascular events as compared to usual care. Using the lowest-cost statin allows for 75% of the target patient population to be treated results in preventing 118,555 cardiovascular events and is cost-saving compared to usual care. **CONCLUSIONS:** Under budget constraints, using lowest-cost statins enables a substantially larger market access to treatment, which according to our model resulted in significantly better health outcomes for the intended-use population.

PCV139

EPIDEMIOLOGY AND ECONOMIC BURDEN OF ATRIAL FIBRILATION TO THE PUBLIC HEALTH CARE SYSTEM IN BRAZIL

Nasciben V[1], Piegas LSP[2], Figueiredo MJDO[3], Martins SCO[4]
[1]*Boehringer Ingelheim Brazil, Sao Paulo, SP, Brazil,* [2]*Dante Pazzanese Institute, Sao Paulo, SP, Brazil,* [3]*UNICAMP, Campinas, SP, Brazil,* [4]*Hospital das Clínicas de Porto Alegre, Porto Alegre, RS, Brazil*

OBJECTIVES: To present Brazilian data on atrial fibrillation (AF) and perform a cost analysis of events related to this disease. **METHODS:** AF is an important risk factor for stroke and ischemic heart failure (HF) and death. It is estimated that in Brazil there are around 1.5 million patients with AF and that this population is correlated with the age pyramid. The prevalence of AF in the general population is estimated between 0.4% and 1%, increasing substantially with age. Among the strokes 20% are related to AF and 85% of these strokes are of ischemic origin and 15% of hemorrhagic origin. The stroke mortality in Brazil is 20.5 per 100,000. A panel of experts examined the resources related to the treatment of events related to AF. The panel was conducted through a questionnaire, where the experts listed all procedures, tests, drugs and materials used in every event. Unit costs for drugs and material were obtained from acquisition lists (BPS and SIMPRO magazine, respectively), hospitalization, exam and procedure costs were extracted from a public reimbursement database (SIGTAP). **RESULTS:** From the expert panel performed, the cost of events were: fatal ischemic stroke (IS) 11,810BRL (7,398USD), non-fatal IS without disability 2,812BRL (1,761USD), non-fatal IS with moderate disability 4,470BRL

(2,800USD), non-fatal IS with total disability 6,280BRL (3,934USD), embolism 11,810BRL (7,398 USD), transient ischemic attack 1,808BRL (1,133USD), fatal intracranial hemorrhage 15,572BRL (9,754USD), fatal hemorrhagic stroke (HE) 23,260BRL (14,570USD), non-fatal HE without disability 2,812BRL (1,761USD), non-fatal HE with moderate disability 4,470BRL (2,800USD), non-fatal HE with total disability 6,280BRL (3,934USD), fatal extracranial hemorrhage 1,018BRL (638USD), minor bleed 19BRL (12USD), fatal acute myocardial infarction (AMI) 15,530BRL (9,728USD) and non-fatal AMI 16,852BRL (10,556USD). **CONCLUSIONS:** Costs of events related to AF were significant, which underscores the importance of preventing it. Further, it is known that as the population ages the prevalence of events increases.

PCV140

THE IMPACT OF NATIONAL MASS SCREENING PROGRAM ON HEALTH SERVICE UTILIZATIONS AND MEDICAL EXPENSES: IN THE CASE OF HYPERTENSION COMPLICATIONS

Hong JM, Lee TJ
Seoul National University, Seoul, South Korea

OBJECTIVES: This study attempts to investigate the impact of national mass screening program on health service utilizations and medical expenses. **METHODS:** Main data is consisted of the subjects (12,449,964) eligible for 2002 screening program provided by the National Health Insurance who were born in even year. To analyze the effect of screening in the case of hypertension, we excluded people who had any medical records of hypertension before 2002. After sorting and random sampling 5%(564,443), we extracted the subjects' medical payments for hypertension complications in 2007. The independent variable of interest is whether screened or not, and the dependent variables are the incidence and costs of hypertension complications. We compared the results obtained using instrumental variable methods with those from conventional logistic and linear regression models. **RESULTS:** Conventional logistic and multiple regression models suggest that the possibility of utilizing medical services is significantly higher in no-screen group and the average medical cost of hypertension complications reduced by 5% in screen group at 10% significant level. However, the results estimated using instrumental variable methods show different results. The screen group has significantly lower possibility to use medical service ($p<0.05$), but the lower average costs in screen group is not significant any more. **CONCLUSIONS:** The different results demonstrate that conventional regression approaches may have limitations in making causal inference using non-experimental data. This study shows that whether one gets medical screen or not affects the possibility of hypertension complications occurring, however it doesn't significantly relate to average costs.

PCV141

CURRENT MANAGEMENT PATHWAY OF PATIENTS WITH ACUTE CORONARY SYNDROME UNDERGOING PERCUTANEOUS CORONARY INTERVENTION IN GREECE. RESULTS FROM APTORII STUDY

Pavlides G[1], Drossinos V[2], Dafni C[2], Antoniadis A[3], Routoulas T[4], Zarifis I[5], Chamouratidis N[6], Tsikaderis D[7], Nanas J[8], Kaprinis I[9]
[1]*Onassis Cardiac Surgery Center, Kallithca, Greece,* [2]*Eli-Lilly Greece, Athens, Greece,* [3]*Athens University General Hospital "Attikon", Athens, Greece,* [4]*1st IKA Hospital of Athens, Athens, Greece,* [5]*Thessaloniki General Hospital "Papanikolaou", Thessaloniki, Greece,* [6]*Interbalkan European Medical Centrer, Thessaloniki, Greece,* [7]*"Saint Luke" Clinic, Thessaloniki, Greece,* [8]*University of Athens School of Medicine Alexandra Hospital, Athens, Greece,* [9]*Thessaloniki General Hospital "Papageorgiou", Thessaloniki, Greece*

OBJECTIVES: To describe current management of acute coronary syndrome (ACS) patients undergoing percutaneous coronary intervention (PCI) over 12 months in Greece. **METHODS:** Prospective observational study in ACS patients undergoing PCI from September 2008 - April 2009, capturing current practices over 12 months. **RESULTS:** Twenty-two sites enrolled 558 eligible patients: 351 patients had unstable angina or non-ST elevation myocardial infarction (UA/NSTEMI) and 207 ST-elevation myocardial infarction (STEMI). Median age was 64 years (IQR 55-73) (UA/NSTEMI) and 56 years (IQR 49-66) (STEMI). Almost all patients (96.4%) received stents: 19% BMS only, 77.5% DES only and 3.5% both. 79% UA/NSTEMI and 86% STEMI patients were admitted to hospital within 1 day from start of ACS symptoms, while 78% UA/NSTEMI and 89% STEMI patients received the first antiplatelet loading dose (LD) in 1 day. Time from start of ACS symptoms to PCI was $\leq$3 days in 76% UA/NSTEMI and $\leq$1 day in 67% STEMI patients. Follow-up data were available for 540 (96.8%) patients. Percentage of patients on antiplatelets and other medications at hospital discharge and 12 months were as follows: aspirin 98%, 97%; clopidogrel 99%, 96%; statins 81%, 79%; beta-blockers 73%, 72%; calcium blockers 11%, 11%; angiotensin II receptor blockers/angiotensin-converting enzyme inhibitors 64%, 62%; proton pump inhibitors 39%, 35%. A formal diet program was followed by 7% patients and a formal exercise program by 6% through the 1st year of follow up. **CONCLUSIONS:** In ACS patients treated with PCI in Greece, dual antiplatelet treatment is maintained in a very high percentage through one year post procedure, and DES use is also high.

PCV142

A REVIEW OF THE PRIMARY CARE PRESCRIBING OF DABIGATRAN ETEXILATE AND RIVAROXABAN IN IRELAND

McCullagh LM, Usher C, Barry M
National Centre for Pharmacoeconomics, Dublin, Ireland **Background:** *In Ireland, the National Centre for Pharmacoeconomics, in collaboration with the Health Service Executive (HSE), considers the cost-effectiveness of all new medicines following an application for reimbursement under the community drugs schemes (CDS). The General Medical Services (GMS) scheme is the largest of the CDS. In 2008, dabigatran etexilate (DBG) and rivaroxaban (RIV) received positive reimbursement decisions for their licensed indication of venous thromboembolism (VTE) prophylaxis in adults after total hip- and total knee-replacement.*

OBJECTIVES: The objective was to analyse prescribing patterns of DBG and RIV on the GMS scheme in Ireland in 2010. **METHODS:** A retrospective analysis of the GMS prescribing database was performed. Analysis was performed using SAS (v9.1, SAS Institute Inc. Cary, US). **RESULTS:** 1098 patients had received DBG. Of these, 37.34% received it for longer than the maximum licensed duration of 35 days. Indeed, 15.94% received it for longer than 3 months and 7.56% for longer than 6 months. 1948 patients had received RIV. Of these, 25.77% had received it for longer than the maximum licensed duration of 35 days. Indeed, 2.1% had received it for longer than 3 months and 0.36% for longer than 6 months. **CONCLUSIONS:** This indicates that DBG and RIV may have been prescribed for unlicensed indications (for which positive reimbursement decisions have not yet been issued). Such indications include stroke prevention in AF and VTE treatment. There are efficacy, safety and budget impact concerns surrounding unlicensed prescribing. Also, should their licenses be extended in the future, prescribing for such indications may increase regardless of reimbursement decisions. There exists a need to introduce a policy in which drugs are only reimbursed for those indications which have received positive reimbursement decisions.

PCV143

IMPLEMENTATION OF EVIDENCE-BASED NATIONAL GUIDANCE ON VENOUS THROMBO-EMBOLISM PROPHYLAXIS FOR HOSPITAL INPATIENTS IN ENGLAND

Gericke CA[1], Boiko O[1], Child S[1], Nokes T[2], Copplestone A[2], Sheaff R[3]
[1]*NIHR Peninsula CLAHRC, Peninsula Medical School/Universities of Exeter and Plymouth, Plymouth, Devon, UK,* [2]*Plymouth Hospitals NHS Trust, Plymouth, Devon, UK,* [3]*University of Plymouth, Plymouth, Devon, UK*

OBJECTIVES: In 2007 the National Institute for Health and Clinical Excellence (NICE) published national guidance for VTE prevention. Hospitals have been expected to implement these preventive measures, beginning with systematic procedures for risk assessment of inpatients. We measured the compliance with NICE guidance in two hospitals in the South West of England two years after the publication of national guidance. **METHODS:** Systematic comparison of the implementation of national guidance on VTE prevention across two clinical specialities (general medicine, orthopaedics) in two hospitals in 2009, using 200 randomly selected longitudinal case studies, complemented by a qualitative study into their origins, development and practical responses to national guidance. Based on the criteria outlined in the NICE guidance we constructed a compliance score (minimum 0, maximum 5). **RESULTS:** We found a mixed picture of compliance with national VTE prevention guidance. Across both hospitals 90% of orthopaedic patients and 70% of general medical patients received VTE prophylaxis. In contrast, the prescribed risk assessment was not systematically carried out or documented: only 68% of orthopaedic and 35% of medical patients were formally risk-assessed. Hospital A achieved a compliance score of 1.28 (SD 0.76) in medicine and of 1.78 (SD 0.93) in orthopaedics. Hospital B achieved a score of 0.88 (SD 0.87) in medicine and of 1.69 (SD 0.59) in orthopaedics. **CONCLUSIONS:** Despite clear national guidance for VTE prevention, hospitals seem slow to implement, document or comply with the recommendation of individual risk assessment to guide the need for prophylaxis. As shown by the high levels of VTE prophylaxis administration in both hospitals and the qualitative interviews with senior clinicians, this is partially attributable to the fact that hospitals had strong internal guidance before the issue of national guidance. The added value of documenting individual VTE risk assessment is doubtful and limited compliance with national guidance is therefore not surprising.

PCV144

STROKE PREVENTION IN PATIENTS WITH ATRIAL FIBRILLATION: INAPPROPRIATE ANTICOAGULATION AND POOR INR CONTROL

Evers T[1], O'Neil WM[2], Ogilvie IM[2], Welner SA[2], Lip GY[3]
[1]*Bayer Schering Pharma AG, Wuppertal, Germany,* [2]*BioMedCom Consultants inc., Montreal, QC, Canada,* [3]*University of Birmingham Centre for Cardiovascular Sciences, Birmingham, UK*

OBJECTIVES: Current guidelines recommend antithrombotic therapy (oral anticoagulant [OAC] or antiplatelet therapy [APT]) to prevent stroke in atrial fibrillation (AF) patients in relation to stroke risk. Given the limitations of vitamin K antagonists [e.g., warfarin], OAC is often underused, and less effective APT is prescribed instead or patients remain untreated. The objectives were: 1) To determine the type of antithrombotic therapy used by AF patients as stratified by stroke risk (using CHADS2 scores) in developed countries. 2) To assess quality of treatment with OAC by time in therapeutic range (TTR) of international normalized ratios (INR). **METHODS:** Studies were identified by literature review that reported 1) AF patients and treatment level categorized by CHADS2 score and 2) TTR for AF patients. **RESULTS:** In line with guidelines for AF treatment, as CHADS2 scores increased (i.e., higher risk for stroke), the percentage of patients receiving OAC±APT increased and of patients receiving APT alone, or no treatment, decreased. A large number of moderate to high risk patients (based on CHADS2 scores), however, were still treated with AP alone (means: 25.6–37.6%; range 0–100%) or were untreated (means: 4.4–10.6%; range:0.0–26.3%). Thus, up to 48% were treated inappropriately. The reported proportion of treated patients with poor INR control ranged from 30-92% and varied according to TTR benchmark (<50% to <75% TTR). **CONCLUSIONS:** A large proportion of AF patients at moderate to high risk for stroke are suboptimally treated. Among those who do receive OAC treatment, many are poorly controlled and therefore receive little benefit. Using the CHA2DS2-VASc score, a more recent risk assessment tool, would result in even higher numbers of patients who are treated suboptimally. To prevent avoidable strokes among AF patients, there is a need for safe and effective treatments that require less complicated management (INR monitoring), therefore likely promoting higher compliance and persistence.

Cardiovascular Disorders – Research on Methods

PCV145
PREDICTING HEALTHCARE EXPENDITURES AND UTILIZATION IN PATIENTS WITH DYSLIPIDEMIA USING THE UPDATED CHARLSON COMORBIDITY INDEX (CCI) AND PRIOR EXPENDITURES

Cheng LI, Rascati KL
University of Texas at Austin, Austin, TX, USA

OBJECTIVES: To assess the utility of the updated Charlson Comorbidity Index (CCI) and prior utilization for the prediction of healthcare expenditures and utilization in patients with dyslipidemia. **METHODS:** Data were retrieved from the Medical Expenditure Panel Survey (MEPS) Panel 12 (2007-2008) for this retrospective cohort study. Annual healthcare expenditures, the original CCI (CCI-1), and the updated CCI (CCI-2) scores were calculated for patients who had dyslipidemia in 2007. Adjusted R2 from linear regression models were used for the estimation of log-transformed healthcare expenditures (COST) in 2008. C statistics from logistic regression models were used to compare the predictive power in the risk of hospitalizations (≥ 1 admission), risk of emergency department visits (≥ 1 visit), and high expenditures (≥ 90th percentile of COST) in 2008. **RESULTS:** The cohort included 1,751 patients with dyslipidemia. The mean (SD) age was 60.7 (14.0) years, and 52% were female. Log-transformed prior-year expenditures showed better power than the CCI-1 or CCI-2 in predicting log-transformed COST (adjusted R2 = 22.4% vs. 13.2% or 14.4%) and individuals incurring ≥ 90th percentile of COST (c = 0.779 vs. 0.690 or 0.704). The CCI-2 was a better predictor of the risk of hospitalizations and the risk of emergency department use (c = 0.674, 0.644) than either the CCI-1 (c = 0.660, 0.629) or log-transformed prior-year expenditures (c = 0.667, 0.624). **CONCLUSIONS:** In a U.S. nationally representative sample of patients with dyslipidemia, prior-year expenditures appeared to be the best predictor of future healthcare expenditures, but the updated CCI was a better predictor of the risk of hospitalizations or emergency department use. Compared with the original CCI, the updated CCI showed improved predictive performance.

PCV146
HOW HAVE QUALITY CHECKLISTS IMPROVED THE QUALITY OF PUBLISHED ECONOMIC EVALUATIONS? AN EXAMPLE OF VENOUS THROMBOEMBOLISM (VTE) PROPHYLAXIS

Yoshida E[1], Plich A[1], Toumi M[2]
[1]*Creativ-Ceutical Ltd., London, UK,* [2]*University Claude Bernard Lyon1, Lyon, France*

OBJECTIVES: Standard quality checklists for economic evaluation (EE) exist and are referred to by journal editors. In addition, there are country- and disease-specific EE guidelines available. We examined if the existence of these checklists and guidelines improve the quality of published EE. **METHODS:** The evaluation was performed for a single therapeutic area, VTE prophylaxis in total hip and knee replacement, to ensure that the studies and interventions were comparable. A systematic review of published literature written in English was conducted using EMBASE, Medline, Cochrane Library, NHS EED, Econlit in July 2010. A number of EE parameters were extracted from each eligible publication, and were analysed over time. The impact of the VTE specific EE guidelines on the quality of published EEs was assessed. A subset of the articles for the UK were evaluated in regards to their adherence to the Drummond quality checklist as well as to the selected items of the NICE reference case. **RESULTS:** Sixty-seven articles were selected for the review, including 13, 24, 23 and 7articles in the year <1996, 1996−2000, 2001−2005 and >2005, respectively. The quality of EEs had generally advanced over time: the time horizon increased, models became more sophisticated, and probabilistic sensitivity analysis was used more frequently. There was a sense of improvement regarding the quality of published EEs after the introduction of the VTE-specific EE guidelines, although a number of recent publications did not refer the guidelines. Few quality requirements from the Drummond checklist were not addressed in the eight UK-specific publications. The adherence to the NICE reference case among the latest UK publications was high. **CONCLUSIONS:** It is questionable whether the quality checklists have contributed any significant improvements to the quality of published EEs. And so there is a need to strengthen the awareness of editors on the availability of the quality checklists and guidelines for EE.

PCV147
FRAMINGHAM RISK SCORE IN HEALTH ECONOMIC MODELLING: A EUROPEAN PERSPECTIVE

Carlqvist P[1], Hermansson J[2], Moorcroft E[3], Hettle R[3]
[1]*Heron AB, Stockholm, Stockholm, Sweden,* [2]*Heron AB, Stockholm, Sweden,* [3]*HERON Evidence Development Ltd, Luton, UK*

OBJECTIVES: Many clinical practice guidelines recommend that providers and patients base their treatment decisions regarding coronary heart disease (CHD) prevention on the assessment of underlying risk. The need to predict the risk of an event in CHD is of importance when modelling the cost-effectiveness of lipid-modification therapies where the outcome is determined by the risk of a CHD event and the change in risk due to the intervention. Risk score equations have been derived from cohort studies or randomised trials and usually estimate the risk of having a CHD event over 5 to 10 years. The Framingham risk score (FRS) is the most famous and used risk calculator and its many adaptations are used to predict the risk for very different populations. In this study we investigate FRS's development into a global tool to estimate CHD events, focussing on its use in health economic modelling to demonstrate the efficacy of lipid modifying therapies in European populations. **METHODS:** A systematic search was undertaken in Embase to identify European health economic studies using FRS. The studies where assessed for information about the implementation of the FRS and any results of the validation of the predicted risk. **RESULTS:** There exist several studies employing the FRS to evaluate the cost-effectiveness of interventions for CHD. However, the Framingham cohort differs from many groups to which it has been applied. There have been several attempts to recalibrate FRS to better its performance toward European populations with varying success. **CONCLUSIONS:** The Framingham risk score is still used in a European setting, even if it is often criticised to misrepresent the CHD risk. There are alternative risk functions, developed in order to better accommodate the risk of specific European populations. However, the use of FRS seems to still be a valid option for a Global or pan-European perspective.

PCV148
MULTIPLE PROPENSITY SCORE ANALYSIS TO ESTIMATE TREATMENT EFFECTS IN PATIENTS WITH HEART FAILURE

Chitnis AS, Aparasu RR, Chen H, Johnson ML
University of Houston, Houston, TX, USA

OBJECTIVES: Propensity scores (PS) are often used with binary treatments. However, in day to day practice multiple treatment options are often available. Therefore extension of binary propensity analysis to multiple PS will add to the empirical knowledge of use of PS. We used multiple PS to determine an association of individual angiotensin -converting enzymes inhibitors (ACEIs) on heart failure (HF) – hospitalization to illustrate the use of multiple PS. **METHODS:** The study was a retrospective analysis of a national cohort of patients diagnosed with HF identified from the Department of Veterans Affairs electronic medical records system. Multiple PS analysis was used to balance 47 baseline patient characteristics between the different ACEIs. Multiple PS were obtained from multinomial logistic regression. Effect of different ACEIs on time to HF-hospitalization was assessed using a multiple propensity weighted Cox proportional hazard model. Captopril was used as reference group. **RESULTS:** The study included 139,998 patients with 69.50% (97,293) on lisinopril, 21.79 % (30,503) on fosinopril, 8.41% (11,775) on captopril, and 0.30% (423) on enalapril. Multiple PS balanced nearly all differences between ACEIs groups. The adjusted hazards ratio from multiple PS-weighted Cox models were 0.800 (95% CI: 0.492-1.297) for enalapril, 0.971 (95% CI: 0.877-1.074) for fosinopril, and 1.005 (95% CI: 0.918-1.101) for lisinopril compared with captopril. **CONCLUSIONS:** We found no difference between four ACEIs in reducing the risk of HF-hospitalization. The use of multiple PS is a straightforward approach when comparing multiple treatments.

Gastrointestinal Disorders – Clinical Outcomes Studies

PGI1
INCIDENCE AND COST OF TREATMENT-EMERGENT COMORBID EVENTS IN AN INSURED POPULATION RECEIVING TREATMENT FOR CHRONIC HEPATITIS C (CHC) VIRUS INFECTION

Sapra S[1], Chang E[2], Broder M[2], L'Italien G[1]
[1]*Bristol-Myers Squibb, Princeton, NJ, USA,* [2]*Partnership for Health Analytic Research, LLC, Beverly Hills, CA, USA*

OBJECTIVES: To estimate the incidence of treatment-emergent comorbid events and incremental costs of treating these events in insured patients initiating pegylated interferon alfa (peg-alfa) and ribavirin (RBV) treatment for CHC. **METHODS:** In a retrospective cohort analysis of healthcare claims from a US insurer, we studied CHC patients newly treated with peg-alfa/RBV between 2006-2008 and continuously eligible for 12 months before/after treatment initiation. Treatment-emergent comorbid events were defined by new medical/pharmacy claims for predefined conditions in the 12 months after treatment initiation. The net incremental cost of treatment-emergent comorbidities was calculated as the difference between baseline and follow-up costs for these comorbidities and their treatment, excluding cost of peg-alfa/RBV. Baseline measures including age, gender, and region were used in a multivariate model to identify factors associated with treatment-emergent comorbid event charges. **RESULTS:** Of 3795 newly treated patients, 1269 (mean age=50.2 [SD 7.7], 36.2% female) met the selection criteria. The mean cost of peg-alfa/RBV treatment was $25,612 (SD $13,289). New treatment-emergent events were common, with 61.6% of patients having ≥ 1 event. Anemia was identified in 29.2% of patients, fatigue in 16.4%, depression in 11.5%, and neutropenia in 10.9%. The mean incremental cost for the pre-defined treatment-emergent comorbid events in the post-index period was $6,377 (SD $22,326); $2,783 for medical and $3,595 for pharmacy claims. Age ≥ 60 and female gender were significantly associated with higher charges in the multivariate model. **CONCLUSIONS:** In an insured US cohort with CHC, treatment-emergent comorbidities with peg-alfa/ RBV were common and increased cost by $6000/treated patient. This excludes indirect costs and is therefore a conservative estimate. Costs might increase with the use of triple therapy with peg-alfa/RBV and a protease inhibitor, as additional treatment-emergent co-morbid events may be expected. Better-tolerated therapies that reduce the financial burden on the health care system costs and improve patient experience are desirable.

PGI2
THE RELATIONSHIP BETWEEN ACUTE AND CHRONIC ACETAMINOPHEN EXPOSURE AND LIVER TOXICITY

Gokhale MN[1], Foster HR[1], Cleves M[2], Hogan WR[2], James LP[2], Martin B[1]
[1]*University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR, USA,* [2]*University of Arkansas for Medical Sciences College of Medicine, Little Rock, AR, USA*

OBJECTIVES: The relationship between acute high dose acetaminophen and hepatotoxicity is well established, however little is known about the relationships with chronic acetaminophen ingestion. This study sought to determine the associations between acute and chronic prescription acquired acetaminophen use and hepatotoxicity. **METHODS:** This was a retrospective case control study of a 10% random sample of the Pharmetrics LifeLink commercial claims data from 1997-

2009. Subjects had to be continuously enrolled and be >= 18 years of age. Cases had to have at least one incident claim with a primary diagnosis of acute liver necrosis, hepatitis, hepatic coma, hepatorenal syndrome, or coagulopathy. 3:1 controls matched on age, gender, and geographic region were randomly chosen. Acetaminophen maximum and average daily doses were calculated in a range of acute periods (7, 20, and 30 days) and in the chronic one year prior period. Conditional logistic regression was used to estimate the risk of acetaminophen exposure adjusted for comorbidities, other hepatotoxic drugs, and health system factors. **RESULTS:** There were 1350 cases and 4050 controls with a mean age of 47.29 years and 53.85% were male. 116 (8.59%) cases and 144 (3.56%) controls were exposed to acetaminophen in the 30-day prior period with mean maximum daily doses of 3234.32 and 3021.40 mgs. Hepatotoxicity was associated with any acute acetaminophen exposure that decreased with longer look back periods; 7 days (OR=2.23, p<0.001), 30 days (OR=1.84, p<0.001). Cumulative dose in the year prior was not associated with hepatotoxicity (OR=1.05, p=0.889). Acute maximum daily doses >4gms/day were associated with greater risks of hepatotoxicity (OR=2.45, p<0.001). **CONCLUSIONS:** Acute exposure to prescription acquired acetaminophen is associated with increased risk of hepatotoxicity, however use over longer chronic periods was not. Further research is necessary before the safety of chronic acetaminophen can be established.

PGI3

CURRENT TREATMENTS FOR CHRONIC HEPATITIS B: A SYSTEMATIC REVIEW

Watt M[1], Mealing S[1], Huerta M[2], Eaton V[2], Lescrauwaet B[3], Mesa OA[4], Thursz M[5], Hawkins N[2]
[1]*Oxford Outcomes Ltd, Oxford, UK,* [2]*Oxford Outcomes Ltd., Oxford, UK,* [3]*Xintera Consulting BVBA, Leuven, Belgium,* [4]*Bristol-Myers Squibb Pharmaceuticals Ltd, Uxbridge, Middlesex, UK,* [5]*Imperial College, London, UK*

OBJECTIVES: The National Institute for Health and Clinical Excellence set the guidance review date for an updated health technology appraisal in the treatment of Chronic Hepatitis B (CHB), including the use of entecavir, as February 2012. The objective of this study was to summarize the published evidence on the clinical efficacy and safety of CHB treatments, through a systematic identification of relevant randomised controlled trials. **METHODS:** A systematic literature search of Embase, Medline, Medline in process and Cochrane CENTRAL databases was conducted based on a research protocol with pre-defined criteria. The search period covered from inception of databases until March 2011. All searches were limited to full publications in the English language pertaining to adults with CHB without HIV co-infection or liver cirrhosis at baseline. The search strategy contains a mixture of free text and index terms. Abstract review and data extraction were performed independently by two members of the project team. The comparators of interest were: Adefovir dipivoxil, Entecavir, Interferon alfa 2a, Interferon alfa 2b, Peginterferon alfa-2a, Peginterferon alfa-2b, Lamivudine, Tenofovir and Telbivudine. Any of the comparisons versus placebo or compared to another drug listed, were included. **RESULTS:** 2,994 articles were identified with 2,107 abstracts reviewed according to the predefined inclusion criteria. A total of 178 full papers were ordered and 27 papers (n=9,033) included in the final analysis. Extensive data was extracted related to key patient population details, interventions used, baseline characteristics, endpoint data at numerous time points (up to 24 months) and adverse events. The methodological quality of trials was assessed using the Cochrane Collaboration's tool for assessing risk of bias. **CONCLUSIONS:** Although the literature base is mature in terms of number of RCTs, due to the number of treatments available the evidence network is weak. From those results, further analysis through a network meta-analysis, adjusting for cross-trial differences between study populations, should be investigated.

PGI4

COST-EFFECTIVENESS OF ESOMEPRAZOLE VERSUS PANTOPRAZOLE IN ACUTE AND MAINTENANCE TREATMENTS OF REFLUX ESOPHAGITIS IN TURKEY

Ormeci N[1], Caglayan B[2]
[1]*Ankara Universitity, Faculty of Medicine,, Ankara, Turkey,* [2]*AstraZeneca Turkey, Istanbul, Turkey*

OBJECTIVES: To assess the cost effectiveness in Turkey of acute treatment of reflux esophagitis (RE) with esomeprazole (ESO) 40mg once daily (od) followed by maintenance treatment with 20mg od versus acute treatment with pantoprazole (PA) 40mg od followed by maintenance treatment with 20mg od. **METHODS:** In the present study, ESO and PA were compared in a decision analytic model in terms of costs and effectiveness. To assess the effectiveness, probabilities for treatment success, which was healing of RE during initial acute treatment or a relapse while on maintenance treatment, were obtained from the randomized, double-blind, multi-center EXPO study. Patients healed after initial four to eight weeks acute treatment received 6 months maintenance treatment. Therefore, all patients were followed for seven months in the model. Direct medical costs were assessed based on the perspective of the health care provider. Association between RE and lost work productivity was regarded as 5.3 hours per employed patient per week. Sensitivity analyses were performed by using upper and lower 95% confidence intervals of the clinical study effectiveness results, as well as by changing patient management assumptions. **RESULTS:** Probability of treatment success per patient in the ESO and PA strategy was 83.4 % and 69.6 %, respectively after 7 months. Mean direct medical costs per patient in the ESO and PA strategy were the same; 152 TL in both strategies. Total costs included direct medical costs and indirect costs, which consisted of work absence and reduced work productivity. Total costs for ESO and PA strategy were 247TL and 274TL, respectively implying a cost-saving of 27TL for ESO. Sensitivity analyses supported stability of main findings for a range of scenarios. **CONCLUSIONS:** When considering total costs from a societal perspective, results indicate that esomeprazole treatment is dominant; esomeprazole provided a better clinical effectiveness at lower costs.

PGI5

IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C): A EUROPEAN-FOCUSED SYSTEMATIC LITERATURE REVIEW OF DISEASE BURDEN

Wiklund I[1], Foster T[2], Travers K[2], Fortea J[3], Prior M[3]
[1]*United BioSource Corporation, London, UK,* [2]*United BioSource Corporation, Lexington, MA, USA,* [3]*Laboratorios Almirall S.A., Barcelona, Spain*

OBJECTIVES: To explore disease burden, economic impact, treatment landscape and unmet medical needs in patients with IBS-C. **METHODS:** We conducted a review of MEDLINE- and EMBASE-indexed and 'grey' literature (citeable material that is often not published in peer-reviewed, indexed medical journals, e.g.,web-based international treatment guidelines) published in the last decade (January 2000 to December 2010) pertaining to the epidemiological, clinical, economic, and humanistic impact of IBS-C with a European country focus (France, Germany, Italy, Spain, UK). **RESULTS:** Altogether 885 unique studies were identified; 106 were included in the analysis. Among patients with IBS, the prevalence estimates of IBS-C range from 24% to 44%. Comorbid conditions such as personality and psychological traits and stress, are common. Patients with IBS-C have lower health-related quality of life (HRQoL) compared with the general population (18 studies); treatment of IBS-C can improve HRQoL. The European societal cost of IBS-C is largely unknown; no European cost-of-illness (COI) studies were identified specifically on IBS-C. In the absence of European data, US data show IBS-C to be cost-intensive. Two cost analyses demonstrated the substantial societal impact of IBS-C, with adult patients experiencing reduced productivity at work or through work absenteeism (mean number of days off work annually: 8.5 to 21.6 days) due to severe, disruptive symptoms. European and local IBS treatment guidelines (where available) offer similar diagnostic/management recommendations; however, IBS-C treatment varies by country. Current monotherapy options for treating IBS-C are suboptimal. 5-HT4 agonists have been evaluated for IBS-C; however, they have been associated with ischaemic colitis or a lack of substantial benefit in IBS-C versus placebo. **CONCLUSIONS:** Our literature search indicates a lack of monotherapy treatment options to adequately manage IBS-C patients, and the need for European focussed burden of disease and COI studies, to address the evidence gaps identified in this systematic literature search.

PGI6

THE DEVELOPMENT AND EXTERNAL VALIDATION OF A MODEL TO PREDICT ONE YEAR ALL-CAUSE MORTALITY FOLLOWING LIVER FUNCTION TESTS IN PRIMARY CARE PATIENTS

Mclernon DJ[1], Dillon JF[2], Donnan PT[3]
[1]*University of Aberdeen, Aberdeen, Aberdeenshire, UK,* [2]*University of Dundee, Dundee, Tayside, UK,* [3]*University of Dundee, Dundee, Tayside, UK*

OBJECTIVES: In patients with raised liver function tests (LFTs) but without clinically apparent liver disease, the appropriate level of follow-up to take can be unclear. Our aim was to develop and validate a prediction model to estimate the risk of one year all-cause mortality in patients with LFTs taken in primary care. **METHODS:** A population-based retrospective cohort of patients, without clinically apparent liver disease, in Tayside Scotland was identified as having their first LFTs performed in primary care and followed for one year. Biochemistry data were record-linked to secondary care, prescriptions and mortality data to ascertain baseline characteristics including LFTs, age, gender, deprivation, comorbidities, alcohol and drug dependency, methadone use, and statin, NSAIDs or antibiotic use. Multiple imputation was used to impute missing values for LFTs. Parametric accelerated failure time survival models were fitted to predict all-cause mortality. The final model was assessed for discriminatory ability using the C-statistic. A separate validation cohort was obtained from 19 general practices across Scotland to externally validate the final model. **RESULTS:** Predictors of all-cause mortality model included male gender, age, social deprivation, history of cancer, renal disease, stroke, ischaemic heart disease and respiratory disease, statin use, and all LFTs. A model integrating these predictors had excellent discriminatory ability (C-statistic (95% CI) = 0.82 (0.80, 0.84)) and calibrated well internally. The external validation had a C-statistic of 0.86 (0.79, 0.90) with very good calibration. The model without LFTs had a C-statistic of 0.63 (95% CI 0.61, 0.66). **CONCLUSIONS:** This study has developed and externally validated a model that predicts risk of mortality in patients with no apparent liver disease but tested for LFTs in primary care. This model can be used in practice by general practitioners and others working in community settings to improve management of these patients with the potential to save costs to the health system.

Gastrointestinal Disorders – Cost Studies

PGI7

IMPACT OF COMPLICATIONS FROM DYSPHAGIA ON HOSPITAL CHARGES IN THE UNITED STATES

Jensen IS, Helm T, Cyr PL
Navigant, Inc., Boston, MA, USA

OBJECTIVES: Unmanaged dysphagia exposes patients to risk of malnutrition, dehydration, urinary tract infections (UTI) and aspiration pneumonia. It has been demonstrated that dysphagia screening and management may reduce the risk of developing complications and incurring increased hospital charges. The objective of this analysis is to quantify the additional charges associated with common complications of dysphagia. **METHODS:** Using 2008 Health Care Utilization Project (HCUP) data, individuals with a recorded diagnosis of dysphagia (ICD-9 CM: 438.82, 787.2-787.29) were identified. The mean (10% trimmed) hospital charges for indi-

viduals with and without a recorded comorbid diagnosis of malnutrition, dehydration, UTI and aspiration pneumonia were compared. As there was a significant interaction between number of comorbidities and hospital charge in the UTI and pneumonia sample, an analysis of covariance (ANCOVA) model was employed to adjust the UTI and pneumonia analyses for this influence. The model was adjusted for complication diagnosis as a factor and both 1) number of comorbidities, and 2) complication diagnosis and number of comorbidities interaction as covariates. **RESULTS:** The most common complications reported in patients with a recorded diagnosis of dysphagia were UTI (27%, n=3424), pneumonia (26%, n=3348), dehydration (12%, n=1507), and malnutrition (8%, n=1027). Dysphagia patients with complications had significantly higher mean hospital charges than those without the complications UTI ($35,358 vs. $30,373, p<0.001), pneumonia ($33,085 vs. $31,184, p<0.001), dehydration ($28,093 vs. $20,850, p<0.001), and malnutrition ($37,192 vs. $34,747, p<0.001), and MS ($32,406 vs. $23,726, p<0.001). **CONCLUSIONS:** Our results demonstrate that having to treat the complications of dysphagia adds significantly to the cost of hospital care. Proactive management of patients with dysphagia may confer substantial savings to hospitals.

PGI8

COST ANALYSIS AND INCIDENCE OF ADVERSE GASTROINTESTINAL EVENTS FOLLOWING BISPHOSPHONATE TREATMENT AMONG WOMEN WITH OSTEOPOROSIS IN TAIWAN

Ling YL[1], Tang CH[2], Huang KC[2]
[1]*The University of Texas at Austin, Austin, TX, USA,* [2]*Taipei Medical University, Taipei, Taiwan*

OBJECTIVES: To investigate the cost and incidence of adverse gastrointestinal (GI) events caused by bisphosphonate therapy in Taiwan. **METHODS:** We conducted a retrospective cohort study based on the National Health Insurance Research database in Taiwan from 2005 to 2009. The inclusion criteria for the study cases were patients 1) who sought inpatient or outpatient care for gastrointestinal problems with ICD9-CM codes of GI-related diagnosis within 4 months after the initiation of filling bisphosphonate prescription (the index date) for bisphosphonate, and 2) who have no prior history of GI treatment 90 days before the index date. The costs and incidence associated with GI adverse events were assessed based upon survival analysis and generalized linear models. **RESULTS:** A total of 114,086 patients were included in this study. The GI incidence rate was lower in the group treated with risedronate (16%) than alendronate (25%). The average time of onset of GI event was longer after taking risedronate (1.6 months) than taking alendronate (1 month). The average direct medical cost associated with a GI event was $3147(USD) and $6235 (USD) in group treated with risedronate and alendronate, respectively. The distribution of costs of GI events was physician consultation fees (35%), examination fee (10%), drug costs including proton pump inhibitors (22%), H2-blocker (14%), cytoprotectants (7%) and other GI related costs (12%). **CONCLUSIONS:** Bisphosphonate treatment of osteoporosis may involve adverse GI events and their associated medical costs should be taken into account when evaluate cost-effectiveness of treatment for osteoporosis.

PGI9

IMPACT OF DYSPHAGIA ON U.S. HOSPITAL CHARGES IN PATIENTS WITH COMORBID CONDITIONS

Helm T, Jensen IS, Cyr PL
Navigant, Inc., Boston, MA, USA

OBJECTIVES: Dysphagia has been previously shown to increase hospital length of stay (LOS) (Altman et al, 2010). The objective of this study was to quantify the difference in hospital charges between patients identified with and without dysphagia among commonly associated neuromuscular, neurologic and cardiovascular diseases. **METHODS:** Using 2008 Health Care Utilization Project (HCUP) data, individuals with a hospital discharge diagnosis of stroke, Alzheimer's disease (AD), ALS, dementia, heart failure (HF), multiple sclerosis, cerebral palsy, Huntington's disease, and Parkinson's disease (PD) were identified using ICD-9 CM diagnosis codes. Within each disease state, the mean (10% trimmed) hospital charges for individuals with a recorded diagnosis of dysphagia (ICD-9: 438.82, 787.2-787.29) were compared to those without dysphagia. An analysis of covariance (ANCOVA) model was employed to account for potential impact of comorbidities on hospital charges. The model was adjusted for dysphagia diagnosis as a factor and both 1) number of comorbidities, and 2) dysphagia diagnosis and number of comorbidities interaction as covariates. **RESULTS:** Dyphasgia was most commonly diagnosed in patients with stroke (41.2%, n=11,736), dementia (0.6%, n=1,126), AD (0.4%, n=489) and HF (0.3%, n=2,087). Cerebral palsy, PD, HD, and ALS were excluded from the analysis due to small dysphagia sample (n<10). Patients with dysphagia demonstrated higher mean hospital charges compared with non-dysphagia patients for stroke ($32,531 vs. $26,004, p<0.001), dementia ($26,836 vs. $23,445, p<0.001), AD ($25,431 vs. $22,915, p<0.001), HF ($30,686 vs. $26,984, p<0.001), and MS ($32,406 vs. $23,726, p<0.001) adjusted for number of comorbidities. The magnitude and direction of the association between dysphagia and hospital charges were consistent in both the bivariate and multivariate analyses. **CONCLUSIONS:** Our results demonstrate that patients with conditions that are complicated by dysphagia cost hospitals significantly more than similar patients without dysphagia and management of these patients can avert significant costs.

PGI10

ANALYSIS OF ORIGINATOR VERSUS GENERIC PRESCRIBING OF PROTON PUMP INHIBITORS

Truter I
Nelson Mandela Metropolitan University, Port Elizabeth, Eastern Cape, South Africa

OBJECTIVES: Generic prescribing is important in South Africa. Many medical aid schemes will only reimburse the cost of the generic product, and a co-payment is required if a patient wants to use the originator product. The primary aim of this study was to investigate originator versus generic prescribing focussing on proton pump inhibitors (PPIs). **METHODS:** Prescription data were obtained from a private medical aid administrator in South Africa. The data covered 2010 and included medication, procedures and devices (a total of 2126264 records). For the purpose of this study, only PPI medicine items were extracted and analysed (MIMS category 12.4.4). Basic descriptive statistics were calculated. **RESULTS:** A total of 20537 PPIs were prescribed (only 18.56% on the chronic option of the medical aid schemes). Five different PPI active ingredients were prescribed to 7060 patients (50.88% female patients). Omeprazole was the most often prescribed PPI, accounting for half of all PPI prescribing (50.78%), followed by esomeprazole (19.83%) and lansoprazole (18.04%). Eight different trade names of omeprazole were prescribed (one generic product accounted for 56.00% of all omeprazole prescriptions and 56.08% of the cost of omeprazole prescriptions). The originator product only accounted for 1.75% of omeprazole prescribing frequency and 3.07% of prescribing cost. Only one trade name of esomeprazole was prescribed (no generic equivalents) and nine trade names of lansoprazole (the originator accounted for 1.43% of prescribing frequency and 2.51% of cost). On average, esomeprazole had the highest average cost of R308.97, followed by rabeprazole (R236.58). Both these products do not have generic equivalents on the South African market. **CONCLUSIONS:** Further studies that include dosage forms and prescribed daily doses (PDDs) should be conducted alongside cost analyses. A clear difference between the prescribing and cost of originator versus generic prescribing was detected in this study.

PGI11

COST ANALYSIS OF ANTIHELICOBACTER THERAPY OF GASTRIC AND DUODENUM ULCER IN UKRAINE

Gerasymova O, Iakovlieva L, Tkacheva O
National University of Pharmacy, Kharkiv, Ukraine

OBJECTIVES: To determine the cost range for different forms of antyhelicobacter therapy (first and second line) of the working age patients with gastric and duodenum ulcer in Ukraine. **METHODS:** Different variants of (triple and quadrotherapy) of traditional schemes of antihelicobacter therapy, recommended by "Maastriht" (2005) have been used in the research. When treatment course costs determination for antihelicobacter therapy for one patient, the expenses only for drugs included in the tested schemes have been taken. The prices for drugs have been taken from the information system "Medicinal preparations", Morion Company (August 2010). The currency rate to dollar (USA) on August 31, 2010 was 7,89:1. Medicinal preparations with minimal and maximal costs for the disease treatment course have been included for the costs range evaluation for the course of antihelicobacter therapy of the first and second line for one patient. **RESULTS:** The costs range of antihelicobacter therapy of the first and second line in Ukraine is rather large, $ 5,71– $ 238,55 and $ 5,78 – $ 149,26, respectively. It is connected with big difference between the cost of original and generic drugs, included into antihelicobacter therapy scheme. **CONCLUSIONS:** The cost for antihelicobacter gastric ulcer and duodenal therapy course with the use of original and foreign generics can be rather high in Ukraine. In connection with it, when drugs choosing it is reasonable to use pharmacoeconomics research results, that will help to optimize the state, insuaring companies and patients expenses for the disease treatment.

PGI12

GASTROESOPHAGEAL REFLUX DISEASE PATIENTS WHO SWITCHED FROM A BRANDED PROTON PUMP INHIBITOR TO A GENERIC ONE AND VICE VERSA: A COST COMPARISON

Xie L[1], Baser E[2], Wang L[3], Baser O[4]
[1]*STATinMED Research, Ann Arbor, MI, USA,* [2]*STATinMED Research, Tilburg, The Netherlands,* [3]*STATinMED Research, Dallas, TX, USA,* [4]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA*

OBJECTIVES: To compare health care costs between patients who switched from a branded proton pump inhibitor (PPI) to a generic PPI and vice versa. **METHODS:** We conducted a retrospective database analysis using commercial enrollees from a large US health plan from February 2008 to March 2010. Continuously eligible adult patients who had gastroesophageal reflux disease (GERD) or GERD-related conditions, and evidence of PPI use during February 2009 to September 2009 were included. The index PPI was defined as the first PPI prescribed during the identification period. The two cohorts in this study included patients who switched from a generic PPI to a branded index PPI versus patients who switched from a branded index PPI to a generic index PPI. Risk adjustment was performed using propensity score matching. We controlled for age, gender, region, GERD severity, plan, pre-index Quan-Charlson comorbidity score (CCI), baseline daily average consumption (DACON), and baseline costs and utilization. **RESULTS:** A total of 9881 patients from each cohort were matched after propensity score matching. During the 6 months after the switch, there were no statistically significant differences between the two cohorts in terms of office visit costs, outpatient costs, emergency services costs, inpatient costs, and other costs., However, patients who switched to a generic PPI had lower pharmacy costs ($1919 vs. $2306, p<0.001). **CONCLUSIONS:** Although pharmacy costs are slightly lower for patients who switched from a branded to a generic PPI, there were no significant differences in other health care costs such as for office visits, emergency room services, and inpatient visits.

PGI13

EVALUATION OF THE CLINICAL AND ECONOMIC BURDEN OF CHRONIC CONSTIPATION IN BELGIUM

Leeuwenkamp O[1], Chevalier P[1], Lamotte M[2]
[1]*IMS consulting group, Vilvoorde, Belgium,* [2]*IMS Consulting Group, Vilvoorde, Belgium*

OBJECTIVES: Constipation is considered an inconvenient problem, however data on the real burden is lacking. The objective of the current analysis was to assess the clinical and economic burden of chronic constipation in Belgium. **METHODS:** From the IMS Hospital Disease Database (year 2007), which includes data on full hospitalizations and day clinic for 34.3% of Belgian hospital beds, stays of patients with constipation were selected based on the ICD-9-CM code (564.0) with constipation as a primary diagnosis. The database allows to estimate length of stay (LOS), in-hospital mortality, performed interventions, ATC classified medication usage, and cost of hospitalisation. Using the 34% coverage, a national projection was made for the number of hospital stays and burden of disease. 2007 costs were extrapolated to 2010 using progression in costs from 2001 to 2007. ATC codes for osmotic/contact laxatives, softeners, bulking agents, enemas and peripheral opioid receptor antagonists were used. Occurrence of relevant co-morbidities was analyzed using applicable ICD-9-CM codes. **RESULTS:** There were 6338 hospital day clinic stays and full hospitalizations (LOS 5.44 days). About 42% of the patients were admitted via the ER. Most occurring co-morbidities were hemorrhoids (174), fecal impaction (74) and intestinal obstruction (53). Mortality rate was 0.46% meaning 29 deaths in hospitalizations for constipation. Especially in hospitalized patients, usage of enemas was pronounced (34.17%). Osmotically acting laxatives are the most used agents (39.58%). The average costs per patient was €1883, consisting of medication costs, procedural costs and stay costs of €112, €675 and €1097, respectively. Extrapolated to Belgium the total hospitalization cost for constipation was approximately €11.9 million. Hospital stay is more frequent in the elderly particularly in elderly females. **CONCLUSIONS:** Constipation is an underestimated disease condition reflected by hospital related costs of about €11.9 million and approximately 29 death cases in Belgium in 2007.

PGI14

RESOURCE USE AND COST OF HEPATITIS C RELATED CARE IN BELGIUM

Caekelbergh K[1], Lamotte M[1], Nevens F[2], Colle I[3], Michielsen P[4], Robaeys G[5], Moreno C[6], Wyffels V[7]

[1]*IMS consulting group, Vilvoorde, Belgium,* [2]*University Hospitals KU, Leuven, Belgium,* [3]*UZ, Ghent, Belgium,* [4]*UZ Antwerp, Edegem, Belgium,* [5]*ZOL, Genk, Belgium,* [6]*Erasme Hospital, Brussels, Belgium,* [7]*Janssen-Cilag, Beerse, Belgium*

OBJECTIVES: The aim of this study was to assess disease stage dependent resource use and costs in chronic genotype 1 hepatitis C (CHC) patients in Belgium. **METHODS:** The medical records of 157 CHC patients were reviewed to identify medical costs over a follow up period of 3 years. Six disease stages were defined based on histology/clinical data: mild disease (F0-F2), moderate disease (F3) or compensated cirrhosis without varices (F4), compensated cirrhosis with varices (F4), decompensated cirrhosis, hepatocellular carcinoma (HCC) and liver transplantation (LT). Data collected were baseline demographic characteristics, HCV-related data and detailed resource use (hospitalizations, day-clinic visits, surgery/interventions, physician visits, diagnostic tests and drug use). Resource use items were multiplied with unit costs (2010) to calculate costs. The public health care payer's (HCP) perspective was taken including the health insurance and patient co-payment. **RESULTS:** Intravenous/intranasal drug use was reported in circa 20% of patients, 63% had co-morbidities at study start. Nineteen patients (12%) died during the study period, whereof 79% attributable to HCV. Average number of hospitalizations during the study period ranged between 0.4 (mild disease) and 5.3 (HCC). Cost of care during the study period ranged from €18,993 for mild disease (in 81% due to HCV drug treatment) to €35,987 for patients with HCC (in 83% due to hospitalization, 11% due to medication and in 6% due to ambulatory care) and €65,120 for patients who underwent a liver transplant (79% hospitalization, 18% medication, 3% ambulatory care). Cost of diagnosis of the disease stage ranged between €790 (F3-F4 without varices) and €4142 (decompensated cirrhosis). **CONCLUSIONS:** Antiviral treatment is the most important cost driver in mild & moderate disease, but once complications of CHC occur, the associated costs far exceed this cost of antiviral therapy.

PGI15

THE COST AND QUALITY OF LIFE OF HEPATITIS C IN THE NETHERLANDS

van Rooijen EM[1], Hotho D[2], Agthoven M[3], Van Der Kolk A[3], Hansen BE[2], Knegt R[2], Uyl-De Groot CA[4]

[1]*institute for Medical Technology Assessment (iMTA), Rotterdam, The Netherlands,* [2]*Erasmus MC, Rotterdam, The Netherlands,* [3]*Janssen-Cilag BV the The Netherlands, Tilburg, The Netherlands,* [4]*Institute for Medical Techonology Assessment (iMTA), Rotterdam, The Netherlands*

OBJECTIVES: Hepatitis C (HCV) is a disease which in the long run can lead to cirrhosis and liver cancer, resulting in liver transplantation or death if not treated properly. So far, there is a paucity of literature on health care costs and quality of life (QoL) of HCV management. This study aims to illustrate the health care costs and QoL associated with HCV in The Netherlands. **METHODS:** This study followed a cross-sectional design for QoL and indirect costs, and a retrospective design for direct costs (these were mapped retrospectively until 3 years ago or diagnosis of HCV if earlier). Patients with HCV genotype 1 at Erasmus MC were invited to participate between November 2010 and April 2011. Patients were asked to complete the EQ-5D, Short form 36 (SF-36), Liver disease symptom index (LDSI) and Short form health and labour questionnaire (SF-HLQ). Resource use data were collected from the hospital information system. Utilities were determined using the UK tariff for EQ-5D The Mann-Whitney U-test was used for comparisons between treated and non-treated patients for the disease categories, mild and moderate disease and cirrhosis. **RESULTS:** Thirty-seven patients had either completed or discontinued treatment during the observation period, 10 had achieved sustained viral response (SVR). Mean direct costs were higher for treated patients, during all 3 years of observation; 3286 versus 5361, 1336 versus 9440, 2538 versus 10.507, ($p<0.01$). Compared to non-responders successfully treated patients had lower follow-up costs 1 year after treatment, 1172 versus 1426, and a higher mean utility, 0.84 versus 0.70, neither result was statistically significant at $p=0.4$ and $p=0.2$. There were no significant differences in indirect costs. **CONCLUSIONS:** This study provides basic information about the costs and utility of hepatitis C treatment. Such information is valuable when considering cost-effectiveness of new treatments for this disease.

PGI16

COMPARISON OF TREATMENT AND INDIRECT COSTS BETWEEN HEPATITIS, CIRRHOSIS, LIVER TRANSPLANTATION AND HEPATIC CARCINOMA: RESULTS OF THE COME STUDY

Fusco F

Charta Foundation, Milano, Italy

OBJECTIVES: As a result of successful treatments for chronic hepatic diseases (CHDs), patients' life expectancy, but also the diseases prevalence and costs are increasing. However, societal costs for CHDs remain little known. We assessed treatment and productivity costs of patients with CHDs in Italy. **METHODS:** a naturalistic multicentre Cost-of-Illness study was conducted. Adult patients (age>18 years) diagnosed with CHDs, consequently accessing at gastroenterology unit of 2 hospitals, were enrolled. Direct and indirect costs were assessed from the societal perspective, reported as mean €/patient-month (treatment cost) and mean days/patient-month of work/school/usual activities lost (productivity loss). The patients were sub-grouped according to their main condition at the enrollment: hepatitis B, hepatitis C, cirrhosis, liver transplantation, hepatic carcinoma. **RESULTS:** We enrolled 1,088 valid patients, 62.0% male (N=675), aged 19-90 (median=60) years: 31.5% (N=342) has hepatitis C, 20.3% (N=220) cirrhosis, 19.8% (N=216) hepatitis B, 11.9% (N=129) had liver transplantation, 7.5%(N=82) hepatic carcinoma, 9.0% (N=99) had other hepatic diseases. Overall, their treatment cost was 278.26 €/patient-month: 96% for conventional drug treatment, 4% for unconventional treatment (homeopathy, preparation of herbs, specific diet, multi-vitamin products). Patients who received liver transplantation were the most expensive (1041.31€/patient-month), followed by hepatitis B (249 €/month), hepatitis C (167 €/month). Productivity loss corresponded to 4.9 days/patient-month, mainly by transplanted patients (8.6 days/patient-month) and those with cirrhosis (8 days/patient-month). **CONCLUSIONS:** CHDs sensitively contribute to the high cost and require appropriate health technology valuations to guide stakeholders to find optimal diagnostic and treatment strategies.

PGI17

COST OF OUTPATIENT ENDOSCOPIC CAPSULE (EC) PROCEDURE IN BRAZIL: A STUDY FROM A PAYER'S PERSPECTIVE

Clark O[1], Paladini L[2], Medina P[1]

[1]*Evidências, Campinas, Brazil,* [2]*Evidências, São Paulo, São Paulo, Brazil*

OBJECTIVES: There is no published study about the direct costs linked to the procedure of the EC in Brazil. Our aim was to determine a base price of a single procedure of EC. **METHODS:** Based on a micro cost approach, we first determined the individual items that compose an EC procedure. Then we conducted a market price search for each of them in order to compose the final total cost. For the permanent equipment needed we considered an amortization time of 24 months and a 1% monthly interest percent rate. **RESULTS:** An EC procedure requires an initial investment in one computer and in one receiver, which is attached to the patient to capture the capsule's signal, known as "belt". Included in the analysis there are also the cost of the capsule per si, some medicines, the physician's and the room fee. The initial investment is US$19,411. Each capsule cost US$647 (single use). A medical fee of US$380 was set, that include the administration of the capsule, the supervision of the patient during the length of the procedure and the interpretation of the exam. Considering a service that performs three exams a month, a cost of US$1645 would be necessary to cover the expenses with material, personnel (doctors included) and to pay the amortization costs, insurance and interests for a 24 months period. **CONCLUSIONS:** In Brazil, the cost of EC procedure may be set at US$1645 in order to cover the expenses of the services.

PGI18

TREATMENT OF CHRONIC HEPATITIS C PATIENTS WITH PEGINTERFERON ALFA-2A OR PEGINTERFERON ALFA-2B: A COST-EFFECTIVENESS ANALYSIS FOR THE PORTUGUESE NHS SETTING

Areias J[1], Branco T[2], Calinas F[3], Carvalho A[4], Macedo G[5], Manata MJ[6], Matos L[7], Rodrigues B[8], Velosa J[9], Pereira C[10], Sanches M[11], Rubio-Terrés C[12]

[1]*Hospital Geral de Santo António, Porto, Portugal,* [2]*Hospital Prof. Doutor Fernando da Fonseca, EPE, Amadora, Portugal,* [3]*Hospital de Santo António dos Capuchos, Lisbon, Portugal,* [4]*Hospitais da Universidade de Coimbra, Coimbra, Portugal,* [5]*Hospital de São João, Porto, Portugal,* [6]*Hospital de Curry Cabral, Lisbon, Portugal,* [7]*Hospital de Egas Moniz, Lisbon, Portugal,* [8]*Hospital de Pulido Valente, Lisbon, Portugal,* [9]*Hospital de Santa Maria, Lisboa, Portugal,* [10]*Roche Farmacêutica Química, Lda., Amadora, Portugal,* [11]*Roche Farmacêutica Química, Lda., Amadora, Portugal,* [12]*HealthValue, Madrid, Spain*

OBJECTIVES: Estimate long-term cost-effectiveness of treatment with peginterferon (pegINF) alfa-2a (180 mcg/week) in combination with ribavirin (RBV) (800 – 1200 mcg/day) versus pegINF alfa-2b (1.5 mcg/kg/week) in combination with RBV (800- 1400 mg/day), in patients with Chronic Hepatitis C (CHC), from the Portuguese National Health System (NHS) perspective. **METHODS:** To project disease progression, a seven-health state Markov model was built based on clinical stages of CHC. Efficacy data was obtained from a published meta-analysis of 8 head-to-head randomized trials that showed higher sustained virological response (SVR) in patients receiving pegIFN alfa-2a compared to pegIFN alfa-2b. Effectiveness was measured in terms of quality-adjusted life years. Transition probabilities and health state utilities were obtained from published literature. Treatment duration was considered to be 48 and 24 weeks for genotypes 1/4 and 2/3, respectively. A Delphi panel with Portuguese experts was conducted to evaluate direct medical resources asso-

ciated with each health state, followed by micro-costing of the results. Costs were calculated according to Portuguese official databases. Only direct health costs were applied. The annual discount rate for costs and outcomes was considered to be 3%, according to Portuguese guidelines. A deterministic and probabilistic sensitive analysis was performed. **RESULTS:** Assuming a lifetime horizon, each patient gained 0.43, 0.55 and 0.63 life years and 0.17, 0.21 and 0.24 quality-adjusted life years with pegIFN alfa-2a plus RBV versus pegIFN alfa-2b plus RBV for all CHC genotypes, genotypes 1/4 and genotypes 2/3 respectively. The savings per patient treated with pegIFN alfa-2a plus RBV were 44€, 259€ and 1.647€ for all genotypes, genotypes 1/4 and genotypes 2/3, respectively. **CONCLUSIONS:** According to the present model, the treatment of patients with CHC with pegIFN alfa-2a plus RBV is a dominant strategy in comparison to pegIFN alfa-2b plus RBV for all genotypes, from the Portuguese NHS perspective.

PGI19

STRESS ULCER BLEEDING PROPHYLAXIS WITH PROTON PUMP INHIBITORS, H2 RECEPTOR ANTAGONISTS OR SUCRALFATE: A COST-EFFECTIVENESS ANALYSIS

Barkun A[1], Adam V[1], Martel M[1], Bardou M[2]
[1]*McGill University Health Center, Montreal, QC, Canada,* [2]*Université de Bourgogne, Dijon, France*

OBJECTIVES: Proton pump inhibitors (PPI), H2-receptor antagonists (H2RA) and sucralfate present varying pharmacological efficacy in preventing stress ulcer bleeding (SUB) in intensive care units. The literature also reports disparate rates of ventilator assisted pneumonia (VAP) as side-effects of these treatments. We compared the cost-effectiveness of these 3 pharmaco-prophylaxis options. **METHODS:** We constructed a decision tree for patients at high-risk for developing SUB (diagnoses of major trauma, hypovolemic shock, sepsis, septicaemia, acute respiratory failure, extensive burns, acute renal failure, shock, acute pancreatitis, coronary artery bypass graft surgery). Probabilities were obtained from a broad literature search. Costs were estimated using the Nationwide Inpatient Sample 2008, a representative US country-wide database and were expressed in 2010 US$. In each of the 3 treatment branches (PPI, H2RA and sucralfate), patients could be in one of three states of health: no complication (NC), SUB or VAP. A third-party payer perspective was adopted. Cost-effectiveness and sensitivity analyses were performed. A 60-day time horizon was adopted. **RESULTS:** PPI, H2RA and sucralfate treatments were associated with SUB and VAP probabilities of 5.9% and 17.2%, 5.1% and 17.7%, and 1.4% and 10.3%, respectively. Lengths of stay and per diem costs were 14 days and $2,993 for NC, 24 days and $2,764 for SUB, and 42 days and $3,310 for VAP. Average costs per no-rebleeding patient were $58,734 for PPI, $77,543 for H2RA, and $77,366 for sucralfate. H2RA and Sucralfate were dominated by PPI. These findings were robust on sensitivity and threshold analyses. Probability of complications would need to increase to 20% in the PPI group or drop to 1% in either of the other two treatment groups in order for PPI to cease being the dominant strategy. **CONCLUSIONS:** PPI prophylaxis is the dominant prophylactic strategy in patients at high-risk of developing SUB when compared to using H2RA or sucralfate.

PGI20

PHARMACOECONOMIC STUDY OF GLUTAMINE DIPEPTIDE USAGE DURING TOTAL PARENTERAL NUTRITION (TPN)

Metelkin I, Yagudina R, Kulikov A
First Moscow state medical university named by I.M. Sechenov, Moscow, Russia

OBJECTIVES: To undertake a comparative analysis of 2 schemes of TPN: isolated standard scheme of TPN (2 types: "all in one bag" and "1+1+1") and scheme of TPN, which includes expenses for purchasing and usage of glutamine dipeptide. **METHODS:** Pharmacoeconomic analysis "cost-effectiveness" was provided. The study estimated direct costs, because appraisal from the stand point of the Russian healthcare system was chosen: expenses for drug therapy, hospitalization (intensive care unit and medical division) and late complications (pneumonia and sepsis) treatment. Effectiveness data was taken from clinical trial: Eandi M., Pradelli S., Lanazzo S.. Alanyl-glutamine Dipeptide (Dipeptiven) in Total Parenteral Nutrition (TPN) Therapy in Critically Ill Italian Patients: A Pharmacoeconomic Simulation Model. AdRes Health Economics and Outcomes Research - Torino (Italy), 2010. Survival rate of patients was the main effectiveness criterion. Three types of TPN were compared: "3 in 1" and "1+1+1" without glutamine dipeptide usage and "3 in 1" system with glutamine dipeptide. Two-factor sensitivity analysis was carried out, which showed that results of our pharmacoeconomic study were stable. **RESULTS:** In the course of analysis the following results were obtained: direct medical expenses for 1 patient treatment with TPN system "3 in 1" were 1561,92 €; "1+1+1" – 1651,25 €; "3 in 1" + glutamine dipeptide – 1652,66 €. Taking into account the value of effectiveness rate of 3 compared TPN systems ("3 in 1" and "1+1+1" – 0,6554 and "3 in 1" + glutamine dipeptide - 0,7624) the results of Cost-Effectiveness Ratio (CER) were the following: "3 in 1" – 2383,15 €; "1+1+1" - 2519,45 € and "3 in 1" + glutamine dipeptide – 2167,71 €. **CONCLUSIONS:** According to the results of our research TPN system "3 in 1" + glutamine dipeptide is a dominant alternative as at the greatest effectiveness rate, CER result is the least of all compared systems.

PGI21

COST-EFFECTIVENESS OF PEGINTERFERON AND RIBAVIRIN FOR ELDERLY PATIENTS WITH CHRONIC HEPATITIS C: RESULTS BASED ON THE NATIONWIDE HEPATITIS REGISTRATION IN JAPAN

Shimbo T, Nagata-Kobayashi S, Masaki N, Study Group Developing Nationwide Database of Hepatitis Japan.
National Center for Global Health and Medicine, Shinjuku-ku, Tokyo, Japan

OBJECTIVES: The cost-effectiveness of peginterferon and ribavirin (PEG_IFN+RBV) for elderly patients with chronic hepatitis C (CHC) was investigated. A nationwide registration of interferon-treated hepatitis patients has been conducted in Japan since 2009. This study was based on individual patient data from the registration for investigation in a real-world setting. **METHODS:** PEG_IFN+RBV-treated CHC patients 65-years or older were analyzed. All registered patients received antiviral treatment, and were assumed to suffer if not treated. The incremental cost and effectiveness of treatment was estimated as the difference between actual events and the assumed longstanding disease status. The individual patient data regarding age, gender, and duration of and response to treatment was used to estimate cost of PEG_IFN+RBV, cost of following CHC, and quality-adjusted life-year (QALY). Incremental cost effectiveness ratio (ICER) and 95% bootstrap confidence interval (CI) were calculated, and probabilistic sensitivity analysis (PSA) was done for assumptions on the distribution of uncertain data. Conservative assumptions were used throughout the analysis. **RESULTS:** There were a total of 1378 patients (median age 68 y; range 65 – 80 y). 1005 patients had hepatitis C virus type 1 (72.9%), and 1269 had a high viral load (92.1%). A platelet count of <100,000/mm3 was found in 152 patients (11.0%), 100,000 – 150,000/mm3 in 541 patients (39.3%), and ³150,000/mm3 in 655 patients (47.5%). 1106 patients completed the planned treatment (80.3%). Sustained viral response was observed in 650 cases (47.2%), relapse in 404 cases (29.3%), and no response in 324 cases (23.5%). Incremental cost was calculated to be 1.885 million yen (approximately 16,390 euros) for a patient, and effectiveness was 0.657 QALY. ICER was 2.869 million yen (approximately 24,950 euros)/QALY (95% CI: 2.665 – 3.089 million yen /QALY). PSA showed that most trials had ICER of less than 4.00 million yen/QALY. **CONCLUSIONS:** The ICER of PEG_IFN+RBV for elderly patients with CHC seemed acceptable.

PGI22

THE EXTRA HEALTH CARE COSTS ASSOCIATED WITHANTIMICROBIAL PROPHYLAXIS IN COLORECTAL SURGICAL PATIENTS: AN EXPLORATION OF PROFILING DATA FROM A UNIVERSITY HOSPITAL IN JAPAN

Hirose M[1], Egami K[2], Tsuda Y[2], Oh EH[3]
[1]*Shimane University Hospital, Izumo, Shimane, Japan,* [2]*St. Mary's Hospital, Kurume, Fukuoka, Japan,* [3]*Hyupsung University, Hwaseong-Si, Gyeonggi-Do, South Korea*

OBJECTIVES: Postoperative infections bring about an expansion of length of hospital stay (LOS) and extra medical costs. **METHODS:** We analyze the relationship between variations in antimicrobial prophylaxis (AMP) and extra medical costs in surgical patients with colorectal malignancies. Utilizing profiling administrative data, we analyzed 161 admitted patients between 2007 and 2009 to a university hospital. We classified the patients into two classes based on AMP duration: the control group (112) and the case group (49). Most patients from both groups were appropriately given AMP agents consistent with the guidelines of infection-related associations. **RESULTS:** The LOS of the control group (24.6 ± 12.1 days) was shorter than that of the case (49.4 ± 35.2) ($p<0.05$). Hospitalization charge of the control group (15130 ± 3930 USD) was lower than that of the case (23130 ± 1212) ($p<0.05$), but hospitalization charge per day of the control group (670 ± 160 USD) was higher than that of the case (530 ± 130) ($p<0.05$). Furthermore, 73 cases of the control group were given on the day of surgery till the first postoperative day, and 39 cases were given to the second and third postoperative days. LOS of the former (22.7 ± 9.5 days) was shorter than that of the latter (28.3 ± 15.5) ($p<0.05$). **CONCLUSIONS:** AMP agents in our hospital were found to generally given according to the recommended guidelines. It is important for the hospital administrators to quantify the additional costs on top of the primary diagnosis in order to properly deal with infection control and hospital management.

Gastrointestinal Disorders – Patient-Reported Outcomes & Preference-Based Studies

PGI23

ECONOMIC IMPACT OF MEDICATION ADHERENCE AND PERSISTENCE IN THE TREATMENT OF ULCERATIVE COLITIS IN CANADA: ANALYSES WITH THE RAMQ DATABASE

Lachaine J[1], Yen L[2], Beauchemin C[1], Hodgkins P[2]
[1]*University of Montreal, Montreal, QC, Canada,* [2]*Shire Pharmaceuticals, Wayne, PA, USA*

OBJECTIVES: The aim of this study was to assess adherence and persistence to mesalamine treatment in ulcerative colitis (UC), and to evaluate the impact on health care resource utilization and cost from a Canadian health care system perspective. **METHODS:** A retrospective prescription and medical claims analysis was conducted using a random sample of UC patients with no diagnosis of Crohn's disease who were initiated on an oral mesalamine formulation from January 2005 to December 2009. Treatment adherence (medication possession ratio [MPR]) and persistence were calculated over a 1-year period after index prescription. To evaluate the economic impact of non-adherence and non-persistence, the number and all-cause costs of physician visits, emergency visits, and hospitalizations were estimated. Statistical comparisons, based on adherence and persistence, were made using the chi-square test for proportions and Student's t-test or the F-test from one-way ANOVA for means. Statistical significance was $p<0.05$. **RESULTS:** A sample of 1681 patients was obtained. The mean age of new oral mesalamine users was 55.3 years (SD=17.8), with a similar proportion of males and females. At month 12, 27.7% of patients had a MPR ≥80%, and 45.5% of patients were persistent on treatment. Over the 12-month period, there was a statistically significant difference in overall health care resource utilization and all-cause costs in non-persistent ($4973.57) versus persistent ($3256.23) patients to UC medications ($p<0.001$, unadjusted), with hospitalizations as the major cost driver. Similar numeric differences were observed for overall health care costs associated with non-adherence versus adherence ($4357.70 versus $3758.81, $p=0.277$, unadjusted). **CONCLUSIONS:** Adherence and persistence to oral mesalamine for the treatment of UC was relatively poor in this patient cohort. Furthermore, patients who were non-persistent

on therapy used more health care resources and were more costly during the 12-month observation period.

PGI24

BURDEN OF GASTROESOPHAGEAL REFLUX DISEASE AMONG PATIENTS WITH PERSISTENT SYMPTOMS DESPITE PROTON PUMP INHIBITOR THERAPY: AN OBSERVATIONAL STUDY IN FRANCE

Bruley des Varannes S[1], Granstedt H[2], Karlsson M[2], Wahlqvist P[2], Ruth M[2], Furstnau ML[3], Despiégel N[3], Stålhammar NO[2]
[1]University of Nantes, Nantes, France, [2]AstraZeneca R&D, Mölndal, Sweden, [3]OptumInsight, Nanterre, France

OBJECTIVES: Proton pump inhibitors (PPIs) are the treatment of choice for gastroesophageal reflux disease (GERD), yet many patients experience persistent symptoms. To date, the burden of illness (BoI) among partial responders to PPI treatment is not well understood. **METHODS:** REMAIN-France was a multicentre, 12-month prospective study of adults with GERD who were newly identified as partial responders to optimised PPI treatment. BoI was evaluated at baseline, 3, 6, 9 and 12 months via patient-completed questionnaires, including the Reflux Symptom Questionnaire with 7-day recall (RESQ-7). Medical evaluations were completed at baseline, 6 and 12 months. Healthcare consumption was evaluated in terms of visits to a primary care physician (PCP) and gastroenterologist, number of endoscopies and days on prescribed GERD medication. All analyses were descriptive. **RESULTS:** A total of 262 patients were enrolled (mean age, 54y; 40.5% men), the majority of whom (n=226, 86%) completed the 12-month study. Using the RESQ-7 questionnaire, 32% of patients reported severe symptoms and 48% reported daily symptoms at baseline despite PPI treatment. Whilst continuing to receive prescribed GERD medication (most commonly daily PPIs), symptoms remained burdensome at 6 and 12 months and indicated a positive relationship with impaired quality of life (SF-36, EQ-5D) and decreased work productivity (WPAI-GERD). Between baseline and 6 months, the mean number of visits to a PCP and gastroenterologist among all patients was 1.9 and 0.5, respectively. For 7-12 months' follow up the corresponding figures were 1.8 and 0.4, respectively. A total of 12 patients (4.6%) underwent endoscopy in the first 6 months of follow-up; thereafter, 10 patients (3.9%) underwent endoscopy between 7 and 12 months. **CONCLUSIONS:** In French patients with GERD who have persistent symptoms despite PPI therapy, the symptom burden is substantial and a positive relationship with impaired quality of life and decreased work productivity is indicated. Supported by AstraZeneca R&D, Mölndal, Sweden.

PGI25

CHRONIC HEPATITIS C (CHC) RELATED FLU-LIKE SYMPTOMS; DEVELOPMENT OF A PATIENT REPORT OUTCOME (PRO) MEASURE AND RESULTS FROM PILOT EFFICACY STUDIES

Mathias SD[1], Crosby R[1], Bayliss MS[2], Hillson J[3], Horga MA[4], L'Italien G[5], Sapra S[6]
[1]Health Outcomes Solutions, Winter Park, FL, USA, [2]QualityMetric Incorporated, Lincoln, RI, USA, [3]Zymogenetics/BMS, Seattle, WA, USA, [4]Bristol-Myers Squibb, Wallingford Center, CT, USA, [5]Bristol-Myers Squibb and Yale University School of Medicine, Wallingford, CT, USA, [6]Bristol-Myers Squibb, Princeton, NJ, USA

OBJECTIVES: Flu-like symptoms (pyrexia, chills, myalgia and arthralgia) are experienced by 30%-50% of chronic hepatitis C (CHC) patients undergoing combination interferon and ribavirin (RBV) treatment and are often cited as reasons for discontinuation. To track these symptoms, the Hepatitis Physical Symptom Severity Diary (HPSS-D), was developed. **METHODS:** Four items from the HPSS-D comprise the Flu-Like Symptom Index (Index): fever, chills, muscle aches/pain, and joint pain. Response options ranged from 0 (no symptoms) to 10 (worst symptom/problem) over the past 24 hours. The diary was completed for 7 consecutive days at baseline and weeks 4, 8 and 12. Data from two Phase 2b studies of treatment-naïve patients comparing pegIFNalpha2a/RBV (peg-alfa) to peg-INF Lambda/RBV (peg-lambda) and peg-alfa to peg-alfa and direct acting antiviral were combined. Measurement properties were assessed. Mean and change scores and proportions of patients reporting flu-like symptoms were calculated. **RESULTS:** Measurement properties of the Index were supported with test-retest ICC value of 0.85, Cronbach's alpha range: 0.73-0.81, low to moderate construct validity [range: 0.23-0.63], and demonstrated known groups validity (based on physician-reported flu symptoms). Responsiveness coefficients suggested a small to medium effect (SES=0.40; SRM=0.39). MIDs were 2.5-3.0 points. Mean Index scores at week 12 for the peg-alfa group (N=36) increased from baseline by 2.39 ± 4.95 versus 0.83 ± 5.05 for peg-lambda patients (N=26). The percentage reporting any flu-like symptoms was significantly higher for peg-alfa (75%) versus peg-lambda patients (27%) at week 12, ($p<0.001$), despite similar baseline rates. Fewer peg-lambda versus peg-alfa patients (50% versus 82%) experienced clinically significant worsening of flu-like symptoms. **CONCLUSIONS:** PRO measures are important parameters to gauge patients' experience with treatment, providing systematic assessment of treatment benefit and side effects. This new Flu-Like Symptom Index from the HPSS-D demonstrated adequate measurement properties and detected lower intensity and frequency of flu-like symptoms for peg-lambda versus peg-alfa patients.

PGI26

EVALUATING THE IMPACT OF GASTROINTESTINAL EPISODES ON THE HEALTH-RELATED QUALITY OF LIFE OF SOLID ORGAN TRANSPLANT RECIPIENTS: VALIDATION OF THE SIGIT-QOL® QUESTIONNAIRE – THE MYPACIENTE 1 & 2 STUDIES

Balaña M[1], Lahoz R[1], Ortega F[2], Puig JM[3], Paul-Ramos FJ[4], Guinea G[1]
[1]Novartis Farmacéutica, S.A., Barcelona, Spain, [2]Hospital Universitario Central de Asturias, Oviedo, Spain, [3]Hospital Del Mar, Barcelona, Spain, [4]Hospital Miguel Servet, Zaragoza, Spain

OBJECTIVES: To develop and validate a clinically useful instrument for assessing the impact of gastrointestinal symptoms (GI) on the health-related quality of life (HRQoL) of solid organ transplant (SOT) patients (kidney, liver, heart or lung). **METHODS:** Two phases: the Mypaciente-1 study was an epidemiological, cross-sectional, multicentre study in which the SIGIT-QoL® questionnaire (17 items) was developed and its reliability, feasibility and validity (content and construct) were proven. At second, an observational, prospective, multicentre study, the Mypaciente-2, was implemented to assess the test-retest reliability and the sensitivity to change of the SIGIT-QoL®. SOT patients aged≥18, who had received the graft 3-24 months before and suffering from GI, were evaluate at baseline, 1-2 weeks and 3 months after baseline. Data recorded: age, sex, SOT type, acute allograft rejection (AAR), GI etiology, Clinical and Patient global Impression scale (CGI-SI&GI and PGI-SI&GI) and the SIGIT-QoL® (range: 0-maximum impact to 68-minimum disruption). Intraclass correlation (ICC), differences between baseline and last visit (Wilcoxon test), effect size (Cohen's d), the minimal important difference –MID- (using CGI & PGI as anchors in General Linear Models) and the cut-off score (ROC analysis) were calculated. **RESULTS:** In the Mypaciente-2 study 277 SOT patients (61.4% males) were included. Mean age (SD) was 52.69(11.65) years, time since transplantation was 12.31(6.74) months and 22.4% suffered AAR. At baseline, SIGIT-QoL® scores: 51.21(11.25) showed an impact on patients' HRQoL that diminished 3 months later: 57.40(8.38;$p<0.001$). SIGIT-QoL® test-retest reliability was adequate (ICC=0.740-0.895). A high-moderate effect size (d=-0.590) was found. Moreover, MID of 4.2 points in total scores were found ($F4,223=16.917, p<0.001$ and $F4,224=25.138, p<0.001$). Finally, a cut-off point (55.00 points) was estimated (AUC=0.846,$p<0.001$; sensitivity=0.793; specificity=0.713; negative likelihood ratio=0.290; positive likelihood ratio=2.762). **CONCLUSIONS:** The SIGIT-QoL® is a feasible (average completion time lower than 6.5 minutes), reliable and valid instrument for assessing the impact of GI symptoms on SOT patients.

PGI27

SLEEP DISTURBANCE AND QUALITY OF LIFE AMONG HEPATITIS C INFECTED INDIVIDUALS

Wagner JS, Gross HJ, DiBonaventura MD
Kantar Health, New York, NY, USA

OBJECTIVES: Hepatitis C virus (HCV) infection is associated with fatigue, anxiety, and depression. Little is known, however, about the effect of sleep disturbances on health-related quality of life (HRQoL), and what factors are associated with such disturbances. **METHODS:** This study is based on data from the EU National Health and Wellness Survey (N=57,805), a cross-sectional database representative of the adult EU population. Patients who reported being diagnosed with HCV by a physician and provided household income and body weight information were included for analysis (N=301). Patients who reported experiencing insomnia or sleep difficulty symptoms in the past year (n=135) were compared with patients who did not experience such symptoms (n=166). Sleep group membership was predicted with a logistic regression model, while mental and physical HRQoL (SF-12) were predicted with multiple regression models. Covariates included age, gender, marital status, education, income, employment, BMI, exercise and smoking habits, alcohol use, and physician diagnosed HIV/AIDS, hepatitis B, anxiety disorder, and depression. **RESULTS:** HCV patients with sleep disturbances were significantly younger (48.8 vs. 51.7) and more likely to be diagnosed with HIV/AIDS (8.1% vs. 2.4%), an anxiety disorder (56.3% vs. 22.9%), and depression (48.9% vs. 10.8%) (ps<0.05) than patients with no sleep disturbances. After controlling for potential confounders, anxiety disorder (OR=2.2) and depression (OR=5.1) were the only significant predictors of sleep disturbances (ps<0.05). SF-12 mental HRQoL scores were significantly associated with age (b=0.2), anxiety disorder (b= -5.7), depression (b= -5.9), and sleep disturbances (b= -5.1, ps<0.05). SF-12 physical HRQoL scores, however, were not associated with sleep disturbance. **CONCLUSIONS:** Despite the strong association of anxiety disorder and depression with sleep disturbances among HCV-infected individuals, sleep disturbances had an independent and significant effect on mental HRQoL in this population. The results suggest effective treatment of disturbed sleep may improve the quality of life of HCV patients.

PGI28

DISEASE-SPECIFIC HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH QUIESCENT ULCERATIVE COLITIS: EFFECTS OF ONE YEAR MAINTENANCE TREATMENT WITH MMX MESALAMINE

Solomon D[1], Yarlas A[2], Yen L[3], Hodgkins P[3], Karlstadt R[1], Kane SV[4]
[1]Shire Pharmaceuticals, Wayne, PA, USA, [2]QualityMetric Incorporated, Lincoln, RI, USA, [3]Shire Development, Inc., Wayne, PA, USA, [4]Mayo Clinic, Rochester, MN, USA

OBJECTIVES: Active ulcerative colitis (UC) negatively impacts patients' health-related quality of life (HRQoL); thus a fundamental goal of treatment is to achieve and maintain disease remission. The current analysis examines how long-term maintenance treatment with a multi-matrix (MMX) oral formulation of mesalamine impacted disease-specific HRQoL in patients with quiescent UC. **METHODS:** This analysis examined the 12-month maintenance phase of a two-phase, multicenter, open-label study, during which patients with quiescent UC at baseline received MMX mesalamine 2.4 g/day QD. Disease-specific HRQoL was measured at baseline, six-month, and twelve-month (endpoint) visits using the Shortened Inflammatory Bowel Disease Questionnaire (SIBDQ), which measures 4 domains: bowel symptoms, systemic symptoms, emotional function and social function. Changes in SIBDQ domains and total score over time were assessed using repeated-measures analysis of variance. Correspondence between disease-specific HRQoL and disease activity was assessed using analysis of covariance to compare SIBDQ scores at month 12 between clinically recurrent and non-recurrent patients while controlling for age, gender, and BMI. **RESULTS:** Data were collected from 203, 144, and 157 patients at baseline, 6-month, and 12-month/early withdrawal visits, respectively.

For the overall patient sample, no statistically significant changes across visits was observed for any SIBDQ domain or total score (all P>0.05); mean change from baseline to endpoint did not exceed 3% for any SIBDQ score. At endpoint, patients exhibiting recurrent UC (n=29) scored significantly lower than non-recurrent patients (n=117) on bowel symptoms, emotional function, and social function domains and total score (P<0.001 for all differences). **CONCLUSIONS:** Patients with quiescent UC receiving daily treatment with MMX mesalamine (2.4 g/day) exhibited high stability, and thus strong maintenance, in disease-specific HRQoL over the course of one year. The majority of patients remained in clinical remission following one year of this treatment regimen. Patients with clinically recurrent UC showed significantly worse HRQoL outcomes than non-recurrent patients.

PGI29

QUALITY OF LIFE IN CHRONIC LIVER DISEASE

Anapaz V[1], Vicente C[2], Almeida A[1]
[1]*Universidade da Beira Interior, Covilhã, Portugal,* [2]*Centro Hospitalar Cova da Beira, Covilhã, Portugal*

OBJECTIVES: Chronic liver disease is responsible for approximately 40,000 deaths annually, which corresponds to about 2% of all deaths worldwide. This study aimed to specify and understand the characteristics of patients with LC service followed in the Gastroenterology at *CHCB* as well as assess the severity of LC using the scale of Child-Pugh-Turcotte and the Health Related Quality Of Life. **METHODS:** This is a retrospective, observational and cross for the evaluation of QdVS a group of patients diagnosed with LC in CHCB. Direct interviews were carried out using questionnaires to a sample of 42 patients with clinical and imaging during the months of January and April 2011. Besides the descriptive analysis we tried to establish some correlations between the variables studied, considered statistically significant when p value is <0.05. **RESULTS:** The mean age of study participants was 62 years, and approximately 31% of patients were between 66 and 75 years. The males and ethylic etiology of cirrhosis accounted for a proportion of over 90% of all patients. The average score obtained after applying the SF-36 was around 49%. After the calculation made to stratify the severity of the disease across the range of CPT, 69% of patients were in class A, class B 21% and 10% to class C. **CONCLUSIONS:** The LC mainly affects males, and regular alcohol consumption the predominant etiology. Regarding the scale of CPT, the results indicate a good survival. We conclude that the QdVS is clearly affected in CLD associated with LC, particularly in terms of physical pain, physical performance and vitality. This study is consistent with national data, where the Liver Cirrhosis is a public health problem, for which measures must be taken concerning the excessive consumption of alcoholic beverages.

PGI30

COMPARISON OF HEALTH RELATED QUALITY OF LIFE BETWEEN HEPATITIS, CIRRHOSIS, LIVER TRANSPLANTATION AND HEPATIC CARCINOMA: RESULTS OF THE COME STUDY

Ciampichini R
Charta Foundation, Milano, Italy

OBJECTIVES: As a result of successful treatments for chronic hepatic diseases (CHDs), patients generally live longer but often with a compromised wellbeing. We assessed Health-Related Quality-of-Life (HRQoL) of CHDs adult patients. **METHODS:** A naturalistic multicentre Cost-of-Illness study was conducted. Adult patients (age>18 years) diagnosed with CHDs, consequently accessing at gastroenterology unit of 2 hospitals, were enrolled. Direct, indirect and intangible costs were estimated from the societal perspective. The patients were sub-grouped according to their main condition at the enrollment: hepatitis B and/or C, cirrhosis, liver transplantation, hepatic carcinoma. HRQoL was assessed with the EQ-5D 3L and 5L versions (the psychometric properties of the 5L new version was previously discussed: podium by Scalone et al, 13th ISPOR Congress 2011, Prague). The following results pertain the EQ-5D-5L results. **RESULTS:** We enrolled 1,088 valid patients, 62% male, aged 19-90 (median=60) years. Patients with hepatitis were 60.4%, 20.2% had cirrhosis, 11.9% had liver transplantation, 7.5% hepatic carcinoma. Among all the patients, the mean+SD VAS was 69.1+20.8. Mobility was an extreme/severe problem for 3.3% and a moderate/slight problem for 22.6% of the patients. Self-care was an extreme/severe problem for 1.2% and a moderate/slight problem for 11.5% of the patients. Usual activities was an extreme/severe problem for 4.0% and a moderate/slight problem for 25.5% of the patients. Pain/discomfort was extreme/severe for 3.2% and a moderate/slight problem for 36.1% of the patients. Anxiety/Depression was extreme/severe for 4.5% and a moderate/slight for 43.5% of the patients. Patients with cirrhosis reported the worst levels of HRQoL, those with carcinoma had a worse HRQoL than patients with transplantation, those with hepatitis reported better levels of HRQoL. **CONCLUSIONS:** Our study shows how HRQoL is negatively related with the severity and chronicity of CHDs. Health technology aimed to improve wellbeing in patients with disabling long term hepatic disease is required.

PGI31

THE MAINTENANCE OF WORK-RELATED PRODUCTIVITY DURING ONE YEAR OF MMX MESALAMINE TREATMENT FOR PATIENTS WITH QUIESCENT ULCERATIVE COLITIS

Yen L[1], Yarlas A[2], Hodgkins P[1], Solomon D[3], Karlstadt R[3], Kane SV[4]
[1]*Shire Development, Inc., Wayne, PA, USA,* [2]*QualityMetric Incorporated, Lincoln, RI, USA,* [3]*Shire Pharmaceuticals, Wayne, PA, USA,* [4]*Mayo Clinic, Rochester, MN, USA*

OBJECTIVES: Ulcerative colitis (UC) impairs patients' productivity in the workplace. While studies have shown increased productivity in patients with active UC following treatment with a multi-matrix (MMX) oral formulation of mesalamine, the current analysis is the first to examine maintenance of work-related outcomes (WRO) in patients with quiescent UC who received one year of MMX mesalamine treatment. **METHODS:** Data were from a multicenter, open-label study of patients with quiescent UC who received MMX mesalamine 2.4 g/day QD for twelve months. The Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP), administered at baseline, six-month, and twelve-month visits, measured the impact of a patient's UC on 4 domains: absenteeism, presenteeism, overall productivity, and impairment in non-work activities. Repeated-measures analysis of variance assessed change in scores across visits. Analysis of covariance assessed the association between WRO and disease activity (covariates: age, gender, and BMI) by comparing WPAI:SHP scores between patients with clinically recurrent and non-recurrent UC at 12 months. **RESULTS:** WPAI:SHP scores were collected from 198 patients at baseline, 142 patients at six months, and 154 patients at 12 months/early withdrawal (endpoint). Stability of WRO across 12 months for the overall sample was evidenced by baseline-endpoint changes in mean scores of <2% for each WPAI:SHP scale, with no statistically significant differences across visits (all P>0.05). Patients with clinically recurrent UC at month 12 (n=29) scored significantly worse than non-recurrent UC patients (n=113) on presenteeism, overall productivity, and activity impairment, P<0.05 for differences. **CONCLUSIONS:** Patients with quiescent UC who received MMX mesalamine 2.4 g/day QD showed stable WRO over the course of one year. Findings indicate that long-term MMX mesalamine treatment was associated with maintenance of WRO for patients with quiescent disease. This treatment regimen maintained clinical remission for the majority of patients, with recurrent patients showing worse WRO than non-recurrent patients.

Gastrointestinal Disorders – Health Care Use & Policy Studies

PGI32

AN INVESTIGATION INTO THE EXTENSIVE SPECTRUM OF AGENTS USED FOR THE MANAGEMENT OF POST-OPERATIVE ILEUS

Richard L[1], Kusel J[2], Hamerslag L[2], Leonard SA[2]
[1]*Norgine Limited, Uxbridge, -, UK,* [2]*Costello Medical Consulting Ltd, Cambridge, UK*

OBJECTIVES: Regardless of the wide variation in estimated incidence rates for post-operative ileus (POI), it is widely understood that gastrointestinal complications represent the most common post-operative morbidity type. In addition to the patient burden, the extension of hospital stay caused by POI (estimated to be between 3.2 and 8 days) can have an enormous economic impact, making this an important area of research. The objective of this literature review was to explore the various interventions investigated for the acceleration of gastrointestinal recovery after surgery and reduction of POI. **METHODS:** Comprehensive literature searches across online databases and horizon scanning were used to identify relevant literature. Literature was gathered on any intervention that had been assessed in a randomised clinical trial for the treatment of POI following abdominal surgery. **RESULTS:** Over 600 studies were identified as potentially relevant. Approximately one quarter of these assessed the broad spectrum of prokinetic pharmacological agents for the treatment of POI, as well as antiemetics, antibiotics and anaesthetics. In particular, research into new ghrelin agonists is underway. Next to this, the unfavourable effects of opioid analgesics on GI recovery were studied in numerous trials. Non-pharmacological methods to enhance recovery after surgery such as gum chewing, acupuncture and early feeding have also been investigated with mixed success. Many of the trials identified were dated, illustrating how long POI has remained an unresolved issue for clinicians and patients. **CONCLUSIONS:** Many different types of treatment, with varying mechanisms of action, have been clinically studied for the prevention or treatment of POI over the past 40 years. However, there is still no standard management paradigm to accelerate post-operative bowel recovery. The absence of an effective pharmacological agent licensed for this indication in Europe and significant variance in practice suggest an unmet clinical need, which should shape future research in this area.

PGI33

PREDICTORS OF DIRECT MEDICAL COSTS OF CROHN'S DISEASE AND ULCERATIVE COLITIS

Stark RG[1], Hunger MF[2], Reitmeir P[1], König HH[3], Leidl R[1]
[1]*Helmholtz Zentrum Munich, Neuherberg (by Munich), Germany,* [2]*Helmholtz-Zentrum München, German Research Center for Environmental Health, Neuherberg, Germany,* [3]*University Medical Centre Hamburg-Eppendorf, Hamburg, Germany*

OBJECTIVES: Cost predictions are useful to identify patients with special needs early. Crohn's disease (CD) and ulcerative colitis (UC) are complex conditions which are classified as Inflammatory Bowel Diseases (IBD). Disease onset in early adulthood leads to a long period of healthcare utilisation. The goal of this study was to determine the effect of disease activity and disease history on overall medical costs and to determine whether additional factors predict costs for CD and UC. **METHODS:** Medical history, demographic information and healthcare use (4 weeks) were reported by German IBD-Association members. Healthcare costs were calculated using national sources. Disease activity was determined using a German IBD Index. Patients classified their disease history as constantly-active, intermittently-active or in remission. Other factors evaluated were education, marital status, health insurance, an IBD-related operation (at least 3 months ago), smoking status and employment status. Missing values for determinants were imputed using the Markov-chain-Monte-Carlo method. Cost determinants were analysed using a gamma regression model, adjusting for age, sex, disease duration and for previous colectomy in UC patients. Costs of CD and UC were analysed separately. **RESULTS:** The 4-week mean direct medical costs were 424.44€ for CD (n=241) and 365.79€ for UC (n=238). Mean disease activity (CD: 3.3 UC: 3.2) was similar between the groups and 46% of both CD and UC subjects reported disease history as in

remission. Significant predictors of medical costs ($p<0.05$) were disease activity, disease history for both groups, age and employment status for CD subjects and previous colectomy for UC subjects. **CONCLUSIONS:** Our analyses show that medical costs of patients with IBD can in part be predicted. However, predictors differ between CD and UC patients: Disease activity and disease history are the most important cost predictors, while age and employment status are only important cost predictors for CD patients.

Individual's Health – Clinical Outcomes Studies

PIH1

COMPARISON OF UNINTENDED PREGNANCY RATES IN USERS OF 84/7, 21/7, AND 24/4 ORAL CONTRACEPTIVE REGIMENS

Brewster C[1], Howard B[2], Lage M[3]
[1]*Teva Pharmaceuticals, Kansas City, MO, USA,* [2]*Teva Branded Pharmaceutical Products R&D, Inc., Horsham, PA, USA,* [3]*HealthMetrics Outcomes Research, Groton, CT, USA*

OBJECTIVES: To compare pregnancy rates post initiation on oral contraceptive (OC) users of 84 days levonorgestrel/ethinyl estradiol (EE) 0.15mg/0.03mg tablets plus EE 0.01mg for 7 days in place of placebo (84/7) or, 21 days combined EE/progestin plus 7 days placebo (21/7) or 24 days EE/progestin plus 4 days placebo (24/4) over the course of 1 year. **METHODS:** Data for this study were obtained from the US i3 Invision™ Data Mart and spanned the period from January 1, 2006 through March 31, 2010. Patients were included if they received the medication of interest (with first such receipt identified as index date), were age 15-40 on index date, and had continuous insurance coverage from index date through 1 year post index date. Two distinct analyses were performed: 1 comparing pregnancy rates post initiation on an 84/7 or 21/7 OC and the other comparing pregnancy post initiation on an 84/7 or 24/4 OC. The 84/7 cohort was matched to each of the alternative cohorts of interest based upon age, sex, region, business type of insurance, insurance product, and year of index date. **RESULTS:** There were 5,821 individuals in the 84/7 cohort, 650,816 individuals in the 21/7 cohort, and 111,540 individuals in the 24/4 cohort. Matching of the 84/7 cohort to each of the alternative cohorts resulted in a successful match rate of over 99% when comparing 84/7 to 21/7 or comparing 84/7 to 24/4. Pregnancy rates in the 1 year post initiation on an OC were found to be statistically significantly lower for initiators of 84/7 compared to 21/7 (3.04% vs. 5.12%; $P<0.0001$) as well as when comparing 84/7 to 24/4 (3.03% vs. 5.28%; $P<0.0001$). **CONCLUSIONS:** In this study, pregnancy rates were significantly lower in women using an 84/7 OC regimen compared to 21/7 or 24/4 regimens.

PIH2

CARESS: THE CANADIAN REGISTRY OF SYNAGIS (2005-2010)

Paes BA[1], Mitchell I[2], Li A[3], Lanctot KL[3]
[1]*McMaster University, Hamilton, ON, Canada,* [2]*University of Calgary, Calgary, AB, Canada,* [3]*Sunnybrook Health Sciences Centre, Toronto, ON, Canada*

OBJECTIVES: To evaluate the current management of children at high-risk of RSV infection who received palivizumab prophylaxis and were enrolled in the Canadian Registry Database. **METHODS:** A prospective, observational, registry of infants who received at least 1 dose of palivizumab during the 2005-2010 RSV seasons across 29 sites. Neonatal and demographic data were collected from the parent/caregiver at enrollment. Data on palivizumab utilization, compliance, and outcomes related to respiratory illness (RI) events were collected monthly. **RESULTS:** A total of 7699 infants were enrolled with an average age of 5.4±6.0 months. Participants were typically male (56.2%), Caucasian (71.5%) with an average gestational age (GA) of 32.2±6.0 completed weeks. A total of 5237 (68.0%) infants received palivizumab for prematurity (≤35 completed weeks GA without underlying medical disorders), 646 (8.4%) had chronic lung disease, 766 (9.9%) hemodynamically significant congenital heart disease and 1050 (13.6%) were prophylaxed for other conditions such as CNS disorders, airway anomalies and cystic fibrosis. Patients received an average of 3.9±1.6 injections and 30,040 doses overall; 5.5% of patients withdrew from the study. No direct, drug related serious adverse events were identified. 460 infants had a total of 541 RI hospitalizations resulting in a hospitalization rate of 6.0%.The overall RSV positive hospitalization (RSVH) rate was 1.47%. Living with siblings ($p=0.046$) and having >5 individuals in the household ($p=0.007$) was significantly associated with time to a patient's first RSVH. Other risk factors traditionally associated with a higher risk for RSV infection, such as gender ($p=0.429$), smoking ($p=0.182$), daycare attendance ($p=0.079$), age ($p=0.213$), and compliance with treatment ($p=0.695$) were not found to be significantly correlated. **CONCLUSIONS:** The RSVH observed from 2005-2010 was 1.4% overall (range 0.3% - 2.1%) and compares favorably with international registry data despite the steady increase in the number of Canadian immunized infants with serious underlying medical disorders.

PIH3

RESPIRATORY SYNCYTIAL VIRUS HOSPITALIZATIONS IN THE CANADIAN REGISTRY FOR SYNAGIS (CARESS)

Paes BA[1], Li A[2], Lanctot KL[2], Mitchell I[3]
[1]*McMaster University, Hamilton, ON, Canada,* [2]*Sunnybrook Health Sciences Centre, Toronto, ON, Canada,* [3]*University of Calgary, Calgary, AB, Canada*

OBJECTIVES: Paediatric advisory committee guidelines recommend palivizumab prophylaxis for specific sub-populations of infants at high risk for respiratory syncytial virus (RSV) infection. However, effectiveness of palivizumab may vary across indications and countries. The objective of our study was to determine hospitalization rates for respiratory illness (RIH) and RSV-positive infections (RSVH) following prophylaxis and compare rates found in this study with other world-wide data from published registries. **METHODS:** Neonatal and demographic data were collected prospectively across 29 national sites as part of an established CAnadian REgistry for SynagiS (CARESS) database from infants who received ≥1 dose of palivizumab during the 2005-2010 RSV seasons. Respiratory illness (RI) events were documented monthly. **RESULTS:** The 7699 infants enrolled were premature (≤35 completed weeks gestational age, without any underlying medical illnesses; n=5237), had chronic lung disease/bronchopulmonary dysplasia (n=646), hemodynamically significant congenital heart disease (n=766), or had other pre-existing conditions such as neuromuscular impairments, Down syndrome, pulmonary or airway malformations, immunocompromise or cystic fibrosis (n=1050). The overall RIH rate was 6.0%. Premature infants had a significantly lower rate (4.1%) than the other groups (range 8.7% -11.5%; B=-0.912, df=1, $p<0.005$). The overall RSVH rate was 1.47% with significant differences between groups (range 1.22% - 2.46%; $\chi 2=22.606$, df=3, $p<0.0005$). Apart from hospital length of stay, morbidities differed significantly across the sub-groups during RSVH including number of ICU admissions and length of stay, number ventilated and duration of intubation, number requiring respiratory support and duration (all $p<0.05$). **CONCLUSIONS:** Hospitalization rates for RI events and RSV illness were different across the groups. Comparisons with other registries indicate that RSVH rates are in the lower range overall (range 1.3 -8.1%); however, comparisons are difficult to establish as most studies do not account for the varying lengths of observation that arise because infants are enrolled at different times during the RSV season.

PIH4

A COMPARATIVE STUDY OF RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLAXIS IN PREMATURE INFANTS

Paes BA[1], Li A[2], Lanctot KL[2], Mitchell I[3]
[1]*McMaster University, Hamilton, ON, Canada,* [2]*Sunnybrook Health Sciences Centre, Toronto, ON, Canada,* [3]*University of Calgary, Calgary, AB, Canada*

OBJECTIVES: Infants 33-35 completed weeks' gestational age (GA) and those ≤ 32 weeks GA incur similar rates of respiratory syncytial virus hospitalization (RSVH) and morbidities which targets them as risk groups for RSV prophylaxis in current international pediatric advisory statements. We examined immunization regimens, compliance and outcomes of premature infants who received palivizumab within the Canadian Registry Database (CARESS). **METHODS:** Neonatal and demographic data were collected from infants receiving ≥1 dose of palivizumab during the 2006-2010 RSV seasons across 29 recruitment sites. Respiratory illness (RI) events were captured monthly. Premature infants' ≤32 weeks GA without pre-existing medical disorders (Group 1) was compared to a similar moderate-high risk group 33-35 completed weeks GA (Group 2) who received prophylaxis. **RESULTS:** 4819 patients were analyzed (Group 1, n=3746; Group 2, n=1073). Mean GA: 30.0± 3.1 versus 34.2±2.0. The groups were similar for proportion of Caucasians, mothers' who smoked daily and during pregnancy, history of atopy and number of multiples in the family. There were significant differences (Group 1, Group 2; $p<0.005$) in: mean birth weight (g) (1445±606 versus 2142±521), proportion of males (54.3% versus 63.1%), and number with siblings (54.2% versus 74.6%), siblings in daycare (13.9% versus 35.0%), ≥2 household smokers (9.9% versus 14.0%) and ≥ 5 individuals living in the household (22.7% versus 44.0%). Group 1 had significantly more complicated neonatal courses. Overall infants received 91.9%±30.7% of expected number of injections. Group 1 received more injections (3.9±1.7 versus 3.5±1.6; $p<0.005$) and had higher compliance rates (92.8% versus 88.9%; $p<0.005$). Respective RI and RSVH rates (4.5% versus 3.4%; hazard ratio=0.852, $p=0.385$) and (1.30% versus 1.3%; hazard ratio=1.233, $p=0.543$) were similar. **CONCLUSIONS:** Overall compliance with RSV prophylaxis in the premature population is high and despite the higher number of palivizumab doses in infants ≤32 weeks GA, group RI and RSVH rates were similar.

PIH5

RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLAXIS IN SPECIAL POPULATIONS

Paes BA[1], Li A[2], Lanctot KL[2], Mitchell I[3]
[1]*McMaster University, Hamilton, ON, Canada,* [2]*Sunnybrook Health Sciences Centre, Toronto, ON, Canada,* [3]*University of Calgary, Calgary, AB, Canada*

OBJECTIVES: To compare palivizumab utilization and compliance in infants who meet standard indications for RSV prophylaxis versus those with pre-existing medical disorders within the Canadian Registry Database (CARESS). **METHODS:** A prospective, observational registry of infants across 29 sites who received at least 1 dose of palivizumab during the 2006-2010 RSV seasons. Neonatal and demographic data were collected from the parent/caregiver at enrollment. Data on palivizumab utilization, compliance, and outcomes related to respiratory illness (RI) events were collected monthly. Premature infants' 35 completed weeks' gestational age (GA) without medical conditions who met standard approval criteria for palivizumab (Group 1) were compared to infants with underlying medical illnesses (Group 2). **RESULTS:** 5832 patients were analyzed (Group 1, n=4880; Group 2, n=952). The two groups were similar in terms of gender (male: 56.4% versus 55.6%; $p=0.829$). Group 2 infants included Down syndrome (n=193, 20.3%), upper airway anomalies (n=178, 18.7%), pulmonary disorders (n=127, 13.3%), cystic fibrosis (n=117, 12.3%), neuromuscular impairment (n=78, 8.2%), multiple system disorders (n=57, 6.0%), cardiac disorders (n=22, 2.3%), immunocompromise (n=17, 1.8%), and miscellaneous (n=163, 17.1%). From 2006-2010, the proportion of Group 2 infants receiving prophylaxis increased 3.4-fold from 5.6% (69/1224) to 19.1% (462/2413). Overall, Group 2 infants were older at enrollment (10.2 ± 9.2 versus 3.5 ± 3.1 months, $p<0.005$), had a significantly higher GA (35.9 ± 6.0 versus 31.0 ± 5.4 completed weeks, $p<0.005$) and had significantly higher RI (9.0% versus 4.2%, $p<0.005$) and RSV hospitalization (2.35% versus 1.32%, $p=0.003$) rates. A lower proportion of Group 2 infants were compliant with treatment (69.4% versus 72.6%, $p=0.048$). There were no serious adverse events directly related to palivizumab.

CONCLUSIONS: Results imply that infants with underlying medical disorders that are not specifically approved for prophylaxis by advisory bodies and current position statements are at significant risk for hospitalization with respiratory illness and RSV infections and may benefit from immunization.

PIH6

TREATMENT PATTERNS AND ASSOCIATED CLINICAL AND ECONOMIC OUTCOMES OF WOMEN TREATED WITH HORMONE THERAPY

Xie L[1], Baser E[2], Baser O[3]
[1]*STATinMED Research, Ann Arbor, MI, USA,* [2]*STATinMED Research, Tilburg, The Netherlands,* [3]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA*

OBJECTIVES: Compare clinical, economic outcomes among women treated with hormone therapy (HT) with different treatment patterns. **METHODS:** We conducted a retrospective database analysis using commercial enrollees from a large US health plan from 2002 to 2010. HT initiators during the identification period from 2005 to 2008 were included. The first HT prescription date was the index date. Women aged 40 and older, having no evidence of pregnancy during the follow-up period were selected. Continuous enrollment for 3 years pre- and 2 years post-index was required. Patients were divided into groups based on HT initiation (Group A: No menopause diagnosis; Group B: within 1 year of diagnosis; Group C: 1-2 years after diagnosis; Group D: 2-3 years after diagnosis). Propensity score matching (PSM) was used to adjust baseline differences in age, region, medication type, prescription fills, and pre-index costs and utilizations. Group B was a reference group (patients with earliest treatment after menopause diagnosis). **RESULTS:** Among 14,008 eligible patients, 8,228 were included in group A, 2,418 in group B, 1,491 in group C, and 1,871 in group D. After comparing A and B using PSM, 2,418 patients from each group were matched. Group A was more likely to have osteoporosis, post-menopausal osteoporosis, hysterectomy, outpatient visits, and had a lower medication persistence ratio (MPR) than Group B. A total of 1480 patients were matched when comparing groups C and B. Group C was more likely to use bisphosphonates. After comparing groups D and B, 1,713 patients were matched. Group D used more bisphosphonates and was more likely to have osteopenia and higher pharmacy costs. **CONCLUSIONS:** HT initiators within 1 year had fewer comorbidities than HT initiators 3 years or more, following menopause diagnosis. Compared to HT initiators after 1 year, but within 3 years of menopause diagnosis, HT initiators within 1 year of diagnosis used fewer bisphosphonates.

PIH7

THE EFFICIENCY OF IN VITRO FERTILIZATION IN HUNGARY 2000-2010

Gresz M[1], Varga S[2], Boncföldi K[3], Sebestyén A[4], Kriszbacher I[2], Boncz I[2]
[1]*National Health Insurance Fund Administration, Budapest, Hungary,* [2]*University of Pécs, Pécs, Hungary,* [3]*Semmelweis University, Budapest, Hungary,* [4]*South-Trasdanubian Regional Health Insurance Fund Administration, Pécs, Hungary*

OBJECTIVES: In Hungary there are 10 institutes doing in vitro fertilization (IVF). The aim of the study was perform a data analyzis of the efficiency in an eleven-year period of Hungary involving all of the institutes' data. **METHODS:** The database of the Hungarian National Health Insurance Fund Administration (NHIFA), the only health care financing agency in Hungary, was taken for the study. The analysis covers an 11 years period between 2000 to 2010. IVF success rate was defined as the proportion of number of live births and the number of IVF treatments. **RESULTS:** A total of 71,634 IVF treatments were done between 2000 and 2011 in the 10 institutes. 50 % of the IVF treatments were done from the age of 30 to 36. The total number of live births was 25,468. The number of single deliveries was 21,400 (84 %), twins 3779 (14.8 %), triplet 284 (1.1 %) and quadruplet 5 (0.02 %). The overall 11 year IVF success rate was 35.6 %. The success rate showed significant differences among IVF centers in a range of 31-49 %. The two largest IVF centres had a market share of 60.9 % and their success rate was 38.4 % and 34.3 % respectively. The highest efficiency was at the age of 34 (43.1 % birth rate). **CONCLUSIONS:** The mean of the IVF efficiency was 35.6 % in Hungary in the last 11 years. The best result was in the group of the patient at the age of 30-36. The efficiency could be increased if the selection of the patients were defined more precisely.

PIH8

IMPACT ASSESSMENT OF SPORT- RECREATION TRAINING

Szovák E, Tóth Á, Boncz I, Jeges S, Kriszbacher I
University of Pécs, Pécs, Hungary

OBJECTIVES: Present research aims at impact assessment of a two-year individualized sports-recreational training programme performed regularly in relation to living profile, self-rated health and salutogenetic sense of coherence (SOC). **METHODS:** Enrolling volunteers participating weekly in sports and recreational trainings for various reasons (health preservation, body toning etc.) were assessed between 2008 and 2010 (n=106, aged 17-61, woman=73). Their health and wellness status was continuously controlled, and duration, type and difficulty of trainings were determined accordingly. At the beginning and at the end of the programme status and changes were assessed by Optimal Life Profile (OLP) worked out by Renger and colleagues, Antonovsky's SOC-scale, the 4-grade self assessment of health and Hennenhofer-Heil's vegetative lability index (VELA). Data were analyzed by paired Wilcoxon-test and multivariate logistic regression model. **RESULTS:** Compared to health and wellness status before the training programme a significantly positive change could be demonstrated both in dimensions of OLP and on VELA and SOC-scales. The global indices in all cases were $p<0.001$ according to the Wilcoxon-test. Age, sex, weekly regularity and duration of trainings were the independent variables in the multivariate logistic regression model. The probability of improving general health status was not influenced by any of the predictors, however, the chance of improving vegetative lability was significantly greater among women (p=0.012, OR= 5,5, CI95% 1,4-8,3), and predominantly increased in those attending the trainings more times a week or for a longer duration. The likelihood of enhancing sense of coherence was also present in women (p=0.034, OR=3,2 CI95% 1,2 - 6,4). **CONCLUSIONS:** Individualized and controlled sports and recreational training has proved to have a positive impact on general health status, and optimal life profile in people aged 18-61 with no respect to age or sex. It has enhanced the individual's sense of coherence that positively affects many aspects of life.

PIH9

FOLLOW UP BALANCE AND GAIT EXAMINATION DURING PREGNANCY

Hock M, Dakos Z, Dálnoki É, Hajnal B, Kránicz J, Kriszbacher I, Boncz I, Bódis J
University of Pécs, Pécs, Hungary

OBJECTIVES: Our aim was to prove the effects of pregnancy on gait and maintaining balance. **METHODS:** Gait and balance testing was performed on 20 young adult - and 21 healthy pregnant women during 3 trimesters. Bretz stabilometer was used to determine balance ability and gait parameters. During stabilometer measurements static balance was examined with Romberg test while dynamic balance with 8 programs on a stabilometer. Duration of swing phase, rate of double-limb support, foot angle and step width were determined during gait study. Allocation of patients was non randomized. Statistical data were calculated according to mean, standard deviation, Fisher's exact test, Student's t-test methods and the results were considered to be significant at $p<0.05$. **RESULTS:** Gait of pregnant women proved to be slower than that of the control group (p=0,046), but the duration of step-cycle decreased during the course of pregnancy. Duration of swing phase in the first trimester is shorter compared to the control group (p=0,040). The rate of double-limb support to the total step-cycle showed an increase (p=0,023) the third trimester with the control group was compared. Foot angle of pregnant women in the first trimester was bigger than that of the control group (p=0,029). Pregnant women's step width in the first trimester was smaller as compared to the control group (p=0,002). Step width of pregnant women compared in the first and third trimesters revealed a significant increase (p=0,049). The difference in average results of Romberg with opened and closed eyes tests was not significant. Examination of dynamic balance showed significant difference between the results of young adults women and pregnant women ($p<0,05$). Examination data obtained during the 1st and 3rd trimesters showed a significant improvement ($p<0,05$) in balance ability as pregnancy progressed. **CONCLUSIONS:** Our study revealed that gait kinematics and balance changed during pregnancy.

PIH10

EXAMINATION OF FEMALE BALANCE MAINTENANCE ABILITY IN MAJOR LIFE STAGES

Hock M, Dakos Z, Dálnoki É, Hajnal B, Kránicz J, Kriszbacher I, Boncz I, Bódis J
University of Pécs, Pécs, Hungary

OBJECTIVES: The aim was to investigate changes of balance maintenance ability in different trimesters and during menopause. **METHODS:** Investigation was performed at the Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Pécs. Bretz stabilometer was used to determine balance- and coordination abilities. Static balance was measured with opened- and closed eyes Romberg-test while dynamic balance was examined with the help of I. and II. programmes of the measuring instrument. The total number of examined subjects' was 60: 20 young adults, 20 pregnant women (follow-up was performed in the 1st, 2nd and 3rd trimesters) and 20 women in menopause. Those suffering from severe locomotor disorders, neurological and internal diseases, in the control group with the existence of gestation and pathological pregnancy were closed out. Statistical data were calculated according to (mean, standard deviation, range, F-test and Student's methods T-probe) MS Excel 2003. **RESULTS:** Comparison of survey results of static balance did not show significant difference in the three groups. During the survey of dynamic balance in the 1st programme significant improvement was observed analyzing the results of young adults and pregnant women ($p<0,05$). Comparing the results in case of young adults and in menopause ($p<0,05$) as well as in groups of pregnant women and in menopause ($p<0,05$) a definite impairment was observed. In the 2nd programme on the basis of the results in the 4th subprogramme a significantly worse performance was measured in menopause ($p<0,05$). **CONCLUSIONS:** Measurement results proved that in major stages of life, with ageing, balance ability decreases. In our case, on the basis of survey data in the 1st and 3rd trimesters it is proved that with the progression of trimesters balance ability significantly improves.

PIH12

PATIENTS WITH BPH IN FRANCE: RESULTS AT SIX MONTHS WITH PHYTOTHERAPY VERSUS OTHER TREATMENTS

Perrin P[1], Auges M[2], Rahhali N[2], Taieb C[2]
[1]*Lyon Sud, Pierre Benite, France,* [2]*PFSA, Boulogne Billancourt, France*

OBJECTIVES: Assess the impact of the treatment of urinary disorders of the lower urinary tract (LUT) suggestive of benign prostatic hypertrophy (BPH) using medical treatment under actual conditions of use. **METHODS:** A pragmatic cohort patients treated medically, was followed up for 6 months, using 3 questionnaires: IPSS and SF12. **RESULTS:** A total of 182 patients under medical treatment were assessed; 146 patients were treated with phytotherapy, versus 36 patients on "other treatments". At inclusion, the patients treated with Serenoa Repens (hexanic extract) versus "other treatments" were different on the following characteristics: age, time since diagnosis, IPSS score, physical and mental dimension of the SF12. The "change from baseline" for the scores of the IPSS and SF12 self-assessment questionnaires between the 2 treatment groups was compared. A linear model was used. We observed an improvement in the IPSS score from 6 weeks. We were not able to demonstrate a significant difference between the 2 treatment groups concerning

the "change from baseline" of the IPSS score (p=0.1464). The same applies to the analyses at 3 and 6 months where the p-values were 0.1156 and 0.1723 respectively. Concerning the 2 dimensions of SF12 score, we observe an improvement but there is no statistical difference between the 2 treatment groups (physical dimension, p=0.6954 and 0.9878 at 6 weeks and 6 months respectively; mental dimension, p=0.5139 and 0.9044 at 6 weeks and 6 months respectively). **CONCLUSIONS:** We observed an improvement in the IPSS and SF12 scores from 6 weeks. This improvement was not significantly different between the 2 treatment groups. Under actual conditions of use, the various medical treatments gave similar improvements.

PIH13

GENERALISING THE OUTPUT OF ROTAVIRUS VACCINATION IMPACT STUDIES: WHAT CAN WE LEARN?

Standaert B[1], Strens D[2], Raes M[3]
[1]GlaxoSmithKline Biologicals, Wavre, Belgium, [2]Deloitte, Diegem, Belgium, [3]Jessa Hospital, Hasselt, Belgium

OBJECTIVES: Impact studies evaluate the benefit of vaccination on specific outcome measures in real live conditions. Those studies collect raw data that do not allow for making general assessments because sometimes the numbers are too low. Modelling techniques can fine-tune the raw data into more harmonised (= parametric) data presentation. But what do we learn after this transformation? **METHODS:** We collected data over 5 years on hospitalisation due to rotavirus infection in children < 5 years old before (2y) and after (3y) the introduction of vaccination in 9 Belgian hospitals. We split the annual data by age-group of 2 to 3 months when < 1-year-old and by year thereafter over the period of the epidemic spread. We harmonised the data using Riskview software in Excel®. The hypotheses tested are that the age-groups most vulnerable to the disease have the largest epidemic spread (highest number of weeks/y of cases reported) and that the less vulnerable age-groups have their spread during the peak weeks of the most vulnerable ones. The latter should indicate a way of disease transmission between age-groups that could be confirmed with vaccination. **RESULTS:** Pre-vaccination data analysis indicates the widest spread of the disease in the age-group of 9 to 11 months (39 wks/52) and the smallest ones in the very young (33 wks/52) and the oldest ones (8 wks/52). The data confirms the spread of the disease in the less vulnerable ones (younger and older ones) occurring during the peak moment of the season of the most vulnerable ones. Post-vaccination analysis shows the same pattern of dependency between the age-groups. **CONCLUSIONS:** Preferential spread of the disease starting from the 9 to 11 months old age-group to younger and older ones can be deduced from the data analysis. This could give an explanation for the annual self-limiting spread of rotavirus disease.

PIH14

RATES AND PREDICTORS OF CHLAMYDIA RE-SCREENING AMONG PRIVATELY INSURED PATIENTS WITH CHLAMYDIA IN 2007- 2009

Shi L[1], Liu J[1], Kissinger P[1], Khan M[1], Wu EQ[2]
[1]Tulane University, New Orleans, LA, USA, [2]Analysis Group, Inc., Boston, MA, USA

OBJECTIVES: Repeat chlamydial infections are known to cause tubal scarring, ectopic pregnancy and infertility. CDC has recommended rescreening 3 months after a diagnosis of Chlamydia. The objective was to examine the rate and predictors of retesting within 3-6 months among patients (15-50 years) diagnosed with Chlamydia in privately insured population. **METHODS:** A commercial insurance database was used to extract patients with Chlamydia (ICD-9-CM codes: 99.5X, 78.88, 79.88, 79.98, 99.41) in year 2007-2009. The date of first Chlamydia diagnosis was used as the index date. Patients were required to have private health insurance >= 6 months before and after the index date. We also defined the re-screening service for Chlamydia by using the CPT codes: 87270, 87320, 87110, 87491, 87492, and 87801 within 3-6 months after the index date. Logistic regression model was used to identify factors affecting the likelihood of Chlamydia retesting. **RESULTS:** Among 2585 persons diagnosed with Chlamydia, the distribution across age group was 59.8% (15-25 years), 31.2% (26-40 years), and 9.0% (41-50). The majority were women (74.2%). Only 9.8% (252/2585) patients were rescreened within 3-6 months. The rate of re-screening in 2007, 2008 and 2009 was 9.1%, 10.3%, and 9.2%, respectively. The rescreened individuals were more likely to be: women but not pregnant (OR=2.36, 95% CI: 1.59-3.50), pregnant women (OR=3.01, 95% CI: 1.76-5.13), compared to men; and age 15-25 years old (OR=2.65, 95% CI=1.33-5.30), compared to the age group 40-50 years. The insurance type, region or index year were not significantly associated with retesting. **CONCLUSIONS:** Low re-screening rates persisted among persons diagnosed with Chlamydia in the private sector. Since insurance type and region show no impact on retesting, low rates may relate to system-wide problems. To improve rescreening rate, policy makers should urgently consider policy options including rescreening of all Chlamydia cases for effective control of the disease.

PIH15

ESTIMATING HERPES ZOSTER DISEASE BURDEN IN GERMANY

Ultsch B[1], Siedler A[2], Rieck T[2], Reinhold T[3], Krause G[2], Wichmann O[2]
[1]Robert Koch Institute/Charité University Medical Center, Berlin, Germany, [2]Robert Koch Institute, Berlin, Germany, [3]Charite University Medical Center Berlin, Germany, Berlin, Germany

OBJECTIVES: Herpes zoster (HZ), which is caused by reactivation of the varicella-zoster-virus (VZV), and its main complication postherpetic neuralgia (PHN) are not notifiable in Germany. HZ disease burden data are needed to i) estimate the economic impact of the disease ii) monitor the impact of routine childhood varicella vaccination on HZ-epidemiology, and iii) guide decision-making related to the development of a possible HZ-vaccination recommendation. **METHODS:** We assessed annual HZ-incidence for 2007/2008 for all ages in person-years (PY). For HZ-outpatient incidence we utilized the Association of Statutory Health Insurance Physicians (ASHIP) database containing nationwide routine accounting data. Annual number of HZ-associated deaths and HZ-inpatients were identified by using the Federal Health Monitoring System (FHM). PHN-incidence and loss of quality-adjusted life years (QALYs) were modelled by multiplying upper and lower limit estimates for proportion of HZ-cases developing PHN and HZ-related QALY-loss with number of identified HZ-outpatients. **RESULTS:** We identified an annual average of 480,927 HZ-outpatient cases, resulting in a HZ-incidence of 5.9/1,000 PY. Of these, 63.5% were 50 years and over. On average, 16,964 HZ-associated inpatients (84% ≥50 years) and 71 deaths (all ≥50 years) were reported annually. HZ-outpatient incidence increased by age from 2.71/1,000 PY in people 0-14 years to 13.18/1,000 PY in people aged 90+. In terms of outpatient (6.94 vs. 4.81/1,000 PY) and inpatient (0.24 vs. 0.17/1,000 PY) HZ-incidence and mortality (0.13 vs. 0.04/100,000 PY) females were significantly more affected. We estimated that PHN-incidence ranged between 0.18 and 1.33/1,000 PY and that HZ-outpatients lost between 4,807 and 27,179 QALYs annually. **CONCLUSIONS:** HZ poses a considerable burden on the health care system in Germany, especially in the elderly. A health economic model for Germany will be developed, and follow-up assessments of epidemiological and economic HZ-related disease burden will be performed to monitor the impact of VZV-vaccinations in Germany.

PIH16

ANALYZING THE ADVERSE DRUG REACTIONS OF GERIATRIC POPULATION AT A REGIONAL ACADEMIC HOSPITAL OF SOUTHERN TAIWAN

Lin PT, Cheng YD
Chiayi Chang Gung Memorial Hospital, Chiayi, Taiwan

OBJECTIVES: The aging of the Taiwan population is one of the major public health issues we face now. The physical difference between young and elderly is significant and may induce many drug-related problems. Once geriatrics suffered from adverse drug reactions, they may need for intensive care and increased the financial burden. Consequently, medication safety is one of the critical issues for elderly. Analyzing the adverse drug reactions in geriatric patients and announce to healthcare related professionals to prevent the incidences. **METHODS:** The data was claimed form Reporting System of Adverse Drug Reaction of a regional teaching hospital from Jan 2010 to Dec 2010. **RESULTS:** Four hundred forty cases were extracted from computer-assisted system. Of 228 geriatrics (51.82%) was enrolled with mean age 77.03 ± 0.74 years old, including 116 female and 112 male. The reason to cause adverse drug reaction is Type 1 (58.26 %), undesired pharmacology reaction, and others were Type 2 (41.74%). The most strategies to management adverse effects were to cease medicine and give another relievable drug (29.82%), only cease medicine (28.51%) and varied to alternative medicine (21.93%). Analyzing the severity of event, 55.26% is moderate (needing therapy or inducing to admit hospital). **CONCLUSIONS:** Over half events happened on elderly and make patients need more advance therapy, and undesired pharmacology effects, which are preventable, are the most reasons. For this reason, health care related professionals should pay more attention and monitor closely to enhance medication safety when a drug was prescribed to elderly.

Individual's Health – Cost Studies

PIH17

BURDEN OF ILLNESS IN PATIENTS WITH NEURAL TUBE DEFECTS IN GERMANY

Bowles D[1], Wasiak R[2], Lindemann M[3], Van nooten F[2], Meinhardt M[4], Greiner W[1]
[1]Herescon GmbH, Hannover, Germany, [2]United BioSource Corporation, London, UK, [3]Bayer Schering Pharma, Berlin, Germany, [4]Bayer Vital GmbH, Leverkusen, Germany

OBJECTIVES: To describe the burden of illness associated with neural tube defects (NTDs) in Germany from a payer perspective. **METHODS:** Retrospective data of patients with Spina Bifida (SB) and Encephalocele were analyzed using 2006-2009 German health insurance fund data (Techniker Krankenkasse). Patients were identified using ICD10 codes, data assessed included outpatient and inpatient care, rehabilitation, remedies and medical aids, and use of pharmacotherapy. The analysis was stratified by age group to provide a lifetime burden estimate and was compared to standardized health care expenditures from the German Risk Compensation Scheme (RSA) to obtain an indicator of incremental burden due to NTD. **RESULTS:** Overall, 4,173 patients were identified, 47.2% of whom were male and 95% had SB. 19.6% and 17.5% patients had an additional diagnosis of depression and incontinence respectively. Costs of patients with SB and Encephalocele were substantially higher than general population in all age strata. The difference was highest for patients ≤10 years old (€10,775 vs. €2,360 for ≤1 year olds, €8,398 vs. €833 for 2-5, and €10,686 vs. €863 for 6-10) and smallest for 41-50 (€2,596 vs. €1,101) and 71+ group (€5,256 vs. €4,389). Inpatient care contributed 78% of total cost for patients 0-1, whereas remedies and medical aids accounted for 60% of total cost for patients 2-5 and 6-10. Among sub-groups, costs of patients with Spina Bifida and Hydrocephalus were highest, especially in the first 10 years of life. **CONCLUSIONS:** The burden of NTD in Germany is substantial and continues throughout the patient life in terms of the level of health care expenditures and relative to overall population. Efforts should be devoted to improving prevention of NTDs and providing appropriate support for patients, parents, and caregivers, especially in early years.

PIH18

ROTAVIRUS GASTROENTERITIS IN VULNERABLE CHILDREN: A UK CASE CONTROL STUDY

Pockett RD[1], Campbell D[2], Adlard NE[3], Rajoriya F[3], Carroll SM[3]
[1]Cardiff Research Consortium, Cardiff, UK, [2]Sheffield Children's Hospital, Sheffield, UK, [3]Sanofi Pasteur MSD, Maidenhead, UK

BACKGROUND: Seasonal epidemics with rotavirus gastroenteritis (RVGE) and respiratory syncytial virus (RSV) represent a significant burden on paediatric clinical

services. For the majority of UK children, length of stay (LOS) in hospital is brief and rehydration alone is sufficient. More complex support is sometimes needed in children with co-morbidities. **OBJECTIVES:** To compare the hospital burden (LOS and cost), of children with RVGE and RSV alone, and vulnerable children with co-morbidities. **METHODS:** Hospital data were obtained from the CHKS database between April 1, 2001 and March 31, 2008, where patients, aged <5 years, were admitted with a primary diagnosis of RVGE or RSV. Patients were categorised into three groups. G1: a primary diagnosis of RVGE/RSV, G2: controls with a primary diagnosis of eczema, G3: vulnerable children with a readmission for RVGE/RSV following a prior admission, within 30 days, with a primary diagnosis of type 1 diabetes (T1D), cystic fibrosis, cancer, or epilepsy. **RESULTS:** A total of 102,270 patients were selected, group one n=101,784 (mean age 0.2 years, LOS 1.9 days, cost £595), group two n=17,420, (mean age 1.1, LOS 1.7, cost £590), and group three n=486, (mean age 1.1, LOS 9.9, cost £3,477). Non-parametric tests showed that mean age, and hospital LOS were significantly different between groups 1 and 2 ($p<0.001$), while mean age, LOS, and cost were significantly different between groups 1 and 3 ($p<0.001$), and groups 2 and 3 ($p<0.001$). When adjusted for age, regression analysis showed that LOS was 5.2 times higher, and cost was 5.8 times higher in group 3 than group 1. **CONCLUSIONS:** This study shows that vulnerable children readmitted to hospital with RVGE/RSV, incur a greater LOS, and subsequent cost, compared to other groups. Universal rotavirus vaccination would substantially benefit vulnerable children through direct or indirect protection and reduce the healthcare resource use resulting from hospital readmissions.

PIH19

PUBLIC HEALTH COSTS ASSOCIATED WITH OUTBREAKS OF MENINGOCCOCAL DISEASE: A SYSTEMATIC REVIEW

Anonychuk A[1], Vyse A[1], Woo G[2], Tricco AC[3]
[1]*GlaxoSmithKline Biologics, Wavre, Brabant wallon, Belgium,* [2]*Toronto Health Economics and Technology Assessment Collaborative, University of Toronto, Toronto, ON, Canada,* [3]*Li Ka Shing Knowledge Institute of St Michael's Hospital, Toronto, Toronto, ON, Canada*

OBJECTIVES: Estimating the costs associated with outbreaks and the prevention of secondary cases of invasive meningococcal disease (IMD) is needed to understand the true economic burden of IMD. We aimed to review the costs associated with IMD outbreaks that occur globally. **METHODS:** Literature searches were conducted in MEDLINE and EMBASE using medical subject headings and key words, such as costs, outbreaks, and IMD. Studies were included if they reported the costs associated with IMD outbreaks and were written in English, French or Spanish. All costs were converted to USD 2010. **RESULTS:** A total of 1672 citations were screened and 323 were potentially relevant. Nine studies fulfilled the inclusion criteria and included IMD outbreaks with cost data from the US (n=4), England, Canada, Guinea, Burkina Faso and Australia (n=1 each) between November 1992 and November 2006. Three outbreaks occurred among high school children, one among boys aged 3-6 years, another among individuals aged <18 years, and two occurred among all ages. The majority were due to serogroup C (n=7/9). The median number of infected per outbreak was 8 (range: 3-2435). The attack rate ranged from <2 per 100,000 to 187 per 100,000, the hospitalization rate from 55.6% to 100%, and the death rate from 0% to 26%. Containment strategies ranged from targeting all members of the school where the outbreak occurred to targeting all students in the community. The overall average cost per containment was $2,368,135 (USD 2010) ranging from an average of $296,821 for small containment strategies (n=3) to $3,403,792 for large containment strategies (n=6). **CONCLUSIONS:** IMG outbreaks were associated with substantial costs. While numerous reports on outbreaks were identified, few reported on the containment costs. More research in this area is warranted, particularly to understand the economic value of new vaccines given that the purpose of vaccination is to prevent potential outbreaks.

PIH20

THE BURDEN OF ENDOMETRIOSIS: COSTS AND QUALITY OF LIFE OF WOMEN WITH ENDOMETRIOSIS TREATED IN REFERRAL CENTRES

Simoens S[1], Hummelshoj L[2], Dunselman G[3], Dirksen C[4], Endocost Consortium W[2], D'Hooghe T[5]
[1]*K.U. Leuven, Leuven, Belgium,* [2]*World Endometriosis Research Foundation, London, UK,* [3]*Maastricht Universitair Medisch Centrum, AZ Maastricht, The Netherlands,* [4]*Maastricht University Medical Center, AZ Maastricht, The Netherlands,* [5]*University Hospitals Leuven, Leuven, Belgium*

OBJECTIVES: Endometriosis (the presence of endometrial-like tissue outside the uterus) affects 10% of women of reproductive age and is associated with dysmenorrhoea, pain at ovulation, dyspareunia, abnormal bleeding, chronic pelvic pain, fatigue, and infertility. This study aimed to calculate costs and health-related quality of life of women with endometriosis-associated symptoms treated in referral centres. **METHODS:** A prospective, international, multi-centre questionnaire-based survey measured costs and health-related quality of life in ambulatory care and in 12 tertiary care centres in ten countries. The study enrolled women with a diagnosis of endometriosis and with at least one centre-specific contact related to endometriosis-associated symptoms in 2008. The main outcome measures included health care costs, costs of productivity loss, total costs and quality-adjusted life years. Predictors of costs were identified using regression analysis. **RESULTS:** Data analysis of 909 women (63% response rate) demonstrated that the average annual total cost per woman was €9,579 (95% CI €8,559-€10,599). Costs of productivity loss of €6298 per woman were double the health care costs (€3113 per woman). Health care costs were mainly due to surgery (29%), monitoring tests (19%) and hospitalization (18%). The cost of medication accounted for 10% of health care costs. At a prevalence rate of 7%, the annual burden of endometriosis-associated symptoms ranged from €0.8 billion in Denmark to €50 billion in the United States. Endometriosis-associated symptoms generated 0.809 quality-adjusted life years per woman. Decreased quality of life was the most important predictor of direct health care and total costs. Costs were greater with increasing severity of endometriosis, presence of pelvic pain, presence of infertility, and higher number of years since diagnosis. **CONCLUSIONS:** The economic burden associated with endometriosis is high and is similar to other chronic diseases (diabetes, Crohn's disease, rheumatoid arthritis). It arises predominantly from productivity loss, and is predicted by decreased quality of life.

PIH21

THE POTENTIAL PUBLIC HEALTH BENEFIT OF PNEUMOCOCCAL CONJUGATE VACCINES IN THE KINGDOM OF SAUDI ARABIA

Shibl AM[1], Al Sogheir MAA[2], Topachevskyi O[3]
[1]*King-saud University, Riyadh, Saudi Arabia,* [2]*Armed Forces Hospital, Al Wazarat Makkah al Mukarramah Rd, Riyadh, Saudi Arabia,* [3]*GlaxoSmithKline Biologicals, Wavre, Belgium*

OBJECTIVES: To evaluate cost–effectiveness of pneumococcal vaccination with 10-valent pneumococcal non-typeable Haemophilus influenzae protein-D vaccine (PHiD-CV) compared with 13-valent pneumococcal conjugate vaccine (PCV-13) and no vaccination in The Kingdom of Saudi Arabia (KSA). **METHODS:** A steady state model with a one-year time horizon was developed to project the impact of vaccination on the incidence of pneumococcal and non-typeable *Haemophilus Influenzae* (NTHi) infections in children aged 0-10 years. Data sources: Pneumococcal serotype distribution is based on 176 invasive *S. pneumoniae* isolates collected in KSA hospitals in 2005 to 2008. IPD, hospitalised pneumonia and acute otitis media (AOM) disease incidence rates were based on a study from 12 hospitals in KSA, data from Turkey and benchmarks with other countries. Vaccines coverage rates for IPD of 79.3 % and 83.9% for PHiD-CV and PCV-13, payer perspective, no herd protection and a (3+1) vaccination schedule was assumed. **RESULTS:** PHiD-CV and PCV-13 are projected to prevent more cases of invasive disease (724; 749 respectively) and equal number of pneumonia hospitalizations (510; 510 respectively) compared to no vaccination. PHiD-CV and PCV-13 are projected to prevent additional myringotomies (4783; 2365 respectively) and GP visits due to AOM (170,936; 84,518 respectively) compared to no vaccination strategy. Vaccinating a birth cohort with PHiD-CV or PCV-13 is expected to generate 8,966; 8,888 more QALYs compared to no vaccination. At vaccine steady state cost-savings related to disease burden reduction are $14.1M and $7.6M for PHiD-CV and PCV-13 respectively compared with no vaccination. Sensitivity analyses indicate that incidence rate of IPD has the biggest impact on results. **CONCLUSIONS:** Incremental cost-effectiveness ratios indicate that both vaccines are cost effective interventions. PHiD-CV dominates PCV-13 because it has a larger potential QALY gain and larger cost offset.

PIH22

COST EFFECTIVENESS OF AN INFANT PNEUMOCOCCAL CONJUGATE VACCINE PROGRAM IN CHINA

Liu G[1], Zhu L[2], Shen D[2], Xu F[2], Wen L[2], Roberts C[3], Dong P[4], Yue N[4]
[1]*Peking University, Beijing, Beijing, China,* [2]*Peking University China Center for Health Economic Research, Beijing, Beijing, China,* [3]*Pfizer, Inc., New York, NY, USA,* [4]*Pfizer China, Beijing, Beijing, China*

OBJECTIVES: A 7-valent pneumococcal conjugate vaccine (PCV7) was launched as a Category II vaccine requiring out-of-pocket payment in China in 2008. This study evaluates the potential economic benefits of introducing a public financed City Immunization Program (CIP) to pay for PCV7 from a payer perspective. **METHODS:** A decision-analytic model was populated with local direct cost and seroprevalence data from case records of 3 hospitals (1 Children's Hospital; 2 Comprehensive Hospitals) and literature to estimate the clinical and economic impact of no PCV7 vaccination, PCV7 Category II listing, and PCV7 CIP in the city of Shenzhen. Various sources of data were used to estimate the primary statistics including age-specific incidence/mortality of invasive pneumococcal disease (IPD), pneumonia and otitis media, local patient demographics, and PCV7 efficacy from clinical trial data. The indirect effect on unvaccinated populations was considered by estimating the reduction in adult IPD cases following PCV7 programs published overseas, and was only applied in the CIP scenario where broad vaccine coverage could be achieved. A discount rate of 5% was applied, and one-way sensitivity analyses were performed as well. **RESULTS:** Under the current setting, the Category II vaccine PCV7 is not cost-effective due to the private market unit price and low penetration rate. However, vaccination of 154,721 children under 2 years old from a public financed CIP in Shenzhen would prevent 18 IPD, 5887 hospitalized pneumonia, 20020 outpatient pneumonia, and 10669 otitis media cases if indirect effects are included, compared to no vaccination program. From a payer perspective, a PCV7 CIP would achieve an ICER of RMB61, 243 (USD9, 141) per QALY versus no vaccination, and dominant versus Category II. **CONCLUSIONS:** Results from this study indicate a PCV7 CIP would be a highly cost-effective intervention from a public payer's perspective.

PIH23

COST-EFFECTIVENESS OF GUANFACINE EXTENDED RELEASE AS AN ADJUNCTIVE THERAPY TO A PSYCHOSTIMULANT COMPARED TO PSYCHOSTIMULANT MONOTHERAPY FOR THE TREATMENT OF ATTENTION DEFICIT/HYPERACTIVITY DISORDER IN CHILDREN AND ADOLESCENTS

Sikirica V[1], Erder M[1], Xie J[2], Macaulay D[2], Diener M[2], Hodgkins P[1], Wu EQ[3]
[1]*Shire Pharmaceuticals, Wayne, PA, USA,* [2]*Analysis Group, Inc., New York, NY, USA,* [3]*Analysis Group, Inc., Boston, MA, USA*

OBJECTIVES: Attention deficit/hyperactivity disorder (ADHD) is a common psychiatric disorder with substantial clinical and economic implications. While psychostimulants are first-line pharmacologic treatment, up to 30% of ADHD children have suboptimal response to psychostimulants and require adjunctive therapy. Our objective was to analyze the cost-effectiveness of adding an alpha-2A agonist,

guanfacine extended release (GXR), to long-acting psychostimulants vs. maintaining existing long-acting psychostimulant monotherapy in children and adolescents with ADHD and suboptimal response to psychostimulant monotherapy. **METHODS:** A one-year Markov model was developed from a US third-party payer perspective. Effectiveness was measured by quality-adjusted life year (QALY). The model assumed patients transitioned among four health states (normal, mild, moderate, and severe), defined based on the Clinical Global Impressions-Severity (CGI-S) scale. Transition probabilities were estimated in an ordered logit model using patient-level data from a Phase III clinical trial comparing psychostimulants plus GXR with psychostimulants plus placebo (n=461). The model assumed that patients in moderate or severe states after week eight would discontinue ADHD treatment and remain in that state. Direct costs included drug wholesale acquisition costs (WAC) and medical costs, in 2010 US dollars. Health state utilities were obtained from the literature. Disutilities associated with adverse events were applied for the first four weeks. One-way sensitivity analyses (SA) were conducted by varying key model inputs. **RESULTS:** Adding GXR to existing psychostimulant monotherapy was associated with an incremental drug cost of $1016 but lower medical cost of $124, resulting in a total one-year incremental cost of $892. The addition of GXR led to an incremental QALY of 0.03 and an incremental cost-effectiveness ratio (ICER) of $31,660/QALY. In one-way SA, ICERs ranged from $19,723/QALY to $46,631/QALY. **CONCLUSIONS:** This is the first cost-effectiveness analysis of psychostimulants with adjunctive medication. Adjunctive therapy of GXR with psychostimulants is cost-effective based on a willingness-to-pay threshold of $50,000/QALY.

PIH24

INTRA MUSCULAR TESTOSTERONE UNDECANOATE (TU) (NEBIDO®) AS TESTOSTERONE REPLACEMENT THERAPY (TRT) FOR ANDROGEN DEFICIENCY IN THE AGING MALE (ADAM) AND DIABETES MELLITUS TYPE 2 (DM2) PATIENTS: BRAZILIAN ECONOMIC MODELING

Silva AP[1], Santoni NB[1], Pepe C[2], Paladini L[3]
[1]*Bayer Brazil, São Paulo, São Paulo, Brazil,* [2]*MedInsight, São Paulo, São Paulo, Brazil,* [3]*Evidências, São Paulo, São Paulo, Brazil*

OBJECTIVES: To determine the cost-effectiveness of TRT with TU (NEBIDO®) compared with placebo for patients with ADAM and DM2, from the Brazilian Private Healthcare System perspective. **METHODS:** The study was a cost-effectiveness analysis based on Markov modeling to estimate costs and consequences of treatments. Epidemiological and efficacy data derived from a critical appraisal of the scientific literature. Only direct medical costs were considered. If available, costs of clinical events (CE) were obtained from burden of disease studies. If not, Brazilian official guidelines were obtained to determine the resources used to treat the CE. Drug, hospital daily admission rates, procedures and laboratory tests unit costs were obtained from Brazilian official databases. Costs and benefits were discounted at 5% yearly. Outcomes were expressed as CE avoided. Probability sensitivity analysis (PSA) was conducted to assess model robustness. Life time horizon was analyzed. **RESULTS:** The systematic review showed that although the absence of studies directly evaluating the impact of TU on cardiovascular events, their favorable influence on cardiovascular disease intermediate markers suggests that TU may have clinically relevant effect in patients at risk, especially in patients with metabolic syndrome and/or DM2. The analysis showed higher clinical benefits and costs for TU. Considering 100 patients, 75.2 and 140.0 CE happen in TU and placebo arms, respectively. The average time-horizon cost per patient was R$34,120(€14,896) and R$23,489(€10,255) for TU and placebo, respectively, resulting in an incremental cost-effectiveness ratio (ICER) of R$16,390/CE avoided (€7,155/CE avoided). PSA demonstrated that in 83.2% of the simulations TU was more effective with higher cost and in 16.8% of the simulations TU was dominant compared to placebo. **CONCLUSIONS:** Our study demonstrated that TU have clinically relevant effect in reducing CE being highly cost-effective for ADAM treatment in patients with DM2 at willingness-to-pay beyond R$19,000/CE avoided (€8,296/CE avoided) (Brazilian GDP per capita). PSA confirmed this determinist result.

PIH25

COST-EFFECTIVENESS OF INTERVENTIONS AGAINST CHILDHOOD OBESITY

Ramos-Goñi JM, Valcárcel-Nazco C, Castilla-Rodríguez I
Servicio de Evaluación del Servicio Canario de Salud, Santa Cruz de Tenerife, Tenerife, Spain

OBJECTIVES: To estimate values for cost and effectiveness that assess the long-term efficiency of public health intervention to prevent and correct childhood obesity. **METHODS:** A Markov model was developed that takes into account five diseases strongly associated with obesity: Diabetes Mellitus Type 2, Heart Disease, Breast Cancer, Colon Cancer and Stroke. Selection of disease was in base of high rates of morbidity and mortality. In the model, we considered 2 main states: normal weight (BMI < 30 kg/m2) and obese (BMI >= 30 kg/m2). From them, individuals can transit to states which representing the 5 diseases and death. Individuals can transit between normal weight and obese until they reach a certain age (30) when they can transit to the rest of states. The time horizon was 70 years. A literature review was performed in order to estimate parameters. The measure of effectiveness was QALYs and a discount of 3% was applied to costs and utilities. A 2-way probabilistic sensitivity analysis was made over 2 parameters which define the intervention: relative risk and cost of intervention. Also, a multivariate and probabilistic sensitivity analysis by 2nd order Monte Carlo (MC) simulations was performed for all parameters. Finally, acceptability curves and the expected value of perfect information were calculated. **RESULTS:** If the willingness to pay is € 30,000/QALY, any intervention that exceeds 1% prevention/correction, incurring in cost not exceeding € 2 per child and per year should be implemented, because the probability of hitting the decision is over 90% and does not incur on any opportunity cost. **CONCLUSIONS:** Long term efficient public health interventions, to prevent/correct childhood obesity, are low cost (not exceeding € 5 per child per year) due to the effectiveness of interventions, usually lower than 2% of prevention/correction over non-intervention.

PIH26

ECONOMIC EVALUATION OF DIENOGEST FOR ENDOMETRIOSIS IN THE CONTEXT OF KOREA NATIONAL HEALTH INSURANCE

Choi SE[1], Lim EA[1], Park JH[2], Lee MK[2], Jung SW[3], Cho HY[3]
[1]*Korea University, Yeongi-gun, Chungnam, South Korea,* [2]*Seoul National University, Gwanak-ku, Seoul, South Korea,* [3]*Bayer HealthCare, Dongjak-ku, Seoul, South Korea*

OBJECTIVES: Dienogest (Visanne ®) is a progestin that has recently been approved in Europe, Australia and Japan (not in Korea yet) for the treatment of endometriosis at a dose of 2 mg orally per day. Dienogest provides potent progestogenic effects, combined with moderate suppression of estrogen levels and has no significant androgenic, mineralocorticoid, or glucocorticoid activity. The aim of this analysis is to evaluate cost-effectiveness of dienogest, thereby assessing its eligibility for National Health Insurance coverage. **METHODS:** We carried out a cost-effectiveness analysis comparing dienogest to leuprolide acetate, a gonodotropin releasing hormone agonist (GnRH-agonist), the current standard treatment for endometriosis associated pain after laparoscopy. Patients requiring additional treatment because of pain after laparoscopy were included in the analysis. A third-party-payer perspective was taken. The time horizon of analysis was one year. Response to treatment, time horizon of analysis, recurrence rate following discontinuation of GnRH-a and the incidence of adverse event were considered as major factors for the decision tree model. An expert survey was conducted to investigate the treatment pattern. Costs of endometriosis were also assessed. In the base case scenario patients do not receive any sequential treatment after non response or pain recurrence. Sensitivity analysis was performed for major variables. **RESULTS:** At the base case analysis, dienogest was dominant. Sensitivity analysis showed that the result was robust for the most variables. Drug cost was the most influential factor of all. **CONCLUSIONS:** Dienogest is a cost-effective and cost-saving alternative in the Korea National Health Insurance context. However the analysis is covering only one year and long-term clinical data is required to draw a solid conclusion.

PIH27

POTENTIAL HEALTH AND ECONOMIC IMPACT OF ADDING ROTARIXTM TO ROUTINE INFANT VACCINATION PROGRAMS IN CANADA

Ismaila A[1], Chu R[2], Standaert B[3]
[1]*GlaxoSmithKline, Mississauga, ON, Canada,* [2]*McMaster University, Hamilton, ON, Canada,* [3]*GlaxoSmithKline Biologicals, Wavre, Belgium*

OBJECTIVES: To evaluate the projected health outcomes, costs, and cost-effectiveness of universal mass vaccination (UMV) with Rotarix™ (GlaxoSmithKline) in Canada compared with no vaccination. **METHODS:** An age-compartmental, deterministic, static Markov cohort model was developed to simulate the disease process of acute diarrhea events caused by rotavirus infection up to the age of 5 years in 'monthly' time cycles, using Canadian demographic and epidemiology data. The base-case analysis was performed to estimate the direct effects of a UMV program with two doses of Rotarix™ at 2 and 4 months of age compared to no vaccination, assuming 90% vaccination coverage. Costs and utilities were discounted at 3.5%. The efficacy of Rotarix™ was based on published clinical trial results. Model outputs include clinical endpoints (deaths, hospitalizations, emergency department (ED) visits and outpatient visits), and economic measures (net costs per case/death prevented and quality-adjusted life year gained). Incremental cost-effectiveness ratios (ICERs) were calculated from the healthcare system perspective, and productivity loss was reported separately. One-way sensitivity analysis was performed to evaluate the robustness of the model to variations in the underlying input parameters. **RESULTS:** Without vaccination, a Canadian birth cohort of 380,000 can be expected to have 152,000 rotavirus diarrhea events, 9,000 hospitalizations, 20,849 ED visits, 2,812 nosocomial infections and 6 deaths over 5 years. The base case results show that a UMV program with Rotarix™ could reduce these events by 69%, 81%, 68%, 76% and 79% respectively over 5 years. At $60 per dose plus $9 administrative fee, the cost per QALY gained over no vaccination is $28,653. **CONCLUSIONS:** A UMV program with Rotarix™ is projected to substantially reduce the health and economic burden of rotavirus infections, and is cost-effective relative to no vaccination in the Canadian health care system.

PIH28

ECONOMIC EVALUATION OF PNEUMOCOCCAL CONJUGATED VACCINES FOR ARGENTINA

Ellis A[1], Lepetic AC[2], Gomez JA[3]
[1]*CEMIC University Hospital, Buenos Aires, Argentina,* [2]*GlaxoSmithKline, Buenos Aires, Other ->, Argentina,* [3]*GlaxoSmithKline, Buenos Aires, other, Argentina*

OBJECTIVES: Evaluate the potential benefits of the 10-valent pneumococcal nontypeable Haemophilus influenzae (NTHi) protein D-conjugated vaccine (PHiD-CV) and the 13-valent conjugated pneumococcal vaccine (PCV-13) for Argentina. **METHODS:** A cohort Markov model was used. The model simulated the impact of pneumococcal and NTHi related diseases (Invasive Disease (ID), Community Acquired Pneumonia (CAP), and Acute Otitis Media (AOM)) in an argentinean cohort followed over lifetime. Argentine epidemiology, disease management, and costs were included in the model. Base case includes conservative assumptions on the rates of NTHi infections. A 2+1 vaccination schedule was assumed, with vaccine coverage of 90% and 2 prices/dose scenarios a) PAHO Revolving Fund 2011 prices, or b) price parity. Results of the quality adjusted life years gained (QALYs) and future averted costs, using a 3.5% discount rate, using the health payer perspective, are presented. **RESULTS:** The model estimated comparable results between vaccines

on mortality associated to ID and CAP, for the base case scenario. It predicts that vaccines would reduce 11.34 deaths (PCV-13) and 11.03 deaths (PHiD-CV) per 100,000 vaccinated infants. Besides, PHiD-CV would reduce 221 more myringotomies and 3,891 more AOM cases than PCV-13, per 100,000 vaccinated infants. The direct medical costs averted (undiscounted) due to ID and CAP is similar for both vaccines. Instead, PHiD-CV would save 1.9 times more AOM medical costs than PCV-13. Both vaccines are cost effective, but PHiD-CV would generate more QALY gains (1176 additional QALYs) and in addition, would be cost saving. It was estimated that PHiD-CV requires a reduced annual investment of 10 million (PAHO prices) or 1.6 million (price parity) US$, compared to PCV-13. **CONCLUSIONS:** Both vaccines would reduce significantly the impact of invasive pneumococcal disease and CAP, but PHiD-CV will generate more QALYs gain and will be cost saving compared to PCV-13, due to its greater effects over AOM.

PIH29

THE COST EFFECTIVENESS OF CLINICALLY PROVEN TREATMENT STRATEGIES FOR ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) IN ADULT PATIENTS

Schlander M[1], Philipsen A[2], Schwarz O[1]
[1]*Institute for Innovation & Valuation in Health Care, Wiesbaden, Germany,* [2]*Universitätsklinikum Freiburg, Freiburg im Breisgau, Germany*

OBJECTIVES: Despite recent progress in our understanding of the economics of ADHD in children and adolescents, little is known about the comparative cost effectiveness of treatment strategies for adult ADHD. Even for ADHD in children, there is a shortage of robust data supporting the cost effectiveness of psychotherapeutic interventions. **METHODS:** A randomized, double-blind, placebo-controlled multicenter study has been initiated in Germany, enrolling 448 adult patients with ADHD. Patients are assigned to one out of four parallel treatment arms: 1) a structured disorder tailored psychotherapy (dialectical behavioral therapy, DBT) plus medication (methylphenidate); 2) DBT and placebo; 3) psychiatric counseling without specific behavioral interventions (clinical management) plus medication; or 4) clinical management and placebo. DBT and clinical management are administered weekly for the first 12 weeks and on a four-weekly basis thereafter, until the end of the one-year-observation period. An additional follow-up investigation is scheduled at 18 months after treatment termination. **RESULTS:** Endpoints include symptomatic improvement (primary endpoint: Conners' Adult Rating Scale, blind-observer rated), general psychopathology, clinical global impression, and a disorder-specific quality of life questionnaire. In order to facilitate cost utility analysis, health-related quality of life is also measured by means of the EQ-5D and SF-36. For primary analysis, the perspective of Statutory Health Insurance will be adopted; resource use and costing from a societal perspective will be done for secondary analyses. Probabilistic sensitivity analyses will be done using nonparametric bootstrapping on the basis of patient-level study data. **CONCLUSIONS:** The COMPAS Study will, for the first time, provide insights into the cost effectiveness of a disorder tailored psychotherapy for adult ADHD. Key hypotheses are: 1) that combined treatment (study arm 1) is more effective than either option (DBT or medication) alone, both short and long term, and 2) that a tailored psychotherapeutic intervention will meet broadly accepted benchmarks of cost effectiveness.

PIH30

ENDOMETRIOSIS-ASSOCIATED PELVIC PAIN TREATED WITH DIENOGEST OR GNRH ANALOGUES: COST-UTILITY COMPARISON WITH 5 YEARS TIME HORIZON

Lukac M[1], Knight C[2], Bielik J[3], Tomek D[4], Petri JC[5], Bojnicky M[1], Kovac A[1]
[1]*Slovak Medical University, Bratislava, Slovak Republic,* [2]*RTI Health Solutions, Sheffield, UK, UK,* [3]*Trencin University, Trencin, Slovak Republic,* [4]*Slovak Society for Pharmacoeconomics, Bratislava, Slovak Republic,* [5]*Bayer Schering Pharma AG, Berlin, Germany*

OBJECTIVES: To estimate the cost effectiveness of dienogest versus GnRH analogue (GnRH-a) for the treatment of endometriosis-associated chronic pelvic pain in Slovakia for 5 years time horizon. **METHODS:** A cost-utility Markov model based on results of randomized controlled trial (AU19) was adapted to a Slovakian setting. The AU19 trial, which compared dienogest and GnRH-a (leuprolide) in the treatment of endometriosis-associated chronic pelvic pain over a 6 month period, showed no statistically significant differences in response rates. The dienogest annual relapse rate was derived from 52-weeks extension study, while relapse rates for the GnRH-a were derived from the literature. Local cost data was based on published price lists, clinical guidelines, product labels and expert opinion. QoL related utilities were derived from individual patient SF-36 scores from AU19 dataset. Effectiveness was measured in quality-adjusted life years (QALY). Time horizon was set at five years and a payers' perspective was adopted. Discount rate was 5% per year for both costs and effects according to valid Ministry of Health (MoH) guidelines for health economic evaluation. Both one-way and probabilistic sensitivity analyses were performed. **RESULTS:** Dienogest showed that it was cost-effective compared to a GnRH-a, with an overall cost reduction of 426 € and a QALY gain of 0.069 per patient. Cost reduction was due to both the differences in the average drug cost during the two year period and the average laparoscopy cost. In probabilistic sensitivity analysis 92 % of simulations were below 18,000 €/QALY, which is the officially published threshold for willingness to pay in Slovakia. In 79% of cases dienogest treatment was dominant over GnRH-a. **CONCLUSIONS:** Dienogest is a cost-effective alternative to GnRH analogue for the treatment of endometriosis-associated chronic pelvic pain in a Slovakian setting in a five-year time horizon.

PIH31

ANTI-VIRAL TREATMENT OF CHRONIC HEPATITIS C IN A PAEDIATRIC POPULATION: A COST-EFFECTIVENESS ANALYSIS

Mernagh P[1], Norris S[2], Del Cuore M[3]
[1]*Health Technology Analysts, Lilyfield, NSW, Australia,* [2]*Health Technology Analysts, Sydney, NSW, Australia,* [3]*Merck Sharp & Dohme, Sydney, NSW, Australia*

OBJECTIVES: The majority of individuals with chronic hepatitis C virus (HCV) are adults, and there is much experience in Australia with interferon-based treatments in adults using combination pegylated- interferon and ribavirin treatment. Pegylated-interferon alfa-2b was first approved for adult use in Australia and for reimbursement in 2003. It is currently reimbursed for initial treatment, and for a single retreatment course. Nonetheless, a limited number of children and adolescents in Australia contract the disease. Currently these individuals have no registered or reimbursed approved therapies available to them. This analysis reports a cost-effectiveness analysis of a single course of initial pegylated-interferon alfa-2b therapy in paediatrics with a bodyweight of at least 27 kg, reflecting the lowest dosage that will be supplied in Australia. **METHODS:** A cost-utility analysis was conducted using a lifetime Markov model. Analysis of paediatric treatment versus no treatment was undertaken to determine the impact expansion of reimbursement would have on the cost-effectiveness of the total population. Data were sourced from a study assessing sustained virological response, and the literature reporting the natural history and utility weights regarding HCV. **RESULTS:** Downstream cost-offsets associated with treatment reduce the total incremental cost from AU$13,208 to AU$4767. These cost-offsets arose from avoidance of downstream transitions to more severe and costly states of health. Treatment was also shown to be associated with improvements in health-related quality of life due to the downstream avoidance of more serious health states as well as the obvious improvement in viral clearance. Over the lifetime of a patient, the base case analysis estimated an improvement of approximately 2.01 QALYs, generating an incremental cost-effectiveness ratio of AU$2373 per QALY. **CONCLUSIONS:** Expanding reimbursement to include paediatric treatment of chronic HCV is a highly cost-effective way to equitably treat chronic HCV, regardless of age.

Individual's Health – Patient-Reported Outcomes & Preference-Based Studies

PIH32

WHAT ARE THE FACTORS INFLUENCING PARENTAL APPREHENSION ABOUT CONSENTING CHILDREN TO PARTICIPATE IN PEDIATRIC OBSERVATIONAL STUDIES? A SURVEY CONDUCTED IN FRANCE WITH IN FINE PHARMA, A PHARMACIST NETWORK

El kebir S[1], Bourhis Y[2], Hussein R[3], Gauchoux R[4]
[1]*Regsitrat Mapi, Lexington, KY, USA,* [2]*Registrat Mapi, Lyon, France,* [3]*Université de Bourgogne, Dijon, France,* [4]*REGISTRAT MAPI, Lyon, France*

BACKGROUND: Conducting pediatric studies is complex and the most significant barrier is infant enrollment by parental consent. This obstacle is currently found both for healthy and sick infants. The reason for the parents' refusal to consent is not obvious and may be due to multiple factors. **OBJECTIVES:** To identify the factors influencing parents' decisions to refuse infant participation in pediatric studies. **METHODS:** Observational, transversal study carried out by French pharmacists randomly selected among the 2,090 pharmacies of the In fine PHARMA® network (representative of French pharmacies in terms of geographic location and sales). Parents presenting to participating pharmacies were eligible. Data were collected through questionnaires fulfilled by participating parents. **RESULTS:** Twenty-one pharmacists agreed to participate and enrolled 105 participating parents. Among them, 78 (74%) filled out a questionnaire. Participating families had an average of 2.3 children, 81% were living in an urban environment, and 51% of the infants were males. Most of the parents (97%) had never enrolled their children in a study. Main deterrents to parental consent were: they viewed pediatric studies as risky (35%), they did not want their infant to be treated as an experimental animal (20%), their infant was not ill (12%), the information provided by the physician was too confusing and/or complicated (10%). Parents may have been willing to have their child participate in a study only if the study was evaluating a new drug, their child's participation would further medical research (31%), their child suffered from a severe illness (24%), and they had great confidence in their physician (22%). **CONCLUSIONS:** The results of this survey show that the factors negatively influencing parents' decisions to consent were the perceived risk presented by the studies, the lack of interest to medical research if their child was not ill, and the lack of information about the study.

PIH34

PATIENT REPORTED REASONS FOR MEDICATION NONADHERENCE: A SURVEY

Lee K[1], Nixon M[2], Cascade E[3], Plummer C[4], Law V[1], Lee M[1]
[1]*UCSF, San Francisco, CA, USA,* [2]*Quintiles, Bracknell, Berkshire, UK,* [3]*MediGuard.org, Rockville, MD, USA,* [4]*MediGuard, Inc, Princeton, NJ, USA*

OBJECTIVES: Medication nonadherence among patients with chronic conditions is a significant barrier to achieving therapeutic outcomes. The objective of this study was to identify patient reported factors and reasons associated with medication nonadherence. **METHODS:** Online cross-sectional survey of patients taking medications for seven chronic conditions: asthma/COPD, bipolar depression, cardiovascular disease, diabetes, neuropathic pain, osteoporosis, and rheumatoid arthritis. The first 50 patients to respond to the survey for each of the seven conditions were evaluated (total n=350). Patients provided demographic information and answered questions about their drug therapy including knowledge and satisfaction with their medications, difficulties in taking their medications, and how often they take their medication as prescribed. Adherence was defined as patients self-reporting that they always take their medication as prescribed. Nonadherence was defined as never, sometimes or often take medications as prescribed. Multivariate logistic regression was performed to identify patient factors and reasons associated with nonadherence. **RESULTS:** Among the 350 patients who completed the survey, the

average age was 54 years (standard deviation + 11 years, range 17-85 years) with the majority being female (78%), white (87%), having a some college education or more (73%) and having health insurance (87%). Approximately 58% of patients reported medication nonadherence. No significant differences were observed between adherent and nonadherent patients with regard to age, sex, race, insurance status, condition, or number of medications taken. Reasons significantly associated with nonadherence were forgetting, don't like to take pills/give injection, cost of medication, symptoms improved so stopped taking medication, side effects too severe, and poor knowledgeable about their medications. **CONCLUSIONS:** Medication nonadherence is common and patient reported reasons for nonadherence include motivational factors, lack of understanding or knowledge, and treatment-related characteristics. Interventions that motivate, educate and individualize drug therapy according to patients' preferences and affordability may improve adherence.

PIH35

THE MEASUREMENT AND VALUATION OF HEALTH STATUS USING EQ-5D IN BRAZIL: A SYSTEMATIC REVIEW

Takemoto MLS, Fernandes RA, Cukier FN, Cruz RB, Takemoto MMS, Santos PML, Tolentino ACM, Ribeiro ACP, Fernandes RRA, Moretti AIP
ANOVA - Knowledge Translation, Rio de Janeiro, Brazil

OBJECTIVES: The EQ-5D has been extensively used to assess health-related quality of life (HRQoL) and utility across different health condition worldwide. The aim of this study was to systematically review studies using EQ-5D in the Brazilian population. **METHODS:** A structured literature search was conducted using free text words related to EQ-5D and Brazil in Pubmed and LILACS database. Original research studies that reported EQ-5D results among Brazilian patients or general population were included. **RESULTS:** Of 23 identified papers (Pubmed=11, LILACS=12, 3 duplicate citations), 4 met the selection criteria, with one study reporting evidence on validity for stroke patients (Pinto 2011), one study reporting EQ-5D responses (index, VAS and self-classification) for caregivers of stroke patients (Carod-Artal 2009) and two publications of the same SF-6D study for rheumatoid arthritis (RA) patients in which EQ-5D was used as a comparison measure (Campolina 2009 and 2010). All 3 studies reported EQ-5D index, 2 of them used the UK tariff and Carod-Artal 2009 did not inform the conversion method. Mean EQ-5D index scores were 0.65 (SD 0.3) for RA patients and 0.7 (SD 0.2) for caregivers of stroke patients. The study which applied EQ-5D to stroke patients did not report the mean scores, only correlation coefficients with stroke severity and impairment on daily living activities scales. EQ-5D showed good correlation with SF-6D in the RA study and with NIH Stroke Scale and modified Barthel Index in the stroke study. Adequate convergent validity between EQ-5D and Zarit Caregiver Burden Interview was observed among caregivers of stroke patients. **CONCLUSIONS:** Although the EQ-5D is the most widely used generic preference-based measure of health-related quality of life, studies reporting results for Brazilian samples are still scarce. Normative reference data for the general population are not available in the published literature which makes interpreting disease-specific scores a complex task.

PIH36

THE QUALITY OF LIFE OF PATIENTS WITH THE TOP 5 DISEASES AND THE WAY TO REFLECT THE BURDEN OF DISEASES IN THAILAND: A COUNTRY-WIDE MULTICENTER EQ-5D MEASUREMENT, 2010

Wongphan T[1], Bundhamcharoen K[2]
[1]*Ministry of Public Health, Muang, Nonthaburi, Thailand,* [2]*International Health Policy Program, Nonthaburi, Thailand*

OBJECTIVES: Thailand's top 5 burden of diseases in 2004 (based on the protocol of global burden of diseases (GBD) 2004) were HIV/AIDS, traffic accident, stroke, diabetes mellitus, and liver cancer, accounting for 947, 718, 652, 474, 407 Disability-Adjusted Life Years(DALYs) per 1000 population, respectively. The technique used by GBD to calculate the disability weight (DW) is based on an expert panel summary. However, this study measured DW directly from the patients and compared the results. **METHODS:** The cross-sectional observational multicenter hospital study was conducted in 2008-2009. The 2,695 sampling patients were selected based on epidemiologic disease data from outpatient, inpatient and primary-care unit in 5 major regional hospitals throughout Thailand. Selected patients were allocated in the quota slot and completed the EQ-5D questionnaires with their capabilities. The EQ-5D states were converted to utility weight (UW) using the Thai preference method and then changed into DW with linear regression function to then compare DALYs directly to the GBD result. **RESULTS:** Of 2695 patients, 56.99% are male, and the age is between 1 to 100 years old. The quality of life was calculated to DW with: DW = 0.688 + (-0.688 x UW). The new DW differs from GBD weight from -47.21 to 53.27 percent and these changes will affect the YLD and change the DALYs -2.83 to 4.84%. **CONCLUSIONS:** The new DW from the diseases and their complications differ from the GBD weight. This technique has the tendency to produce more DW that GBD's. To establish the burden of diseases, we use the quality of life to reflect the true disability. The limitation that we have to improve is the way to calculate the disability weight from EQ-5D for the best prediction.

PIH37

THE ROYAL ROAD OR THE MIDDLE WAY? PUBLIC AND PATIENT PREFERENCES FOR HEALTH OUTCOMES

Versteegh M, Brouwer W
institute for Health Policy & Law, Rotterdam, The Netherlands

OBJECTIVES: In economic evaluations of health care interventions, outcomes are often expressed in terms of Quality-Adjusted Life-Years (QALYs). Deriving QALY weights, operationalized as preferences for health states, requires important normative choices. One important choice is the question whose preferences we wish to capture. Currently, preferences are commonly derived from the general public, rather than from actual patients. This choice, which has large consequences on final outcomes of economic evaluations, is increasingly topic of debate. In the current study, arguments for and against public preferences are discussed and alternatives are suggested. **METHODS:** We highlight and critically assess the different viewpoints put forward in the health economic literature regarding the public and patient perspective. Patient preferences are considered to reflect true patient experiences, but are troublesome because preference values elicited from patients are 'unusually' high due to adaptation. Public preferences are argued to be less sensitive to adaptation, but are troublesome because they do not adequately forecast experience. **RESULTS:** The arguments put forward in the literature do not provide straightforward support for assessing outcomes QALY weights derived the general public. The exclusion of patient values in public decision-making is not sufficiently argued. With patient preferences life saving interventions are likely to become more cost-effective. **CONCLUSIONS:** Arguments for and against both positions represent different normative positions regarding the appropriate measure of outcome in health care decisions. To date, the debate seems to have focused on the question which of the two would be most appropriate. However, it seems unclear why such a dichotomy would be necessary or, in fact, useful. Both public and patient preferences appear to be important sources of information for the allocation of health care resources in society. Perhaps the question should be how to intelligently combine the two.

PIH38

SELF REPORTED HEALTH STATUS AND QUALITY OF LIFE AMONG COASTAL RURAL POPULATION IN SOUTH INDIA

Muragundi PM[1], Udupa N[2], Naik AN[1], Tumkur A[1], Shetty R[3]
[1]*Manipal College of Pharmceutical Sciences, Manipal, India, India,* [2]*Manipal University, Manipal, Karnataka State, India,* [3]*K M C, Manipal, India, India*

OBJECTIVES: To assess the health status and health related quality of life among rural population residing in coastal region of South India. **METHODS:** Randomly selected population attending health awareness camp in rural village of South India were recruited for the study. Kannada version of EQ-5D5L questionnaire was used to assess the health related quality of life. Both descriptive and VAS scores were used for assessment. The population recruited was having the age >18 years and <75 years having the family history of either diabetes, CVD or both. **RESULTS:** A total of 126 patients were recruited with the mean±SD age of 45.95±13.44. The descriptive scores ranging between minimum 1 and maximum 5 for different health related quality of life indicators were, mobility score 2.11±0.88 (mean±SD), self-care score 1.55±0.83, activity score 2.07±0.94, pain score 2.38±0.86 and anxiety score of 1.96±1.01. Among the different health states, 11,121 health state was found as more common (mode). The VAS score found to be 67.56±14.64. **CONCLUSIONS:** There was considerable impact of pain and activity on the health related quality of life among rural coastal population in south India who had the family history of diabetes, CVD or both. There is a need to study the risk factors and other quality of life indicators among the rural costal population in India.

PIH39

HOW DO POSTMENOPAUSAL WOMEN DESCRIBE BREAST PAIN AND BREAKTHROUGH BLEEDING ASSOCIATED WITH HORMONAL TREATMENTS FOR MENOPAUSAL SYMPTOMS: QUALITATIVE INTERVIEWS WITH POSTMENOPAUSAL WOMEN IN THE UNITED STATES, CHINA, MEXICO AND ITALY

Abraham L[1], Arbuckle R[2], Dennerstein L[3], Humphrey L[2], Maguire L[2], Mirkin S[4], Simon JA[5], Symonds T[1], Walmsley S[2]
[1]*Pfizer Ltd, Tadworth, Surrey, UK,* [2]*Mapi Values Ltd, Bollington, Cheshire, UK,* [3]*University of Melbourne, Melbourne, VIC, Australia,* [4]*Pfizer Inc, Collegeville, PA, USA,* [5]*George Washington University, Washington, DC, USA*

OBJECTIVES: Estrogen plus progestin therapies (EPT) represent the current standard of care for postmenopausal women with a uterus for the treatment of symptoms associated with menopause. While successfully treating climacteric symptoms, the presence of progestin is necessary to prevent endometrial proliferation. Progestins contained in EPT are associated with side effects such as breast pain/tenderness and vaginal spotting/bleeding. The objective of this study was to conduct qualitative interviews with menopausal women to better understand the patient experience of breast pain and vaginal bleeding symptoms associated with EPT, and the language patients use to describe them, to inform the development of new measurement tools for these symptoms. **METHODS:** Fifty-nine postmenopausal women in the USA (n=14), China (n=15), Mexico (n=15) and Italy (n=15) (aged 40-63) taking EPT and experiencing breast pain and/or vaginal bleeding/spotting (47/59 were experiencing both) participated in in-depth interviews concerning their experiences of EPT and impact on quality of life. Thematic analysis was conducted to identify concepts describing the experiences of the participants using Atlas Ti. **RESULTS:** In all 4 countries, breast sensations experienced while taking EPT were described as 'pain and tenderness', 'feeling swollen' and 'sensitivity' to touch or contact. Vaginal bleeding and spotting were commonly described in terms of frequency, volume, colour and consistency. Frequency of both symptoms ranged from 'daily' to 'occasionally'. Both symptoms impacted on psychological well-being, activities of daily living and sex life. Items for new measurement tools were developed using this qualitative data with clinical input from experts in menopause. **CONCLUSIONS:** In-depth interviews with a geographically diverse sample elicited common descriptors for the symptoms of breast pain and vaginal bleeding and allowed items to be developed that are applicable across cultures, conceptually consistent and easily translated. Accurately capturing descriptors used by patients is critical to ensure new outcome tools have content validity and cross-cultural reliability.

PIH40

DESIGNING A DISEASE-SPECIFIC PATIENT REPORTED OUTCOME (PRO) FOR A RARE DISEASE: ASSESSING THE RELIABILITY, VALIDITY, AND RESPONSIVENESS OF THE HUNTER SYNDROME - FUNCTIONAL OUTCOMES FOR CLINICAL UNDERSTANDING SCALE (HS-FOCUS)

Wiklund I[1], Raluy M[1], Jangelind Y[2], Whiteman DAH[3], Conway AM[4], Pang F[5], Stull DE[6], Chen WH[7]

[1]*United BioSource Corporation, London, UK,* [2]*Shire Human Genetic Therapies, Danderyd, Sweden,* [3]*Shire AG, EYSINS, Switzerland,* [4]*Shire HGT, Cambridge, MA, USA,* [5]*Shire Human Genetic Therapies, Inc, Basingstoke, UK,* [6]*United BioSource Corporation, Bethesda, WA, USA,* [7]*United BioSource Corporation, Bethesda, MD, USA*

OBJECTIVES: Hunter syndrome (HS) is a rare X-linked progressive multi-systemic lysosomal storage disease. The 55 item child and 68 item parent versions of the 8 domain HS-FOCUS questionnaire were used to monitor the safety and efficacy with enzyme replacement therapy (ERT) in clinical trials. The objective was to validate HS-FOCUS according to the FDA PRO Guidance. **METHODS:** HS-FOCUS data collected in a placebo-controlled trial (53 weeks, plus 36 months extension) were used to evaluate item performance, reliability, validity, and responsiveness. **RESULTS:** Altogether, 55 children and 84 parents completed the HS-FOCUS at baseline and follow up visits. High percentage of lowest item response (> 60%) and high average inter-item correlations suggested that some items were less informative or redundant. The internal consistency met the >0.70 criteria for all domains in parents and children, except the breathing domain in children. The test-retest reliability was >0.70 for Walking/Standing, School/Work, Activities, and Overall Function domains in parents, and for Walking/Standing and Activities domains in children. The construct validity correlating the HS-FOCUS with Childhood Health Assessment Questionnaire (CHAQ) showed moderate to high correlations in related concepts, especially in activity related domains. Correlations with lung function (FEV1) ranged from -0.06 (School/Work) to -0.48 (Breathing). Significantly score differences were found in most domains among tertiles based on overall-well being and pain VAS. Responsiveness showed large effect sizes, especially for Sleep, Breathing and School/work domains (0.50-1.07). **CONCLUSIONS:** Developing disease-specific PROs for rare diseases is challenging due to the nature of the evidence base. This study demonstrates HS-FOCUS to be a reliable, valid, and responsive instrument which can be applied in clinical trials or disease registries. The questionnaire can be streamlined by reducing item redundancy without compromising its validity. Simultaneously, an item bank may be generated which could serve as a basis for developing questionnaires for other mucopolysaccharidosis disorders.

PIH41

ARE DIFFERENT SPANISH VERSIONS OF PRO MEASURES NECESSARY? THE CASE STUDY OF THE PEDSQL™ 4.0 GENERIC CORE SCALES

Mear I[1], Conway K[2], Acquadro C[2], Varni JW[3]

[1]*MAPI Institute, Lyon, France,* [2]*MAPI Research Trust, Lyon, France,* [3]*Texas A&M University, College Station, TX, USA*

OBJECTIVES: The PedsQL™ Measurement Model is a modular approach to measuring health-related quality of life (HRQOL) in healthy children and adolescents and those with acute and chronic health conditions. Several Spanish versions for use in different Spanish speaking countries were developed. The objectives of this study were to compare these Spanish versions, quantify and qualify the differences and conclude on the need (or not) for country-specific Spanish versions. **METHODS:** Our study focused on the Teen form (13-18) and included the following steps: 1.Collection of the validated Spanish versions in collaboration with the author; 2.Identification of the differences in items, and response scales; and 3. Coding of the differences as Cultural (C), Lexical (L), Idiomatic (I) and Syntactical (S). **RESULTS:** Six validated Spanish versions were retrieved: Spanish for US, Spain, Argentina, Chile, Mexico and Peru. Since it was the first translated, the US Spanish version served as comparator. All versions showed differences. Spanish for Spain showed the highest number of differences (57), then Chile (47), Argentina (36), Peru (20) and Mexico (18). None of the differences were cultural. In 65% of the cases, the divergences were idiomatic. For instance, the expression "Se me hace difícil" (It is hard for me) used in US Spanish was replaced in all corresponding items by "Me cuesta" (Literally "It costs me") in Spain, Argentina and Chile. The time recall sentence and item 3 of the School Functioning Scale showed most of the differences. One of the reasons could be the use of a very idiomatic form in the original US English version: "I have trouble keeping up". It should be noted that items of the Emotional Functioning Scale showed very few differences. **CONCLUSIONS:** Numerous changes in wording for idiomatic reasons indicating respondents preferences point to the necessity of developing specific Spanish versions of the PedsQL™.

PIH42

PATIENTS WITH URINARY DISORDERS, EVOCATIVE OF BPH: WHAT ARE THEIR EXPECTATIONS IN FRANCE, IN ITALY AND IN PORTUGAL?

Perrin P[1], Auges M[2], Rahhali N[2], Taieb C[2]

[1]*Lyon Sud, Pierre Benite, France,* [2]*PFSA, Boulogne Billancourt, France*

OBJECTIVES: The individualised expectations of the patient will undoubtedly be one of the major preoccupations in the next few decades to guarantee optimal treatment through compliance. **METHODS:** A pragmatic, European cohort (France, Italy, and Portugal) of 477 patients presenting with urinary disorders, evocative of BPH, was followed-up over 6 months. A questionnaire regarding expectations was handed out at the first consultation. **RESULTS:** A total of 441 patients were evaluated. The symptom that 31,11% of patients wished to see improved with the highest priority were "getting up in the night to urinate", then for 20%, "sensation of not emptying the bladder after urinating ". Amongst the symptoms that patients were the least concerned about were "the effort or force needed to start urinating" for 26,80% of responders, then "size and force of the stream of urine" for 15,38% and "the interruption of the flow of urine" for 13,40%."Getting up in the night" was the principal complaint in all 3 countries (36,30% in France, 29 and 27,54% in Portugal and Italy), whereas "the effort or force needed to start urinating" is the symptom that preoccupies the patients the least in France and Italy, and the "size and force of the stream of urine" preoccupies the Portuguese the least.Nearly 87% of the Italians claimed that they would only be satisfied if they never had to get up in the night again, (35% for the French, 67% for the Portuguese).Overall, 60% of the subjects questioned said that they would be satisfied if they were "markedly" improved. **CONCLUSIONS:** The expectation of patients in the treatment of BPH is very important, and undoubtedly difficult to satisfy entirely. These results are probably due to the fact that our population was composed of patients that had been diagnosed recently.

PIH43

CHANGES IN HEALTH-RELATED BEHAVIOURS AND THEIR IMPACT ON ACADEMIC ACHIEVEMENT AND HEALTH-RELATED QUALITY OF LIFE (HRQOL) AMONG SPANISH ADOLESCENTS

Rajmil L[1], López-Aguilà S[2], Palacio-Vieira JA[3], Alonso J[4]

[1]*Agència d'Informació Avaluació i Qualitat en Salut, Barcelona, Spain,* [2]*Agència d'Informació Avaluació i Qualitat en Salut (AIAQS), Barcelona, Spain,* [3]*Direcció General de Salut Pública, Barcelona, Spain,* [4]*IMIM-Institut d'Investigació Hospital del Mar, Barcelona, Spain*

OBJECTIVES: The objective of the study was to assess the effect of changes in health-related behaviours on academic achievement and on HRQOL of children and adolescents aged 8 – 18 years in a 3 years follow-up study. **METHODS:** A representative sample of Spanish children and adolescents aged 8-18 years participating in the KIDSCREEN follow-up study completed the self-administered HRQOL questionnaire KIDSCREEN-27, and questions regarding smoking and drinking habits (binge drinking), among others at baseline (2003) and 3 years after (2006). Academic achievement, a scale of the Child Health and Illness Profile (CHIP), was collected at follow-up. Data on gender and family socio-economic status was also collected. Multivariate linear regression analysis was performed to assess the influence of changes in health-related behaviours on academic achievement and HRQOL controlling for socioeconomic and family factors. **RESULTS:** Response rate at follow-up was 54% (n=454). Twenty six percent of the sample reported ever use of tobacco, while 4.6% reported to have started or to be a current regular smoker at follow-up; 18% reported starting or increasing alcohol consumption, and 16.5% on substance consumption (mainly cannabis). Preliminary multivariate analyses show that becoming a current smoker during the follow-up period was associated to worse Academic achievement among girls (beta coefficient=-5.0; p= 0.02); reporting ever drug consumption was associated with worse Psychological well-being among girls (beta= -3.1; p=0.04), and with worse Physical well-being among boys (beta= -5.9; p=0.004), at the follow-up. **CONCLUSIONS:** Changes in health-related behaviours are associated with worse outcome at 3 years of follow-up. Future studies should analyse factors related to susceptibility for regular use of tobacco and other drugs. Policy initiatives, and other factors should be taken into account preventing tobacco and other substance use at these ages.

PIH44

HEALTH-RELATED QUALITY OF LIFE FOR PATIENTS WITH CHRONIC CONDITIONS: REVEALING THE PROFILE OF BURDEN ASSOCIATED WITH CO-MORBID PHYSICAL AND MENTAL CONDITIONS IN RESPONDENTS FROM FIVE EUROPEAN COUNTRIES

Rendas-Baum R[1], Smith KJ[1], DiBonaventura MD[2], Bayliss MS[1], Alonso J[3], Ferrer M[4], Vilagut G[5]

[1]*QualityMetric Incorporated, Lincoln, RI, USA,* [2]*Kantar Health, New York, NY, USA,* [3]*IMIM-Research Institute Hospital del Mar, Barcelona, Spain, Spain,* [4]*IMIM-Hospital del Mar, Barcelona, Barcelona, Spain,* [5]*IMIM (Institut de Recerca Hospital del Mar), Barcelona, Catalunya, Spain*

OBJECTIVES: Studies often examine the impact of specific chronic conditions (CC) in isolation or in conjunction with another specific CC. Our aims were to compare: 1) the effect of physical CCs (PCC) in addition to mental CCs (MCC) to the effect of PCCs only; 2) the effect of MCCs in addition to PCCs to the effect of MCCs only; and 3) effects across country. **METHODS:** Data from the 2010 EU National Health and Wellness Survey were used (N=57,805; France, Germany, Italy, Spain, and the UK). Respondents were categorized as: 'Healthy' (no mental or physical CC); 'Physical' (physician indicated 1+ physical but no mental CCs); 'Mental' (physician indicated 1+ mental but no physical CCs); 'Physical and Mental' (1+ mental and 1+ physical CCs). Differences across groups were assessed using multivariate regression with SF-12v2® Health Survey summary measures (PCS & MCS) as outcomes and controlling for age and gender. **RESULTS:** Relative to 'Healthy' respondents, the presence of 1+ PCC was associated with a significant decrement in both PCS (-3.04 to -5.18, p<.05) and MCS (-1.23 to -2.53, p<.05). The presence of 1+ mental condition was also associated with decreased MCS (-7.10 to -13.30, p<.05) and PCS (-1.23 to -2.53, p<.05). Interestingly, the impact of co-morbid conditions, physical or mental, varied as a function of other existing conditions (physical or mental). The impact of adding 1+ PCC to an existing MCC was associated with a larger decrement in PCS (-4.34 to -6.92, p<.05) and MCS (-8.54 to -11.70, p<.05) as compared to adding 1+ PCC to those who were healthy. Results were consistent across gender and country. **CONCLUSIONS:** These findings (which are largely consistent an earlier US study) highlight the complexity of managing patients with co- or multi-morbid CCs as the measurable burden of CCs varies with the presence of other conditions.

PIH45

BURDEN OF HERPES ZOSTER AND POST-HERPETIC NEURALGIA: FINDINGS FROM A CROSS-SECTIONAL PATIENT REPORTED OUTCOMES STUDY

Carroll S[1], Gater A[2], Abetz L[2], Demuth D[3], Smith F[3], Mannan A[1]

[1]*Sanofi Pasteur MSD, Maidenhead, Berkshire, UK,* [2]*Mapi Values Ltd, Bollington, Cheshire, UK,* [3]*Adelphi Real World, Bollington, Cheshire, UK*

OBJECTIVES: Herpes zoster (HZ) and post-herpetic neuralgia (PHN) are painful conditions that can have a substantial negative impact on patients' lives. UK-specific patient reported outcome (PRO) data on the debilitating impact of these conditions is limited, however. A large-scale UK cross-sectional study, therefore, has recently been conducted to address these limitations and further inform the scientific community. Findings from this study are summarised. **METHODS:** A combined total of 382 HZ and PHN patients over the age of 50 were recruited from 49 sites throughout the UK. Participants were required to complete validated PRO measures of pain and health-related quality of life (HRQoL), including the Zoster Brief Pain Inventory (ZBPI) and the Medical Outcomes Study Short-Form 36 (SF-36). **RESULTS:** Pain was a prominent symptom among patients, with more than 50% reporting experiencing pain in the preceding 24 hours at levels typically considered to have a significant impact on HRQoL (i.e. ZBPI worst pain > 5). This was reflected in SF-36 domain and summary scores that were significantly lower in HZ and PHN patients compared to age-matched norms ($p < 0.05$). When compared to normative samples, clinically meaningful differences were observed among HZ and PHN samples across SF-36 domains assessing aspects of physical and mental well-being. In both groups, HRQoL was inversely associated with levels of reported pain. **CONCLUSIONS:** Findings indicate that the acute presentation of HZ and the development of PHN, the most common complication of HZ and that can persist for several months, are painful experiences that can have a significant impact on the physical and mental wellbeing of HZ/PHN sufferers.

PIH46

SATISFACTION WITH PRESCRIPTION AND OVER-THE-COUNTER MEDICATIONS: RESULTS FROM A NOVEL PATIENT REGISTRY

Kamble S[1], Cascade E[2], Cox T[1], Gemmen E[1]
[1]*Quintiles, Rockville, MD, USA,* [2]*iGuard, Inc, Rockville, MD, USA*

OBJECTIVES: There is a growing debate regarding switching prescription (Rx) drugs to over-the-counter (OTC) for chronic conditions as a viable option in the brand lifecycle management and cost control. Further, patients are increasingly involved in making informed treatment-related decisions. Using a novel patient registry, the current study assessed satisfaction across ten widely used Rx and OTC medications and evaluated the impact of Rx versus OTC status on treatment satisfaction for these medications. **METHODS:** The registry recruited patients from multiple sources: physicians, pharmacies, and online referrals, to report ongoing medications on www.MediGuard.org. A random sample of these patients was contacted to complete the Treatment Satisfaction Questionnaire for Medication (TSQM) Version-I, a 14-item reliable and valid instrument to capture patients' satisfaction with medication. The TSQM yields scores on four domains: effectiveness, side-effects, convenience, and global satisfaction. The study included patients on any of the ten Rx-levothyroxine, metformin, atorvastatin, simvastatin, lisinopril, zolpidem, aripiprazole, esomeprazole, duloxetine, montelukast (n=9,387) or OTC medications- ibuprofen, acetaminophen, aspirin, multivitamin, cetrizine, omeprazole, omega, naproxen, calcium carbonate, and loratadine (n=7,226). Descriptive statistics and regression analyses explored the differences in patients' satisfaction across Rx versus OTC medications. **RESULTS:** Overall, patients had mean (SD) age of 56.9 (12.4) years; 70.5% females and 73.8% White. The mean TSQM scores ranged from 61.4, 63.2 (acetaminophen, metformin) to 72.7, 76.4 (omeprazole, esomeprazole) on effectiveness, from 93.0, 81.5 (cetirizine, aripiprazole) to 99.1, 97.6 (multivitamin, esomeprazole) on side-effects, from 76.4, 78.1 (acetaminophen, metformin) to 88.2, 89.1 (loratadine, montelukast) on convenience and from 61.7, 61.1 (naproxen, metformin) to 73.8, 75.4 (cetirizine, esomeprazole) on global satisfaction. Compared to Rx, OTC showed better side-effects profile and global satisfaction but had lower effectiveness and convenience ($p < 0.001$) after adjusting for age, gender, race, self-reported severity, and co-medications. **CONCLUSIONS:** The findings suggest that differences in patients' satisfaction profiles are associated with Rx versus OTC medications.

PIH47

MEASURING THE BURDEN OF DISEASE AND INJURY IN SPAIN USING DISABILITY-ADJUSTED LIFE YEARS: A POPULATION-BASED STUDY

Gènova-Maleras R[1], Álvarez-Martín E[2], Morant-Ginestar C[3], Fernández de Larrea N[4], Catalá-López F[5]
[1]*Primary Care General Directorate, Regional Health Council, Madrid, Spain,* [2]*Rey Juan Carlos University, Madrid, Spain,* [3]*Regional Health Council, Madrid, Spain,* [4]*Laín Entralgo Agency, Regional Health Council, Madrid, Spain,* [5]*Centro Superior de Investigación en Salud Pública (CSISP), Valencia, Spain*

OBJECTIVES: We provided a comprehensive and detailed overview of the Spanish burden of disease study for the year 2008. **METHODS:** We calculated disability-adjusted life years (DALYs) at a country level using the methodology developed in the Global Burden of Disease (GBD) study. DALYs were divided into years of life lost because of premature mortality (YLLs) and years of life lived with disability (YLDs), and are presented by sex and by age groups. Results were obtained using Spanish specific-mortality data for the year 2008 and morbidity data estimated for Euro-A region (European countries with very low mortality, including Spain) of the GBD study. Data were analysed and prepared in GesMor and Epidat software. **RESULTS:** In the year 2008, DALYs lost due to all diseases and injuries was estimated at 5.1 million (DALY rate per 1000 Spanish people of all ages and both sexes: 111.0). From the total number of DALYs, 41.4% were due to premature mortality (YLLs) and 58.6% were due to disability (YLDs). Chronic non-communicable diseases accounted for 89.2% of the total number of DALYs. The three main causes of DALYs were neurological and mental disorders (29.9%), malignant neoplasms (15.8%), and cardiovascular diseases (12.5%). The leading specific causes of DALYs were unipolar depression (5.5%), ischaemic heart disease (5.5%), lung cancer (5.3%) and alcohol abuse (4.7%) among males, and unipolar depression (11.7%), dementias (10.0%), hearing loss (4.2%) and cerebrovascular disease (3.5%) among females. **CONCLUSIONS:** Measuring DALYs specifically for Spain provides a systematic analysis of health losses at a population level. The findings from this study suggest that chronic non-communicable diseases would benefit from increased evidence-based public health actions.

PIH48

ASSESSMENT OF COUNTRY-LEVEL HEALTH-RELATED QUALITY OF LIFE (HRQL) OUTCOMES AND TREATMENT EFFECT OF LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM (LNG-IUS) IN WOMEN WITH IDIOPATHIC MENORRHAGIA

Stull DE[1], Vanness D[2], Lambrelli D[3], Filonenko A[4], Franke E[4], Wittrup-Jensen K[4]
[1]*United BioSource Corporation (formerly), London, UK,* [2]*University of Wisconsin, Madison, WI, USA,* [3]*United BioSource Corporation, London, UK,* [4]*Bayer Schering Pharma, Berlin, Germany*

OBJECTIVES: Calculate the country-level scores for the SF-36v2 subscales and components for women with idiopathic menorrhagia treated with LNG-IUS; explore between-country variability in HRQL experience of this condition; and evaluate the treatment effect in different geographical settings. **METHODS:** Baseline and 12-month data from a prospective, observational study of women with idiopathic menorrhagia from 9 countries (Bulgaria, Croatia, India, Jordan, Romania, Russia, Saudi Arabia, Serbia and Montenegro, and Turkey) were analyzed. Scores were calculated for each of the eight domains and Physical and Mental component summaries (PCS and MCS) of the SF-36v2. Hierarchical modeling was applied to account for nested nature of observations within the countries. Frequentist mixed effects regressions in STATA and Bayesian Markov Chain Monte Carlo simulation in WinBUGS were used to calculate country-level estimates, controlling for covariates. **RESULTS:** Idiopathic menorrhagia negatively affects HRQL in different geographic settings; in most countries baseline mean MCS scores are more than one standard deviation (10 units) below the normative UK mean. Between-country variability was confirmed in Bayesian and Frequentists analysis for baseline subscales (range: 36-86) and MCS and PCS (range: 35-51), indicating variation in experience with menorrhagia. In general, 12-month estimates were much higher than those at baseline, indicating substantial improvement in HRQL while on treatment, regardless of country. In addition, there was a consistent, positive relationship of haemoglobin with the SF-36v2 subscales and the MCS. **CONCLUSIONS:** Women in 9 countries in the study are negatively affected by menorrhagia, though country-level variation was seen. Improvement in HRQL while on treatment was consistent across geographic settings. Exploration of potential country- or patient-level effects is recommended in future research.

PIH49

OTIS: AN AID TOOL FOR THE MANAGEMENT OF ITCHY SCALPS

Perrin P[1], Auges M[2], Rahhali N[2], Taieb C[2]
[1]*Lyon Sud, Pierre Benite, France,* [2]*PFSA, Boulogne Billancourt, France*

OBJECTIVES: Assess the impact of the treatment of urinary disorders of the lower urinary tract related to benign prostatic hypertrophy (BPH) using medical treatment under actual conditions of use. **METHODS:** A pragmatic cohort of patients treated medically, was followed up for 6 months, using several validated questionnaires: IPSS, MSF4, and SF12. **RESULTS:** A total of 146 patients treated with Serenoa Repens (hexanic extract) were evaluated, the mean age was 65.64± 8.82 years, and on average the diagnosis had been made 11 months previously. At 6 weeks, the IPSS was significantly improved ($p<0.0001$). This improvement in the IPSS score between 6 weeks (11.08±6.17) and inclusion (15.05±6.80) was 4 points. An improvement was also observed at 3 months. At 6 months, the p-value was also significant ($p<0.0001$). The improvement in the IPSS score between 6 months (7.78±423) and inclusion (14.79±6.90) was 7 points.The physical dimension (50.18±7.39 at inclusion) of the SF12 improved significantly ($p=0.0005$) from the 6th week (52.46±6.10), an improvement (2.51 points) that was confirmed at 6 months (52.07±6.54) ($p=0.0052$) in comparison with inclusion (49.56±7.53). The mental dimension (49.18±7.63 at inclusion) of the SF12 improved significantly ($p=0.0069$) at 6 month (51.81±6.59). Improvement of 2.63 points. The MSF4 was unchanged. **CONCLUSIONS:** We observed an improvement in the IPSS score from the 6th week; this statistical improvement was confirmed by a significant clinical improvement in the 6th month. This favourable progression is consistent with the improvement observed for both dimensions of the SF12.

PIH50

QUALITY OF LIFE OF STUDENTS FROM THE FACULTY OF PHARMACY AT MEDICAL UNIVERSITY OF WARSAW IN 2011

Zawodnik S, Kiljan A, Hermanowski T, Golicki D, WQOLSWG Quality of Life Students Working Group
Department of Pharmacoeconomics, Medical University of Warsaw, Warsaw, Poland

OBJECTIVES: The aim of this study was to measure Health Related Quality of Life among Pharmacy students at Medical University of Warsaw. **METHODS:** In March 2011, students from the Faculty of Pharmacy, Medical University of Warsaw were surveyed with a set of HRQoL questionnaires. The survey was conducted in the middle of the semester, when students have no exams, nor tests and was a part of long-term Pharmacoeconomic Student Chapter's project. Students self-completed pen and pencil versions of questionnaires and didn't receive any compensation. They were asked to give information regarding sex, age, year of study, average grade during the previous year of study and to complete final official Polish version of EQ-5D-5L, followed by EQ-VAS, SF-36 v.1 and EQ-5D-3L. **RESULTS:** Three hundred eighty three students were approached, 369 responded to EQ-5D-5L and SF-36 and were included in the final analysis. Missing data included: sex in 1 respondent, age in 2 and EQ-VAS in 6 respondents. Concerning SF-36 dimensions, students reported major problems in vitality 53.69 ± 18.47 as opposed to physical function-

ing 95.51 ± 10.09. Mean rate of own health on EQ-VAS was 80.30 ± 15.21 and mean EQ-5D index, based on Polish TTO value set, was 0.94 ± 0.07 (in the range from -0.523 to 1). Students of 1st year reported lowest QoL independently of the measure used: EQ-VAS 76.4 ± 17.72 and EQ-index 0.92 ± 0.07. **CONCLUSIONS:** Generic questionnaires used in the survey are sensitive enough for measuring quality of life in young and relatively healthy population. Students of 1st year reported lowest quality of life with all questionnaires. The survey needs to be continued in next years.

PIH51

WHAT DO PATIENTS WITH RARE DISEASES EXPERIENCE IN THE MEDICAL ENCOUNTER? EXPLORING PATIENT-PHYSICIAN-INTERACTION PATTERNS, ITS ANTECEDENTS AND ITS CONSEQUENCES

Budych K[1], Helms TM[1], Schultz C[2]
[1]*German Foundation for the chronically Ill, Fuerth, Germany,* [2]*Berlin Institute of Technology, Berlin, Germany*

OBJECTIVES: A growing body of evidence links effective physician-patient communication to desirable outcomes such as improved adherence to treatment and higher satisfaction of both patient and physician. However, when it comes to rare diseases, the patient is forced to become knowledgeable about his own disease state and therapies. Our objective was to describe and specify the experiences of patient-physician-interaction in rare diseases, to develop an empirically derived typology of interaction patterns and to explore the challenges associated with each of these patterns. **METHODS:** We designed a multi-case study as a series of semi standardized interviews with patients suffering from rare diseases. Therefore we extracted six different rare diseases: Amyotrophic lateral sclerosis, Marfan's syndrome, Wilson's disease, Epidermolysis bullosa, Duchenne muscular dystrophy and Neurodegeneration with brain iron accumulation. A total of 120 interviews were recorded, transcribed and analyzed thematically based on emerging codes. **RESULTS:** As suggested, insufficient expertise of the health care providers proved to be a major problem in the highly specialized treatment process of rare diseases. Here, it is often the patient himself who becomes an expert to determine what kind and how much service he needs. Thus, we could identify the patient-directed interaction as a widely experienced communication pattern among patients with rare diseases. Physician's ability and willingness to accept the patient as an expert emerged as a major determinant for patient satisfaction. **CONCLUSIONS:** People with rare diseases often face challenges due to the low prevalence and the resulting lack of knowledge among their providers. Our study showed the relevance of the provider's ability to acknowledge the active role of the patient as an informed, involved and interactive partner in the treatment process. However, allowing the patient to control therapy may require a change of mind-set with some long-standing traditional roles in healthcare.

Individual's Health – Health Care Use & Policy Studies

PIH52

MEDICINE PRESCRIBING PATTERNS IN HIV/AIDS AND NON-HIV/AIDS CHILDREN: A COMPARITIVE STUDY IN THE PRIVATE HEALTH CARE SECTOR OF SOUTH AFRICA

Mocke M, Lubbe MS, Burger JR
North-West University, Potchefstroom, South Africa

OBJECTIVES: Although the prevalence of human immunodeficiency virus (HIV) infection among children is reported to be high, little is known about antiretroviral (ARVs) treatment patterns. This study aims to compare medicine prescribing patterns of children with HIV/AIDS to those without HIV in the private health care sector of South Africa. **METHODS:** A quantitative, retrospective drug utilisation review was performed utilising medicine claims data of a pharmacy benefit management company. Data for a four-year period (January 1, 2005 to December 31, 2008) were analysed. The study population consisted of all children ≤12 years, divided into those receiving ARV medications and a control group (not receiving ARVs). Data were analysed using the SAS® Programme (9.1). **RESULTS:** A total of 0.2% of all children in 2005 (N = 197 323) received ARVs versus 0.4% in 2008 (N = 98 939). HIV/AIDS children received 7.39 ± 4.69 prescriptions for ARVs per year during 2005 versus 9.72 ± 4.49 in 2008. An average 3.05 ± 0.65 ARVs were prescribed per prescription in 2005 versus 3.19 ± 0.58 in 2008. HIV/AIDS children received 11.51 ± 7.17 prescriptions for other medication (non-ARVs) per year during 2005 and 13.46 ± 7.14 during 2008 compared to 3.86 ± 3.71 (d = 0.8) prescriptions per year in 2005 and 4.36 ± 4.05 (d = 1.25) in 2008 for the control group. HIV/AIDS children received mostly sulphonamides and combinations, followed by antitussives and expectorants, penicillin and combination analgesics whereas the control group received mostly penicillin followed by antitussives and expectorants, combination analgesics and analgesics/antipyretics. **CONCLUSIONS:** There was an increase in the number of children with HIV/AIDS over the study period. These children received significantly more prescriptions per year than the control group. Further research is needed to investigate the future medicine treatment cost of HIV/AIDS children in the South African private health care sector.

PIH53

ALPHA BLOCKERS, 5-ALPHA REDUCTASE INHIBITORS, PDE-5 INHIBITORS AND ANTIMUSCARINIC MEDICATION USE IN US PATIENTS DIAGNOSED WITH BENIGN PROSTATIC HYPERPLASIA, AND LOWER URINARY TRACT SYMPTOMS WITH AND WITHOUT ERECTILE DYSFUNCTION

Burge R, Le TK, Viktrup L, Watts S
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: To evaluate the alpha blockers, 5-alpha reductase inhibitors, PDE-5 inhibitor and antimuscarinic medication use in US patients diagnosed with benign prostatic hyperplasia (BPH), lower urinary tract symptoms (LUTS) and erectile dysfunction (ED). **METHODS:** Employing a retrospective study design on a large US healthcare claims database (MarketScan), male patients aged 18+ with a diagnosis for BPH, LUTS and/or ED between 1/1/07 and 12/31/09 were identified. Patients with prostatectomy were excluded. Eligible patients had 24 months of continuous pharmaceutical and medical benefit coverage. Chi-square and Wilcoxon tests were used to make statistical comparisons between cohorts: BPH Only (BPH), ED Only (ED), BPH+ED, BPH+LUTS w/o ED and BPH+LUTS w/ED. **RESULTS:** There were 308,844 patients that met inclusion criteria, and overall 33%, 15%, 19%, and 6% had a prescription for alpha-adrenergic antagonist, 5-alpha-reductase inhibitor, phosphodiesterase-inhibitor, and antimuscarinic, respectively. Overall, 53% had medication use where 6% received combination therapy, 19% switched therapy and 36% discontinued therapy. BPH patients had higher rates of combination medication use (8% vs. 1%, $p<0.0001$); switching (8% vs. 7%, $p=0.0017$) and medical visits (17 vs. 14 mean visits, $p<0.0001$) than ED patients. However, ED had higher rates of therapy discontinuation (27% vs. 15%, $p<0.0001$) than BPH and ED. In addition, BPH+ED had higher switching (15% vs. 8%, $p<0.0001$), discontinuation (24% vs. 15%, $p<0.0001$) and medical visits (19 vs. 17 mean visits/yr, $p<0.0001$) than BPH. Furthermore, BPH+LUTS w/ED had higher switching (24% vs. 18%, $p<0.0001$), discontinuation (27% vs. 22%, $p<0.0001$) and incurred more medical visits (25 vs. 23 mean visits/yr, $p<0.0001$) than BPH+LUTS w/o ED. **CONCLUSIONS:** BPH and BPH+LUTS patients with ED had higher switching and discontinuation rates than patients without ED. Thus, patients with comorbid ED may require more extensive pharmacologic management and monitoring, resulting in more medical visits than patients without ED.

PIH54

ANALYSIS OF THE FORMULARY ENSURE CHILDREN'S HOSPITALS IN UKRAINE: FIRST RESULTS

Zalis'ka O, Maynych Y
Danylo Halytsky Lviv National Medical University, Lviv, Ukraine

OBJECTIVES: The Order of Ministry of Health (N 529 from July 22, 2009) was introduced system of formulary medicines in Ukraine. In 2011 the third edition of the Ukrainian State Formulary of medicines was made. However, the State formulary for children in Ukraine has not been adopted. **METHODS:** We conducted a retrospective analysis of a local formulary for children, according to two divisions - Children's neonatology and intensive care for children in an Lviv medical hospital. We used the method of ABC-analysis, the costs and rates of provision children's medicines for public funds and resources for parents. **RESULTS:** Established that the local formulary of children's health-care setting contains 443 medicines with 14 ATC -groups. The major share of exchanges takes four groups: A-20%; R-16%; J -14%; N - 12%. Determined that the cost of treatment of pulmonary surfactant preparations is 1175 euros for one child (at June 1, 2011, 1 Euro = 11,40 UAH). Provision of surfactant for infants for the budget is only about 28%, the rest is funded by parents. In the Formulary 17 includes antibiotics, of which only 24% provided by the budget, the rest - at the expense of patients.Innovational antibiotics financed only by 2-4% of the requirement. In children's hospitals 2.5% took medication extemporal production, in particular vitamin powders, solutions, powders with folic acid, solution for rehydration, and others. **CONCLUSIONS:** Real data of medicines in children's hospitals do not meet the need. Necessary to create the State formulary for children, costs to be financed from public funds. The method of "willingness to pay" to determine the list of medicines that will pay parents.

PIH55

NECESSITY OF ADMISSIONS AND HOSPITALIZATIONS IN SELECTED TEACHING UNIVERSITY AFFILIATED AND PRIVATE HOSPITALS OF SHIRAZ, IRAN IN 2007

Hatam N[1], Askarian M[2], Sarikhani Y[3], Ghaem. H[3]
[1]*Shiraz University of Medical Sciences(SUMS) -Shiraz - Iran, shiraz, Iran,* [2]*Shiraz University of Medical Sciences (SUMS, shiraz, Iran,* [3]*Shiraz University of Medical Sciences (SUMS), shiraz, Iran*

OBJECTIVES: The use of acute hospital beds is an issue of concern both to policymakers and practitioners. In most countries attempts to improve efficiency and reduce costs in this sector. One of the most widely used instruments for assessing inappropriate hospital use is Appropriateness Evaluation Protocol (AEP), which consists of a set of standards based on objective criteria relating to the condition of the patient or clinical services received. The aim of this study was to measure inappropriateness of admission and inpatient stays in four major hospitals of Shiraz, Iran. **METHODS:** One of the most widely used instruments for assessing inappropriate hospital use is Appropriateness Evaluation Protocol (AEP), which consists of a set of standards based on objective criteria relating to the condition of the patient or clinical services received **RESULTS:** Results: The results showed that 22% of the total admissions in four hospitals were rated as inappropriate. Most and least inappropriate admissions were found in both teaching university affiliated hospitals. Our data show that a total of 29.6% (average 6.40%) of the hospital stays in the sample were judged to be inappropriate. The result of Least Significant Difference (LSD) Test showed a significant association between the mean days of inappropriate stay and turn of admission in all hospitals. In all hospitals, a significant association was observed between inappropriateness of hospital stay, costs and length of stay. **CONCLUSIONS:** Considering the findings of this study and other studies in Iran and other countries, we can conclude that factors involving in inappropriate admission of patients in the hospitals are mostly fixed and similar factors. To solve this problem we can use some strategy such as: Improving the performance of the referral system, using standard criteria for an appropriate evaluation protocol by the medical staff, Extending of outpatient diagnosis services for reducing of inappropriate hospitalization.

PIH56
PERFORMANCE ASSESSMENT OF GA DISTRICT MUTUAL HEALTH INSURANCE SCHEME IN THE GREATER ACCRA REGION IN GHANA
Nsiah-Boateng E
National Health Insurance Scheme (NHIS), Accra, Ghana
OBJECTIVES: Ghana established National Health Insurance Scheme (NHIS) in 2004 to replace out-of-pocket payment popularly referred to as 'cash and carry', which created financial barrier to health care access to the poor and vulnerable. However, the NHIS was fully implemented in 2005 and has since faced operational challenges such as delays in issuance of membership cards to registered members and payment of providers claims. The study assessed performance of the Ga District Mutual Health Insurance Scheme over the period, 2007-2009 and provided recommendations to improve on its operations. **METHODS:** Desk review method was employed to review membership, revenue, expenditure, and medical claims data of the Scheme. A household survey was also conducted in the Madina township to determine community coverage rate of the scheme. **RESULTS:** The study shows a membership coverage of 22.6% and a community coverage of 22.2%. About one-third of the registered members are paying premium to the scheme and this affects revenue. Financially, the scheme depends largely on subsidies and reinsurance from National Health Insurance Authority (NHIA) for 89.8% of its revenue. Approximately 92% of the total revenue was spent on medical bills. About 99% of provider claims are settled beyond the stipulated 4 weeks period. This poses financial challenge to healthcare providers and may force them to take measures that defeat the purpose of the scheme. **CONCLUSIONS:** There are downward trends in membership coverage and revenue from contributions. Also, there are lengthy delays in claims settlements. Establishment of district schemes in the Ga East and Ga West sub-districts will be necessary to improve membership coverage and revenue mobilization from the informal sector. Whilst the claims are being vetted, it will be important for the scheme to advance part-payment to healthcare providers to ensure continuous provision of services to insured members.

PIH57
PEDIATRIC DAYCARE IN BELGIUM
Cohen L[1], Benahmed N[2], Laokri S[2], Zhang WH[3], De Wever A[2], Alexander S[2]
[1]*Université Libre de Bruxelles, Anderlecht, Belgium,* [2]*Université Libre de Bruxelles, Brussels, Belgium,* [3]*Université Libre De Bruxelles, Brussels, Belgium*
OBJECTIVES: To evaluate a possible switch from traditional pediatric hospitalization to pediatric medical daycare in Belgium. **METHODS:** Observational prospective survey was performed in 12 Belgian hospitals during fifteen days in autumn 2010. Characteristics of the patients including main chronic pathology were recorded, as were the cause of the hospitalization (work-up with or without anesthesia, treatment with or without anesthesia, other) and the different acts possibly done. **RESULTS:** Among the 592 children (<16 years old), 41.3% had a chronic disease. The most common conditions reported were neoplasia-related (61.0%). The main causes to admit daycare were a work- up (46.9%) or a treatment (46.1%). 24.5% of the children underwent anesthesia. 10.0% of all the technical acts performed were neoplasia-related (chemotherapy, blood transfusion. . .), which means that 90% of the acts were not neoplasia-related and could have be done regardless of any chronic condition. **CONCLUSIONS:** According to international convention and parental will, traditional overnight hospitalization of a child, if not avoidable, should be as short as possible. If there is no need of special techniques (e.g. O2therapy) or an overnight treatment, a short stay in a pediatric medical daycare unit helps treating children without conventional hospitalization, regardless of an eventual chronic condition.

PIH59
ARE OLDER MOTHERS MORE PRONE TO HAVING CHILDREN WITH DISABILITIES? LIFETIME DISABILITY OUTCOMES VERSUS MULTIPLE BIRTH REDUCTIONS ARISING FROM IN-VITRO FERTILIZATION (IVF) TREATMENTS IN CANADA
Zowall H[1], Brewer C[2]
[1]*McGill University, Montreal, QC, Canada,* [2]*Zowall Consulting Inc., Westmount, QC, Canada*
OBJECTIVES: We investigated the clinical and economic consequences of reductions in multiple births disabilities, according to mothers' age, resulting from switching from private to public provisions of IVF services in Canada. **METHODS:** Using the Canadian Fertility Cost Model we estimated the potential decrease in lifetime disability rates arising from the reduction of multiple pregnancies. Net lifetime disability rates/costs were compared across mothers' ages 28 to 45, by singleton, twin, and triplet+ births. Probabilistic sensitivity analyses were performed to account for the effect of uncertainty in lifetime disability rates/costs. Incremental net benefits (INB) of reducing multiple births, confidence intervals around the INB and cost-effectiveness acceptability curves (CEAC) are reported. **RESULTS:** Assuming reductions in multiple birth rates equal to those reached by selected European countries, where pregnancy rates are unaffected by decreases in multiple birth rates, the proportions of multiple births could be reduced from 28.8% to 13.4%. Switching from private to public provisions (multiple birth reduction scenario), lifetime disability rates for multiple birth rates are lower in older woman (40+), due to low birth success rates, hence low multiple births. For women under 35, aged 35-39, and over 40, net reductions in lifetime disability due to decreases in multiple births are 3.6%, 3.2% and 2.6%. Women under 35, aged 35-39 and over 40 had cost savings of $31 M, $22 M and $4.5 M per 1% decrease in net lifetime disability. Within a range of $150 M and $558 M, the proportion of the total cost savings, attributable to mothers in the three age groups are 56%, 38%, and 6%, respectively. **CONCLUSIONS:** Majority of potential cost savings accrues to women under 40 years old. Relatively higher reductions in lifetime disability in younger women indicate that efforts to reduce multiple births should primarily be aimed at woman under 40 years old.

PIH60
CHANGES IN BLOOD COAGULATION PROPERTIES MEASURED BY THROMBELASTOMETRY DURING SPIROERGOMETRY IN SPORTSMEN AND IN SPORTSWOMEN
Paska T[1], Kriszbacher I[2], Sipos E[3], Magyarlaki T[4], Sarszegi Z[3], Toth A[5], Jeges S[1], Szabados S[3], Kovacs GL[2]
[1]*Faculty of Health Sciences of University of Pecs, Pecs, Hungary,* [2]*University of Pécs, Pécs, Hungary,* [3]*Heart Center of University of Pecs, Pecs, Hungary,* [4]*University of Pecs, Pecs, Hungary,* [5]*Insititution of Physical Education and Sport Sciences, Pecs, Hungary*
OBJECTIVES: The physical exercise is known to associate with multiple changes in blood haemostasis parameters in healthy individuals. **METHODS:** In the current study haemostatic alterations induced by physical exercise were measured by rotational thrombelastometry (ROTEM, Pentapharm) in 13 healthy sportsmen and 10 healthy sportswomen. Venous blood was drawn immediately before and after finishing spiroergometry for rotational thrombelastometry analyses. The 3 basic dedicated ROTEM test applications NATEM (recalcification), INTEM (intrinsic pathway) and EXTEM (extrinsic pathway) were performed. The following key parameters were recorded: clotting time (CT), clot formation time (CFT), alpha angle, maximum clot firmness (MCF), maximum lyses (ML), amplitude reduction 5,-10,-15,-20 min after MCF (A5, A10, A15, A20). Statistical analysis was performed using the Wilcoxon-test. **RESULTS:** In case of sportsmen all significant statistical differences related with physical exercise were obtained by NATEM (but not with INTEM or EXTEM) measurements. After the exercise the mean CT was shorter (315.7 +/− 91.8 seconds vs. 255.3 +/− 75.9 seconds, P= .039). The MCF was broader (53.9 +/− 4.23 mm vs. 65.0 +/− 12.87 mm, P= .004). In case of sportswomen the MCF was broader after exercise (60,0+/−3,7 mm vs. 66,7+/−10,4 mm, P= .04) by NATEM measurements. Other parameters were not statistically significant. Emphasize the importance of change in CT values which were decreasing after exercise but did not reach the significant level. **CONCLUSIONS:** On the basis of our data we could demonstrate that ROTEM is sensitive to exercise-induced hemostatic alterations. It was shown that during physical load hyper-coagulation processes occurred. In this processes there seem not to be differences due to gender. Our study might be able to help point out the differences in exercise-induced alterations of hemostatic regulation related to gender.

PIH61
A QUALITATIVE EVALUATION OF THE INTEGRATED MANAGEMENT OF CHILDHOOD ILLNESS (IMCI) IN NORTHEASTERN BRAZIL AND PERU: THE MANAGERS' PERSPECTIVE
Borda A[1], Palma M[2], Amaral J[3], Conde P[2]
[1]*ENS (Instituto de Salud Carlos III. ISCIII), Madrid, Spain,* [2]*AETS (Instituto de Salud Carlos III. ISCIII), Madrid, Spain,* [3]*Universidad Federal do Ceará, Fortaleza, Ceará, Brazil*
OBJECTIVES: In 1996 PAHO/WHO and UNICEF developed the IMCI strategy with the aim of improving the health workers' performance, strengthening the health system support and improving the knowledge about the children care best practices at home and in the community. The objective of this study is to evaluate the IMCI strategy through the health managers' perceptions. **METHODS:** Qualitative design using semi-structured interview. Population Study: key persons, governmental and nongovernmental health organizations managers who participated in the IMCI strategy in the State of Ceará (Northeast Brazil) and in Peru. The interviews were conducted during May-June 2011. They were tape recorded and transcribed later. For the analysis, a triangulation method was carried out with another researcher, reviewing the literature and other documents. **RESULTS:** An important reduction in infant mortality rate was observed in Ceará (from 32 per 1000 live births in 1997 to 15.6 in 2009) and in Peru (from 43 per 1000 live births in 1996 to 17 in 2008) by the decrease in post-neonatal mortality due to diarrhea and pneumonia. In both places at the beginning there was a large-scale training for the health staff, doctors and nurses, and less for the community health agents. The evolution of the strategy has been different. In Ceará there was a decrease of the interest and a lack of support from governments. In Peru, the government adopted the strategy; likewise there was a greater incorporation into the university teaching, distance learning and the addition incorporation of new content (perinatal/neonatal, asthma and bronchoobstructive syndrome, child development, oral health, abuse, violence and accidents, diabetes and obesity). **CONCLUSIONS:** The IMCI strategy has been developed differently in the studied countries. This information can be used to evaluate the strategy and the participation of the different sectors responsible for the child health.

PIH62
COMPARATIVE PRICING AND REIMBURSEMENT ANALYSIS IN FOUR EAST EUROPEAN COUNTRIES
Peev S[1], Petrova G[2], Baran A[3], Petrikova A[4], Daneasa D[5]
[1]*Medical University, Sofia, Bulgaria,* [2]*Medical University, Faculty of Pharmacy, Sofia, Bulgaria,* [3]*Medical University of Warsaw, Warsaw, Poland,* [4]*VFU Brno, Brno, Czech Republic,* [5]*Universitatea din Bucuresti, Bucharest, Romania*
OBJECTIVES: To analyse and compare the pricing and reimbursement procedures of pharmaceuticals in Bulgaria (BG), Czech Republic (CZ), Poland (PL), and Romania (RO). **METHODS:** Health legislation including corresponding laws and regulations determining pricing and reimbursement procedures was reviewed. Countries were selected on the basis of their mutual referencing. **RESULTS:** In all four countries health insurance is obligatory and medicines prices are regulated applying the reference pricing system for prescription medicines. In BG, RO and PL positive drug lists constitute reimbursement approach. Bulgaria's reference countries include RO and CZ, not PL. Romania's reference basket encloses 12 countries including BG

and CZ, while PL references to all EU countries. CZ and RO employ the average among the three lowest reference prices and BG and PL the lowest reference price. There is a regressive margin scale in all countries. In BG, RO and PL margins are separated for wholesalers and retailers, while in CZ they are negotiated. In CZ and PL there are multiple insurance companies compared to BG and RO, where there is only one. Currently RO's reimbursement is 50% of the price for all prescription drugs, BG and PL use 4 reimbursement levels, PL and CZ employ a complex external and internal referencing. In CZ the reimbursement base is the cheapest medicinal price in the group. In BG, PL and RO the reimbursement level is the cheapest price per DDD for every INN. All countries require pharmacoeconomic evidences, but CZ and PL employ guidelines, while BG and RO apply criteria for evaluation. **CONCLUSIONS:** We deem BG and RO systems less adaptable, but clearer to follow. CZ and PL systems show greater flexibility, due to existence of negotiation and freedom.

Individual's Health – Research on Methods

PIH63

THE KIGS QUALITY INSIGHT PROGRAM ASSESSING THE QUALITY OF CARE FOR SHORT CHILDREN TREATED WITH GROWTH HORMONE USING THE OUTPUT FROM A LARGE PHARMACO-EPIDEMIOLOGICAL SURVEY

Kaspers S[1], Ranke M[2], Loftus J[1], Wollmann H[1], Doerr HG[3]
[1]*Pfizer Ltd, Tadworth, UK,* [2]*University Children's Hospital, Tuebingen, Germany,* [3]*Universitätsklinik für Kind und Jugendliche, Erlangen, Germany*

OBJECTIVES: Despite nearly 25 years of experience with recombinant human growth hormone (GH) treatment modalities vary significantly between centres and regions and final outcome of GH therapy varies widely . In a country like Germany, for example, children with growth disorders are treated with Genotropin® (Pfizer Inc, New York) in more than 150 institutions with different levels of experience. **METHODS:** Data collected from more than 75,000 children with growth disorders treated with Genotropin are followed-up worldwide in a large, pharmaco-epidemiological database (KIGS, Pfizer International Growth Study). Country specific datasets are used to compare treatment standards and demonstrate differences between individual centres and the country as a whole. Site-specific, individualized reports enable clinicians to anonymously benchmark the quality of care in their treatment centre. Quality indicators (like diagnostic tests, height and height velocity, GH dose, treatment response and responsiveness, treatment duration, adverse events, completeness of documentation) are followed and compared. **RESULTS:** Structural aspects as well as process and outcome indicators differed between the paediatric endocrinology centres, e.g. age at start of therapy, GH doses and diagnostic procedures. The reports allowed self-audit of clinical practice, sharing of best practice and promote discussion of clinical decision making in paediatric specialist care forums. **CONCLUSIONS:** The KIGS Quality Insight (KIGS QI) program provides a successful approach to unmask deficits and to improve the outcome of care. The output from the centre and country specific analysis allows identification and follow-up of GH non-responders and assists with demonstration of standard of care and treatment outcomes in the country to hospital managers, guidelines committees and payers. Results from KIGS can be successfully used to enable investigators to compare their treatment centre with the country as a whole and to assess changes over time.

PIH64

FEMALE URINARY INCONTINENCE IN GERMANY– COST EXPLOSION TOMORROW?

Zakrzewska K[1], Henkel I[2]
[1]*Ethicon, Spreitenbach, Switzerland,* [2]*Johnson and Johnson Medical, Norderstedt, Germany*

OBJECTIVES: To estimate costs of routine care for female urinary incontinence in nursing care in Germany. The management of female urinary incontinence is considered as the most cumbersome task in nursing homes for the elderly. Despite the great economic burden of incontinence, the largest cost category, routine care costs, is poorly described, and there are limited data on cost in nursing homes **METHODS:** In cooperation with a nursing home, cost of managing incontinent patients was evaluated. Both direct patient-material and laundry costs were considered. Time required to manage an incontinent patients was also evaluated. Data were collected on randomly selected female patients. The determination of the cost was based on the existing prices and the usual salary of employees in nursing homes. **RESULTS:** Total cost of managing an incontinent patient sums up to €2260.06/month/patient. Cost calculation of nursing care was based on a 4 times/day changing of diapers. This accounted in total €434.40 for the material costs (anatomical pads, disposable gloves, hand and surface disinfectants, incontinence bed cover, mattress protectors, pants, wound cream, protective aprons and diapers). The costs for the nursing staff work amounted to €1825.66. The results are in contrast to the publication of Schulenburg et. al who analyzed the material costs in German Health Care System by incontinence patients. The annual costs were calculated with 261 €. Personnel costs were not calculated. **CONCLUSIONS:** Female urinary incontinence demands highest attention and should not be taken as symptom of aging. Rather, the urinary incontinence is treatable disease, which improves the quality of life and reduces the cost of health care. Female urinary incontinence should be perceived as a widespread disease. Approaches would include the development of a disease management program and the implementation in German social act.

PIH65

WHAT ARE WE MISSING IN MENINGOCOCCAL DISEASE MODELLING TO BETTER UNDERSTAND THE HEALTH AND ECONOMIC IMPACT OF NEW VACCINES?

Vickers DM[1], Anonychuk A[2], De Wals P[3], Bauch CT[4]
[1]*University of Saskatchewan, Saskatoon, SK, Canada,* [2]*GlaxoSmithKline Biologics, Wavre, Brabant wallon, Belgium,* [3]*Centre de Recherche du CHUQ – University of Laval, Quebec, 2M2, Canada,* [4]*University of Guelph, Guelph, N1G 2W1, Canada*

OBJECTIVES: Neisseria meningitidis (Nm) is a leading cause of bacterial meningitis and bacteremia worldwide. While infection (or carriage) is common throughout a person's life history, invasive meningococcal disease (IMD) is rare and is disproportionately observed in infants and adolescents. Previous models that evaluated the health and economic impact of meningococcal vaccines have not always considered key epidemiological features such as transmission mechanisms, or risk of IMD outbreaks. Our objective was to understand which natural history assumptions best matched the observed time trends in disease notification data, in order to use the most realistic model to economically evaluate new meningococcal vaccination policies. **METHODS:** We formulated two dynamic stochastic compartmental models of Nm transmission within a population of hosts: the first assumed transient natural immunity entailing perfect cross-protection between serogroups; the second assumed partial (and thus imperfect) cross-immunity amongst serogroups. In both models, Nm infection and IMD were assumed to be distinct stochastic processes and IMD was assumed to occur in a small fraction of the population at the time infection is acquired. **RESULTS:** Model parameters were calibrated to carriage data and 62-year case notification data from Canada. Sustained oscillations and co-circulation of multiple serogroups are ubiquitous in the IMD case notification data of many countries. Only the second model captured these patterns, while the first model unrealistically predicted that one serogroup would always disappear from the population. **CONCLUSIONS:** The predicted impact of various meningococcal vaccines will likely depend strongly on assumptions about strain interactions, some of which lead to dynamics that are inconsistent with observations. While empirical unknowns about strain interactions between Nm serogroups remain, our results suggest that cross-protection and natural immunity assumptions significantly impact predicted multigroup dynamics, and hence may affect predictions of the health and economic impact of new vaccination policies.

PIH66

TRAIT OR STATE: AN EXPLORATION OF SELF-ESTEEM, HAPPINESS AND QUALITY OF LIFE BY TIME SERIES

Yang JJ, Yao G
National Taiwan University, Taipei, Taiwan

OBJECTIVES: Mainstream of psychological researches usually utilizes large samples, cross-sectional studies and aggregate frames to analyze data and interpret them. However, the limitations are that the specific features of individuals are not easy to be revealed and the time effect has been ignored. This study explores both of the trait-like and state-like properties including global self-esteem, happiness and the quality of life. By using time series analysis which can examine individual, longitudinal and non-aggregate data, the properties of psychological measures can be investigated. **METHODS:** Ten college students (mean age=20.6 year, SD=2.18) and four adults (mean age=30.27 year, SD=1.23) participated in this study. Each subject completed six 10-cm visual analogue scale items, once a day for 2 months. These items measure subject's global self-esteem, happiness, the quality of life, positive life events, negative life events as well as random error (i.e., Participant was asked to make a mark on the center of a line). Time series analysis, including autoregressive and moving average modeling procedures, was used to examine the time dependency (i.e., more trait-like) for each item. **RESULTS:** For the college sample, 80% of autocorrelation and partial-autocorrelation coefficients were not significant across time lag. This result doesn't fully support the existence of time dependency for each item. On the contrary, 55% of autocorrelation and partial-autocorrelation coefficients were statistically significance for the adult sample. Both samples showed significant correlations among psychological measures (self-esteem, happiness and the quality of life) and life events (positive and negative). **CONCLUSIONS:** In conclusion, the results support that self-esteem, happiness and quality of life may contain both trait-like and state-like properties, and the time dependency of psychological measures is more stable especially in adults.

PIH67

SUCCESSFUL DEVELOPMENT OF ANNUAL AND LONG TERM PREDICTION MODELS TO ESTIMATE HEIGHT OUTCOME FOLLOWING GROWTH HORMONE (GH) THERAPY IN CHILDREN USING DATA FROM KIGS – A LARGE PHARMACOEPIDEMIOLOGICAL SURVEY

Loftus J[1], Ranke M[2], Lindberg A[3], Brosz M[4], Kaspers S[5], Wollmann H[5], Koltowska-Haggstrom M[6], Roelants M[7]
[1]*Pfizer Ltd, Tadworth, UK,* [2]*University Children's Hospital, Tübingen, Germany,* [3]*Pfizer, Sollentuna, Sweden,* [4]*StatConsult, Magdeburg, Germany,* [5]*Pfizer, Tadworth, UK,* [6]*Pfizer, Sollentuna, Sweden,* [7]*Laboratory of Anthropogenetics - University of Brussels, Brussels, Belgium*

OBJECTIVES: Annual growth prediction models following growth hormone (GH) treatment have been developed to facilitate treatment guidance. However, accurately predicting height over the long term, during pre-pubertal treatment years has not been assessed and is a prerequisite for modelling of cost effective optimum height outcomes. **METHODS:** Annual prediction models utilised data from large cohorts sourced from the KIGS database (Pfizer International Growth Database, comprising 75,000 children with growth disorders) and describe the likely annual height gain based on patients' auxological and biochemical characteristics (e.g. GH dose, age, mid parental height standard deviation [SDS] and weight SDS score) at treatment start. The most likely long-term height development was simulated prospectively up to 4 years by sequential application of existing yearly prediction algorithms for height velocity (HV) and newly developed algorithms for weight gain

in pre-pubertal children with idiopathic GH Deficiency (GHD) and Turner Syndrome (TS). The long-term prediction of height was validated in new cohorts of pre-pubertal children with GHD (n= 664) or TS (n=607) from KIGS. **RESULTS:** When height was simulated from GH start in GHD, the predicted mean (SD) gain after 4 years was 30.4 (3.4) cm; the observed height gain was 30.0 (5.0) cm. In TS the corresponding predicted and observed mean gains were 27.2 (2.2) and 26.5 (3.8) cm. **CONCLUSIONS:** Sequential application of annual KIGS growth prediction models permits accurate simulation of height development during the first four years of GH treatment in GHD and TS and is applicable for patient groups from GH start. Long-term growth simulation helps managing patient's expectations and facilitates an individualised, cost effective growth hormone (GH) therapy in children.

PIH68

STUDYING HETEROGENEITY IN TREATMENT RESPONSE IN WOMEN WITH IDIOPATHIC MENORRHAGIA TREATED WITH LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM (LNG-IUS): APPLICATION OF INNOVATIVE METHODS TO IDENTIFY DIFFERENTIAL RESPONSE

Stull DE[1], Houghton K[1], Filonenko A[2], Wittrup-jensen K[2]
[1]*United BioSource Corporation (formerly), London, UK,* [2]*Bayer Schering Pharma, Berlin, Germany*

OBJECTIVES: To establish whether there are subsets of women with idiopathic menorrhagia who experience differential health-related quality of life (HRQL) benefits with LNG-IUS treatment, and which factors could be attributed to those differences. **METHODS:** Data for women with idiopathic menorrhagia residing in India, Russia and Turkey were derived from a prospective, 12-month observational study. Latent profile analysis (LPA) was used to identify unknown subgroups of differential responders on the Mental Component Summary (MCS) of the SF-36v2. Post hoc analyses were performed to characterize identified subgroups using baseline and 12 month data. **RESULTS:** Overall improvement in MCS scores from baseline to 12 months was 8.4 points. LPA analyses revealed two distinct subsets of patients: one smaller subset (30% of the sample) showed a smaller improvement (2.3 points) than the improvement overall and are thus referred to as 'partial-responders.' A larger subgroup (70% of the sample) was identified with a much greater improvement (11.3 points) than that overall, thus referred to as 'responders'. Post hoc analyses revealed statistically significant differences between MCS responders and partial-responders: significantly greater proportion of MCS responders had university-level education, were more likely to reside in India or Russia and be employed, reported'none' or 'light' bleeding intensity while on treatment, reported greater patient and physician satisfaction with treatment, and had higher 12-month haemoglobin levels. **CONCLUSIONS:** Understanding of heterogeneity of treatment response is critical for routine clinical practice. Application of LPA identified two distinct subgroups of women showing differential response to HRQL from LNG-IUS treatment. All women showed a statistically significant improvement in HRQL as measured by the MCS, although this improvement was greater for a large subset of women in the sample. Country-level differences in treatment effect on mental HRQL may be subject to cultural or health care practice differences.

Systemic Disorders/Conditions – Clinical Outcomes Studies

PSY1

TOLERABILITY OF ORAL LONG-ACTING OPIOIDS IN THE TREATMENT OF CHRONIC PAIN: A SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS

Nalysnyk L[1], Kavanagh S[2], Xu Y[1], Mercaldi K[3], Martin A[1], Merchant S[4]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Janssen Global Services, Beerse, Belgium,* [3]*United BioSource Corporation, Bethesda, MD, USA,* [4]*Janssen Global Services, LLC, Raritan, NJ, USA*

OBJECTIVES: To evaluate the tolerability of oral long-acting opioids (LAOs) in patients treated for chronic pain. Opioid analgesia is the mainstay of treatment for moderate to severe chronic pain. While highly effective in relieving pain, it is limited by adverse events (AEs), especially gastrointestinal and central nervous system events. AEs may result in additional treatment costs and discontinuation of therapy, compromising pain management. **METHODS:** A systematic review of English-language literature published through February 2009 was performed. Randomized controlled trials comparing commonly used oral schedule II LAOs with placebo or another opioid were included. Data on pain measures and pre-specified AEs (nausea, vomiting, somnolence, constipation, headache, pruritus, and dry mouth) were collected from each study. For descriptive statistics, treatment-arm data on tapentadol, oxycodone, oxymorphone, morphine, hydromorphone, and placebo were pooled across trials. Direct and indirect meta-analyses were performed to compare AE rates of individual LAOs with placebo and with tapentadol. **RESULTS:** Seventy-one published studies met the inclusion criteria. Tapentadol was associated with the lowest incidence of AEs across the 5 LAOs, with the exception of headache and dry mouth. The AE incidences for tapentadol, oxycodone, oxymorphone, morphine, hydromorphone, and placebo were: nausea: 19.5%, 32.5%, 38.8%, 29.7%, 33.5%, and 8.4%, respectively; vomiting: 7.9%, 16.1%, 19.9%, 15.5%, 15.1%, and 2.4%; somnolence: 10.2%, 24.8%, 18.3%, 33.6%, 50.4%, and 3.7%; constipation: 14.1%, 34.7%, 26.9%, 43.2%, 27.6%, and 6.1%; headache: 13.3%, 11.3%, 9.7%, 3.8%, 5.7%, and 10.4%; pruritus: 5.2%, 16.6%, 15.7%, 20.1%, 20.8%, and 1.5%; and dry mouth: 6.8%, 11.8%, 10.0%, 31.4%, and 2.6% (placebo), with no data for hydromorphone. Indirect meta-analyses further revealed a significantly favorable tolerability profile of tapentadol when compared to oxycodone, oxymorphone, and morphine. **CONCLUSIONS:** Opioid-associated AEs are common, but the incidence varied across the LAOs reviewed. Indirect meta-analyses suggest that tapentadol has a better tolerability profile than other LAOs.

PSY2

COEXISTENCE OF IMMUNO-MEDIATED INFLAMMATORY DISEASES: AN ANALYSIS OF THE QUEBEC ADMINISTRATIVE HEALTH DATABASES

Lachaine J[1], Beauchemin C[1], Martel MJ[2], Parison D[3]
[1]*University of Montreal, Montreal, QC, Canada,* [2]*Abbott Laboratories, St-Laurent, QC, Canada,* [3]*Abbott Canada, St-Laurent, QC, Canada*

OBJECTIVES: Immuno-mediated inflammatory diseases (IMIDs) may coexist within the same patient. Anti-TNFs have been shown to be effective at treating IMIDs. The present study aimed at evaluating the prevalence of the coexistence of selected IMIDs and other comorbidities, characterizing the patient population and assessing the use of anti-TNFs from a populational standpoint. **METHODS:** A cohort of patients who had received at least one diagnosis of rheumatoid arthritis (RA), ankylosing spondylitis, psoriatic arthritis, psoriasis (Ps), Crohn's disease (CD), ulcerative colitis, or uveitis, between January 2005 and December 2009, was randomly selected from the Régie de l'assurance-maladie du Québec (RAMQ) databases. The coexistence and temporality of the above diagnoses as well as other predefined chronic conditions were assessed. Characterization and stratification according to demographics and anti-TNF use (use or no-use) were also performed. **RESULTS:** A total of 80,566 patients who had at least one diagnosis of an IMID were included in this cohort. The study population was on average 53.6 years old (SD: 21.3 years) and was in majority female (60,1%). Most common primary diagnoses were RA (33.4%), Ps (33.8%) and CD (22.8%) while 3.9% of patients had received at least one prescription of an anti-TNF medication. In this population, 9.1% of patients presented with one coexisting IMID diagnosis and 1.4% with 2 or more coexisting diagnoses. Among patients who had used an anti-TNF, 27.9% had one coexisting IMID diagnosis and 9.1% had 2 or more coexisting diagnoses. Other chronic comorbidities were found in 82.8% of patients. The most frequent comorbidities were hypertension (37.2%), cardiovascular diseases (22.4%), diabetes (16.7%) and osteoporosis (15.7%). **CONCLUSIONS:** Coexisting IMID diagnoses and comorbidities are often present in patients with IMID and greatly contribute to the burden of disease.

PSY3

THE POTENTIAL IMPACT OF OBESITY DEGREE ON DIABETES, HEART ATTACK, HYPERTENSION, CHRONIC ANXIETY AND DEPRESSION IN ADULT SPANISH POPULATION

Espallardo O[1], Busutil R[1], Ribaric G[2], Lopez-belmonte M[1]
[1]*Johnson & Johnson Medical, Madrid, Madrid, Spain,* [2]*Ethicon Endo-Surgery (Europe) GmbH, Hamburg, Hamburg, Germany*

OBJECTIVES: Obesity is considered a major Public Health issue in most developed countries nowadays for its wide spread across population groups, as well as its contribution to the development of chronic diseases. Our objective was to estimate and better understand the impact of progressively increasing Body Mass Index (BMI) on diagnosed Diabetes, Heart Attack (HA), Hypertension, Chronic Anxiety (CA) and Chronic Depression (CD) in adult population. **METHODS:** Retrospective analysis of the Spanish 2009 European Health Survey System data base was conducted. Data from population under 18 years old or with BMI under 18.5 or with not reported BMI were excluded. Sample size of 19,880 adults (89.6% of the initial sample) was available for analysis. A logistic regression model was constructed for each of the five dependent variables. Age groups were divided by quartiles. BMI groups were "18.5–24.9", "25–29.9", "30–34.9" (g3) and "35 or more"(g4). **RESULTS:** Diabetes prevalence was 7.7%; (OR adjusted for g3:2.3; 95% CI: 2.0–2.7; OR_g4: 4.2; CI:3.4-5.3), Hypertension prevalence was 23.6%; (OR_g3: 3.4; CI:3.0–3.8; OR_g4: 5.8; CI: 4.8–6.9), HA prevalence was 2.8%; (OR_g3: 1.7; CI: 1.3–2.1; OR_g4: 1.6; CI: 1.1–2.5), CA prevalence was 8.2%; (OR_g3: 1.6; CI: 1.3–1.8; OR_g4: 2.3; CI: 1.8–2.9), CD prevalence was 7.9%; (OR_g3: 1.7; CI: 1.4–2.0; OR_g4: 2.7; CI: 2.2–3.4). All the stated OR reached statistical significance ($p<0.05$ for OR_g4 in HA and $p<0.001$ for all the rest of them). **CONCLUSIONS:** The results show how the risk of the examined comorbidities largely increases in those patients with BMI>35. Considering its potential economical impact on Public Health, it would be required to design and implement effective strategies aimed at the early detection of subjects at risk and the provision of adequate treatment, as well as to establish suitable preventive programmes.

PSY4

COMPARISON OF INFLIXIMAB AND USTEKIMUMAB FOR TREATMENT OF MODERATE TO SEVERE PSORIASIS: A MIXED TREATMENT META-ANALYSIS

Fan T[1], Bennett H[2], Smith N[1], Marin M[2], Sen S[1]
[1]*Merck & Co., Inc., Whitehouse Station, NJ, USA,* [2]*OptumInsight, Burlington, ON, Canada*

OBJECTIVES: No direct comparisons have been made between infliximab and ustekinumab in the treatment of moderate to severe psoriasis. A mixed treatment comparative (MTC) meta-analysis was conducted to compare the relative efficacy of infliximab and ustekinumab for the treatment of moderate to severe plague psoriasis. **METHODS:** Randomized clinical trials that included infliximab, 5 mg/kg, ustekinumab 45 mg or ustekinumab 90 mg in the treatment arm and reported PASI 75 and PASI 90 endpoints were identified from a systematic literature search. The log odds ratio (log OR) was used as the treatment effect measure using both fixed-effects and random-effects MTC models. Six trials meeting the inclusion criteria were included in the mixed treatment networks to estimate relative efficacy. **RESULTS:** The pooled odds ratio of achieving PASI 75 was 164.4 (95% (CI): 78.3 – 330.1) for infliximab, 77.9 (95% CI: 49.3 - 121.1) for ustekinumab 90 mg and 59.8 (95% CI: 37.9 - 92.3) for ustekinumab 45 mg compared to placebo. Pairwise comparison suggested that infliximab is significantly better than and ustekinumab 45 mg to achieve PASI 75 ($p < 0.05$). Pooled odds ratio of achieving PASI 90 was 172.6 (95% CI: 46.7 - 525.2) for infliximab, 79.6 (95% CI: 39.2 - 155.2) for ustekinumab 90 mg and 65.5 (95% CI: (32.1 - 127.8) for ustekinumab 45 mg. Similarly, there was a statistically significant difference between infliximab and ustekinumab 45 mg in attaining PASI

90. Results from random effect models were consistent with fixed effect models. **CONCLUSIONS:** Based on this network meta-analysis, a significantly greater proportion of patients with plaque psoriasis are expected to achieve a PASI 75 or PASI 90 response when treated with infliximab 5 mg/kg than with ustekinumab 45 mg or ustekinumab 90 mg.

PSY5

A SYSTEMATIC REVIEW OF TAPENTADOL IN CHRONIC MODERATE TO SEVERE PAIN

Riemsma R[1], Forbes C[2], Harker J[2], Misso K[2], Liedgens H[3], Schaefer M[4], Kleijnen J[5]
[1]*Kleijnen Systematic Reviews Ltd, York, North Yorkshire, UK,* [2]*Kleijnen Systematic Reviews Ltd., York, UK,* [3]*Grünenthal GmbH, Aachen, Germany,* [4]*Charité University, Berlin, Germany,* [5]*Kleijnen Systematic Reviews ltd., York, UK*

OBJECTIVES: A systematic review of chronic non-malignant pain treatment with tapentadol and strong opioids. **METHODS:** Thirteen electronic databases and other sources were searched until November 2010 for relevant RCTs in chronic moderate/severe pain investigating at least one WHO step 3 opioid. Two separate analyses were performed, one for trials reporting the outcome in patients with severe pain, the other including both moderate and severe pain conditions. Indirect comparisons were performed based on a network analysis. Trials with an enriched or an enriched withdrawal design were excluded. Primary (pain intensity) and a number of secondary endpoints were evaluated, including pain relief (30% and 50%), patient global impression of change, quality-of-life, quality-of-sleep, discontinuations, and selected adverse events. **RESULTS:** Only 10 trials were eligible for analysis of patients with severe pain (8 investigating tapentadol and 2 trials comparing buprenorphine patch (TDB) vs placebo). For moderate/severe pain, 42 relevant trials were identified and indirect comparisons with TDB, transdermal fentanyl (TDF), hydromorphone, morphine, and oxymorphone were performed. Tapentadol showed statistically favourable results over oxycodone for pain intensity, 30% and 50% pain relief, patient global impression of change, and quality-of-life. Some of the most important adverse events of chronic opioid treatment were significantly less frequent with tapentadol as compared to oxycodone i.e. constipation, nausea, and vomiting; discontinuations due to these adverse events were found significantly reduced with tapentadol. Similar results were obtained for the network analysis, i.e. tapentadol was superior for the primary outcome (pain intensity) to hydromorphone and morphine, whereas fentanyl and oxymorphone showed trends in favour of these treatments. Significantly less frequent gastrointestinal adverse events were observed using tapentadol in comparison with fentanyl, hydromorphone, morphine, and oxymorphone, apparently leading to significantly reduced treatment discontinuations (for any reason). **CONCLUSIONS:** The benefit risk ratio of tapentadol appears to be better compared to other step 3 opioids.

PSY6

THE HEALTH IMPROVEMENT NETWORK (THIN) 2008-2009 ESTIMATES OF PSORIASIS INCIDENCE AND PREVALENCE IN UK PRIMARY CARE

Khalid JM[1], Globe G[2], Fox KM[3], Chau D[2], Maguire A[1]
[1]*United Biosource Corporation, London, UK,* [2]*Amgen Inc, Thousand Oaks, CA, USA,* [3]*Strategic Healthcare Solutions, LLC, Monkton, MD, USA*

OBJECTIVES: With previous estimates dating back to 1996-1997, new estimates of incidence and prevalence are needed to accurately assess the current burden of psoriasis in the UK. We examined incidence and prevalence in the UK primary care setting using data from 2008 and 2009. **METHODS:** THIN, an electronic database recently validated to study psoriasis in a population-based setting, was used. For incidence, newly diagnosed patients aged ≥18 were identified by a psoriasis diagnosis ("Read Code") in medical records between January 1, 2008 and December 31, 2008. For prevalence, a cross-section of patients aged ≥18 on July 1, 2009 were selected who had received a psoriasis Read Code in their medical history. Total person time for 2008 and mid-year patient counts for 2009 were provided as denominators to calculate incidence and prevalence, respectively. Age and sex-specific rates were calculated and standardized to the UK 2008/2009 population, respectively. **RESULTS:** The standardized incidence rate of adult psoriasis in 2008 was 28 (95% CI: 28-29) per 10,000 person-years and highest in 60-69 year olds at 34 (95% CI: 31-36) per 10,000 person-years. Psoriasis prevalence at 01July2009 was 2.83% (95% CI: 2.81-2.86) and highest in 70-79 year olds at 3.49% (95% CI: 3.42-3.56). Overall, incidence did not vary by sex. However, prevalence in females under 40 was significantly higher than in males of the same age group: 2.69% (95%CI: 2.65-2.73) vs. 2.42% (95%CI: 2.37-2.44). **CONCLUSIONS:** Incidence of psoriasis was higher than rates previously reported in the UK. The high prevalence estimates reported in this primary care database confirm findings from other European countries and indicate that psoriasis is a condition for which medical attention is commonly sought and that psoriasis represents a significant burden on the UK healthcare system.

Systemic Disorders/Conditions – Cost Studies

PSY7

BUDGET IMPACT ANALYSIS OF BENDAMUSTINE IN THE TREATMENT OF MULTIPLE MYELOMA IN SPAIN

Mateos MV[1], Collar JM[2]
[1]*Hospital Universitario de Salamanca, Salamanca, Spain,* [2]*Mundipharma Pharmaceuticals, Madrid, Spain*

OBJECTIVES: To estimate the Budget Impact of Bendamustine introduction as a treatment option for Multiple Myeloma (MM) patients, non-candidates for transplantation, who are likely to be treated with high priced citostatic combinations. **METHODS:** A Budget Impact model assuming a prevalent treatable population of 4826 patients with MM, with an incremental rate of 3% per year. The time horizon considered was three years and the analysis was made from the perspective of the Spanish Health System. Nine treatment cycles were considered for all the drug regimens and for the treatment lines included (3 or more). Pharmaceutical expenditure on citostatic agents was analyzed, excluding other medical costs. The drug costs were based on the official ex-factory prices (EFP), discounting the price reduction recently established by the Spanish Government. The base case scenario was based on prevalent epidemiological, market research data available and experts opinion input. The bendamustine scenario considered different drug combinations and different dosages (90-120mg/m^2), depending on the treatment line to analyze. **RESULTS:** The drug expenditure for MM treatment is slightly under €120 Mio/year in Spain. The single cycle costs range from €3 (Melphalan+Prednisone) to €5969 (Lenalidomide+Dexamethasone). Bendamustine based treatments would reach 7% to 21% of the treated patients from the first to the last year analyzed. Fifty-four percent of the Bendamustine treatments considered were combinations with other expensive drugs (Bortezomib or Thalidomide), where the Bendamustine cost was only 17% or 21% respectively of the whole treatment regimen. The introduction of Bendamustine would reduce drug expenditure in €6.6 Mio during the 3 years considered, expressed in €2011. **CONCLUSIONS:** The introduction of Bendamustine would produce drug cost savings in the MM patients, mainly from the 2nd treatment lines onwards. The savings observed in the model were mainly due to the substitution of high cost combinations like those based on Bortezomib, Thalidomide or Lenalidomide therapies.

PSY8

NEUROPATHIC PAIN: A BUDGET IMPACT ANALYSIS TO ESTIMATE COSTS DUE TO THE INTRODUCTION OF QUTENZA® ON THE SPANISH MARKET

Darba J[1], Kaskens L[2], Perez-Alvarez N[2]
[1]*Universitat de Barcelona, Barcelona, Spain,* [2]*BCN Health, Barcelona, Spain*

OBJECTIVES: Qutenza® is a novel method of action for the treatment of patients with peripheral neuropathic pain. Therefore it is important to assess the economic impact of introducing Qutenza® in the Spanish market for the treatment of neuropathic pain in adult patients. **METHODS:** A budget impact model was developed using published data on disease prevalence and treatment, population growth, drug tariffs, health care resource utilization, unit costs and market shares forecasts for Spain. The perspective of the Spanish national health care system was chosen, using a 5-year time horizon. Treatments analyzed in this study were carbamazepine, capsaicin cream, pregabalin, lidocaine, duloxetine, amitriptyline, gabapentin and Qutenza®. Costs considered included drug costs, physician visits, diagnostic tests, hospitalisation and complementary non-pharmacological treatment. All costs referred to EUR 2010. Direct medical annual costs per patient for each treatment were estimated before and after the introduction of Qutenza® in order to estimate the total annual healthcare costs. **RESULTS:** Based upon the Spanish adult population data, the diagnosed population for 2010 suffering from neuropathic pain was estimated at 235,480 adult patients of whom 217,819 were assumed to receive treatment for their disease. Increases in the diagnosed and treated population were expected with estimates of 236,224 and 218,507 patients in 2015, respectively. Total health care costs over the next 5 years were estimated at €2695 million. Qutenza® was estimated to grow from 1.6% in the first year up to 5.6% in the fifth year. Under these conditions, total healthcare costs were estimated at €2,679 million. Mean annual costs per patient before the introduction of Qutenza® were estimated at €2,059 and at €2,046 after its introduction. **CONCLUSIONS:** The introduction of Qutenza® is likely to decrease the budget impact of neuropathic pain treatments for the Spanish national health care system. Overall savings in the economic burden of €16.7 million were found over the next 5 years.

PSY9

A BUDGET IMPACT MODEL OF RITUXIMAB INTRODUCTION IN WEGENER GRANULOMATOSIS THERAPIES

Ndir A[1], Pagnoux C[1], Mahr A[1], Guillevin L[1], Vidal-Trécan G[2]
[1]*Groupe Hospitalier Saint Vincent de Paul, Paris, France,* [2]*Université Paris Descartes U4169, Groupe Hospitalier Saint Vincent de Paul, Paris, France*

OBJECTIVES: Wegener's granulomatosis (WG) is a rare disease, fatal without therapy. Cyclophosphamide (CYC) administered by oral or intravenous route is the gold standard. Intravenous CYC (IVCYC) is the reference in France. However, rituximab, mainly used for treating B-cell lymphomas, is being tested in clinical trials for treating WG. To estimate the economic impact of using rituximab to induce remission in WG patients. **METHODS:** The six months induction treatment cost was evaluated for treating a hypothetical cohort of prevalent cases constituted by newly diagnosed and relapsing cases. In France, WG prevalence was estimated at about 3 per 100 000 inhabitants. Treatment cost included costs of hospital stays, drugs, follow-up and therapeutic acts. The costs over five years were estimated by a model which take into account efficacy data of each treatment (rates of remission, failure and infectious complications) and the proportion of patients treated each year. Scenarios (S) were tested on hypothetical rituximab indications: prescribed to 10% of newly diagnosed patients and 50% of relapsing patients in S1 and 100% of relapsing patients in S2. **RESULTS:** The number of prevalent cases was estimated to be about 1,884 in France in 2010. Treatment of these cases with the reference strategy using IVCYC costed 166 millions € over 5 years. The introduction of rituximab in WG therapies induced an overcost of 900 K€ in S1 and 2 millions € in S2 over 5 years. **CONCLUSIONS:** In our analysis which is not exhaustive, others treatments used to induce remission were not evaluated. Results revealed that rituximab should possibly be indicated when cyclophosphamide is contra-indicated and when patients are refractory to previous treatments. Efficacy data of rituximab use in long term (remission, relapses and complications induced) are expected. Results of rituximab efficacy evaluated as a maintenance therapy are also expected.

PSY10

BUDGET IMPACT ANALYSIS OF SOMATULINE AUTOGEL IN THE MANAGEMENT OF ACROMEGALY IN SPAIN

Brosa M[1], Betoret I[2], Tapias G[2]
[1]Oblikue Consulting, Barcelona, Spain, [2]Ipsen Pharma, Sant Feliu de Llobregat, Barcelona, Spain

OBJECTIVES: Acromegaly is a rare disease with an estimated incidence of 2.5 cases per million (cpm) and a prevalence of 50-60 (cpm) per year according to Spanish national data. Somatuline Autogel (Ipsen property) and Sandostatin LAR (Novartis property) are associated with similar efficacy and together they represent more than 90% of long-acting somatostatin analogs sales in Spain. Somatuline Autogel has been approved of an injection extended dosing interval for 6 or 8 weeks with the dose of 120mg. This study is aimed to estimate the potential budgetary consequences of increasing the use of Somatuline Autogel in the treatment of acromegaly in Spain. **METHODS:** A budget impact model was developed to compare annual treatment costs of acromegaly patients with either Somatuline Autogel and Sandostatin LAR, including drug acquisition costs and administration costs. Disease prevalence and IMS sales data were used to estimate total number of patients using both treatments, and the potential budget impact of increasing Somatuline Autogel was calculated under different scenarios based on the proportion of patients using different dose ranges. **RESULTS:** Overall treatment costs were 11,857€ and 12,165€ per patient/year for Somatuline Autogel and Sandostatin LAR respectively (monthly treatment), as a result of the higher acquisition cost and administration costs of the latter. Furthermore, assuming that 30% of patients with Somatuline Autogel may benefit of the extended dose interval (every 6 or 8 weeks), mean cost savings per patient may rise to 2,019€ (10,147€ vs. 12,165€). When applying these patient-level cost savings with Somatuline Autogel to total treated patients, acromegaly treatment costs could be reduced by 0.3 M€ to 1.2 M€ by increasing the proportion of patients treated with Somatuline Autogel from current 42% up to 50% and 70% respectively in Spain. **CONCLUSIONS:** Using Somatuline Autogel in acromegaly patients is associated with favorable economic outcomes when compared to other long-acting somatostatin analogs in Spain.

PSY11

BUDGET IMPACT MODEL OF HEMOPHILIA A TREATMENT IN TURKEY: A PAYER'S PERSPECTIVE

Kayadibinli M, Ulus P, Durguner B
Pfizer Pharmaceuticals, Istanbul, Turkey

OBJECTIVES: According to World Federation of Hemophilia, more than 90% of cost of hemophilia treatment is the cost of factor replacement. Currently, 13 different Factor VIII products are available in Turkish market. These are classified as "bioequivalent" and these products are neither included in a willingness to pay threshold nor in a pharmacoeconomic analysis before the reimbursement decision. The aim of this study is determining the budget impact of possible cost minimization strategies in reimbursement of Factor VIII products via investigating current reimbursement conditions and evaluation of possible ways for inserting cost minimization from the Payer's perspective. **METHODS:** IMS data (September 2009-2010) is evaluated for Factor VIII products in Turkish market. Current reimbursed prices are evaluated for determination of particular patterns of reimbursement. Annual volume of Factor VIII consumption and annual cost of Factor VIII consumption are linked and re-defined for cost minimization estimates in Microsoft 2003 Excel. TreeAgePro2011 is used for calculations and decision tree structuring. **RESULTS:** Annual consumption of Factor VIII products constitutes 128,319,000 IU and an annual cost of 129,806,872.88 TL. The Payer can imply cost minimization strategies (change reimbursement strategies and/or eliminating waste) resulting in gradual reduction from total expenditure as 2.6% (3,390,029.43 TL/year), 2.8% (3,610,300.16 TL/year), 5.7% (7,357,325.35 TL/year), 18.9% (24,595,818.19 TL/year) and 20.8% (27,059,457.55 TL/year). **CONCLUSIONS:** Payer may apply following steps for cost minimization, therefore obtaining a positive budget impact for Factor VIII spending in Turkey; Step1: Evaluation of all Factor VIII products according to the reimbursed prices; Step2: Classification of reimbursement pattern for each product; Step3: Standardization of reimbursement patterns for all products; Step4: Promotion of differentiation for availability of forms; Step5: Monitoring annual budget impact effect of all previous steps.

PSY12

COMPARISON OF THE MOST COMMON REASONS FOR INPATIENT ADMISSIONS AMONG FIBROMYALGIA PATIENTS ON DULOXETINE VERSUS PREGABALIN

Zhao Y[1], Sun P[2], Sun S[3]
[1]Eli Lilly and Company, Indianapolis, IN, USA, [2]Kailo Research Group, Fishers, IN, USA, [3]Kailo Research Group, Milpitas, CA, USA

OBJECTIVES: To examine the most common reasons for inpatient admissions among fibromyalgia patients who initiated duloxetine or pregabalin. **METHODS:** Using a large US national commercial healthcare claims database, fibromyalgia patients aged 18-64 who initiated duloxetine or pregabalin in 2006 were identified. All patients included had 12-month continuous enrollment before and after the initiation, and at least 31 total duloxetine or pregabalin supply days over the 12-month post-index period. Propensity scoring was applied to construct duloxetine and pregabalin cohorts with similar demographics, pre-index clinical and economic characteristics, and pre-index treatment patterns. Reasons for inpatient admissions between the cohorts were examined. Logistic regressions were used to assess the contribution of duloxetine versus pregabalin initiation to the top reasons for inpatient admissions controlling for cross-cohort differences. **RESULTS:** Per our study design, duloxetine (n=3,711) and pregabalin (n=4,111) patients had similar demographics with a mean age of 51 years and 83% females. Both cohorts had similar co-morbidities, with cardiovascular disease being the most common. Duloxetine and pregabalin patients, by the study design, also had similar total health care costs over the 12-month pre-index period ($18,970 vs. $19,019, p=0.994) with 22% contributed by inpatient care. Eight of the top 10 reasons for inpatient admissions over the 12-months post-index period were the same for both groups with intervertebral disc disorder, osteoarthritis of lower leg, and chest pain being the top 3 leading reasons. Controlling for cross-cohort differences, duloxetine patients were at a significantly lower risk for hospitalizations due to intervertebral disc disorder or major depression disorder (MDD) (odds ratios=0.44, 0.81, respectively; both p<0.0001). **CONCLUSIONS:** Among similar commercially-insured fibromyalgia patients who initiated duloxetine or pregabalin, the leading reasons for inpatient admissions were somewhat different between groups. Compared to pregabalin initiators, duloxetine initiators tended to be less likely to have inpatient admissions due to intervertebral disc disorder or MDD.

PSY13

COMPARING TOP REASONS FOR PRIMARY CARE OR SPECIALTY CARE VISITS AMONG FIBROMYALGIA PATIENTS INITIATED DULOXETINE VERSUS PREGABALIN

Sun P[1], Sun S[2], Zhao Y[3]
[1]Kailo Research Group, Fishers, IN, USA, [2]Kailo Research Group, LLC, Milpitas, CA, USA, [3]Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: To examine the most common reasons for primary or specialty care visits among fibromyalgia patients initiated duloxetine or pregabalin. **METHODS:** Using a large US commercially-insured administrative claims database, we examined fibromyalgia patients aged 18-64 who initiated duloxetine or pregabalin in 2006. All patients were required to have 12 months of continuous enrollment prior to and after the initiation. Applying propensity scoring, we constructed the duloxetine and pregabalin cohorts to have similar demographics, comorbid medical conditions, prior healthcare utilization and costs, and prior medication use. Using the first diagnosis recorded in all outpatient claims, we examined the reasons for primary vs. specialty care over the 12-month post-index period. Controlling for cross-cohort differences, we assess the impact of duloxetine vs. pregabalin initiation on the top reasons for primary care or specialty care visits via logistic regressions. **RESULTS:** The study sample included 3,711 duloxetine and 4,111 pregabalin patients with a mean age of 51 years and around $19,000 prior total healthcare costs. Duloxetine and pregabalin patients shared 8 (9) out of the 10 top reasons for primary (specialty) care visits, with most of the prevalence rates/10,000 being higher (lower) among the duxeteine patients. Controlling for cross-cohort differences, duloxetine patients were more likely to have a primary care visit due to disorder of soft tissue, essential hypertension, or other general symptoms (odds ratios=1.12, 1.16, 1.14, respectively), but less likely to go to specialty care due to disorder of soft tissue, nonspecific backache/other back/neck pain, or intervertebral disc disorder (odds ratios=0.83, 0.69, 0.63, respectively) (all p<0.05). **CONCLUSIONS:** Among commercially-insured fibromyalgia patients who initiated duloxetine or pregabalin, the most common reason for primary or specialty care was somewhat different. Duloxetine initiators tended to be less likely to use specialty care, and more likely to use primary care for disorder of soft tissue.

PSY14

DIFFERENCES IN OUTPATIENT CARE AMONG FIBROMYALGIA PATIENTS ON DULOXETINE VERSUS PREGABALIN

Zhao Y[1], Sun P[2], Sun S[3]
[1]Eli Lilly and Company, Indianapolis, IN, USA, [2]Kailo Research Group, Fishers, IN, USA, [3]Kailo Research Group, Milpitas, CA, USA

OBJECTIVES: To examine the most common reasons for physician office visits, outpatient hospital visits, and emergency room (ER) visits among fibromyalgia patients who initiated duloxetine or pregabalin. **METHODS:** Commercially-insured fibromyalgia patients aged 18-64 who initiated duloxetine or pregabalin in 2006 were examined. All patients selected had continuous enrollment during the 12 months before and after the initiation. Each patient was classified into the duloxtetine or pregabalin cohort based on the index medication, and both cohorts were constructed via propensity scoring to have similar demographics, comoribidities, prior healthcare costs, and prior pain-related medication use. Reasons for physician office, outpatient hospital, and ER visits over the 12 months post-index period were examined for both cohorts. The impact of duloxetine vs. pregabalin initiation on the top reasons leading to physician office, outpatient hospital, or ER visits was examined via logistic regressions controlling for the cross-cohort differences. **RESULTS:** A total of 3711 duloxetine and 4111 pregabalin patients were included with a mean age of 51 years and 83% being female. Duloxetine and pregabalin patients had similar total healthcare costs ($18,970 vs. $19,019, p=0.994) over the 12 months pre-index period, with 52-53% contributed by the outpatient care. Both groups shared 9 out of the top 10 reasons for physician office visits, 7 of the 10 most common reasons for outpatient hospital visits, and 8 of the top 10 reasons for ER visits. Controlling for cross-cohort differences, duloxetine patients were less likely to have a physician office visit due to nonspecific backache/other back/neck pain but more likely to go to the ER due to other general symptoms (odds ratios=0.91, 1.43, respectively, both p<0.001). **CONCLUSIONS:** Among commercially-insured fibromyalgia patients who had similar demographic and clinical characteristics and initiated duloxetine or pregabalin in 2006, the leading reasons were somewhat different for physician office visits, outpatient hospital or ER visits.

PSY15

STRIVING FOR AFFORDABLE TREATMENTS WITHIN THE GREEK ENVIRONMENT: DO EPOETIN BIOSIMILARS HELP?

Kani C[1], Litsa P[1], Alexopoulou E[1], Hatzikou M[2], Delibasi S[3], Geitona M[2]

[1]*IKA ETAM, Athens, Greece,* [2]*University of Peloponnese, Athens, Greece,* [3]*Evangelismos Hospital, Athens, Greece*

Erythropoiesis' Stimulating Factors (ESAs) are among the top ten therapeutic groups with the highest pharmaceutical expenditure in Greece. **OBJECTIVES:** To explore the penetration of ESAs in the Greek pharmaceutical market and differences in pricing levels between originals and biosimilars. **METHODS:** Data derived from the IKA-ETAM Social Security Fund, covering almost 50% of insured population. Consumption of ESAs (epoetin alfa, darbepoetin alfa, epoetin beta, methoxy polyethylene glycol epoetin beta, epoetin zeta) was collected from the Central & Peripheral Pharmacy, dispensing high value medicines for serious diseases on outpatient basis covering almost 70% geographical area of Greece. Consumption of epoetins was recorded from 2008 to 2010, classified per strength (IU/mcg), separated in originals and biosimilars. The average price per 1000IU of each category was also estimated for the respective years based on NHS hospital prices. **RESULTS:** ESAs consumption in 2008 and 2009 was approximately the same (26 & 27% respectively) while decreasing by 4% reaching 23% in 2010. A 13,8% decrease was also observed in IKA-ETAM total pharmaceutical expenditure in 2010. ESAs expenditure in 2008, was €41,4 million corresponding to 99% market share (MSH) of originals epoetins, leaving only 1% MSH in biosimilar epoetin zeta launched in that year. In 2009 ESAs expenditure reached €43 million, with 94% and 6% MSH for original and biosimilar ESAs respectively. In 2010 ESAs expenditure was almost halved (€22million), due to price cuts and stricter control of prescriptions. Specifically, the MSH of originals reached 81% and biosimilars 19% respectively. In the reported years prices of biosimilars were slightly different from that of originals, however as of 2011 higher price differences are observed, favoring the use of biosimilars. **CONCLUSIONS:** Biosimilars penetration in Greece is similar with EU, 6% and 6,64% in 2009 respectively, presenting an increasing rate in 2010. Under the economic recession Greece is experiencing, biosimilars seem to be a cost saving option.

PSY16

COST AND QUALITY OF LIFE BENEFITS OF FASTER BLEED RESOLUTION WITH AN RFVIIA ANALOGUE: A MATHEMATICAL SIMULATION STUDY FOR THE GERMAN POPULATION

Pokras SM[1], Petrilla AA[1], Weatherall J[2], Lee WC[1]
[1]*IMS Consulting Group, Alexandria, VA, USA,* [2]*Novo Nordisk A/S, Soeborg, Denmark*

OBJECTIVES: On-demand treatment for haemophilia patients with inhibitors is burdensome to patients and practitioners. Newer bypassing agents with shortened bleed resolution time resulting in fewer infusions, may impact costs and patient quality of life (QoL). The study objective was to model the lifetime costs and health-related QoL outcomes associated with bypassing agents, recombinant activated Factor VIIa and plasma-derived activated prothrombin complex concentrate (rFVIIa, pd-aPCC) in Germany, and investigate the impact of faster bleeding resolution of a new rFVIIa analogue. **METHODS:** Assuming a German payer perspective, this literature-based model tracks a hypothetical cohort of severe haemophilia patients with inhibitors over their lifetime. A semi-Markov model was used to simulate patient movement through health states at 3-month intervals. Modeled outcomes include lifetime direct treatment costs, cost per bleeding episode, life-years, and quality-adjusted life years (QALYs) across a continuum of home and inpatient care. One-way sensitivity analyses were performed on all model variables and two-way sensitivity analyses on key variables. **RESULTS:** Using base-case assumptions from the literature, rFVIIa was associated with measurable lifetime cost savings compared with pd-aPCC (€ 2,962,833 vs. € 4,664,971, respectively) and reduced total cost per bleed compared with pd-aPCC (€ 17,614 vs. € 19,435, respectively). Reducing the number of rFVIIa infusions per bleed from 2.3 to 1.5 resulted in incremental cost savings of € 248,033, while 20% utility improvement in rFVIIa conferred a 3.14 additional QALY gain. Sensitivity analyses confirmed the robustness of base case findings. **CONCLUSIONS:** This exploratory model is a valuable tool for physicians to assess the impact of current treatment patterns over a patient's lifetime and to potentially identify optimal practice patterns. Availability of bypassing agents with improved efficacy profiles could result in significant improvement of patient care.

PSY17

RETROSPECTIVE CHART REVIEW STUDY OF THE COST OF CARE OF SYSTEMTIC LUPUS ERYTHEMATOUSUS (SLE) IN FIVE EUROPEAN COUNTRIES

Doria A[1], Amoura Z[2], Richter J[3], Cervera R[4], Khamashta M[5], Guillemin F[6], Garofanno A[7], Maurel F[7], Roset M[8], Perna A[9], Schmitt C[10], Ager M[9], Boucot I[11], Gonzalez McQuire S[10], Birch H[10]
[1]*University of Padova, Padova, Padova, Italy,* [2]*Université Paris VI Pierre et Marie Curie, Paris , France,* [3]*Heinrich-Heine-University, Düsseldorf, Germany,* [4]*Hospital Clínic, Barcelona, Spain,* [5]*The Rayne Institute, London, UK,* [6]*Centre d'épidémiologie clinique, Vandoeuvre-les-Nancy, France,* [7]*IMS Health, Paris, France,* [8]*IMS Health, Barcelona, Spain,* [9]*GlaxoSmithKline, Brentford, UK,* [10]*GlaxoSmithKline, Uxbridge, UK,* [11]*GlaxoSmithKline, Marly-le-Roi, France*

OBJECTIVES: Evaluate rate of flares in adult SLE patients with active antinuclear autoantibody positive SLE disease and estimate the incremental direct costs of flare management. **METHODS:** A multi-centre retrospective chart review study extracting patient characteristics, disease activity and severity, and medical resource utilization in 5 European countries (France, Germany, UK, Italy and Spain). Patients were stratified by disease severity at inclusion visit (50% severe) and followed-up for 2 years. Severe disease defined as having at least one major domain actively involved (renal, neurological, cardiovascular or respiratory) and requiring >7.5 mg/day of corticosteroids and/or immunosuppressants. A modification of SELENA-SLEDAI Flare Index collected retrospectively was used for identifying mild/moderate and severe flares. Unadjusted mean costs associated with management of flares were assessed. Health care perspective and country specific data was used for resources and costs analysis. **RESULTS:** The total sample included 427 SLE patients (212 severe, 215 non-severe), mean age: 43.4 years, female: 90.5%. Total mean number of flares over the study period was 2.29 compared to 1.83 ($p<0.001$) for severe and non-severe patients respectively. Mean number of mild/moderate flares was 0.87 compared to 1.32 ($p<0.001$), while mean number of severe flares was 1.42 compared to 0.52 ($p<0.001$) for severe and non-severe patients, respectively. The mean two year costs for patients experiencing at least one flare over study period was €9607 compared to €3910 ($p<0.001$) without flares. Exploratory flare analysis showed a mean 2 year increase in costs of €4525 ($p<0.01$) per severe flare (no statistical significance for mild/moderate flares). **CONCLUSIONS:** Severe patients experience both a higher number of flares and more severe flares compared to non-severe patients. Patients experiencing at least one flare over the study period are 2.5 times more costly than patients without flares; the presence of severe flares in SLE patients has a significant impact on the healthcare system.

PSY18

RESOURCE CONSUMPTION EVALUATION FOR KETOPROPHENE, KETOROLAC, PARECOXIB AND TENOXICAM AT ORTHOPEDIC SURGERY POST-OPERATION IN BRAZILIAN PATIENTS FROM PRIVATE PAYERS PERSPECTIVE

Fujii RK[1], Mould JF[2], Lanzara G[3]
[1]*Pfizer Pharmaceutics inc., São Paulo, São Paulo, Brazil,* [2]*Pfizer, Inc., New York, NY, USA,* [3]*Pfizer Parmaceutics Inc., São Paulo, São Paulo, Brazil*

OBJECTIVES: The rational use of resources is essential for granting sustainability at any healthcare system. This study aims to evaluate the best anti-inflamatory medication regarding costs consumption from private payer's perspective. **METHODS:** 400 medical charts from 3 private hospitals in Curitiba city were accessed retrospectively from November to April (2010) and selected based on the use of intravenous ketoprophene (200mg/day), ketorolac (60mg/day), parecoxib (40mg/day) or tenoxicam (40mg/day) at the immediate post-operative adult patients from orthopedic surgeries period and based on the existence of hospital's billing information. One hundred twenty-one cases were recruited. Resource use considered were antacid, antiemetic and analgesic drugs, infusion equipment, medication costs (factory list prices) and labor costs were estimated from the amount of minutes per day to administering the medications. The minimum monthly wage for a nurse according to the Brazilian nurses union was considered (593.75 USD). Costs are expressed in 2010 USD. **RESULTS:** Parecoxib presented the least daily resource consuming profile with an average of 33.52 USD compared to 68.27; 67.16 and 75.05 USD for ketoprophene, ketorolac and tenoxicam. Daily average expenditure on the consumption of antacid analgesic and antiemetic medications was 6.00, 10.19, 12.43 and 8.50 USD for parecoxib, ketoprophene, ketorolac and tenoxicam (PC/KP/KL/TM) respectively. Total time expenditure per day and costs were 12.5 min (4.96 USD), 26.75 min (10.59 USD), 27.43min (10.85 USD) and 25.20 min (9.97 USD) for PC/KP/KL/TM respectively. Daily savings by using parecoxib were found in 2.53, 13.04 and 7.16 USD against KP/KL/TM, respectively. **CONCLUSIONS:** Parecoxib was found to be the less costly alternative to the hospital by rationing the number of administrations per day, the use of antacid, analgesic and antiemetic medications and the total labor time costs for administering the medications.

PSY19

ECONOMIC COSTS OF CHEMOTHERAPY-INDUCED FEBRILE NEUTROPENIA AMONG PATIENTS WITH NON-HODGKIN'S LYMPHOMA IN EUROPEAN CLINICAL PRACTICE

Weycker D[1], Danel A[2], Marciniak A[3], Bendall K[3], Lipsitz M[1], Pettengell R[4]
[1]*Policy Analysis Inc. (PAI), Brookline, MA, USA,* [2]*Amgen (Europe) GmbH, Zug, Switzerland,* [3]*Amgen Ltd, Uxbridge, UK,* [4]*St. George's University of London, London, UK*

OBJECTIVES: Cost of chemotherapy-induced febrile neutropenia (FN) in the United States has been reported to be substantial. Little is known about the cost of FN in other countries or about costs of follow-on care and subsequent FN events. **METHODS:** Data were obtained from an observational study of supportive care in patients with non-Hodgkin's lymphoma (NHL) receiving CHOP-14 or CHOP-21 chemotherapy (±rituximab) predominantly across Europe. FN was defined as single oral temperature of ≥38.3°C or temperature of ≥38.0°C for ≥1 hour, and neutrophil count of <0.5x109/L or <1.0x109/L and predicted to fall below 0.5x109/L. Patients developing FN in a given cycle ("FN patients"), starting with the first cycle, were matched (1:1, without replacement) on age, tumor stage, chemotherapy, and other factors to those not developing FN in that cycle ("comparison patients"), irrespective of FN experience in subsequent cycles. FN-related healthcare utilization and costs (estimated from UK National Health Service perspective [2010]) were tallied for patients from the match cycle through the last chemotherapy cycle ("follow-up"). **RESULTS:** Eighteen percent of patients (331/1829) in the observational study experienced a total of 479 FN events, the majority (77%) of which required inpatient care. A total of 295 FN patients were matched to comparison patients for these analyses; baseline characteristics were similar between groups. During follow-up, FN patients averaged 1.44 (95%CI 1.34-1.56) FN events and comparison patients averaged 0.15 (0.10-0.21) FN events, and corresponding mean number of FN-related hospital days was 6.21 (5.28-7.17) and 0.63 (0.30-1.02). Mean total cost was £5744 (£4893-£6664) higher for FN patients than comparison patients, with 71% of the difference attributable to care in the index cycle (£4051 [£3633-£4485]) and 29% attributable to care in post-index cycles (£1693 [£917-£2447]). **CONCLUSIONS:** Cost of chemotherapy-induced FN among NHL patients in European clinical practice is substantial, with a sizable percentage attributable to follow-on care and subsequent FN events.

PSY20

THE ANNUAL DIRECT MEDICAL COST OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) PATIENTS AND COSTS DRIVERS (LUCIE STUDY): FRENCH RESULTS

Amoura Z[1], Pennaforte JL[2], Hamidou M[3], Arfi S[4], Lazaro E[5], Hachulla E[6], Pourrat J[7], Queyrel V[8], Aubin C[9], Garofano A[10], Levy-Bachelot L[9], Maurel F[10], Boucot I[9]

[1]Internal Medecine Department, La Pitié Salpétrière Hospital, Paris, France, [2]Internal Medecine Department, Robert Debré Hospital, Reims, France, [3]Internal Medecine Department, Hôtel Dieu Hospital, Nantes, France, [4]Internal Medecine and Rheumatology Department, Fort de France Hospital, Fort de France, France, [5]Internal Medecine Department, Pellegrin Hospital, Bordeaux, France, [6]Internal Medecine Department, Hurriez Hospital, Lille, France, [7]Nephrology and Clinical Immunology Department, Rangueil Hospital, Toulouse, France, [8]Internal Medecine Department, l'Archet Hospital, Nice, France, [9]Glaxo Smith Kline, Marly-le-Roi, France, [10]IMS Health, Puteaux, France

OBJECTIVES: To determine the annual direct medical cost of the management of adult patient with active antinuclear autoantibody positive SLE. **METHODS:** LUCIE is a multicenter, observational, retrospective study carried out in five European countries, including France. SLE patients characteristics, disease severity (severe patient defined as having at least one major domain actively involved at inclusion: renal, neurological, cardiovascular or respiratory AND Requiring corticosteroids > 7.5 mg/day and/or immunosuppressants), flares rate, health care consumption (laboratory tests, biopsies and/or imaging tests, medications, specialist visit, hospitalisations) were collected retrospectively over a two-years period. The French national health insurance perspective was considered when estimating the average annual direct cost using official cost database. Major cost drivers associated with SLE and flares management were identified by multivariate regression models. **RESULTS:** Eight French SLE centres participated in the study, and included 96 consecutive patients: mean age 39.9±11.9 years, 93.5% females. The mean SLE duration was 9.8±6.6 years, the mean SELENA-SLEDAI score, a semiquantitative index of SLE activity was 7.7±5.1. On average, SLE patients had 1.1±0.59 flares/year. The annual unadjusted mean direct medical cost of SLE patients was €4116 (SD5498). In severe patients the cost was 1.3 times higher: €4660 versus €3560 in non-severe patients (NS). Medical treatment represents the largest component of the average annual direct cost of SLE patients (61.8%) and was higher in severe patients (7214€ versus 1855€, p=0.030). Biological drugs, even though prescribed to only 10.8% of patients, represented 3.4% of the annual total medical treatment cost. The multivariate regression model showed that each severe flare increases cost by €1230 (p=0.2). **CONCLUSIONS:** The annual direct medical cost of active SLE is significant especially for patients experiencing severe flare and is mostly driven by the cost of medication.

PSY21

PREDICTORS OF DULOXETINE ADHERENCE AND PERSISTENCE IN PATIENTS WITH FIBROMYALGIA

Cui Z[1], Zhao Y[1], Fang Y[2], Chen Y[3], Novick D[1], Faries D[1]
[1]Eli Lilly and Company, Indianapolis, IN, USA, [2]inVentiv Clinical Solutions, Indianapolis, IN, USA, [3]inVentiv Clinical Solutions LLC, Indianapolis, IN, USA

OBJECTIVES: Medication adherence and persistence are important in the treatment of fibromyalgia. The objective of this study is to examine the predictors of adherence and persistence to duloxetine therapy among commercially-insured fibromyalgia patients. **METHODS:** This study analyzed medical and pharmacy records for commercially-insured patients aged 18-64 with fibromyalgia who initiated (no prior 90-day use) duloxetine in 2008. Patients selected had continuous health insurance enrollment for 12 months preceding and following duloxetine initiation, at least 1 fibromyalgia diagnosis during the 12 months before, or 1 month after, the initiation date, and at least 30-day cumulative duloxetine supply over the 12-month post-index period. Adherence to duloxetine was measured by medication possession ratio (MPR = post 1-year total duloxetine supply days/365), with high adherence defined as MPR ≥0.8. Persistence was defined as the length of therapy (LOT) from the index date to the earliest of the ending date of the last prescription, the date of the first gap of more than 15 days between prescriptions, or the end of study period (12 months). Demographic and clinical predictors of adherence and persistence were examined via multivariate logistic regression (MLR) and classification and regression trees (CART). **RESULTS:** Among 4,660 duloxetine patients, 33% achieved high adherence. Factors associated with high adherence from MLR included older age, North Central and Northeast regions, prior venlafaxine, pregabalin, SSRIs or other antidepressants use, or comoribid dyslipidemia, osteoarthritis, or skin and subcutaneous tissue disorders (all p<0.05). CART analysis revealed that patients with prior use of antidepressants, age ≥46, or prior osteoarthritis disorder had higher MPR (all p<0.05), and patients aged ≥45 with a history of SSRI, venlafaxine or anticonvulsant use had longer LOT (all p<0.05). **CONCLUSIONS:** One-third of fibromyalgia patients on duloxetine achieved high adherence. Patients with high adherence and persistence to duloxetine were significantly older and had prior antidepressant use.

PSY23

PREGABALIN IS ASSOCIATED WITH LOWER HEALTH CARE COSTS AND LESS ABSENTEEISM THAN GABAPENTIN WHEN ADDED TO THE TREATMENT OF NEUROPATHIC PAIN

Sicras-Mainar A[1], Rejas J[2], Navarro-Artieda R[3], Planas A[4], Ruiz L[2]
[1]Directorate of Planning, Badalona Serveis Assistencials, Badalona, Barcelona, Spain, [2]Pfizer España, Alcobendas/Madrid, Spain, [3]Hospital Universitari Germans Trias i Pujol, Barcelona, Spain, [4]Hospital Municipal de Badalona, Badalona, Barcelona, Spain

OBJECTIVES: To compare the costs of adding pregabalin or gabapentin to existing therapy in patients with peripheral neuropathic pain (PNeP) in routine medical practice in a Spanish setting. **METHODS:** A retrospective database analysis was performed using patients' medical claims records. Medical records from male and female patients, with PNeP, >18 years, in whom pregabalin, or gabapentin was initiated between 2006 and 2008 were included in the analysis. The economic model included health care resource utilization and corresponding costs, from a third-payer perspective. Estimates of indirect costs, due to sick leave were included. **RESULTS:** A total of 1160 records were eligible for analysis: 764 (65.7%) treated with pregabalin and 399 (34.3%) gabapentin. Patients in both groups were comparable. No significant differences were observed for previous average number of analgesics: pregabalin 2.7 (0.1); gabapentin 2.8 (0.1), p=0.362. However, concomitant use of analgesics was higher in gabapentin cohort; 3.2 (0.1) versus 2.7 (0.1); p=0.003, mainly due to a higher utilization of NSAIDs (74.9% versus 69.5%; p=0.018) and opioids (27.7% vs. 17.9%; p=0.031). Adjusted mean (95% CI) total costs per patient were significantly lower in pregabalin group; €2514 (2228-2800) versus €3241 (2853-3630); p= 0.003, due to minor labour productivity losses; €1067 (790-1345) versus €1633 (1256-2009); p=0.018, and lower adjusted health care costs; €1447 (1380-1513) versus €1609 (1519-1698); p=0.004. The higher drug acquisition costs for pregabalin [€351 versus €191; p<0.001) was compensated for by lower overall health care costs, mainly in medical visits, physiotherapy, hospitalization days and concomitant analgesics. **CONCLUSIONS:** In a population setting in Spain, pregabalin treated patients with PNeP were considerable less costly for the healthcare provider than those treated with gabapentin in routine clinical practice. The higher acquisition cost of pregabalin was compensated largely by lower costs in the other components of health care costs. Patients treated with pregabalin had significantly less sick leaves than gabapentin treated patients.

PSY24

PREGABALIN IS COST-SAVING IN COMPARISON WITH GABAPENTIN TREATED PATIENTS WHEN ADDED TO EXISTING THERAPY IN THE MANAGEMENT OF PAINFUL RADICULOPATHIES

Sicras-Mainar A[1], Navarro-Artieda R[2], Planas A[3], Ruiz L[4], Rejas J[4]
[1]Directorate of Planning, Badalona Serveis Assistencials, Badalona, Barcelona, Spain, [2]Hospital Universitari Germans Trias i Pujol, Barcelona, Spain, [3]Hospital Municipal de Badalona, Badalona, Barcelona, Spain, [4]Pfizer España, Alcobendas/Madrid, Spain

OBJECTIVES: Adding pregabalin or gabapentin to existing therapy in patients with painful radiculopathies in routine medical practice in a Spanish health care setting. **METHODS:** A retrospective database analysis was performed using patients' medical claims records from BSA. Medical records from male and female, with cervical, dorsal or lumbar painful radiculopathy, >18 years, in whom pregabalin, or gabapentin was initiated between 2006 and 2008 were included in the analysis. The economic analysis included healthcare resource utilization and corresponding costs from a third-payer perspective. Estimates of indirect costs, due to sick leave were also included. **RESULTS:** A total of 571 records were eligible for analysis: 378 (66.2%) treated with pregabalin and 193 (33.8%) gabapentin. Time since diagnosis, duration of treatment, prevalence of most comorbidities and previous use of analgesics were comparable. However, concomitant use of analgesics was higher in gabapentin cohort; 3.1 (1.7) versus 2.8 (1.8); p<0.05, mainly due to a higher utilization of opioids (31.1% vs. 21.2%; p<0.05) and non-narcotic (63.7% vs. 52.1%; p<0.01) drugs. Adjusted total costs per patient were significantly lower in pregabalin group; €2472 (2101-2836) versus. €3346 (2866-3825); p= 0.005, due to minor absenteeism costs; €1012 (658-1365) versus €1595 (1129-2062); p=0.042, and lower adjusted health care costs; €1,460 (1,360-1,560) versus €1750 (1618-1882); p=0.001. The higher drug acquisition costs for pregabalin [€343 vs. €222; p<0.001) was largely compensated for by lower overall health care costs, mainly in primary care medical visits, hospitalization days and concomitant analgesics. **CONCLUSIONS:** In a population setting in Spain, pregabalin treated patients with painful radiculopathies were considerable less costly for the health care provider than those treated with gabapentin in routine clinical practice. The higher acquisition cost of pregabalin was compensated largely by lower costs in the other components of health care costs. Patients treated with pregabalin had significantly less sick leaves than gabapentin treated patients.

PSY25

WHAT IS THE ECONOMIC IMPACT OF OBESITY ON HOSPITAL INPATIENT CARE?

Pereira J[1], Ribeiro V[2], Mateus C[2]
[1]Escola Nacional de Saúde Pública, Universidade Nova de Lisboa, Lisboa, Portugal, [2]Universidade Nova de Lisboa, Lisboa, Portugal

OBJECTIVES: In recent years there has been a large increase in the number of morbidly obese persons subject to hospital surgery. In Portugal, 14% of the population of working age is obese. As in other countries these numbers have been rising and it is well known that obese individuals have an increased risk of morbidity and premature death from various diseases. We estimate the impact of obesity on the health sector by calculating the costs of hospital inpatient care associated with obesity in Portugal. **METHODS:** A prevalence-based cost of treatment approach is adopted. Hospital episode micro data are drawn from the National Health Service's (NHS) DRG information system for 2008 (n=965 212). Besides episodes where the main diagnosis is obesity, population attributable fractions are calculated for 16 co-morbidities (CID-9-MC), including diabetes type 2, musculoskeletal diseases, cardiovascular conditions and some types of cancer. Relative risks are drawn from a recent meta-analysis of large-scale prospective studies and prevalence data from a nationally representative examination survey that recorded anthropometric data. Unit cost data are taken from an NHS database. **RESULTS:** The hospital inpatient costs of obesity in NHS hospitals in 2008 are estimated as € 85.9 million. This corresponds to 0.92% of annual NHS expenditure. The three major contributors to this total are osteoarthritis (19.9%), obesity (15.4%) and ischemic heart disease (14.7%). If circulatory and cerebrovascular system diagnoses are grouped together, they become the largest contributors to total costs. **CONCLUSIONS:** The structure of costs by diagnosis is different to that commonly found in ambulatory care. Despite the sharp increase in the number of persons subject to obesity surgery the overall inpatient care costs have remained largely stable over time. There has been a large increase in the resources used to treat

obesity directly, but a corresponding decrease in resources used to treat co-morbidities.

PSY26

COST BENEFIT ANALYSIS OF A WORKSITE WEIGHT MANAGEMENT PROGRAM

Idris A[1], Fernandez ID[1], Fiscella KA[1], Noyes K[2]
[1]*University of Rochester, Rochester, NY, USA,* [2]*University of Rochester School of Medicine and Dentistry, Rochester, NY, USA*

OBJECTIVES: Obesity has reached epidemic proportions and has many cost implications. Being overweight and obese is associated with higher rates of many chronic health conditions, which in turn leads to increases in medical spending and productivity losses. Many worksites have implemented weight management programs for employees to offset the cost burden of disease. This study modeled the potential cost savings for an employer from a 2-year worksite weight management program over ten year time horizon. **METHODS:** We used data from a group randomized control trial of a worksite weight management program and published healthcare utilization data to model long term net costs. Using a Markov decision analytic modeling technique, we conducted a cost benefit analysis of weight management program versus usual practice. Program costs, health care utilization and prevalence of overweight and obesity in the study population were used to assess program impact. Sensitivity analyses were conducted to find a threshold at which the intervention would have a positive net benefit. **RESULTS:** The study population showed had a 1.44% decrease in the overweight/obesity in one year. When modeled over 10 years, this program incurred an excess cost of $206 per person compared to usual practice. The threshold at which this program would have a positive net benefit is when there is a 5.8% decrease in the overweight/obese population annually. **CONCLUSIONS:** Worksite weight management programs may yield cost savings with modest reduction in the percentage of overweight or obese employees. This evidence may encourage employers to implement and support weight management programs that have empirically demonstrated higher rates of weight loss in employees. More research is needed to understand why some individuals are more successful at weight reduction and to evaluate long-term effectiveness of weight management at worksites.

PSY27

COST-CONSEQUENCE ANALYSIS COMPARING ROMIPLOSTIM TO RITUXIMAB IN THE TREATMENT OF ADULT PRIMARY IMMUNE THROMBOCYTOPENIA (ITP) IN FRANCE

Chiche L[1], Lefrere F[2], Chulikavit M[3], Perrin A[3], Stern L[3], Bischof M[4], Cohen S[5]
[1]*Hôpital de la Conception, Marseille, France,* [2]*Hopital Necker, Paris, France,* [3]*Analytica International, New York, NY, USA,* [4]*AMGEN (Europe) GmbH, Zug, Switzerland,* [5]*Amgen S.A.S., Neuilly-sur-Seine, ILE, France*

OBJECTIVES: Romiplostim stimulates platelet production via the thrombopoetin-receptor and is recommended for second- and third-line treatment of chronic ITP in adults. Traditional treatment options in this setting have included unapproved use of the immunosuppressant rituximab. This analysis assessed the cost per responder of romiplostim compared to rituximab in adult ITP patients in France. **METHODS:** A decision analytic model was developed to estimate the six-month cost per patient responding to treatment. A systematic literature review was performed to obtain response rates (achieving a platelet count ≥50x109/L) for each treatment. Romiplostim patients received weekly administrations; rituximab patients received 4 weekly intravenous infusions. Resource utilization was based on French and international treatment guidelines, and clinical expert opinion. Unit costs were derived from published literature and French reimbursement lists, and included the costs of routine physician visits, treatment administration and emergency care. Non-responders incurred the cost of rescue therapy (IVIg and prednisone) and hospitalizations/physician visits associated with bleeding-related events (BREs). **RESULTS:** Although the comparability of existing literature for romiplostim and rituximab was limited, several fulfilled the literature review selection criteria. Response rates were 83% and 62.5%, as per the romiplostim pivotal trial and a meta-analysis on rituximab, respectively. Mean cost per patient for romiplostim and rituximab was €17,486 and €17,086 respectively. Dividing mean cost per patient by response rates, cost per response was €27,337 for romiplostim and €25,178 for rituximab. The main cost-offsets were due to reduced rescue therapy and BREs, with romiplostim resulting in a 23% reduction in cost per platelet response. Across sensitivity analyses, romiplostim consistently produced a lower cost per response. **CONCLUSIONS:** In adult ITP patients, romiplostim yields a lower cost per response over 6 months compared to rituximab, indicating romiplostim represents an efficient use of resources for the French health care system.

PSY28

COST-EFFECTIVENESS ANALYSIS COMPARING EPIDURAL, PATIENT-CONTROLLED IV MORPHINE, AND CONTINUOUS WOUND INFILTRATION FOR POSTOPERATIVE PAIN MANAGEMENT AFTER ABDOMINAL SURGERY

Burke MJ[1], Tilleul P[2], Hutton J[1], Aissou M[2], Beaussier M[2]
[1]*York Health Economics Consortium, Heslington, York, UK,* [2]*Saint Antoine Hospital, Paris, France*

OBJECTIVES: Continuous wound infiltration (CWI), intravenous patient controlled analgesia (iv-PCA) and epidural analgesia (EDA) are analgesic techniques commonly used for pain relief after open abdominal surgery. The aim of this study was to evaluate the cost-impact and cost-effectiveness of these analgesic techniques. **METHODS:** A decision tree model was developed in which patients entered after successful colorectal surgery and received post-operative analgesia. The pathways consist of a number of particular events including patient eligibility given their agreement to benefit from the technique, rate of intra-operative technical failure, successful pain relief and potential adverse events. Data was retrieved from clinical trials and from an observational prospective cohort of 85 patients. Efficacy criteria were based on pain at mobilisation. Healthcare resource use and costs were evaluated from medical records measurements and published data. The incremental cost-effectiveness ratio (ICER) was expressed as the ratio between differential total cost of procedures and differential efficacy. Probabilistic sensitivity analysis (PSA) was performed around the willingness to pay per controlled patient. **RESULTS:** When taking into account all the healthcare resources consumed, the CWI arm (€4,044) is economically dominant compared to iv-PCA (€4,779). EDA is more costly, but also more effective than CWI, with an estimated ICER of €27,446 for each additional controlled patient. PSA analysis shows that CWI remains cost-saving in 71.3% of cases. **CONCLUSIONS:** Device-related costs of using CWI for pain management after abdominal laparotomy are partly counterbalanced by a reduction in healthcare resource consumption. It is also important to consider that a proportion of patients do not have the capacity to benefit from epidural techniques and some may also refuse the technique. This economic evaluation may be useful for clinicians to design algorithms for pain management after major abdominal surgery.

PSY29

ECONOMIC EVALUATION OF CAPSAICIN PATCH 8% IN THE TREATMENT OF NEUROPATHIC PAIN IN AUSTRIA

Brennig C, Walter E, Schöllbauer V
Institute for Pharmaeconomic Research, Vienna, Austria

OBJECTIVES: About 5% of the population (400,000 in Austria) suffer from neuropathic pain. Fifty percent of them denominate their pain as "very strong". Neuropathic pain patients consult on average 5 different doctors before the main diagnosis is found. The aim of this study was to evaluate the cost-effectiveness of treatment of neuropathic pain with topical Capsaicin Patch 8% versus current standard of care (pregabalin) in Austria. **METHODS:** The analysis was performed using a Decision Tree Model combined with a Markov model adapted for Austria. The model is based on an indirect comparison, which results in a conservative estimation, as the efficacy of capsaicin patch 8% is underestimated due to a large placebo effect. Efficacy assessment was based on the outcome measure QALY. Costs were captured for the year 2011. Resource use was determined by literature research and expert opinion and accurately reflects the Austrian treatment path. The study time horizon was 5 years. The analysis was performed from the perspective of social health insurance. The analysis was conducted according to Austrian Guidelines for Health Economic Evaluations. **RESULTS:** The results are shown for a time horizon of 5 years. The cost per patient (30% pain reduction) for capsaicin patch 8% amount to €4898 for a time horizon of 5 years and to €4745 for Pregabalin. Treatment with capsaicin patch 8% leads to 3.011 QALYs, treatment with Pregabalin to 2.964 QALYs. The cost per QALY is €1627 (capsaicin patch 8%) versus €1611 (Pregabalin) with an ICER of €2358. **CONCLUSIONS:** In Austria, the treatment of neuropathic pain with Capsaicin Patch 8% is a cost-effective alternative compared to Pregabalin from the perspective of the social health insurance.

PSY30

COST EFFECTIVENESS OF TRAMADOL VERSUS DICLOPHENAC IN PAIN MANAGEMENT AFTER CESAREAN DELIVERY

Farshchi A, Farshchi S, Merrikhi Haghi S
Tehran University of Medical Sciences, Tehran, Iran

OBJECTIVES: Postoperative pain is one of the main adverse outcomes causing distress to patients after cesarean delivery. Meanwhile the main analgesic drugs are opioids and nonsteroidal anti-inflammatory drugs (NSAIDs), more over side effects such as nausea, vomiting, sedation were reported with opioids. **METHODS:** This study was undertaken based on our clinical trial that evaluated postoperative pain in a double-blinded, randomized, single-dose comparison of Tramadol IM injection, 100 mg (Group T) and Diclophenac suppository, 100 mg (Group D) given alone-single dose in 100 patients who had elective cesarean delivery. All patients were assessed at 0, 6, 12 and 24 hours post operation for pain degree (by Visual Analogue Score: VAS 1-10), nausea and vomiting. Our outcomes were the reduction in pain. For the cost estimates of therapeutic schemes, we computed the direct costs of the analgesics (unitary cost) and disposable material (needles, syringes, padcol). Cost-Effectiveness Ratio was calculated. **RESULTS:** The efficacy of Tramadol and Diclophenac were not different significantly (P=0.06). Nausea and vomiting were minimal with all treatments. Total costs in T group were $52.38 and in D group were $161.90. Cost-Effectiveness Ratio of Tramadol to Diclophenac was 2.76. **CONCLUSIONS:** Cost-Effectiveness Ratio showed that the cost of Tramadol in this study was 2.76 times more than Diclophenac with the same efficacy, thus the analgesic effect of Diclophenac is more cost-effective than Tramadol.

PSY31

COST-EFFECTIVENESS OF TAPENTADOL PROLONGED-RELEASE (PR) COMPARED TO OXYCODONE CONTROLLED RELEASE (CR) IN PATIENTS WITH CHRONIC SEVERE NON-CANCER PAIN IN IRELAND

Obradovic M[1], Ikenberg R[2], Hertel N[3], Liedgens H[1]
[1]*Grünenthal GmbH, Aachen, Germany,* [2]*IMS Health GmbH Und Co. Ohg, Nürnberg, Germany,* [3]*IMS Health, London, UK*

OBJECTIVES: To assess the cost effectiveness of tapentadol PR compared with oxycodone CR for the treatment of patients with chronic severe non-cancer pain in Ireland. **METHODS:** A Markov model was developed to assess the costs and benefits of tapentadol PR and oxycodone CR treatment over a 1 year time horizon from the Health Service Executive perspective (GMS and DP/LTI Scheme). Patients tolerating the treatment or having mild adverse events remained on tapentadol or oxycodone. Patients who were lacking efficacy or had poor tolerability switched to either transdermal fentanyl or morphine. 3rd line therapy was defined as absorbing state. Data regarding efficacy, tolerability and utility values (EQ-5D) were de-

rived from the 3 phase III clinical trials of tapentadol PR in osteoarthritis and lower back pain and published literature. Switch rates to 2nd line therapies and co-medication costs were provided by the National Centre of Pharmacoeconomics based on the GMS database analysis. Costs of physician visits were obtained by applying local costs to the number of physician visits in each therapy line obtained from a retrospective analysis of the UK THIN database of GP patient records. One-way deterministic and probabilistic sensitivity analyses were undertaken to assess the impact of parameter uncertainty. **RESULTS:** Mean annual total costs per patient from GMS Scheme perspective amount to 4,367€ for tapentadol vs. 4,381€ for oxycodone. Tapentadol generates 0.6316 QALYs compared to 0.6122 QALYs for oxycodone, resulting in tapentadol being a dominant treatment. For DP/LTI Scheme, tapentadol had an ICER of 1,662 €/QALY gained. Results were robust in a broad range of sensitivity analyses. Probability that tapentadol is cost-effective vs. oxycodone at threshold of 20,000 €/QALY gained exceeded 95%. **CONCLUSIONS:** Compared to oxycodone CR, the most commonly used oral drug for chronic severe non-cancer pain in Ireland, tapentadol PR appears to be a highly cost-effective treatment option.

PSY32

MODELING COST-EFFECTIVENESS OF DRUG TREATMENTS FOR SEVERE CHRONIC NON-CANCER PAIN IN PORTUGAL

Obradovic M[1], Hertel N[2], Ikenberg R[3], Gouveia M[4], Liedgens H[1]
[1]*Grünenthal GmbH, Aachen, Germany,* [2]*IMS Health, London, UK,* [3]*IMS Health GmbH Und Co. Ohg, Nürnberg, Germany,* [4]*Catholic University of Portugal, Lisbon, Portugal*

OBJECTIVES: To assess the cost-effectiveness of tapentadol PR compared to opioids (morphine, oxycodone, transdermal buprenorphine [TDB] and transdermal fentanyl [TDF]) for the treatment of severe chronic non-cancer pain from the societal perspective in Portugal. **METHODS:** A one year Markov transition state model with monthly cycles was built. Four health states were defined: 'no withdrawal and no adverse events treated', 'occurrence of adverse events (AEs) with need for medical treatment', 'withdrawal due to AEs', and 'withdrawal due to lack of efficacy'. If patients did not adequately respond to treatment or withdraw, switching to alternative second line opioid (morphine, hydromorphone, TDB or TDF) was considered. Third line therapy was the absorption state. Data regarding efficacy, tolerability and utility values (EQ-5D) were derived from clinical trials and published literature. Switch rates to subsequent opioid therapies and resource consumption were estimated by clinical experts. Costs were calculated from the societal perspective. Direct costs were calculated based on official Portuguese prices/tariffs, indirect costs derived from the National Health Survey. One-way and probabilistic sensitivity analyses were conducted. **RESULTS:** Mean annual total costs per patient amounted to 3793 € for morphine, 3,804€ for TDF, 3891 € for TDB, 3964 € for oxycodone, and 4117 € for tapentadol. Total QALYs generated were 0.6102 (morphine), 0.6062 (TDF), 0.6026 (TDB), 0.6096 (oxycodone), and 0.6287 (tapentadol). The resulting ICERs (€/QALY gained) for tapentadol yield 7,995 versus oxycodone, 8,685 versus TDB, 13,943 versus TDF, and 17,547 versus morphine. Varying costs, probabilities, and utilities by ±50%, ±10%, and ±10%, respectively, resulted in an ICER range from tapentadol being dominant (vs. oxycodone) to 26,000 €/QALY gained (vs. morphine). **CONCLUSIONS:** To improve pain relief and quality of life in patients with severe chronic pain tapentadol appears to be the favourable and cost-effective treatment option from the societal perspective in Portugal.

PSY33

CLINICAL AND ECONOMIC ANALYSIS OF ELTROMBOPAG IN CHRONIC IDIOPATHIC THROMBOCYTOPENIC PURPURA IN CONTEXT OF RUSSIAN HEALTH CARE SYSTEM

Vorobyev PA[1], Krasnova L[2], Borisenko O[1]
[1]*Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia,* [2]*Moscow State Medical University named after I.M.Sechenov, Moscow, Russia*

OBJECTIVES: The emergence of new drugs for the treatment of patients with chronic idiopathic thrombocytopenic purpura (ITP), stimulates the proliferation of megakaryocyte germ (eltrombopag), stresses the need to conduct a comparative analysis in their cost-effectiveness, compared with other modern treatment options. **METHODS:** Markov modeling was used. Markov model, developed by GlaxoSmithKline, was adapted to the context of Russian health care system to assess cost-utility and cost-effectiveness of eltrombopag and romiplostim for treatment of chronic ITP in patients, for whom splenectomy is contradicted. Eltrombopag and romiplostim were used as first-line options. The simulation was performed taking into account the time perspective for 2 years, 10 and 20 years. Data about diagnosis and treatment of ITP in "real world" settings was collected by interviewing 5 expert-hematologists with expertise in the treatment of chronic ITP, working in different health facilities in Russia. Only direct medical costs were calculated. **RESULTS:** Cost-effectiveness ratio for criterion "additional years of life" after 2 years of onset was $27,703 for eltrombopag and $31,988 for romiplastim, after 10 years of onset – $21,758 and $24,700 respectively, after 20 years of onset – $17,257 and $19,577 respectively. Cost of QALY after 2 years of onset was $39,000 for eltrombopag and $45,530 for romiplastim, after 10 years of onset – $35,108 and $40,218 respectively, after 20 years of onset – $32 527 and $37,204 respectively. **CONCLUSIONS:** Eltrombopag is cost-effective compared with romiplostim as a first-line therapy in treatment of chronic idiopathic thrombocytopenic purpura in patients, for whom splenectomy is contradicted.

PSY34

ECONOMIC EVALUATION OF FERINJECT IN THE TREATMENT OF ANEMIA PATIENTS IN THE GREEK HOSPITAL SETTING: A COST MINIMIZATION ANALYSIS

Fragoulakis V[1], Kourlaba G[1], Goumenos D[2], Konstantoulakis M[3], Maniadakis N[1]
[1]*National School of Public Health, Athens, Greece,* [2]*University Hospital of Patras -Greece, Patras, Greece,* [3]*Athens Medical School, Athens, Greece*

OBJECTIVES: To conduct an economic evaluation comparing, ferinject (Ferric Carboxymaltose) with Venofer (iron sucrose), iron sucrose similars (ISS-generic forms of iron sucrose) and Cosmofer (low molecular weight-LMW iron dextran) in the management of anaemia patients in Greece. **METHODS:** A cost-minimization analysis, from National Health System (NHS) perspective, was conducted since there are no clear data indicating that one of these regimens is superior to the others in terms of efficacy. Because iron could be administered either to inpatients (i.e., surgical patients or patients hospitalized due to a disease related to chronic or acute blood loss) or to outpatients (i.e. non-dialysis chronic kidney disease patients etc), the economic evaluation was undertaken for these two large categories of patients, separately. Total cost related to each treatment includes the cost of drugs, the cost of disposables for each infusion, the monitoring cost during infusion (salaries of personnel), the cost for management of adverse events, the cost of visits, the productivity loss, and the travelling cost of patients. A supplementary budget impact analysis was also conducted. **RESULTS:** The mean total (direct) cost of therapy with Ferric Carboxymaltose was €216.32, in the iron sucrose arm the cost was €296.34, in the LMW iron dextran arm was €251.12, while in the ISS the cost was estimated at €324.47 for inpatients. In the case of outpatients the cost of ferric carboxymaltose was €152.66, the cost of iron sucrose was €285.10, the cost of LMW iron dextran was €459.88 and the cost of ISS was estimated at €313.13. Various sensitivity analyses showed that the main results were robust, reaching a statistical significant difference in 95% level of significance. **CONCLUSIONS:** Ferric Carboxymaltose represents a cost-saving option compared with other alternative therapies used in the management of anaemia in the National Health Service of Greece.

PSY35

ECONOMIC EVALUATION OF DARBEPOETIN ALFA IN THE MANAGEMENT OF END STAGE RENAL DISEASE (ESRD) PATIENTS WITH ANEMIA IN THE GREEK NHS SETTING

Fragoulakis V[1], Iatrou C[2], Maniadakis N[1]
[1]*National School of Public Health, Athens, Greece,* [2]*General Hospital of Nikaia, Athens, Greece*

OBJECTIVES: To conduct an economic evaluation for End Stage Renal Disease (ESRD) diabetic and non diabetic patients treated with Darbepoetin alfa, Epoetin alfa, Epoetin beta and Epoetin Beta (Methoxy polyetylene Glycol). **METHODS:** A cost-minimization analysis was conducted since there are no clear data indicating differences in terms of efficacy. A probabilistic Markov model was constructed to simulate during a 20-year time span the progress of patients through four health states: "dialysis", "transplantation", "dialysis after graft failure" and "death". The dose required to maintain the desirable Hb level (10 – 12 g/dL) was obtained from the literature alongside transition probabilities for the baseline cohort (mean age 65, diabetics 54%). Costs were estimated from the perspective of the healthcare system and reflect the drug administration, the monitoring of patients, transplantations and other resources consumed by patients valued at €2011. A 3.5% discount rate was used for outcomes. **RESULTS:** The mean survival (common for all comparators) expressed in terms of QALY's was 2.16 (95%Uncertainty Interval (UI): 2.11-2.21) overall, and 2.23 (95%UI: 2.18-2.29) and 2.10 (95%UI: 2.05-2.14) for patients without and with diabetes, respectively. The mean total treatment cost for patients on Darbepoetin alfa was 11,505 (95%UI: €11,322-€11,680) for the entire population, €11,103 (95%UI: €10,906-€11,299) for diabetic and €11,976 (95%UI: €11,739-€12,197) for non-diabetic patients. The mean cost of patients on Epoetin alfa was €15,340 (95%UI: €15,118-€15,554), €14,720 (95%UI: €14,466-€14,976), and €16,068 (95%UI: €15,760-€16,343) respectively. The cost of Epoetin beta was €15,038 (95%UI: €14,783-€15,292), €14,435 (95%UI: €14,160-€14,707) and €15,746 (95%UI: €15,434-€16,063) respectively. Finally, for patients on Epoetin Beta (Methoxy polyetylene Glycol), it was €12,057 (95%UI: €11,868-€12,238), €11,624 (95%UI: €11,416-€11,823) and €12,566 (95%UI: €12,320-€12,796) respectively. **CONCLUSIONS:** Darbepoetin alfa (AranespÒ) may represent a cost saving option, compared to other alternative therapies used in the management of ESRD patients in the National Health Service of Greece.

PSY36

MODELLING THE COST-EFFECTIVENESS OF ORLISTAT AS A TREATMENT FOR OBESITY IN PRIMARY CARE

Ara R[1], Blake L[2]
[1]*University of Sheffield, Sheffield, UK,* [2]*Univrsity of Sheffield, Sheffield, UK*

OBJECTIVES: Obesity represents a considerable and increasing health problem. The objective of this research was to assess the clinical and cost-effectiveness of orlistat in overweight and obese patients in primary care. **METHODS:** A cohort simulation model was built in Simul8 to explore the potential benefits of treatment with orlistat compared with standard care. The model used a lifetime horizon to estimate the incremental cost per quality adjusted life-year (QALY) gained. Clinical effectiveness was modelled using the results of a mixed treatment comparison. Longitudinal analyses of the General Practice Research Database (n=100,000) were used to derive BMI related estimates for times to death, primary myocardial infarction or stroke, onset of type 2 diabetes, and to estimate the natural history of body mass index (BMI) in people who are obese. Annual probabilities of subsequent cardiovascular events were estimated using data from the Nottingham Heart Attack register and South London Stroke register. Health related quality of life values were modelled using a relationship between BMI and EQ-5D data controlling for age an comorbidities. Current event and post-event health states were used to incorporate changes in health related quality of life and costs. **RESULTS:** Deterministic analysis gave a cost per QALY gained (versus placebo) of £1,665, although this figure is sensitive to the baseline BMI, due to the strong correlation of BMI and the risk of

CV events and T2DM. **CONCLUSIONS:** Orlistat is a cost-effective treatment to aid weight reduction in primary care when using a threshold of £20,000 per QALY.

PSY37

ASSESSMENT OF THE GLOBAL COST OF TRANSFUSION IN FRENCH ORTHOPEDIC SURGERY WARDS

Dos-Reis J[1], Bernard M[2], Beucher S[3], Catonné Y[4], Massin P[2], Sautet A[3], Tilleul P[3]
[1]*Paris Descartes University, Paris, France,* [2]*Bichat Hospital, Paris, France,* [3]*Saint Antoine Hospital, Paris, France,* [4]*Pitié-Salpétrière Hospital, Paris, France*

OBJECTIVES: As part of a medico-economic study on a fibrin sealant used in orthopedic surgery to decrease allogeneic transfusion requirement, this study was conducted to evaluate the overall cost of transfusion from hospital perspective. **METHODS:** A multicenter prospective study was carried out from March 14, 2011 to June 1, 2011 in orthopedic surgery wards of 3 French university hospitals. A microcosting has been developed to identify global costs of transfusion through: the acquisition cost of red blood cell (RBC), supplies used for a transfusion, and times spent by medical and nurse staff for the management of the transfusion timed by a pharmacy resident with a stopwatch. Corresponding costs for staff were estimated from mean salaries for medical and non medical staff in 2011. **RESULTS:** Five transfusions were observed in each site. A physician spent 1'01"± 43" (mean ± standard deviation) for the prescription of RBC. Personal care assistants and hospital workers brought samples to the Blood Bank (BB), transmitted the document to the BB, and delivered RBC to the ward which took 10'17"± 05'46" and 10'47"± 03'20" respectively. Nurses spent 52'23"± 04'39" for the control of the documents, the ultimate pre-transfusion control at patient's bedside, the administration of RBC and the monitoring of the transfusion. No adverse event occurred during the study. The mean global cost of the transfusion of a RBC was estimated at 254 Euros. Regarding global cost, management of transfusion was estimated at 31 Euros representing 12% of the overall cost of transfusion. **CONCLUSIONS:** The study shows the heavy workload represented by each transfusion for a nurse in the context of shortage of nurses. These results may be helpful to fill a pharmacoeconomic model used to estimate the incremental cost effective of using fibrin sealant in orthopedic surgery.

Systemic Disorders/Conditions – Patient-Reported Outcomes & Preference-Based Studies

PSY38

ESTIMATING HEALTHY-TIME EQUIVALENTS FOR MIGRAINE TREATMENT OUTCOMES FROM CONJOINT ANALYSIS MEASURES OF PATIENT PREFERENCES

Gonzalez JM[1], Johnson FR[1], Runken MC[2], Poulos C[1]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*GlaxoSmithKline, Research Triangle Park, NC, USA*

OBJECTIVES: Evaluate the relative impact of migraine-related outcomes using generalized healthy-time equivalences (HTE). **METHODS:** A best-practice conjoint analysis or discrete-choice experiment (DCE) evaluated migraine-related outcomes reported in the Completeness of Response Survey (CORS). We elicited patients' trade-off preferences for migraine symptoms with different clinically relevant durations, including symptom-free time. Preference-parameter estimates were used to determine the amount of symptom-free time that was utility-equivalent to 24-hour migraine episode profiles described by acute headache, post-headache, and symptom-free phases. These HTEs quantify the impact of migraine-related outcomes using a fully general utility-theoretic conceptual framework. Unlike quality-adjusted life years (QALYs), HTEs do not require assuming that utility of a brief, but severe, outcome is a simple fraction of a quality-adjusted year. Also unlike QALYs, HTEs do not require risk neutrality, and easily account for personal characteristics that may determine preferences for health outcomes. **RESULTS:** A total of 539 people with a self-reported physician diagnosis of migraine completed the survey. As expected, migraineurs were negatively affected by the duration of headache-phase and post-headache-phase symptoms. However, for some groups in the sample we found no statistical difference in relative preferences for different pain severities in the acute headache phase. Subjects had clear preferences for different levels of daily-activity limitations experienced during the post-headache phase. Results also showed that subjects in the sample were averse to risk. We also found preference heterogeneity based on individual characteristics. **CONCLUSIONS:** This study demonstrates the feasibility of obtaining standardized healthy-time equivalences derived from clinically-relevant symptom-duration tradeoff data as a feasible alternative to QALYs for acute, self-limiting conditions. The results also suggest that the assumptions associated with the use of conventional QALYs are not met by our sample of migraineurs; adding to the mounting body of evidence that encourages the use of more flexible utility-theoretic measures of quality-adjusted time.

PSY39

PREDICTORS OF HEALTH UTILITIES AMONG PATIENTS WITH RHEUMATOID ARTHRITIS IN EUROPE

Dibonaventura MD[1], Pisa G[2], Schwankl M[2]
[1]*Kantar Health, New York, NY, USA,* [2]*Kantar Health, München, Germany*

OBJECTIVES: Previous studies have examined the humanistic burden of rheumatoid arthritis; however, less research has been conducted to understand the factors that are most strongly associated with the health-related quality of life of these patients. **METHODS:** Data from the European 2010 National Health and Wellness Survey (an annual survey of respondents from France, Germany, Italy, Spain, and the UK) were used in the current study. Only respondents who reported being diagnosed with RA (N=498) were included in the analyses. Health state utilities (SF-6D), derived from the SF-12, were examined on a bivariate level across a variety of subgroups (e.g., years diagnosed, treatment status, comorbidities, joints affected, etc). Health state utilities were also predicted from demographic and patient characteristic information using multiple regressions. **RESULTS:** A total of 498 patients (0.86%) reported being diagnosed with RA. These patients were mostly female (64.3%) and had an average age of 52.3 years. Most patients were diagnosed with RA for more than 10 years (55.8%). Several demographic and patient characteristic factors were significantly associated with health state utilities. RA patients in Spain (Adjusted Mean=0.60) and Italy (Adjusted mean=0.53) had the highest and lowest, respectively, utility scores. Severe RA (Adjusted mean=0.51), comorbid Crohn's disease (Adjusted mean=0.52), and RA affecting the spine (Adjusted mean=0.54) were associated with the largest decrements in utility scores (all ps<.05). **CONCLUSIONS:** Although previous studies have documented the burden of RA in Europe, the current study suggests that burden is not uniform. Certain geographies, particularly Italy, are associated with a greater burden for patients with RA. Similarly, patient characteristics, such as arthritis of the spine and comorbid Crohn's disease, have a large effect on the quality of life of these patients. These results suggest a more comprehensive assessment of patient characteristics is necessary to fully capture the quality of life burden of RA.

PSY40

EQ-5D UTILITIES IN PATIENTS WITH CHRONIC PAIN DUE TO OSTEOARTHRITIS OF THE KNEE OR LOW BACK PAIN TREATED WITH TAPENTADOL AND OXYCODONE

Obradovic M, Lal A, Liedgens H
Grünenthal GmbH, Aachen, Germany

OBJECTIVES: To analyze QoL of patients with chronic pain due to osteoarthritis of the knee (OA) or low back pain (LBP) using the EQ-5D questionnaire in phase III trials with tapentadol prolonged release (PR) and oxycodone controlled release (CR). **METHODS:** Three phase III trials in OA and LBP with the same design included the EQ-5D questionnaire to measure utilities of patients with chronic pain treated with either tapentadol PR, oxycodone CR or placebo. Utilities were obtained at baseline and endpoint (15 weeks). An analysis was performed to explore how EQ-5D distinguished among various health states. **RESULTS:** Mean utility of all patients treated with tapentadol PR (N=978) increased from 0.42 at baseline to 0.60 at endpoint, and for patients treated with oxycodone CR (N=998) from 0.43 at baseline to 0.56 at endpoint, and for patients treated with placebo (N=990) from 0.41 at baseline to 0.55 at endpoint. The increase in utility was significantly higher ($p<0.001$) in patients treated with tapentadol compared to those treated with oxycodone or placebo. Presence and severity of adverse events, as well as insufficient pain relief substantially decreased utility values in both tapentadol and oxycodone treatment groups. Whereas the highest utilities were seen in the groups of patients who had >30% pain improvement and patients who tolerated the treatment (0.69-0.72), patients who withdrew due to an adverse event or due to lack of efficacy had much lower utilities (0.40-0.51). **CONCLUSIONS:** EQ-5D utilities of OA and LBP patients increased significantly compared to baseline when treated with tapentadol PR or oxycodone CR, whereby the increase was significantly higher with tapentadol PR. Sufficient pain relief and reduction of severe treatment-related adverse events resulted in a large beneficial impact on EQ-5D utility values. This analysis clearly demonstrates that the EQ-5D is a useful tool to measure QoL in pain studies.

PSY41

HEALTH STATUS AND HEALTH-RELATED QUALITY OF LIFE REPORTED BY FEMALES WITH BLEEDING DISORDERS FROM THE CANADIAN NATIONAL HAEMOPHILIA REGISTRY

Horsman JR[1], Rae CS[2], Furlong W[3], Barr RD[2], Lillicrap D[4]
[1]*Health Utilities Inc, Dundas, ON, Canada,* [2]*McMaster University, Hamilton, ON, Canada,* [3]*Health Utilities Inc., Dundas, ON, Canada,* [4]*Queen's University, Kingston, ON, Canada*

OBJECTIVES: Compare health measurements of females with bleeding disorders (FBD) to males with von Willebrand disease (VWD) and females in the general population (FGP). **METHODS:** Subjects >12yrs of age, with VWD and FBD in the Canadian national registry were eligible for assessment. Health status and health-related quality of life (HRQL) were measured using the Health Utilities Index Mark 3 (HUI3). The results were compared with normative data by age and gender from the 2002/3 Joint Canada / United States Survey of Health and from the 1991 Canadian General Social Survey. Mean differences and proportions were assessed using t-test and chi square, respectively. Differences >0.05 in mean HRQL scores and >10% for proportions were considered important. Statistical significance was set at $p<0.05$. **RESULTS:** 411 HUI3 assessments were analyzed. Among 20-79 year old FBD, mean HRQL scores were lower (diff>0.150; $p<0.05$) than in FGP. For those <45 years, FBD had lower HRQL scores (diff=0.080; $p=0.027$) than males with VWD. No difference between males with VWD and FBD >45 years of age was observed ($p=0.871$). Excellent health was self-reported by 18.4% of females from the registry compared to 22.7% ($p<0.05$) of FGP and 29.9% ($p=0.02$) of males with VWD. Between FDB and FGP important differences ($p<0.001$) in the proportion reporting disability were observed for HUI3 attributes vision, emotion, cognition, and pain for those <45 years, and ambulation, dexterity, emotion and pain for those >45 years. Between FBD and males with VWD an important difference ($p=0.005$) in the proportion reporting disability was observed for pain. FBD have similar HRQL (0.72) to moderate (0.73) and severe (0.71) HIV-negative haemophiliacs. **CONCLUSIONS:** Females with bleeding disorders have greater morbidity than females in the general population or males with VWD.

PSY42

CHRONIC PAIN: PATIENT TREATMENT PREFERENCES - A DISCRETE CHOICE EXPERIMENT

Mühlbacher A[1], Ezernieks J[2], Nübling M[3]

[1]Hochschule Neubrandenburg, Neubrandenburg, Germany, [2]Pfizer Deutschland GmbH, Berlin, Germany, [3]Gesellschaft für empirische Beratung mbH, Denzlingen, Germany

OBJECTIVES: Chronic pain is a common and universal phenomenon that appears at all ages and in all populations. It has a substantially impact on the quality of patients' daily life as well as their physical and mental function. The objective of this study was to document attributes of a pain medication that are relevant from the perspective of patients with chronic pain. **METHODS:** In a first step literature review, focus groups with patients and one to one interviews with highly accepted experts in the field of indication were conducted to identify relevant treatment attributes of a pain medication. A pretest was conducted to verify the structure of relevant and dominant attributes using factor analysis and choosing the most frequent mentioned representative of each factor. The discrete choice experiment (DCE) itself used a self administered survey including sociodemographics and an indication specific parameter (pain). For statistical data analysis of the DCE, a random effect logit model was used and coefficients were presented. **RESULTS:** In a first step we detected 36 attributes. Factor analysis revealed seven remaining attributes. A total of N=1324 German patients participated in the self administered survey, resulting in the following ranking of relevant attributes for treatment decision: "no character change", "less nausea and vomiting", "pain reduction" (Coefficient: > 0.9 for all attributes, "high impact"); "rapid effect", "less danger of addiction" (Coefficient ~ 0.5, "middle impact"); "applicability with comorbidity" (Coefficient: ~ 0.3), "improvement of quality of sleep" (Coefficient ~ 0.25). All attributes were highly significant ($p < 0.001$). **CONCLUSIONS:** Due to the subjective nature of pain, the management of chronic pain needs to be patient centered. Therefore an understanding of patient preferences is essential for inclusion in treatment decisions. In summary, DCE and direct assessment proved to be valid instruments to elicit treatment preferences in chronic pain treatment.

PSY43

THE TRANSLATION AND LINGUISTIC VALIDATION OF THE TREATMENT RELATED IMPACT MEASURE – WEIGHT (TRIM-WEIGHT)

Ellis G[1], Kragh N[2], Brod M[3], Wild D[1]
[1]Oxford Outcomes Ltd, an ICON plc company, Oxford, UK, [2]Novo Nordisk A/S, Søborg, Denmark, [3]The Brod Group, Mill Valley, CA, USA

OBJECTIVES: The TRIM-Weight is a Patient-Reported Outcome (PRO) questionnaire designed to assess the efficacy and tolerability of weight loss medication. The objective of this study was to produce translations into number of languages that are conceptually equivalent to the original and to other language versions, ensuring the validity of the translations within the target cultures. **METHODS:** The standard linguistic validation methodology was followed: two forward translations with reconciliation, two back translations and review, developer review, cognitive interviews with five obese people for each language, and proof reading. **RESULTS:** Numerous cultural and linguistic issues became apparent throughout the translation process, including the following: The term for 'craving' proved difficult to translate into Spanish, Italian, French (France) and French (Canada). The developer's input and cognitive debriefing interviews were used to find appropriate terminology to convey the intended meaning. For example, it had to be specified in French (France) that this related to one particular food; 'Jitteriness' was mentioned in the scale as a physical side-effect of the drug; this word was problematic in Dutch (where the translator had to use a term related to 'trembling'), and Brazilian Portuguese (where the translator used a term related to being physically anxious and unable to relax); Brazilian respondents had difficulty understanding that they must respond only concerning prescription weight loss medication and the related instruction had to be underlined to clarify this; several vocabulary problems occurred, e.g. finding terms for 'isolated' in Russian, 'embarrassment' in Brazilian Portuguese and 'weight loss plateaus' in Austria German. Each issue was discussed until a suitable alternative was found which could be tested in cognitive interviews with patients. **CONCLUSIONS:** The TRIM-Weight questionnaire was translated and linguistically validated using a rigorous translation process. A number of cultural and linguistic issues became apparent and were resolved. TRIM-Weight is now validated for use in multinational trials.

PSY44

ASSOCIATION OF THE OBESITY AND WEIGHT-LOSS QUALITY-OF-LIFE SCORE WITH PATIENT DEMOGRAPHICS AND MEASURES OF OBESITY

Lee LJ, Nelson DR, Curtis B, Gaich GA
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: As the incidence of obesity continues to rise, there is pressure to find and evaluate new weight loss interventions; understanding the impact of obesity and weight loss on patients is an invaluable part of this process. We aimed to examine associations among patient characteristics, self-reported depression, vitality and the obesity and weight-loss quality-of-life (OWL-QOL) instruments in a population of overweight and obese patients. **METHODS:** We analysed baseline data from a clinical trial involving patients with body mass index (BMI) between 27–45kg/m^2. Data included: patient demographics; obesity measures including BMI, weight and body composition; responses to the OWL-QOL questionnaire; responses to the Patient Health Questionnaire (PHQ), assessing depression; and responses to the SF-36 vitality subscale. Least angle regression (LAR) was used to select the most relevant obesity measures to include in multivariable regression models. Univariate associations were examined using Spearman's correlations. **RESULTS:** Baseline data were available for 341 patients with a mean age of 44.2 (SD=10.7) years, mean BMI of 35.2 (SD=4.67) kg/m^2, and mean OWL-QOL total score of 55.3 (SD=24.2). 83.3% were female. LAR showed that among obesity measures, percentage of total fat was most significantly associated with the OWL-QOL total score. Based on Spearman's correlations, the OWL-QOL total score was significantly correlated with gender (ρ=0.233, p<0.001), total fat (ρ=-0.264, p<0.001), PHQ (ρ=-0.138, p=0.035), and vitality (ρ=0.456, p<0.001). In the final model (R2=0.34), vitality (β=0.55, p<0.001), female gender (β=-8.71, p=0.026) and race/ethnicity (β=12.3, African American versus Other, β=1.08 White versus Other; p=0.002 for both comparisons), but not percentage of total fat, were significantly associated with the OWL-QOL total score. **CONCLUSIONS:** The OWL-QOL was significantly associated with gender, race/ethnicity and vitality. Importantly, based on LAR, percentage of total fat was more significantly associated with the OWL-QOL total score than other obesity measures, including BMI.

PSY45

IMPACT OF LUPUS ON CAREER CHOICES AND WORK PRODUCTIVITY IN FIVE EUROPEAN COUNTRIES: RESULTS FROM THE LUPUS EUROPEAN ONLINE (LEO) SURVEY

Schneider M[1], Gordon C[2], Lerstrøm K[3], Govoni M[4], Nikaï E[4], Isenberg D[5]
[1]Heinrich-Heine-University Duesseldorf, Duesseldorf, Germany, [2]University of Birmingham, Birmingham, UK, [3]Lupus Europe, Romford, UK, [4]UCB, Brussels, Belgium, [5]University College London Hospitals, London, UK

OBJECTIVES: A previous survey distributed in Europe and the US found that lupus affects patients' career, physical well-being and everyday living. The LEO survey was developed to explore further the effect of lupus on work productivity, fatigue and health-related quality of life (HRQoL) in Europe. **METHODS:** The survey had four sections. Section 1 included patient-developed questions on demographics, lupus diagnosis and impact of lupus on work and career. Sections 2–4 used lupus-specific patient-reported outcomes (PRO) instruments to assess work impairment (Work Productivity and Activity Impairment Questionnaire, Lupus V2.0), fatigue (lupus-specific Fatigue Severity Scale) and HRQoL (LupusQoL). The survey was available May–August 2010 and in five European languages. **RESULTS:** A total of 1566 participants with self-reported lupus completed the survey: from France (n=139), Germany (n=537), Italy (n=357), Spain (n=267) and the UK (n=266). Most were female (93%, 1440/1557) and aged 26–55 years (81%, 1253/1550). In section 1, over two-thirds (70%, 1028/1475) of participants reported that lupus affected their career (highest UK, 79% [199/252]; lowest France, 56% [73/131]). Of these, 31% (288/928) now work flexible hours, 29% (265/928) applied for sick leave, 24% (219/928) applied for social or disability allowance and 17% (156/928) changed career. Of those who reduced work hours, almost a quarter (23%, 150/646) had to reduce by >75%. In the WPAI assessment, participants reported missing an average of 13% (SD=24.2) of their working time because of lupus. At work, productivity was reduced by an average of 40% (SD=25.8). Overall, an average of 43% (SD=27.1) of total work hours available to participants were lost due to lupus. Ability to carry out non-work activities such as housekeeping, childcare and studying was, on average, impaired by 56% (SD=26.7). **CONCLUSIONS:** Lupus diminishes European patients' likelihood of working and their productivity while at work. These findings emphasise the need for improved management of lupus.

PSY46

COMPARISON OF EQ-5D AND SF-6D UTILITIES IN POMPE DISEASE

Kanters T[1], Redekop W[1], Hagemans MLC[2], Van der Ploeg AT[2], Rutten-van Mölken MP[1], Hakkaart L[1]
[1]Erasmus University Rotterdam, Rotterdam, The Netherlands, [2]Erasmus University Medical Center, Rotterdam, The Netherlands

OBJECTIVES: Comparative studies between Euroqol-5D (EQ-5D) and Short-form 6D (SF-6D) utilities have been performed for a number of diseases, but not for patients with Pompe disease. Pompe disease is a rare disease (prevalence of <5/10,000). Characteristic features of late onset Pompe disease are impaired ambulatory and respiratory functioning. We compared the psychometric properties of EQ-5D and SF-6D in these patients and assessed the convergent validity and the ability of the instruments to discriminate with respect to functional capabilities and subjective health. **METHODS:** EQ-5D utilities were calculated using the Dutch value set. EQ-5D and SF-6D domains and utilities were compared by correlation coefficients and descriptive statistics. We assessed whether EQ-5D and SF-6D were able to discriminate between different levels of Pompe disease severity as defined by subjective health status (SF36 rating scale and Visual Analogue Scale (VAS) divided into tertiles) and functional capabilities (use of wheelchair and respiratory support). **RESULTS:** Eighty-two patients (82% of the total Dutch Pompe population) completed both EQ-5D and SF-6D (average follow-up 3.8 observations; 3.1 years). Correlations between theoretically related domains were highly significant and moderately strong (range rho=0.392 – rho=0.632). The SF-6D domain "vitality" had no EQ-5D counterpart. Utility values were comparable (mean EQ-5D = 0.739; mean SF-6D =0.710), and moderately correlated (r=0.544). Discriminative properties of EQ-5D and SF-6D were comparable; patients using wheelchair, or respiratory support and patients with a lower VAS score reported lower EQ-5D and SF-6D utilities. **CONCLUSIONS:** The descriptive system of the SF-6D described Pompe disease more accurate. Discriminative properties of EQ-5D and SF-6D outcomes were similar in this population.

PSY47

EVALUATING THE CROSS-OVER EFFECT ON HEALTH-RELATED QUALITY OF LIFE IN A RANDOMIZED CROSS-OVER STUDY OF HEMOPHILIA-A PATIENTS

Jo H[1], Gringeri A[2], Leissinger C[3], Mantovani L[4], Cortesi P[5], Gemmen E[1]
[1]Quintiles, Rockville, MD, USA, [2]University of Milan, Milano, Italy, [3]Tulane University, New Orleans, LA, USA, [4]Federico II University of Naples, Naples , Italy, [5]Fondazione Charta, Milano, Italy

OBJECTIVES: To investigate the cross-over effects on health-related quality of life (HRQoL) in an randomized cross-over design study for hemophilia-A patients. **METHODS:** HRQoL via SF-36 Health Survey was measured every 3 months in a prospective, randomized, cross-over, investigator-initiated study comparing 6

months of AICC infused prophylaxis (PX) with 6 months of on-demand (OD) therapy, separated by a 3-month washout period during which patients used on-demand therapy. HRQoL was summarized in two continuous variables: Physical Component Score (PCS-36) and Mental Component Score (MCS-36). The difference between two study periods for 6-month change from baseline in PCS-/MCS-36 are compared using Wilcoxon signed-rank test to measure the difference between two groups regardless of the sequence of medications. To investigate the effect of random sequence in the change of HRQoL, the difference between two study periods for 6-month change from baseline in PCS-/MCS-36 is compared by random sequence using Wilcoxon-Mann-Whitney U test with exact statement. **RESULTS:** Twenty-six patients completed both study periods. 17 of them were >14 years old and thus completed QoL questionnaires and are included in this analysis. The difference between PX and OD in 6-month change from baseline was 2.83 for PCS-36 (p=0.378) and 1.29 for MCS-36 (p=0.890), favored PX on both measures. Regardless of random sequence of medication, HRQoL showed a moderate improvement with PX. When comparing the difference of 6-month change by treatment sequence, patients who initiated with PX then switched to OD had a greater improvement compared to the opposite sequence (PX->OD: 6.59, OD->PX: 0.19 for PCS-36 (p=0.475); PX→OD: 2.66, OD→PX: 0.33 for MCS-36 (p=0.601)). **CONCLUSIONS:** A cross-over effect, albeit statistically non-significant, was observed when the difference of 6-month change was compared by treatment sequence. Patients who started with more favorable medication tended to show a greater improvement, whereas patients in opposite sequence showed a slight improvement.

PSY48

HEALTH-RELATED QUALITY OF LIFE IN RUSSIAN PATIENTS WITH INHIBITOR HEMOPHILIA

Vorobyev PA[1], Krasnova L[2], Borisenko O[1], Zhulyov Y[3], Bezmelnitsyna L[1]
[1]*Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia,* [2]*Moscow State Medical University named after I.M.Sechenov, Moscow, Russia,* [3]*Russian Hemophilia Society, Moscow, Russia*

OBJECTIVES: Russian Society of Pharmacoeconomics and Outcomes Research jointly to Russian Hemophilia Society carried out postal and telephone health survey of all known Russian patients with hemophilia in the period 2009-2010. Aim of the study was to assess health status, treatment patterns and quality of life in patients with inhibitory form of hemophilia. **METHODS:** Postal and telephone health survey. The questionnaire contained questions on clotting factor level and presence of antibodies to it, names of used medications. Health-related quality of life was assessed with self-administrated validated version of Russian version of Euroqol-5D questionnaire, comprising a dimensions of health and visual-analog scale. Statistical analysis of data was performed with χ^2 criteria. **RESULTS:** The results of principal methods of treating inhibitory form of hemophilia in 60 patients with haemophilia A were analysed. Health-related quality of life was assessed for patients older than 11 years (n = 56). More than half of patients reported problems within each of EQ-5D dimensions of health. Thus 76.6% of patients reported of problems with mobility; 48.4% of patients informed of difficulties with self-care; 75% of patients had difficulties with usual activity; 81.7% of patients reported of presence of pain or discomfort; 50.1% of patients had an anxiety or depression. The average value of quality of life evaluated with visual-analog scale (VAS) was 0.57 (SD 0.17), median – 0.52. **CONCLUSIONS:** The study of quality of life in patients with hereditary coagulopathies was performed for the first time in Russian. Results of the study shown high rate of pain/discomfort, of problems with movement, usual activity and low rate of problem with self-care and anxiety/depression.

PSY49

PAIN MANAGEMENT: IMPACT ON QUALITY OF LIFE

Bertin P[1], Auges M[2], Rahhali N[2], Taieb C[2]
[1]*Comité LUtte contre la Douleur, Limoges, France,* [2]*PFSA, Boulogne Billancourt, France*

OBJECTIVES: To assess the quality of life in patients suffering from intense pain which has progressed since less than 7 days treated by a combination of paracetamol and codeine. **METHODS:** A multi-centre longitudinal observational prospective study carried out in metropolitan France using data collected by general practitioners who agreed to participate. **RESULTS:** A total of 804 patients treated by a paracetamol-codeine combination (600mg/50mg and 400mg/20mg) were included; at inclusion the quality of life assessed using SF-12 was affected as much in terms of the mental component (41.4 ± 11.6) as the physical component (35.4 ± 8.04) – the norm of the scores for each component is equal to 50 – on D7, the quality of life assessed in a similar manner using SF-12 was 43.31 ± 9.89 for the mental component and 40.93 ± 7.92 for the physical component. A statistically significant improvement was noted for each of the 2 mental (p=0.001) and physical (p<0.001) components between the first day of treatment and the seventh day. On D7, 95.9% declared treatment to be effective, 87.2% were satisfied with their treatment and 89.2% did not observe any side effects to the treatment. 9 out of 10 patients did not complain about side effects related to the treatment. **CONCLUSIONS:** The improvement in quality of life observed directly through SF-12 was also confirmed by patient satisfaction: from the first day, 61% of patients declared themselves to be satisfied. On the 7th day of treatment, 87.10% were satisfied with their treatment. 2/3 patients declared the treatment to be effective from the 1st day, and 91% of them declared this on the 3rd day: It shows the pertinence of the treatment.

PSY50

MANAGING PAIN MANAGEMENT: A PUBLIC HEALTH CHALLENGE

Bertin P[1], Auges M[2], Rahhali N[2], Taieb C[2]
[1]*Comité LUtte contre la Douleur, Limoges, France,* [2]*PFSA, Boulogne Billancourt, France*

OBJECTIVES: A daily assessment of the speed of action and effectiveness of treatment of a combination of paracetamol and codeine in patients suffering from intense pain, which has progressed since less than 7 days. **METHODS:** A multicentre longitudinal observational prospective study carried out in metropolitan France using data collected by general practitioners who agreed to participate. **RESULTS:** A total of 804 patients treated by a paracetamol-codeine combination (600mg/50mg and 400mg/20mg) were included. The severity of pain measured at inclusion using a visual numeric scale was 7 ± 1.3. The severity of pain measured after half a day of treatment was 5.29 ± 1.87 and 5.65 ± 1.85 at the end of the first 24 hours of treatment. A significant improvement in pain was observed from the first half-day (p<0.001). The severity of pain on the 2nd, 4th and 7th evenings was respectively 4.09 ± 1.87; 2.74 ± 1.8 and 1.78 ± 1.7. On D1, 70.8% declared treatment to be effective, 62.56% were satisfied with their treatment and 80.5% did not observe any side effects to the treatment. On D3, 91.5% declared treatment to be effective, 82.4% were satisfied with their treatment and 83.12% did not observe any side effects to the treatment. On D7, 95.9% declared treatment to be effective, 87.2% were satisfied with their treatment and 89.2% did not observe any side effects to the treatment. 9 out of 10 patients did not complain about side effects related to the treatment. **CONCLUSIONS:** A reduction in pain within the first 12 hours showed the pertinence of treatment using a paracetamol-codeine combination. This pertinence was confirmed by 2/3 patients who declared the treatment to be effective from the 1st day, and 91% of them declared this on the 3rd day.

Systemic Disorders/Conditions – Health Care Use & Policy Studies

PSY51

EPIDEMIOLOGY AND TREATMENT PATTERNS OF INHIBITOR HEMOPHILIA IN RUSSIA: PATIENT-REPORTED DATA

Vorobyev PA[1], Krasnova L[2], Borisenko O[1], Zhulyov Y[3], Bezmelnitsyna L[1]
[1]*Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia,* [2]*Moscow State Medical University named after I.M.Sechenov, Moscow, Russia,* [3]*Russian Hemophilia Society, Moscow, Russia*

OBJECTIVES: Russian Society of Pharmacoeconomics and Outcomes Research jointly to Russian Hemophilia Society carried out postal and telephone health survey of all known Russian patients with inhibitor hemophilia in the period 2009-2010. Aim of the study was to assess health status, treatment patterns and quality of life in patients with inhibitory form of hemophilia. **METHODS:** Postal and telephone health survey. The questionnaire contained questions on clotting factor level and presence of antibodies to it, number of bleeding in last month, number of injections of clotting factors per month, names of used medications, ways of receiving medications, number of ambulance calls and hospitalizations, and the way of administration of medicines. The patients' education level and employment data was collected. Analysis of experimental data was performed with such statistical parameters as χ^2 and Student's criteria. **RESULTS:** The presence of antibodies was detected in 60 patients with haemophilia A (47 patients (78.3%) were adults, 4 (6.7%) – adolescents, 9 (15%) - children upward 11 years old). Mean age was 30 years. 90% of patients experienced bleeding in the last month (median – 3). 85% of patients used clotting factor VIII in the last month (median – 12 times). 13.3% of patients called for an ambulance in a last month and 21.7% of patients were hospitalized during last month. 68.3% of patients perform the injections of clotting factor themselves. **CONCLUSIONS:** The study revealed epidemiologic characteristics and treatment patterns of inhibitor hemophilia in Russia.

PSY52

IMPACT OF TWO DIFFERENT TREATMENT APPROACHES ON EPIDEMIOLOGY OF INHIBITOR HEMOPHILIA IN RUSSIA

Vorobyev PA[1], Borisenko O[1], Krasnova L[2], Zhulyov Y[3], Bezmelnitsyna L[1]
[1]*Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia,* [2]*Moscow State Medical University named after I.M.Sechenov, Moscow, Russia,* [3]*Russian Hemophilia Society, Moscow, Russia*

OBJECTIVES: Russian Society of Pharmacoeconomics and Outcomes Research jointly to Russian Hemophilia Society carried out postal and telephone health survey of all known Russian patients with hemophilia in the period 2009-2010. Aim of the study was to assess health status, treatment patterns and quality of life in patients with inhibitory form of hemophilia. **METHODS:** Postal and telephone health survey. The questionnaire contained questions on number of bleeding in last month, number of injections of clotting factors per month, names of used medications, number of ambulance calls and hospitalizations. The patients' education level and employment data was collected. Analysis of experimental data was performed with such statistical parameters as χ^2 and Student's criteria. **RESULTS:** The presence of antibodies was detected in 60 patients with hemophilia A (47 patients (78,3%) were adults, 4 (6,7%) – adolescents, 9 (15%) - children upward 11 years old). All patients were divided into 3 subgroups: 31.7% patients received immunological tolerance (IIT), 31.7% - therapy with NovoSeven, 36.6% - mixed therapy. During one month bleeding was indicated in 78.9%, 100%, 90.9% patients in 3 subgroup respectively; clotting factor VIII was used in 100%, 73.7%, 95.4% patients respectively; emergency calls were made by 10.5%, 5.3%, 22.7% patients; 26.3%, 31.6%, 13.6% patients were hospitalized; 63.2%, 68.4%, 72.7% patients made injections of clotting factor themselves. **CONCLUSIONS:** The rate of ambulance calls and hospitalizations was comparatively low. Most patients made injections of clotting factor themselves.

PSY53

CHANGES IN CONCOMITANT THERAPY FOR WEIGHT-RELATED ILLNESS FOLLOWING INITIATION OF WEIGHT LOSS PHARMACOTHERAPY

Agatep BC[1], Charland SL[1], Herrera V[2], Hawk G[2], Stanek EJ[1]

[1]Medco Research Institute, LLC, Medco Health Solutions, Inc, Bethesda, MD, USA, [2]Medco Research Institute, LLC, Medco Health Solutions, Inc, Franklin Lakes, NJ, USA

OBJECTIVES: Over two-thirds of the US population are overweight or obese. While current pharmacotherapy options for weight loss are limited, new weight loss products have not been approved partly over safety concerns, including some linked to weight-related illnesses such as hypertension. However, very little is known about the association of available weight-loss pharmacotherapy with changes in drug therapy for weight-related illnesses. **METHODS:** A retrospective cohort analysis of a deidentified pharmacy claims database evaluated adult patients initiating weight-loss pharmacotherapy (no weight-loss drug prescriptions 6 months prior) between November 1, 2007 – October 31, 2010. Patients with continuous eligibility for 6 months pre- (baseline) and 6 months post- weight-loss drug initiation were evaluated for changes in concomitant drug therapy associated with weight-related illnesses (hypertension, dyslipidemia, type 2 diabetes, anxiety, gastrointestinal disorders, depression, and hypothyroidism). Six-month outcomes included concomitant therapy incidence, and net change (% patients adding ≥1 drug minus % discontinuing ≥1 drug in each illness category) analyzed using t-test (significance at $p<0.05$). **RESULTS:** A total of 91,160 patients initiated weight-loss pharmacotherapy: phentermine (N=67,434), sibutramine (N=13,438), orlistat (N=8,047), phendimetrazine (N=4,631), and diethylpropion (N= 4,350); mean±SD age 44±12 years (96%, 18-64 y/o), 82% female. Patients received 1.5±0.8 concomitant weight-related illness drugs at baseline for hypertension (21.6%) depression (14.9%), dyslipidemia (11.5%), hypothyroidism (9.2%), gastrointestinal disorders (9.6%), anxiety (6.7%), and diabetes (5.5%). Incident/net therapy change over 6 months for each illness category: hypertension (3.2%/-6.5%), depression (0/-16.0%), dyslipidemia (1.1%/-12.2%), hypothyroidism (1.2%/+0.7%), gastrointestinal disorders (0.2%/-17.1%), anxiety (1.1%/-19.4%), and diabetes (0.6%/-8.9%). All net changes from baseline are significant ($p<0.05$), with the exception of hypothyroidism therapy. **CONCLUSIONS:** Concomitant therapy for obesity-related illnesses generally has a low incidence and declines significantly over 6 months after initiating weight-loss pharmacotherapy. Antihypertensive and hypothyroidism therapy appear to follow different patterns, and whether this reflects disease progression, effect of weight-loss therapy, genetics, or other factors warrants further investigation.

PSY54

A COST ESTIMATION OF THE NEW GUIDELINE TO TREAT BLEEDING EPISODES IN PATIENTS WITH HAEMOPHILIA AND INHIBITORS IN IRAN

Jaberidoost M[1], Abdollahiasl A[1], Nikfar S[1], Khatibi M[2]
[1]Tehran University of Medical sciences, Tehran, Iran, [2]Shahid Beheshti University of Medical Sciences, Tehran, Iran

OBJECTIVES: Haemophilia is one of the rare diseases in Iran; the government legally has to cover its costs completely. Total drug subsidies are 320 millions USD and 30% of subsidies have been allocated for the blood coagulating factors. There are 3900 and 1100 registered patients with haemophilia A and B respectively which 190 of them are haemophilia with inhibitors. 17% of total drug subsidies have been allocated for two bypassing agents; recombinant Factor VIIa and activated prothrombin complex concentrate. The ministry of health has proposed a new guideline for managing costs of haemophilia with inhibitors so this study tries to estimate cost of bypassing agents in this protocol and compares it with the current situation. **METHODS:** For estimating the costs of new protocol, the price of medicines and the patients' information and statistics were taken from the Ministry of Health and National Haemophilia Foundation. Information about responding to different treatments and effectiveness of these two medicines were extracted from evidence based literatures and systematic reviews. **RESULTS:** Based on new protocol the average cost for each bleeding episode is 1960 USD; it means 9 million USD for 190 patients annually. A sensitivity analysis shows it can vary from 4 to 14 million USD. The current expenditure for these two bypassing agent is more than 45 million USD annually. **CONCLUSIONS:** The study shows the cost of new protocol for 190 patients with inhibitors is 9 million USD annually; it could be 14 million USD in the worst situation. This is 25 percent of current cost that has been paid for these two bypassing agents. This notable gap may occur because of some reasons such as smuggling to neighbors, off label uses, irrational drug use, inefficient patient management and moral hazards. The absence of efficient guideline not only causes wasting limited resources but also increases risky behaviors.

PSY55

COST OF AUTOLOGOUS AND ALLOGENEIC STEM CELL TRANSPLANTATIONS FOR HAEMATOLOGICAL DISEASE: A DUTCH MULTICENTRE DAILY PRACTICE STUDY

Blommestein H[1], Verelst S[2], Cornelissen J[2], Huijgens P[3], Blijlevens N[4], Uyl-de Groot C[1]
[1]Erasmus University, Rotterdam, The Netherlands, [2]Erasmus MC, Rotterdam, Zuid-Holland, The Netherlands, [3]VU University Medical Center, Amsterdam, Noord-Holland, The Netherlands, [4]Radboud University Medical Center, Nijmegen, Gelderland, The Netherlands

OBJECTIVES: Peripheral blood stem cell transplantations (PBSCT) are very expensive life-saving medical procedures carried out in patients with haematological disease. The current tariffs are expected to be too low due to developments in treatment protocols. A revision of the tariffs is urgently necessary. We calculated the cost of PBSCT for treating haematological diseases in Dutch daily practice, to provide a proper basis for revising hospital budgets. **METHODS:** From three Dutch university hospitals, we randomly selected 191 patients who underwent an autologous (auto) or allogeneic (allo) PBSCT in 2008 or 2009. The alloPBSCT were subcategorised into sibling, matched unrelated donor (MUD) and unrelated cord blood (UCB). We obtained data from hospital registrations to study all treatment related activities. Unit prices were based both on real costs and tariffs (base year 2010). Thereafter, the average costs per patient per PBSCT and per period were calculated. The total cost included the selection and harvesting, transplantation and 1-year follow-up. **RESULTS:** The average cost per patient of autoPBSCT were € 45,670. The cost of sibling alloPBSCT were € 101,919. The average cost of transplantations from an unrelated donor were much higher: € 171,478 for MUD and € 254,689 for UCB alloPBSCT. Hospital days, laboratory procedures and donor search were the largest cost components and mainly responsible for differences between the four types of PBSCT. None of the patient characteristics were correlated with average cost. The costs calculated in this study are above current reimbursement. The difference is significant ($p=0.043$) and depending on the type of PBSCT, the shortfall varied between 2% and 100%. **CONCLUSIONS:** Average cost of AutoSCT and alloSCT laid above current reimbursement levels. Appropriate financing is necessary to guarantee the continuation of PBSCT in Dutch patients according to current indications. The costs calculated in this study provide reliable input for economic evaluations.

Systemic Disorders/Conditions – Research on Methods

PSY56

EFFECT OF WORKSITE WEIGHT MANAGEMENT PROGRAM ON WORKERS PRODUCTIVITY

Idris A[1], Fernandez ID[1], Fiscella KA[1], Noyes K[2]
[1]University of Rochester, Rochester, NY, USA, [2]University of Rochester School of Medicine and Dentistry, Rochester, NY, USA

OBJECTIVES: Obesity has reached epidemic proportions and has many cost implications, including increases in medical spending and productivity losses in the workplace. Many studies have found a correlation between workers obesity and absenteeism (days missed from work) and presenteeism (losses in on the job productivity). Our study examines the impact of a worksite weight management program on workforce productivity. **METHODS:** The Work Limitations Questionnaire (WLQ) was administered to study participants (N=379) at beginning and end of 2-year trial. Employees were asked about their productivity during the previous 2 weeks of work and to rate any impairment they had in the areas of time, physical, mental-interpersonal and output demands on a five-point scale. The resulting WLQ productivity loss score was converted to a percent of time lost. Using a t-test, we compared mean productivity and BMI changes over 2 years between the study groups. **RESULTS:** The intervention arm had a mean BMI of 27.85 and 27.93 at baseline and follow-up, respectively, vs. 28.22 and 28.46 in the control arm. The average percent lost productivity for the intervention group was no different from that in the control group (2.20% vs. 2.37%, $p>0.05$). At the two year follow-up, the intervention group saw an increase in lost productivity at 2.44% and the control group saw a decrease at 2.11%. **CONCLUSIONS:** Our results suggest that having a weight management program does not necessarily improve productivity of the workforce. Future studies should further examine the relationship between obesity, weight loss and productivity as well as methods to increase productivity of the working population.

PSY57

WAIST CIRCUMFERENCE AND BODY MASS INDEX RECORDING – A THIN DATABASE STUDY

Thompson M, Hards M, Blak BT
Cegedim Strategic Data Medical Research Ltd, London, UK

OBJECTIVES: Waist circumference (WC) is considered an indicator of cardiovascular and metabolic risk therefore it is important to assess electronic WC recording in general practice. This study evaluated the level of WC recording in UK primary care and its association with body mass index (BMI). **METHODS:** WC recording in The Health Improvement Network (THIN) between 2007 and 2010 was assessed. Patients with and without WC records were counted by practice, year and BMI category (underweight $<18.5 kg/m^2$, normal ≥ 18.5-$<25 kg/m^2$, overweight ≥ 25-$<30 kg/m^2$, obese $\geq 30 kg/m^2$, no BMI record). Patients were registered at the practice for the entire year. Only WC and BMI records during the year of interest were included. **RESULTS:** From 2007-2010 there were 59,193 patients (1.4%) with a WC record. WC recording increased over time from 0.9% of patients in 2007 to 1.6% in 2010. However, there were still 69 practices (15.7%) with no WC records during 2010. Overall, patients with a WC record had a mean age of 60.9 years (standard deviation (SD): 17.4), mean WC of 90.4cm (SD:15.0) and 53.2% were male. Patients without a WC record had a mean age of 49.5 years (SD:21.5) and 49.5% were male. 2.1% and 78.2% of patients with and without a WC record respectively did not have a BMI record. Of patients with BMI and WC, 0.7% were underweight, 20.9% normal, 36.4% overweight and 42.0% obese, whereas patients without WC were categorised as 2.8%, 32.7%, 33.2% and 31.3% respectively. **CONCLUSIONS:** Despite the WC recording percentage being low, nearly sixty thousand patients had a WC record and recording increased over time. Research would therefore benefit from investigating later years. GPs seemed more likely to record WC for patients with high BMI, therefore research using WC should investigate any potential bias this may introduce. Future studies could investigate associations between WC recording and other factors.

PSY58

RESPONSIVENESS OF THE TREATMENT SATISFACTION WITH MEDICINES QUESTIONNAIRE (SATMED-Q) IN A LONGITUDINAL SAMPLE OF PATIENTS WITH NEUROPATHIC PAIN

Rejas J[1], Ruiz MA[2], Pardo A[2], Ruiz L[3], Soto J[1]
[1]Pfizer España, Alcobendas/Madrid, Spain, [2]Universidad Autonoma de Madrid, Madrid, Spain, [3]Trial Form Support, S.L., Madrid, Madrid, Spain

OBJECTIVES: The Treatment Satisfaction with Medicines (SATMED-Q) questionnaire has shown appropriate psychometric properties exploring patient's satisfac-

tion with treatment in chronic health conditions. However, responsiveness (sensitivity to change) still remained unknown. Thus, the goal of this study in a prospective cohort of subjects with refractory Neuropathic pain (NeP) was to explore the ability of SATMED-Q to detect changes in patient's satisfaction with therapy. **METHODS:** We used data from a 6-month cohort prospective study carried-out in pain clinics, which included patients with NeP referred to pain clinics to change their pain therapy because of its resistance to previous treatments (pain score in a 0-100 mm VAS above 40 mm after, at least, one course of an analgesic at standard doses. Sensitivity to change of the SATMED-Q was assessed by mean of comparing changes in the overall and sub-domains satisfaction scores between baseline and end-of-trial visits according with patients response criterion; end-of-trial pain reduction > 50% (responder). Also, correlations between baseline to end-of-trial change in pain intensity and satisfaction scores were computed. **RESULTS:** The sample was formed with 755 subjects with refractory NeP; mean age: 57.8 years, 60.6% women, mean pain score of 74.2 (15.1) mm. After changing their therapy, 47% of patients were considered responders, and pain intensity was reduced by an average 42.9% (32.4), $p<0.001$, which was significantly correlated ($r=-0.524$, $p<0.001$) with overall treatment satisfaction improvement in SATMED-Q which varied from 50.3 (17.3) to 74.2 (14.4) pts, $p<0.001$. Pearson r-coefficients between pain variation and SATMED-Q subdomains changes were significant and ranged between -0.189 and -0.465 ($p<0.01$ in all cases). Overall sore in SATMED-Q was significantly higher in responders than in non-responders; 80.9 (79.6-82.3) versus 66.5 (65.0-98.0), respectively, $p<0.001$. **CONCLUSIONS:** The SATMED-Q demonstrated to be sensitivity to patient's satisfaction with treatment change in resistant NeP patients.

POSTER SESSION III
RESEARCH ON METHODS STUDIES

Research On Methods – Clinical Outcomes Methods

PRM1
ATTACHING VALUE TO NON-EFFICACY METRICS: A PRICING STUDY
Forster L[1], Kleinlankhorst E[2], Sagar A[2]
[1]*Double Helix Consulting, London, UK,* [2]*Double Helix Consulting, London, Other ->, UK*
OBJECTIVES: With fewer products in the development pipeline new technologies entering the market often rely on demonstrating alternative value offerings. Improvements in administration and patient convenience are often desired but our aim is to discover whether this leads to a tangible pricing and reimbursement opportunity. **METHODS:** In-depth analysis was conducted across an array of products in a variety of disease areas where improvements in administration were the only main differentiating factor. A variety of national and regional payers were interviewed across European markets to gain an understanding of the value attributed to these factors. Payer advising key opinion leaders, influential in aiding decision making, were also key to the research as they gave a more clinical perspective. In addition to value seen through administration, other endpoints such as quality of life were assessed in terms of offering a potential price premium. Qualitative analysis of these findings permitted us to place markets in the framework and extrapolate key findings to other key markets. **RESULTS:** With increased scrutiny of new medicinal products entering European markets since the economic uncertainty of the past 2 years, administration advantages only pertain to a marginal price premium opportunity. Priority, in terms of pricing potential, is predominantly derived from value attributed to a product's efficacy. **CONCLUSIONS:** Stakeholders, while enthusiastic about products offering patient advantages, had a low willingness to pay for administration improvements. Physicians however were more positive towards the value they placed on patient convenience and would be willing to pay for administration and quality of life advances.

PRM2
THE REPORTING OF OBSERVATIONAL STUDIES IN SPAIN: ANALYSIS USING THE STROBE STATEMENT
Galera J, Lahoz R, Roig F
Novartis Farmacéutica, S.A., Barcelona, Spain
OBJECTIVES: To assess the communication of observational studies of Cardiovascular and Metabolism therapeutic area (CVM) published in 6 Spanish journals in 2009 using the STROBE statement (Strengthening the Reporting of Observational Studies in Epidemiology). **METHODS:** It were identified all published observational studies in Atención Primaria, Gaceta Sanitaria, Hipertensión, Medicina Clínica, Revista Clínica Española y Revista Española de Cardiología related to CVM therapeutic area. For each paper, three independent reviewers applied the 34 items of the STROBE statement. **RESULTS:** Throughout 2009, 74 CVM observational studies were published in the evaluated journals. The most frequent design was prospective (43.15%) and cross-sectional (37.5%), and the least retrospective (19.4%). The study main objective was on pathology (74.3%), followed by drug and non-pharmacological interventions (20.3%) and diagnosis (5.4%). The mean of complied items was 20 on 34 (SD ± 3.7), with a maximum of 24 (SD ± 2) in Gaceta Sanitaria and a minimum of 19 (SD ± 2.8) in Hipertensión. The Methods and Results sections showed more deficiencies. **CONCLUSIONS:** Evaluated papers comply with slightly more than a half items (58%) of the STROBE recommendations. Increasing STROBE use could improve the quality of the communication of these studies results, providing greater transparency for analysis and increasing its usefulness in clinical practice.

PRM3
CHALLENGES TO OBTAIN REAL-LIFE DATA IN OBSERVATIONAL STUDIES: WHAT ARE THE SOLUTIONS WHEN THE PATIENT IS THE MAIN DATA PROVIDER?
El kebir S[1], Bourhis Y[2], Fournie X[3]
[1]*Regsitrat Mapi, Lexington, KY, USA,* [2]*Regsitrat Mapi, Lyon, France,* [3]*Registrat Mapi, Lyon, France*
BACKGROUND: Collecting patients' data in observational longitudinal studies is often a concern in terms of data accuracy and patient follow up. Depending of the study design, the physicians' assessment might be not sufficient and/or non-feasible. Direct to patient contact (DtPC) process is commonly used to maximize the long-term follow up and ensure continuity and quality in data collection. **OBJECTIVES:** To demonstrate the benefit of DtPC, through example of multinational study. Challenges were to implement feasible and robust methods to collect and confirm Events of Interest for the study (EoI) in 'real-life' settings, fitting health care standards, regulatory and cultural requirements of countries involved. **METHODS:** Longitudinal, international, observational study. Enrolling physicians were not primary patient's Health Care Providers; consequently, patients had to be the main contact to capture the EoI. Patients had to complete and sign a Contact Order Form that allowed trained interviewers performing follow-up calls at regular time points during the follow up period. Baseline clinical and demographic data were collected by enrolling physicians. Then, the medical confirmation of EoI detected through telephone interviews was ensured by the involvement of the concerned EoI's treating physician. **RESULTS:** On average 85% successful interviews were performed, 2% patients withdrawn their consent, 3% patients were lost to follow up. On average, 80% of the EoI's treating physicians accepted the process for medical confirmation and data collection of the EoI, despite strong variations depending on the country. **CONCLUSIONS:** The results of this study are in accordance with our previous experiences and confirms the benefits of using DtPC in international observational and longitudinal studies. This process enabled a harmonised and centralised method to obtain real life data overview for all patients included, whatever their country, a high level of patient adherence and a low rate of patient withdrawal, despite the large number of countries involved.

PRM4
MEASURING COMORBIDITY IN ADMINISTRATIVE DATA
Hermansson J[1], Carlqvist P[2], Kennedy K[3], Pietri G[3]
[1]*Heron AB, Stockholm, Sweden,* [2]*Heron AB, Stockholm, Stockholm, Sweden,* [3]*HERON Evidence Development Ltd, Luton, UK*
OBJECTIVES: Comorbidities, conditions or diseases besides the one of primary interest is often measured using a comorbidity index condenses all the coexistent conditions to a single score. As the use of administrative data is gaining more and more attention within health economics there is a need for summarising the indexes validity such use. The objective of this study was to review published methods to measure comorbidity in administrative data. **METHODS:** A structured search, using as primary search terms comorbidity, multimorbidity, and coexisting disease, to find comorbidity indexes validated for use in administrative data analysis was undertaken in Embase.com to identify studies published since 2000 in which an index to measure comorbidity was described. For purposes of validation, correlation coefficients, ratios, explained variance, and the area under the receiver operating characteristic curve were used. Regression models predicting future events that were significant or significantly improved after adding comorbidity as a covariate was considered to support validity. Parameters used to assess reliability were among others correlation coefficients. **RESULTS:** Sixtyfour publications were studied resulting in two different indexes, to measure comorbidity in administrative data were identified. The Charlson Comorbidity Index (CCI) generated the greatest number of studies on comorbidity assessment in administrative data and it had the most consistent results regarding validity and reliability. CCI compiles the weighted mortality association of nineteen different diseases with a number of adaptations for specific circumstances. **CONCLUSIONS:** The main finding is that the CCI remains the most used and validated index for assessment of comorbidity in administrative data. Assessment of comorbidity is an area of interest for both health economists and epidemiologists and it seems to be receiving increased attention.

PRM5
NOVEL PATIENT REPORTED OUTCOMES AND DATA TOOL FOR CHRONIC DISEASE MANAGEMENT (PROCDIM): CASE IN POINT PROSTATE CANCER
Aggarwal S
Novel Health Strategies, Bethesda, MD, USA
OBJECTIVES: Patient Reported Outcomes (PROs) play an important role in evaluating patient quality of life and comparative efficacy of various treatments. Another potential use of PROs is for chronic disease management, which can provide useful data to physicians and patients. We developed a novel web and phone based PROs tool for management of prostate cancer disease. **METHODS:** PRO methods for prostate cancer were reviewed by analyzing published clinical studies. KOLs and patient advocacy groups were interviewed to obtain their input for design of PRO disease management tool. Recent technologies for developing such tools were reviewed by analyzing available electronic PRO tools. PROCDIM design was developed based on secondary research and primary interviews. **RESULTS:** PROCDIM was designed to capture patient reported outcomes data such as Quality of Life (using five attributes), adverse events (six commonly reported AEs), medications and OTC drugs history, PSA antigen score, past surgery and radiation therapy and record of physician appointments. Patients could enter data into PROCDIM using web or phone (iphone or andriod) based systems. Data from PROCDIM could be emailed by patient to provider or could be downloaded by tethering phone to computer. Pilot data was captured by testing PROCDIM with physicians and patient advocacy groups. Based on interviews, PROCDIM was rated superior and highly user friendly compared to current chronic disease management tools. Patient outcomes data would be collected from a planned IRB approved study. **CONCLUSIONS:**

PROCDIM is a valuable tool to capture several patients reported outcomes and data for chronic disease management. Such tools could be used for collecting data for disease management, clinical trial and for observational studies for various chronic diseases.

PRM6

VALIDATING AN ALTERNATIVE WEIGHTING ALGORITHM OF THE CHARLSON COMORBIDITY INDEX (CCI) FOR RISK ADJUSTMENT IN PREVIOUSLY HOSPITALIZED PATIENTS

Cheng LI, Rascati KL
University of Texas at Austin, Austin, TX, USA

OBJECTIVES: To validate an alternative weighting algorithm of the Charlson Comorbidity Index (CCI) for the prediction of health care expenditures and utilization in previously hospitalized patients. **METHODS:** Data from the Medical Expenditure Panel Survey (MEPS) Panel 12 (2007-2008) were retrieved for this retrospective cohort study. Two CCI scores were calculated for patients who were hospitalized in 2007: one based on the original weights (Charlson-CCI) and the other based on the weights updated by Quan et al. (Quan-CCI) [both were developed to predict mortality]. Adjusted R2 from linear regression models were used to estimate log-transformed healthcare expenditures (COST) in 2008. Odds ratios and c statistics from logistic regression models were used to compare the predictive power of the risk of hospitalizations (≥ 1 admission), risk of emergency department visits (≥ 1 visit), and high expenditures (≥ 90th percentile of COST) in 2008. **RESULTS:** Seven hundred patients who had been previously hospitalized were included in the study. The mean (SD) age was 52.5 (15.3) years, and 65% were female. In the linear regressions, the Charlson-CCI explained more variance in COST than the Quan-CCI (adjusted R2 = 20.7% vs. 19.9%), adjusting for age and sex. The Charlson-CCI was a better predictor of the risk of emergency department visits (c=0.600) than the Quan-CCI (c=0.571). Compared with the Quan-CCI, the Charlson-CCI showed better discriminatory power for the prediction of high-expenditure individuals (c=0.770 vs. 0.743) and the risk of hospitalizations (c=0.589 vs. 0.581). The Quan-CCI did not significantly predict high-expenditure individuals (OR=1.15; 95% CI=0.99-1.33) or the risk of hospitalizations (OR=1.14; 95% CI=0.99-1.30). **CONCLUSIONS:** In a group of previously hospitalized patients, the original CCI exhibited better discrimination for the prediction of healthcare expenditures, hospitalizations, and emergency department visits. The weights updated by Quan et al. were developed to predict mortality and may have limited utility in predicting health care utilization.

Research On Methods – Cost Methods

PRM7

USING PROBABALISTIC SENSITIVITY ANALYSIS IN BUDGET IMPACT MODELS TO REDUCE UNCERTAINTY AND IMPROVE DECISION-MAKING

Latif F, Roberts G
Double Helix Consulting, London, UK

OBJECTIVES: Budget impact analysis (BIA) is formally required by many national HTA regulatory agencies including NICE and the PBAC, in the UK and Australia, respectively. Current practice only involves the use of point estimates to serve as "best guess" for decision-makers. However, using probabilistic sensitivity analysis (PSA) can serve to reduce parameter uncertainty in order to generate discussion and ultimately improve decision-making. **METHODS:** Using the same techniques applied to cost-effectiveness analysis, a PSA was incorporated into a budget impact model used for a client's medical device. This involved creating and running a Monte-Carlo simulation (MCS) over 10,000 iterations to generate a 95% confidence interval (CI) around the overall budget impact in addition to a probability curve. **RESULTS:** Point-estimate budget impact was found to be a saving of £4,736,893 based on a number of pre-defined input parameters in the model. Running a MCS generated a 95% CI: a saving of £10,367,403 and an incremental cost of £861,166 either side of the point-estimate. In addition, a probability curve was generated with overall budget impact on the x-axis and probability on the y-axis. 25 data points were generated running from a maximum potential saving of approximately £12m (1% probability) to an incremental cost of approximately £3m (100% probability). **CONCLUSIONS:** Using PSA in this budget impact model demonstrates that there is a significant likelihood this medical device could actually generate an incremental cost rather than saving (which the point-estimate shows). This serves as an example of how using this technique could serve to generate discussion among decision-makers in order to make more informed and improved budget impact decisions in the future.

PRM8

COULD CORPORATE SOCIAL RESPONSIBILITY PREDICT PHARMACEUTICAL CORPORATE FINANCIAL PERFORMANCE?

Auamnoy T, Areepium N
Chulalongkorn University, Bangkok, Thailand

OBJECTIVES: 1) To quantify CSR concept by developing a pharmaceutical companies namely Auamnoy's visual analogue scales—a 24 measurement indicators in 6 dimensions to make a composite variate; 2) To perform a retrospective research to explore relationship between CSR activities and corporate financial performance (CFP); and 3) To discover prediction model to predict pharmaceutical CFP by CSR. **METHODS:** Challenging literature reviews were executed on and on to find the valid and reliable scales to measure CSR. Twelve appropriate CFP indicators were discussed and then selected to evaluate 43 pharmaceutical companies performance. The α value was set at 0.05, one side using SPSS version 17.0 to calculate all statistical analysis. **RESULTS:** The six dimensions Auamnoy's scales were Drug development, Patients, Environment and safety, Social issues, Philanthropy and Business ethics and – yielded acceptable Cronbach's alpha 0.7415, 0.7154, 0.7151, 0.7426, 0.7217 and 0.7466 respectively. Pearson's product moment correlation confirmed that CSR showed a significant positive correlated with (ROI, Sales, EPS, DPS, BV, %Sales Growth, %ROA and %ROI) (r=+0.832, +0.489, +0.789, +0.631, +0.351, +0.298, +0.455, +0.336, p=0.000, 0.000, 0.000, 0.000, 0.011, 0.030, 0.001, 0.008 respectively). Finally, Regression analysis estimated significant seven models of pharmaceutical CFP–ROI, Sales, EPS, DPS, BV, %ROA and %ROI by CSR. **CONCLUSIONS:** The answer was yes, pharmaceutical CSR could predict CFP. The more the pharmaceutical companies invested in CSR. the more CFP they obtained.

PRM9

WHAT GUIDANCE IS AVAILABLE FOR BUDGET IMPACT ANALYSIS?

Kusel J[1], Costello S[2]
[1]*Costello Medical Consulting Ltd, Cambridge, UK,* [2]*Costello Medical Ltd, Cambridge, UK*

OBJECTIVES: There is a wealth of literature and guidance available for cost-effectiveness research, but the guidance available on budget impact analysis (BIA) is less familiar to many investigators. In times of increased budget constraint, however, the importance and popularity of BIA is growing. The objective of this review was to assess whether guidance on BIA methodology is available and consistent. **METHODS:** Online searches were performed to identify published guidelines or recommendations on BIA from any country. The guidelines were then reviewed for whether they gave advice on certain pre-determined methodological categories. **RESULTS:** National guidelines have been produced in Canada, Ireland, Scotland and Poland specifically on how BIA in each of these countries should be performed. Other countries such as the UK, Italy and Hungary include recommendations on BIA within guidelines on health care economic assessment, but their focus is largely on cost-effectiveness analysis. The national guidelines were consistent in whether they made recommendations on perspective and time horizon, but varied in whether they gave advice on market share determination, sources of costs, inclusion of treatment of adverse events and the presentation of resource use and costs separately. The definition of the term 'incremental BIA' was also used inconsistently. An ISPOR Task Force has produced international guidance for budget impact methodologies, which is designed to support national guidelines rather than supersede them and also to improve consistency across BIAs developed for different settings. **CONCLUSIONS:** Several national and international bodies have developed guidelines or tools for developing and reporting budget impact models. However, different specifications exist and not all methodological aspects are made explicit in every case. Consensus guidelines such as those produced by the ISPOR task force are required to shape future national BIA recommendations.

PRM10

TO GET THE RIGHT PRICE – A DECISION SUPPORT METHOD TO OPTIMIZE MANAGERIAL DECISIONS ON PUBLIC FUNDING PRICE TO APPLY FOR

Wilk NM[1], Kloc K[2]
[1]*Arcana Institute, Krakow, Malopolskie, Poland,* [2]*Arcana Institute, Krakow, malopolskie, Poland*

OBJECTIVES: In challenging economic times public funding decision makers are getting tougher, so the managers have to be smarter to choose the right price and optimally justify it. The objective is to present our method which rationally supports managerial decisions on pricing in public funding. **METHODS:** The decision support method consists of the following steps: 1) identify all arguments relevant to different price levels – e.g. based on prices of similar drugs that were accepted by public payer or related to prices of the drug in other countries; 2) calculate maximum price that may be justified with each piece of an argument; 3) sort arguments in price ascending order; 4) rank arguments in a pairwise manner against their impact on probability of public funding acceptance using 5-point Likert scale; 5) plot all arguments on a graph with price level on X axis and cumulative impact on probability of acceptance on Y axis; and 6) calculate first derivative to identify local maxima. The seventh step is the manager's decision on choosing the right price from the subset of local maxima. Local maxima represent the price levels for which a relatively large increase in price associates with a relatively small decrease in acceptance for public funding. **RESULTS:** The decision support analysis results in a subset of price levels that the manager is recommended to choose the right price from. The final choice may depend on acceptance/avoidance of risk or necessity to achieve a specific turnover. All arguments that justify the chosen and higher prices may be used to justify this price to public funding decision makers. **CONCLUSIONS:** To ensure a pricing success to their companies and their own career development Market Access managers should use the presented decision support method to make possibly best informed choices concerning official prices of their drugs.

PRM11

LEARNING EFFECT IN ECONOMIC EVALUATIONS OF HEALTH CARE INTERVENTIONS

Chang S, Sungher D, Diamantopoulos A
Symmetron Limited, Elstree, Herts, UK

OBJECTIVES: The presence of the learning effect has an impact on the effectiveness of health technologies and so, it is relevant to capture this in an economic analysis. The aim of this study is to explore the bibliography of learning curves in health care economic evaluations. **METHODS:** In order to understand the bibliography of learning curves in economic evaluations, a systematic review was conducted to identify economic analyses that include a formal description of a learning effect. The following databases were searched: Medline, Medline (R), Embase, EconLIT, HEED and NHS EED. For a study to be included in the review, it had to be an economic evaluation defined as a cost, utility or cost-effectiveness study. In addition, the study also had to formally analyse the learning effect by using statistical analysis, graphs or tables. All non-human and non-English studies were also ex-

cluded from the review. The studies included were categorised based on criteria such as type of study, statistical methods for the learning effect, mathematical framework for the economic analysis, year of publication, country and intervention. **RESULTS:** The database search produced 930 articles. Only 2% of the studies obtained were included given the above criteria. Of the excluded studies, 70% were excluded as they were not economic evaluations and 23% were excluded as they did not formally present the learning effect. The remaining 7% were excluded based on other reasons: duplicates, non-English, non-human. The majority of the studies are published after 2000. Of the included studies, the majority presented a learning effect related to health care costs. Two percent of the included studies referred to utilities. Only one study synthesised cost and utilities. **CONCLUSIONS:** Although the learning effect can have a notable impact on the effectiveness of health care interventions, the economic evaluation literature on the subject is very limited.

PRM12

AN APPLICATION OF A PROPOSED FRAMEWORK FOR FORMULARY LISTING IN LOW-INCOME COUNTRIES: CASE OF CÔTE D'IVOIRE

Diaby V[1], Lachaine J[2]
[1]*University of Montreal, Île de Montréal, QC, Canada,* [2]*University of Montreal, Montreal, QC, Canada*

OBJECTIVES: The Mutuelle Générale des Fonctionnaires et Agents de l'État de Côte d'Ivoire (MUGEFCI) is a health mutual providing coverage services for its enrolees (medical consultations, lab tests, medication expenses). This organization aims at improving its current drug reimbursement process because of budgetary constraints. This study, therefore, aims at evaluating the feasibility of developing a new formulary for the MUGEFCI in Côte d'Ivoire, by implementing a formulary-listing framework specifically designed for under researched settings. **METHODS:** The application of this framework, based on Multi-criteria Decision Analysis (MCDA), consisted in four steps. First of all, we identified and weighted relevant formulary listing criteria with their levels of variation. Then, we determined a set of priority diagnostic/treatments to be assessed. Furthermore, scores were assigned to these treatments according to their performance on the formulary listing criteria levels. Last, we constructed a composite league table to rank the set of treatments by priority order of reimbursement. A budget impact analysis was also conducted to appraise the economic implications of the new composite drugs league table. **RESULTS:** Policymakers in Côte d'Ivoire consider targeting cost-effectiveness and severity of diseases as the most significant criteria for priority reimbursement of drugs. This translates into a general preference for antimalarial, treatments for asthma and antibiotics for urinary infection. Moreover, the results of the BIA suggest that the new priority list of reimbursable drugs will be affordable when the real economic impact of drugs per patient is under 66 US dollars. Over this threshold, the MUGEFCI will have to select the reimbursable drugs according to their rank in the priority list along with their respective budget impact per patient (cost per patient). **CONCLUSIONS:** It is feasible to use MCDA to establish a formulary for low-income countries. The application of this method is a step forward to transparency in policymaking.

PRM13

ASSESSING THE METHODS FOR SYSTEMATIC REVIEWS OF ECONOMIC EVALUATIONS

Paone S[1], Di Tanna GL[2], Corio M[1], Jefferson T[1], Cerbo M[1], Migliore A[1]
[1]*Agenas, Agenzia nazionale per i servizi sanitari regionali, Rome, Italy,* [2]*Sapienza University of Rome, Rome, Italy*

OBJECTIVES: Robust and explicit methods to conduct systematic reviews of economic evaluations are required to guarantee quality of reviews and their findings. This is especially needed when assessing high resource-consuming topics such as those related to the introduction of new imaging technologies. Our aim is to analyse the methods for systematic reviews of economic evaluations of health technologies. **METHODS:** We carried out a systematic review of methods for systematic reviews of economic evaluations by reading relevant parts of HTA methodological manuals ("manuals") and HTA reports from UK ("reports") in English and Italian at September 2010. **RESULTS:** We identified 27 manuals and 53 potential reports. Among them, 6 and 40 contained relevant information respectively. None of the 6 manuals described the criteria used for the identification or formulation of the methods, or gave guidance on which method to follow. Among the 40 reports included, 38/40 (95%) reports described search strategy and data bases used to identify studies and inclusion criteria were presented in 21/40 (53%) reports. The reports did not use a study quality assessment instrument were 9/40 (22.5%) while 20 different instruments were identified in the remaining reports. No report carried out a quantitative synthesis of the data from the systematic review and 9/40 reports (22.5%) clearly stated this. The reports that appear to include the data selectively in their economic evaluation were 13/40 (32.5%). **CONCLUSIONS:** The absence of clear methodological guidance in manuals is reflected in the reports. These show unclear rationale, methods and use of data from systematic reviews of economic evaluations.

Research On Methods – Databases & Management Methods

PRM14

MONDRIAAN: A DUTCH 'POPULATION' LABORATORY

Klungel O
Utrecht University, Utrecht, The Netherlands

OBJECTIVES: Many excellent health care databases are available in The Netherlands for (pharmaco-)epidemiologic research. However, in isolation these data remain scattered and have limitations with regard to sample sizes and/or detail of the registered information.The objective of Mondriaan is to optimize access to en linkage of routine health care databases in the The Netherlands for (pharmaco-)epidemiologic research. **METHODS:** We have built an ICT infrastructure for collection and linkage of healthcare/research data in The Netherlands. To protect privacy, pseudonimisation and linkage is performed by a trusted third party (TTP). A data catalogue on subject level has been developed to allow queries within the integrated databases to support designing (pharmaco-) epidemiologic studies (incl. sample size calculations, assessment of completeness of data). **RESULTS:** We are able to routinely link all pharmacy records from the National Foundation of Pharmaceutical Statistics (SFK) (n>14,000,000) on a patient base to several routine health care databases such as the Almere Health Care database (n=200,000), the Julius GP Network (n=200,000), and the AGIS claims database (n=1,200,000). Currently we are integrating several other databases in the The Netherlands. **CONCLUSIONS:** The project will deliver a large-scale, high-quality data platform for innovative (pharmaco-)epidemiologic research.

PRM15

THE OUTCOME OF ISPOR EUROPEAN AND INTERNATIONAL CONGRESSES BETWEEN 2005-2009

Boncz I[1], Sebestyen A[2], Kriszbacher I[1]
[1]*University of Pécs, Pécs, Hungary,* [2]*Baranya County Health Insurance Fund, Pécs, Hungary*

OBJECTIVES: Many of the former socialist countries of Central and Eastern Europe (CCEE) joined to the European Union in 2004. The aim of this study is to analyse to outcome of ISPOR European and international congresses between 2005-2009 with a special respect to the activity of CCEE. **METHODS:** We analysed the abstracts presented at the ISPOR European or International cogresses and published in the Value in Health journal between 2005-2009. We performed a database analysis of value in Health journal on the Web of Science (Thomson Reuters) electronic database of scientific publications. Three indicators were selected: author's country, institution (university) and name. **RESULTS:** The top-10 most active countries were (abstract/1 million population): Switzerland (48.3), Wales (31.0), Sweden (26.2), Denmark (25.3), Belgium (25.0), The Netherlands (23.0), England (19.3), Canada (18.3), Scotland (16.0) and Hungary (14.7). Furthermore Slovakia (8.2) was ranked 16th, Czech Republic (5.0) 24th, Poland (4.1) 26th and Serbia (3.3) 29th. The top-10 most active universities were (number of abstracts): Univ So Calif (140), Univ Toronto (107), Univ Washington (100), Ohio State Univ (98), Erasmus Univ & MC (94), Univ Maryland (93), Univ Pécs Hungary (93), Univ York (92), Harvard Univ (89) and McMaster Univ (76). Three more CCEE university were ranked: Med Univ Warsaw from Poland (38), Corvinus Univ Budapest from Hungary (30) and Comenius Univ from Slovakia (27). The most active 10 authors were (number of abstracts): Boncz, I (Hungary, 96), Taieb, C (France, 83), Balkrishnan, R (USA, Ohio, 77), Sebestyén, A (Hungary, 71), Valentine, WJ (Switzerland, 65), Mantovani, LG (Italy, 60), Caro, JJ (USA, MA, 57), Annemans, L (Belgium, 54), Kriszbahcer, I (Hungary, 52), Rejas, J (Spain, 50). **CONCLUSIONS:** Former socialist countries of Central and Eastern Europe (CCEE) showed a significant activity at ISPOR European and International congresses.

Research On Methods – Modeling Methods

PRM16

COVARIANCE STRUCTURES FOR MODELING LONGITUDINAL DATA

Purdy C
AHRM Incorporated, Buffalo, NY, USA

OBJECTIVES: The objective of this analysis is to compare several covariance structures which are used in the modeling of longitudinal data. **METHODS:** A PUBMED search reveals is a steady increase in prospective observational studies over the past five years. Repeated measures models are frequently used to analyze longitudinal data. For the purpose of these comparisons, a series of longitudinal datasets are simulated. In order to facilitate comparisons with applications to longitudinal datasets involving utilities; the dependent variable in the simulation datasets is a continuous variable restricted to the support interval [0, 1]. The predictor variables include a set of categorical and continuous variables, including a time varying covariate. Datasets with four different types of time dependence were compared (no time trend, log time trend, linear trend, exponential trend). Models with the following covariance structures were evaluated: compound symmetry, unstructured, autoregressive, heterogeneous autoregressive, variance components and toeplitz. Model comparisons were based upon Akaike information criteria (AIC) and the Bayesian information criteria (BIC). **RESULTS:** The preferred covariance structures for the dataset without a time trend were heterogeneous autoregressive (AIC) and unstructured (BIC). The preferred covariance structure for the log trend dataset was unstructured (AIC and BIC). The preferred covariance structures for the linear trend dataset were variance components (AIC) and heterogeneous autoregressive (BIC). The preferred covariance structure for the exponential trend dataset was variance components (AIC and BIC). **CONCLUSIONS:** The unstructured covariance matrix is often the default choice for the covariance matrix for longitudinal models. This model has the least number of assumptions and allows for the modeling of each patient individually. However, the unstructured covariance structure requires the most degrees of freedom and in some cases the estimated covariance matrix does not converge. In these cases, covariance structures such as variance components and heterogeneous autoregressive may present attractive options.

PRM17

SUITABILITY OF CLAD-CQR MODELS FOR OBTAINING QALYS

Cunillera O[1], Vilagut G[1], Medina A[2], Tresserra R[2], Alonso J[1], Brugulat P[2], García C[1], Ferrer M[3]

[1]IMIM (Institut de Recerca Hospital del Mar), Barcelona, Catalunya, Spain, [2]Departament de Salut de la Generalitat de Catalunya, Barcelona, Catalunya, Spain, [3]IMIM-Hospital del Mar, Barcelona, Barcelona, Spain

OBJECTIVES: The EQ-5D is the most used questionnaire to obtain utilities. Because of its index ceiling effect, Tobit and CLAD-CQR (Censored Least Absolute Deviations – Censored Quantile Regression) models are often used instead of Ordinal Least Squares for its modelization. CLAD models are usually presented as a robust alternative to the Tobit misspecification problems in presence of heteroskedasticity. The aim of this study is to evaluate the suitability of the CLAD-CQR models for the estimation of utilities and QALYs (Quality-Adjusted Life Years), to evaluate the impact of different chronic conditions in Catalan population's health. **METHODS:** The EQ-5D was interview-administered in the 2006 Catalan Health Interview Survey, a cross-sectional study of a representative sample of the non-institutionalised general population (n=15,926). As well as CLAD-CQR, Tobit model was adjusted to assess utility losses associated with 15 chronic conditions. Goodness of fit was assessed by cross-validation (Mean Square Error –MSE-, Mean Absolute Deviations –MAD-). **RESULTS:** As ceiling effect was over 50%, CQR models on the 30 percentile had to be applied instead of CLAD models on the median. CQR showed a slightly worse fit to data (MSE=0.084, MAD=0.246) than Tobit (MSE=0.068, MAD=0.218). The impact of the different chronic conditions measured in QALYs obtained from the CQR was on average around 70% larger than the ones of the Tobit model. **CONCLUSIONS:** Tobit and CLAD-CQR model latent quality of life, not anchored in 0=death and 1=perfect health. While Tobit allows an estimation of observed utilities and marginal effects, interpretable as QALYs, CQR do not in the case of right-censoring. This leads to overestimation of effects and makes CLAD-CQR models inappropriate for obtaining QALYs, just as the untransformed Tobit's latent variable. Moreover, the suitability of modelling percentiles differing from the median should be discussed.

PRM18

SENSITIVITY ANALYSIS IN MULTI-CRITERIA DECISION (MCDA) MODELS FOR BENEFIT-RISK ASSESSMENT

Ijzerman MJ[1], Groothuis-Oudshoorn K[1], Hummel JM[2]
[1]University of Twente, Enschede, The Netherlands, [2]University Twente, Enschede, The Netherlands

OBJECTIVES: Regulators of medical technologies are facing increasing pressure to make their deliberations concerning the benefits and risk more transparent. Both benefits and risks are often measured via multiple competing outcomes. Hence, MCDA models like the Analytic Hierarchy/Network Process are valuable tools in quantifying decision trade-offs. The objective of this paper is to demonstrate the use of MCDA models for benefit-risk assessment and the use of sensitivity analysis to assess the impact of uncertainty and patient heterogeneity. **METHODS:** Using an existing data set about anti-depressants we construct a decision model for use with AHP weights, including clinical endpoints, adverse events and quality of life. AHP priorities for the main criteria (benefits and risks) were obtained from the general public (n=15) using face–to-face interview. After base-case analysis of decision trade-offs, three forms of sensitivity analysis for MCDA models were employed. **RESULTS:** We applied three forms of sensitivity analysis, including 1) manual adjustment of criteria weights using a slider; 2) probabilistic sensitivity analysis (PSA) of the criteria weights; and 3) PSA of the expected drug performance on each of the criteria. Examples will be graphically presented and discussed. **CONCLUSIONS:** One of the advantages of AHP/ANP is its ease of use. However, in order to make judgments about benefits and risks decision makers, may wish to generalize to a wider population and as well as to quantify decision trade-offs in subgroups of patients. The methods employed provide this flexibility. However, the strategy chosen should not be more complex than necessary to support the decision maker.

PRM19

MODELLING THE IMPACT OF MULTIPLE INDICATION DRUG LAUNCH ON TOTAL REVENUE

McConkey D, Wild L
Double Helix Consulting, London, UK

OBJECTIVES: It is becoming increasingly common that early stage drug candidates have potential applications in several therapy areas. This is especially prevalent where several diseases share a similar aetiology. Areas such as immunology, oncology and metabolic disorders can have ailments that are characterised by different physiological involvement but share a similar underlying cause. The objective of this study was to model the impact of a multiple indication launch on drug revenue over time, as well as develop a tool to enable launch strategy scenario testing. **METHODS:** The attractiveness and potential NPV of each therapy area is assessed using a combination of qualitative and quantitative methods. Therapy areas are scored and ranked by defined metrics allowing the optimum therapy area to be selected as the first launch indication. The assessment is repeated for the remaining therapy areas to account for changes in pricing dynamics from the initial launch indication, to generate the next most attractive therapy area and so on. NPV for the drug is then calculated based on a trade-off between patient population size and pricing dynamics across indications. **RESULTS:** In general, the larger patient populations translate into lower drug costs to meet with budget impact thresholds. It is therefore vital for manufacturers to understand the optimal trade-off between price and population size across indications in order to maximise the overall commercial potential of a drug. When different indications have significantly differently sized patient populations, drug pricing becomes an issue. The research concluded that if the correct strategy is employed, a drug launch strategy can be optimised to generate the maximum possible revenue over the greatest number of indications. **CONCLUSIONS:** Modeling changes in price and population size during multiple-indication launches can be a vital tool in understanding total revenue potential of a new product, and optimal launch sequencing.

PRM20

COMPARISON OF THREE METHODS FOR MEASURING MULTI-MORBIDITY ACCORDING TO THE USE OF HEALTH RESOURCES IN PRIMARY HEALTH CARE

Sicras-Mainar A[1], Navarro-Artieda R[2], Violan-Fors C[3], Aguado-Jodar A[4], Ruíz-Torrejón A[5], Prados-Torres A[6]
[1]Badalona Serveis Assistencials, Badalona, Barcelona, Spain, [2]Hospital Universitari Germans Trias i Pujol, Badalona, Barcelona, Spain, [3]Jordi Gol i Gurina Primary Health Care Research Institute, Barcelona, Spain, [4]Dirección de Atención Primaria, Consorci Sanitari Integral, Barcelona, Barcelona, Spain, [5]Primary Health Care Management of Mallorca, Palma de Mallorca, Baleares, Spain, [6]Health Sciences Institute of Aragon, Zaragoza, Spain

OBJECTIVES: To compare three methods of measuring multimorbidity according to the use of health resources (cost of care) in primary health care (PHC). **METHODS:** Design: retrospective study using computerized medical records. Setting: thirteen PHC teams in Catalonia (Spain). Participants: assigned patients requiring care in 2009. Main measurements: the socio-demographic variables, co-morbidity and costs. Methods of comparison were: a) Combined Comorbidity Index (CCI): an index itself was developed from the scores of acute and chronic episodes; b) Charlson Index (ChI); and c) Adjusted Clinical Groups case-mix: resource use bands (RUB). The cost model was constructed by differentiating between fixed (operational) and variable costs. Statistical analysis: was developed 3 multiple lineal regression models to assess the explanatory power of each measure of co-morbidity were compared from the of determination coefficient (R2), $p<0.05$. **RESULTS:** A total fo 227,235 patients were included. Woman: 55.6%, average age was 44.1 years, mean episodes/year: 4.5; average visits/patient/year: 8.1, the mean unit of cost was €654.2. The CCI explained a R2=50.4%, the ChI a R2=29.2% and RUB a R2=39.7% of the variability of the cost. The ICC is acceptable behaviour, albeit with low scores (1 to 3 points), showed no conclusive results. **CONCLUSIONS:** The CCI may be a simple method of predicting PHC costs in routine clinical practice. If confirmed, these results will allow improvements in the comparison of the case-mix.

PRM21

VALIDATING A MULTI-CRITERIA DECISION ANALYSIS (MCDA) FRAMEWORK FOR HEALTH CARE DECISION MAKING

Lieferink MA[1], Til JAV[1], Groothuis-Oudshoorn K[1], Goetghebeur MM[2], Dolan JG[3]
[1]University of Twente, Enschede, The Netherlands, [2]BioMedCom Consultants Inc., Dorval, QC, Canada, [3]University of Rochester, Rochester, NY, USA

OBJECTIVES: When evaluating healthcare interventions, decision-makers are increasingly asked to consider multiple criteria to support their decision. The MCDA-based EVIDEM framework was developed to support this process. It includes a simple weight elicitation technique, designed to be easily applicable by a broad range of users. The objective of this study was to compare the EVIDEM technique with more traditional techniques. **METHODS:** An online questionnaire was developed comparing the EVIDEM technique with four alternative techniques including AHP, best/worst scaling, ranking and point-allocation. A convenience sample of 60 Dutch and Canadian students were asked to fill out the questionnaires as if they were sitting in an advisory committee for reimbursement/prioritization of healthcare interventions. They were asked to provide weights for 14 criteria using two techniques, and to provide feedback on ease of use and clarity of concepts of the different techniques. **RESULTS:** Results based on the first 30 responses show that EVIDEM is easy to understand and takes little time to complete, three minutes on average. Criteria weights derived using the EVIDEM technique and best/worst scaling are divergent. Comparing the rank order of criteria respondents gave using these two techniques; there is more resemblance in rank order of criteria weighted with the EVIDEM technique. Compared to AHP/ranking/point-allocation, EVIDEM takes less time to complete but is only preferred by 33% of decision-makers. AHP/ranking and point allocation were often described as clearer and more reflective of the respondents' opinion. **CONCLUSIONS:** The simple technique is proposed as a starting point for users wishing to adapt the EVIDEM framework to their own context. Other techniques may be preferred and their impact on the MCDA value estimate generated by applying the framework is being explored. This project is part of a large collaborative work that includes developing and validating this framework to facilitate sound and efficient MCDA-applications.

PRM22

MICROSIMULATION METHODS USED FOR HEALTH POLICY DECISIONS IN PERSONALIZED MEDICINE UNDER CONSTRAINED RESOURCES

Jahn B[1], Rochau U[1], Mühlberger N[1], Sroczynski G[1], Conrads-Frank A[1], Siebert U[2]
[1]UMIT - University for Health Sciences, Medical Informatics and Technology; Oncotyrol - Center for Personalized Cancer Medicine, Hall i.T./Innsbruck, Austria, [2]UMIT/ Oncotyrol/ Harvard University, Hall i.T./Innsbruck, Austria

OBJECTIVES: Personalized medicine (PM) takes into account that diagnostic and therapeutic health technologies should be based on individual characteristics of patients such as risk profile and treatment response. Health policy decisions under constrained resources in PM require adequate evaluation methods that incorporate economic aspects and multiple characteristics (e.g., genotypes, blood markers). Microsimulation is a technique to evaluate health technologies, policies and interventions based on individual characteristics. Our goal was to identify and contrast different microsimulation approaches and discuss the applicability of these approaches in the evaluation of PM. **METHODS:** We performed a review on microsimulation and applications in social sciences, health care and politics. Assessment criteria include the modeling of patient characteristics/patient history/prior events, the way events or transitions between health states are modeled, the inclusion of life years/utilities/costs, open/closed cohort approach, and the way time is modeled. **RESULTS:** Identified approaches range from state-transition mod-

els, discrete-event-simulation models to equation-based models. Individual characteristics relevant for PM include individual risk factors, clinical properties, patient history, severity of disease, number of repeated events. Different approaches were used to link risk factors and predictors to prognosis and treatment decisions and success as well as resource use. E.g., POHEM is a leading Canadian microsimulation for health care policies. Applications range from lung cancer treatment, breast cancer prevention to the evaluation of cardiovascular diseases. To support decisions on HIV prevention Rauner et. al. built a discrete-event-simulation where breast feeding mothers are even linked to their children. Overall microsimulation has been successfully applied e.g., in cancer research, chronic diseases or screening and prevention. **CONCLUSIONS:** Microsimulation techniques are broadly applied but still underrepresented in economic evaluations for health care policies. Microsimulation is a powerful tool for evaluating PM-strategies, because it can be used to incorporate the genetic and clinical heterogeneity of individuals as well as personalized decision algorithms.

PRM23

GENERAL METHODOLOGICAL ISSUES IN COST-EFFECTIVENESS ANALYSIS INSPIRED BY THE ASSESSMENT OF DASATINIB, NILOTINIB AND IMATINIB FOR CHRONIC MYELOID LEUKAEMIA

Hoyle MW
University of Exeter, Exeter, UK

OBJECTIVES: In 2009, the cost-effectiveness of drugs for chronic myeloid leukaemia for use in the UK NHS was evaluated by the National Institute of Health and Clinical Excellence (NICE). Two questions were considered: a) dasatinib vs. nilotinib vs. high-dose imatinib vs. interferon-alpha for imatinib-resistant patients, and b) dasatinib vs. nilotinib vs. interferon-alpha for imatinib-intolerant patients. Here, three methodological issues are discussed which strongly influenced the cost-effectiveness of these drugs. These issues are also important in estimation of the cost-effectiveness of many other drugs and other health technologies. **METHODS:** 1) Overall survival: Several methods were considered for estimating overall survival, including those used by the drug sponsors, Novartis and Bristol-Myers Squibb; 2) Sources of mortality: Two approaches were considered: a) split by mortality due to chronic myeloid leukaemia and general mortality or b) both combined; 3) Treatment duration: This was reported in none of the trials. Several methods of estimating treatment duration were considered. **RESULTS:** 1) Overall survival: It was not possible to extrapolate overall survival because it was very immature in the trials. Instead, the preferred method was estimation via a surrogate relationship using major cytogenetic response; 2) Sources of mortality: Option (a) was preferred; and 3) Treatment duration: the preferred method was by reference to mean progression-free survival, adjusted for treatment cessation due to adverse events. **CONCLUSIONS:** To estimate the cost-effectiveness of health technologies for a variety of conditions, it is recommended that 1) if overall survival from a trial is immature, it can be estimated by surrogate relationships; 2) for chronic conditions, the analyst should consider modelling separately disease-specific mortality and general mortality; and 3) for drugs, the mean number of doses in clinical trials should be reported so that it is not necessary to estimate this important information using indirect methods.

PRM24

SCAN: AN INTEGRATED SYSTEM FOR MARKET ACCESS OF NEW DRUGS IN ITALY

Lanati EP[1], Lidonnici D[1], D'Ausilio A[1], Iorio A[2], Jommi C[2]
[1]*MA Provider, Milan, Italy, Italy,* [2]*Università del Piemonte Orientale, Novara, Italy, Italy*

OBJECTIVES: Objective of the SCAN project is to support pharma companies in Italy, in managing the complexity of the new drugs pricing process approval at both National and regional level, by identifying a fair price based on the real new drug value. The rationale behind SCAN is first to analyze in a structured and evidence based way all benefits related to a new drug vs a comparator, from clinical to pharmacoeconomic point of view, and then to get a fair price weighting all benefits with a National Board of expert who validate the whole process and result. **METHODS:** SCAN is an integrated method of data analysis, software platform and expert opinion, where all the required market access tools are linked: marketing forecasts, market analysis and budget impacts at both National and Regional level. Added value of the platform is the value-based pricing that determines the price of the new drug based on its added value (ie efficacy, safety) compared to the standard of care for a certain disease, validated by a multidisciplinary National Board of expert, made of pharmacologists, pharmacoeconomists and clinicians. Some trials have been done comparing lapatinib (that has recently got the price in the metastatic breast cancer indication from the National Drug Agency) versus trastuzumab. **RESULTS:** The price obtained with the software simulations produced a value-based ex factory price/pack of 1500€, compared to 1225€ determined by the Italian National Agency (AIFA). **CONCLUSIONS:** The performed simulation shows that the system is a robust tool to determine a value based price which takes into account the innovativeness of the drug.

PRM25

SWITCH OF PRESCRIPTION DRUGS TO THE OVER-THE-COUNTER STATUS (RX-TO-OTC): THE DEVELOPMENT OF A FLEXIBLE AND GENERIC EUROPEAN BUDGET IMPACT MODEL

Plich A[1], Karray SM[2], Flostrand S[3], Toumi M[4]
[1]*Creativ-Ceutical Ltd., London, UK,* [2]*Creativ-Ceutical, Tunis, Tunisia,* [3]*Creativ-Ceutical, Paris, France,* [4]*University Claude Bernard Lyon1, Lyon, France*

OBJECTIVES: To develop a flexible and generic economic model quantifying potential savings associated with Rx-to-OTC switches from the perspective of European policy makers and health care budget holders. **METHODS:** A systematic review of the literature of Rx-to-OTC switches was performed to understand the populations involved, key drivers of economic benefits and the factors impacting these. To ensure applicability across Europe, health care settings were analysed for the UK, France, Germany, Italy, Spain and Poland. Experts were consulted to validate the model structure and assumptions. **RESULTS:** A budget impact framework was used and the model was developed primarily for acute conditions. The model considers six patient groups which may initiate the switched-to-OTC drug: those on the Rx drug, other Rx drugs, OTC-treated, untreated, and undiagnosed (OTC-treated and untreated). From the budget holder perspective, the model includes savings due to avoided: Rx drug acquisition, doctor's visits to obtain a prescription and emergency room visits or hospitalisations due to easier access to an effective or safer therapy. The policy-maker perspective also includes employers' benefits, such as less time-off work to obtain a prescription and less absenteeism & presenteeism due to easier access to therapies that improve employee productivity. The algorithm to estimate cost consequences of potential adverse events due to lack of doctor's supervision was developed. The model has a 5-year time horizon with a function to conduct an analysis for one year which may represent the savings at the forecast peak uptake. An option to estimate the consequences of the disreimbursement policies was incorporated. The model is particularly sensitive to uptake rates across different groups of patients. The model is flexible and easily adaptable to different acute conditions and countries in Europe. **CONCLUSIONS:** The economic impact associated with Rx-to-OTC switches can be credibly estimated in Europe. Preliminary analyses suggest that such switches are cost-saving.

PRM26

A LITERATURE REVIEW OF METHODS USED TO ESTIMATE MEAN PREFERENCE-BASED UTILITIES FOR COMORBIDITIES USING PUBLISHED SUMMARY STATISTICS

Ara R, Wailoo AJ
University of Sheffield, Sheffield, UK

OBJECTIVES: There is currently no consensus on the appropriate method to estimate utilities for joint health conditions. We reviewed the literature to understand reasons for differences in conclusions drawn and to identify where further research is required. **METHODS:** We conducted a systematic literature search to identify studies that evaluated methods used to estimate mean utilities for comorbidities using mean values from cohorts with the corresponding single conditions. We extracted the preference-based utility measure used, the number and range of estimated utility values, the baseline used to value utility decrements, the statistics used to compare estimates, and the conclusions of the authors. **RESULTS:** Four of the six studies identified used EQ-5D data, one used SF-6D and one used HUI3. One presented the multiplicative method, one compared the additive and multiplicative methods, and four compared the additive, multiplicative, and minimum methods with the results obtained from linear models. The number of mean utility values estimated ranged from 32 to 760 and the range of actual mean values ranged from 0.465 to 0.607 for SF-6D, to -0.01 to 1 for HUI3. Systematic errors were observed in the values estimated using all methods. While the simple linear models produced the most accurate results these require validation. Of the other three, on average the multiplicative method estimated the most accurate values across the full range of actual utilities assessed. **CONCLUSIONS:** While additional research is required before a particular method can be advocated, based on the current evidence base we would recommend the multiplicative method is used if data are not available from cohorts with the comorbidities.

PRM27

MODELLING THE BRAZILIAN EXTENDED CONSUMER PRICE INDEX FOR PHARMACEUTICAL PRODUCTS: COMPARISON BETWEEN EXPONENTIAL SMOOTHING AND BOX-JENKINS METHODS

Santos PML, Takemoto MLS, Fernandes RA, Tolentino ACM, Takemoto MMS, Fernandes RRA, Padula AC, Cukier FN, Cruz RB
ANOVA - Knowledge Translation, Rio de Janeiro, Rio de Janeiro, Brazil

OBJECTIVES: The Brazilian Extended Consumer Price Index (IPCA) for Pharmaceutical Products (IPCA-Pharmaceuticals) measures changes in the prices of a fixed basket of medicines purchased by Brazilian households. Monitoring, modeling and prediction of the index are important because adjustments for inflation must be made in accordance with the principles of good practice in health economic analyses. In addition, the index has an important weight in the calculation of the General IPCA, the official index to guide inflation-related policies, and is used to regulate pharmaceutical products prices. The objectives of this study are: 1) to model the IPCA-Pharmaceuticals time series during the sample period 2006-2010; and 2) predict the rate of inflation for the year 2011. **METHODS:** Two classical methodologies of time series analysis were employed: Holt-Winters exponential smoothing and the Box-Jenkins approach. Both methods were compared across three statistics based on errors measures: mean squared error, mean absolute percent error, and Theil's U coefficient. The best fitted model was chosen based on minimizing the error statistics and was used to forecast the IPCA-pharmaceuticals in 2011. **RESULTS:** Monthly IPCA-Pharmaceuticals data was collected from July 2006 to December 2010 (n=54) from Brazilian Institute of Geography and Statistics. The IPCA-Pharmaceuticals percentage change time series was converted to index number on base July 2006=100. The Holt-Winters additive method was adjusted and compared with a SARIMA (0,1,1)x(1,0,0)12 model estimated through the Box-Jenkins approach. The between-methods comparison showed a large advantage for the Box-Jenkins, which minimized the three errors measures. **CONCLUSIONS:** The Box-Jenkins method presented better results as compared to the Holt-Winters method. The final forecasting predicted a 2% inflation rate for pharmaceutical products by the end of 2011, which is lower than the general inflation target rate

established by the Brazilian government (2.5-6.5%) and below the observed mean rate in the last three years (4.4%).

PRM28
BAYESIAN INFERENCE IN MIXED TREATMENT COMPARISONS (MTC) WITH CONTINUOUS OUTCOMES
Osiewalski K, Szmurlo D, Rogoz A
HTA Consulting, Krakow, Poland
OBJECTIVES: The aim of this paper is to present a compact and coherent within the Bayesian inference method of best meta-analysis model selection as well as to present analytical results in performing Gibbs sampling within the MTC framework. **METHODS:** In order to perform Gibbs sampling from the posterior distribution in the random effects model of MTC we evaluate the formulas for the conditional distributions for all parameters. We test for the existence of between study heterogeneity and other parametric restrictions by comparing marginal data densities of competing models. We show how the prior distribution on the model space may affect the inference about best model selection. As an empirical example we present an analysis of effectiveness of two real (although blinded) drugs and placebo. **RESULTS:** We present the marginal posterior distributions of key parameters as well as the comparison of a few restricted models. Among 18 studies from the systematic review dealing with treating the analyzed medical issue with drugs of interest there exist a significant effect of heterogeneity. The a priori distribution on the space of models does not affect this final conclusion (Bayes factor varies from 185 to 190 in favor of the unreduced model). The posterior odds ratio (which equals around 293.1) points that the treatment with Medicine A brings a stronger effect than with Medicine B or placebo. **CONCLUSIONS:** Our results show, that using pure Bayesian techniques can be widely used within the MTC framework. We present an easy to operate and coherent inference in performing complex meta-analyses. We also found confirmed, that Medicine A significantly better increases the level of observed outcome than other treatments.

Research On Methods – Patient-Reported Outcomes Studies

PRM29
TRANSLATION AND VALIDATION STUDY OF MORISKY MEDICATION ADHERENCE SCALE (MMAS): THE URDU VERSION
Saleem F[1], Hassali MA[2], Shafie AA[3], Al-Qazaz HK[1], Atif M[4], Haq N[1], Ahmad N[1], Asif M[5]
[1]*Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia,* [2]*Universiti Sains Malaysia, Minden, Penang, Malaysia,* [3]*Universiti Sains Malaysia (USM), Penang, Penang, Malaysia,* [4]*Universiti Sains Malaysia (USM), Pinang, Malaysia,* [5]*The Islamia University of Bahawalpur, Bahawalpur, Punjab, Pakistan*
OBJECTIVES: To translate, validate and examine the psychometric properties of the Urdu version of the Morisky Medication Adherence Scale (MMAS) among patients with hypertension. **METHODS:** A systematic procedure of ''forward–backward'' was used to translate MMAS into Urdu (official language of Pakistan). It was later validated on a convenience sample of 272 established hypertensive patients between July and October 2010 visiting outpatient department of cardiac ward at Bolan Medical College Hospital, Quetta, Pakistan. For test-retest reliability, data was available for 42 patients. Internal consistency was taken as a measure to test reliability of the MMAS. Convergent and known group validity was taken into account to confirm the validity. **RESULTS:** The mean ± SD of MMAS score was 6.19 ± 1.81, which was measured by applying the recommended scoring method of Morisky Scale. Internal consistency was found to be moderate (Cronbach's a = 0.621). Test–retest reliability value was 0.801 ($p < 0.001$). By applying Spearman's rho, positive correlation between the eight- and four item MMAS was found ($r = 0.792$; $p < 0.01$). A significant relationship between MMAS categories and blood pressure control ($\chi 2 = 20.121$; $p<0.001$) was found. The MMAS sensitivity and specificity, with positive and negative predictive values were 71.54%, 41.48%, 44.74% and 75.56%, respectively. **CONCLUSIONS:** The findings of this validation study indicate that the Urdu version of the MMAS is a reliable and valid tool for the measurement of medication adherence in Pakistani health system.

PRM30
A COMPARISON OF THE PATIENTSLIKEME QUALITY OF LIFE QUESTIONNAIRE (PLMQOL) WITH THE RAND SF-36
Slawsky KA, Massagli MP, Wicks P
PatientsLikeMe, Cambridge, MA, USA
OBJECTIVES: PatientsLikeMe developed the 24-item PLMQOL to be a brief, easy-to-complete online patient-reported assessment of health-related quality of life. The instrument consists of three domains: physical, social, and mental function. As part of the validation process, we examined the performance of the PLMQOL compared with the RAND SF-36 in a population of patients with chronic disease. **METHODS:** Both the PLMQOL and the RAND SF-36 were administered via internet to 2042 invited members of PatientsLikeMe, a novel health data-sharing website allowing patients to monitor multidimensional aspects of health and well-being. Patients were randomized to questionnaire order and were required to have filled out at least one PLMQOL in the 30 days prior to the Jun 9, 2011 survey deployment date in order to be eligible. **RESULTS:** 1228 patients opened the survey invitation, and 660 (54% of those who opened the invite; 32% of eligible sample) patients completed the survey over the 10-day window of availability. No significant differences were seen between the randomized samples by age, sex, condition, or response. Respondents represented approximately 100 chronic conditions; most commonly reported were multiple sclerosis (n=147), fibromyalgia (n=112), Parkinson's disease (n=43), and amyotrophic lateral sclerosis (n=42). The PLMQOL demonstrated high reliability across domains of physical (11 items, α=0.940-0.944), mental (8 items, α=0.909-0.917, and social function (5 items, α=0.810-0.828). In addition, the PLMQOL was highly correlated with relevant domains of the RAND SF-36 as demonstrated by Pearson correlation: RAND physical function and PLMQOL physical function (r=0.838-0.855, $p<0.001$); RAND emotional well-being and PLMQOL mental function (r=0.832-0.852, $p<0.001$); RAND social function and PLMQOL social function (r=0.795-0.823, $p<0.001$). **CONCLUSIONS:** The PLMQOL is a reliable and valid instrument for online assessment of health-related quality of life, demonstrating high correlations with relevant domains of the RAND SF-36. Further research is required to assess disease-specific psychometric properties and clinical validity.

PRM31
DATA POOLING OF PATIENT-REPORTED OUTCOMES IN CLINICAL TRIALS: EVALUATION OF STRUCTUAL EQUATION MODELLING FOR ASSESSING EQUIVALENCE
Nixon M, Burgess AJ
Quintiles, Bracknell, Berkshire, UK
OBJECTIVES: This analysis describes the development, application and comparison of three different equivalence approaches to evaluate equivalence properties of a patient reported outcome (PRO) questionnaire applied to two treatment groups for gastroesophageal reflux disease (GERD). The data used in this analysis was obtained from a medication-monitoring disease registry (iGuard). Patients using either of the two treatments were randomly invited to complete a measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication (TSQM). **METHODS:** Three statistical applications of Confirmatory Factor Analysis (CFA) using a special case of Structural Equation Modelling (SEM) were used to evaluate the equivalence of the TSQM in the two patient populations: 1) equality of the factor scores (measurement equivalence); 2) equality of the variance-covariance matrix (structural equivalence); 3) equality of the measurement error (reliability equivalence). **RESULTS:** Each statistical test agreed that equivalence had been achieved between the two treatment populations for all the three domains of the TSQM. The effectiveness and global satisfaction domains exhibited the strongest significant results on all three tests. However, while the convenience domain exhibited strongly significant equivalence for the measurement equivalence, it only exhibited significant results for the structural and reliability equivalence. **CONCLUSIONS:** While all three methods indicated the same overall results, there is some suggestion of differing sensitivity amongst the tests.

PRM32
FEASIBILITY AND VALIDITY OF THE TIC-P
Bouwmans C[1], De Jong K[2], Timman R[2], Hakkaart-Van Roijen L[1]
[1]*Erasmus University Rotterdam, Rotterdam, The Netherlands,* [2]*Erasmus University Medical Center, Rotterdam, The Netherlands*
OBJECTIVES: In economic evaluation patient-reported questionnaires are frequently used for data collection on medical consumption and productivity losses. The TiC-P is a comprehensive questionnaire focused on establishing costs incurred within the health care system and costs arising from production losses. The questionnaire was developed for a broad application of collecting data in patients treated in mental health care. The aim of this study is to assess the questionnaire's feasibility and validity. **METHODS:** Validation included feasibility, consistency (test-retest) and reliability of reported data. Data were derived from a number of patients included in a study evaluating the cost-effectiveness of alternative feedback mechanisms during psychotherapy. Consistency of the data was assessed using Cohen's kappa coefficients (categorical variables) and intraclass correlation coefficients (ICC) (measurements on interval level). The following values were attached to the coefficients: modest (0.21-0.40); moderate (0.41-0.60); satisfactory (0.61-0.80) and almost perfect (0.81-1.00). Reliability was assessed comparing reported data with registered contacts with psychiatrist, psychologist or psychotherapist. Feasibility was based on response rate, and completeness of report on medication. **RESULTS:** Re-test analyses were based on retest questionnaires of 99 respondents. Agreement regarding medical services was as follows: moderate: 3 items; satisfactory: 8 items; almost perfect: 1 item. Categorical items related to productivity losses included short-term and long-term absence from work and impediment at work. Agreement on these items was satisfactory. ICC's were calculated for 7 items presenting the number of contacts with health care providers. For the remaining items on medical services, ICC's could not be assessed due to insufficient variation in the data. Agreement was considered modest on 1 item, satisfactory on 3 items and almost perfect on 3 items. Reliability of reported and registered number of contacts was 82%. **CONCLUSIONS:** These preliminary results indicated that the TiC-P is a valid instrument for measuring medical consumption and productivity losses.

PRM33
SYSTEMATIC REVIEW OF HEALTH STATE UTILITIES IN SPAIN
García-Pérez L[1], Aguiar-Ibáñez R[2], Linertová R[1], Rivero-Santana A[1], Abásolo-Alessón I[3]
[1]*Fundación Canaria de Investigación y Salud (FUNCIS), Santa Cruz de Tenerife, Spain,* [2]*Amaris, London, UK,* [3]*Universidad de La Laguna, San Cristóbal de La Laguna, Spain*
OBJECTIVES: The objective is to identify published studies reporting utility values or preferences for health states elicited from the Spanish population with the long-term purpose of maintaining an updated database of utilities that can be of help for the research community. **METHODS:** A systematic review was conducted to identify studies that elicited utilities by means of questionnaires validated in Spain (EQ-5D, SF-6D, etc.) or accepted techniques (time trade-off, standard gamble, etc.), from healthy or non-healthy populations. We initially focused in cancer, diabetes and heart diseases. An electronic search was developed and run in MEDLINE, EMBASE, PsycINFO, NHS CRD, Cochrane Central Register of Controlled Trials, CINAHL and Spanish databases. Original utility sources were identified from clin-

ical trials, observational studies, systematic reviews and economic evaluations. Studies that fulfilled the inclusion criteria were reviewed and data-extracted. The synthesis was narrative. **RESULTS:** After discarding duplicates, 1528 citations were screened, and 833 full papers were retrieved for consideration. Eight out of 145 studies were included, which focused in either diabetes or heart disease. From these, 21 utility values were identified and included in the database. Most of the excluded studies used SF-36 or EQ-5D, but only for descriptive purposes, and did not calculate the utility index. **CONCLUSIONS:** Few studies were available providing utilities elicited from the Spanish population for prevalent diseases such as diabetes or heart disease. As next steps, other diseases will be explored, searches will be conducted in other databases, authors and experts will be contacted to identify additional, relevant information, and included studies will be quality-assessed. This ongoing review and the database of Spanish utilities will be useful for researchers developing economic evaluations or requiring information on quality of life derived from the Spanish population. The project will also allow us to identify data gaps for which further research is needed.

PRM34

EXAMINING VARIATIONS IN ITEM STRUCTURE AND CONTENT IN PRO INSTRUMENTS, OR, THERE MUST BE 50 WAYS TO EXPRESS YOUR DISTRESS

Erickson P[1], Willke RJ[2]
[1]*O.L.G.A., State College, PA, USA,* [2]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: The content validity of an instrument depends not only on the concepts embodied in the items but also on how the items are structured to elicit responses from patients. This research explores the "grammar" of individual items and how it varies across a number of instruments in selected disease areas. The goal is to understand how such considerations affect consistency of content and to classify items by concept. **METHODS:** The structure of each item is characterized as an item stem with a core concept, with an implicit or explicit context (e.g., a disease), event (e.g. "felt frustrated or impatient"), and stimulus (e.g., "about your symptom"), as well as the recall period and response options. Concepts are classified using the WHO International Classification of Functioning (ICF). Similarities and differences across instruments within disease areas are analyzed. **RESULTS:** We decomposed over 600 items in at least 23 instruments across 5 disease areas and several generic instruments, capturing and classifying each aspect of the structure of each item. Most physical function items could be matched with specific 3-4 digit ICF codes; most emotional function items could not be matched as specifically. There was considerable variation across instruments regarding the explicit statement of context as well as the presence of a stimulus. We observed at least 8 different recall periods ranging from an implied present to "in the past year" to "in 10 years" with distinct patterns by disease area. We observed at least 9 types of response options, but the majority of items used 5-point scales. **CONCLUSIONS:** There are some commonalities but little standardization in how items are structured, within or across diseases. Classification and comparison of items and evaluating comparative content validity is complicated by the variation in most aspects of how the items are phrased.

PRM35

AGREEMENT BETWEEN PATIENTS' SELF-REPORT AND PHYSICIANS' PRESCRIPTIONS ON DRUGS AND VACCINE EXPOSURE: THE INTERNATIONAL PGRX DATABASE EXPERIENCE

Grimaldi-Bensouda L[1], Rossignol M[2], Aubrun E[1], Benichou J[3], Abenhaim L[4]
[1]*LA-SER, Paris, Paris, France,* [2]*LA-SER Centre for Risk Research Inc., Montreal, Montreal, Canada,* [3]*INSERM U=, Rouen, Rouen, France,* [4]*LA-SER Europe Ltd, London, London, UK*

OBJECTIVES: Patients' self-reporting of drug exposure is subject to memory errors and varying degrees of bias. Utilisation of prescription records is often impaired by non-compliance and use of over-the-counter (OTC) drugs. Our study compared patient self-reports (PSR) to physician's prescription reports (PPR) for: cardiovascular drugs (CVDs), allegedly used on a daily basis to treat chronic conditions; drugs for musculoskeletal disorders (MSDs) used intermittently; and vaccines. **METHODS:** The reference pool from the PGRx database consists of several networks of general practitioners. For every referent included, data was obtained for all drugs used within the two years preceding the consultation date via: 1) a structured telephone interview assisted by a guide listing pathologies and packaged visual display of drugs; 2) and physician's prescriptions reports. Both PSR and PPR measurements were obtained independently and blindly by investigators. Comparisons were made on exposure to CVDs, MSDs and vaccines, for different time-windows up to 24 months prior to the index date. **RESULTS:** The concordance between physician and patient reports was assessed on 2702 and 4152 patient-physician pairs for CVDs and MSDs, respectively. Overall, agreement between PSR and PPR for all classes of CVDs was excellent (kappa = 0.83 [95% confidence interval (CI): 0.81 – 0.85]). Agreement was substantial for drugs for osteoarthritis (kappa = 0.62 [0.55 – 0.68]), fair for non-aspirin NSAIDs (kappa = 0.31 [0.26 – 0.36]) and low for muscle relaxants and non-narcotic analgesics. Use of OTC drugs was associated with greater disagreement (Odds ratio = 2.2 [95% CI: 1.1 – 1.4]), but not age. **CONCLUSIONS:** The PGRx standardised and systematic collection of drug exposure directly from patients provided similar data to physician prescription records for chronic drug exposure. Differences between PSR and PPR in estimating prevalence for drugs used in MSDs varied by type of drug and time elapsed up to the index date.

PRM36

COMPARING THE PERFORMANCE OF THE SF-6D AND EQ-5D ACROSS DISEASES

Ferreira L[1], Ferreira P[2], Pereira L[1]
[1]*University of the Algarve-ESGHT, Faro, Portugal, Portugal,* [2]*University of Coimbra-Faculty of Economics, Coimbra, Portugal, Portugal*

OBJECTIVES: Given that the number of preference-based instruments has been growing over the past years, it is important to compare their performance. This work seeks to compare the performance of the SF-6D and EQ-5D across four diseases: asthma, COPD, cataracts and rheumatoid arthritis. **METHODS:** The overall sample consists of 643 cases. The indexes are analysed by disease group to explore the instruments' ability to distinguish between socio-demographic groups. Ceiling and floor effects are calculated for both instruments. The level of agreement between the instruments is analyzed using correlation coefficients. Paired samples t-tests are used to identify differences between the indexes. Regression analyses are used to explore the relationship between the indexes. The discriminative properties of both indexes are also compared using ROC curves. **RESULTS:** Mean values were the same for both indexes (0.72). However in the analysis by disease the mean EQ-5D index was 0.05 higher than the mean SF-6D index for asthma and COPD. There was a strong correlation between both indexes (0.68). Similar results were found by disease group. The agreement level between both instruments was higher between similar dimensions. Both instruments showed a similar ability to distinguish between socio-demographic groups. There was a significant ceiling effect in the EQ-5D. The results of the regression models indicate that the relationship is not uniform between the two indexes. These results are supported by specific hypothesis tests. The analysis of the area under the curves showed that the SF-6D is more efficient in detecting differences between groups in almost all cases. **CONCLUSIONS:** The SF-6D generates higher values in disease groups. The SF-6D and the EQ-5D perform differently in each of the diseases studied. These results do not allow looking for a global adjustment between both measures regardless of the health state of the individual. These differences should be further investigated.

PRM37

ASSESSING THE HEALTH STATUS OF ROMA POPULATION BY USING SF-36 HEALTH SURVEY: EVIDENCE FROM GREECE

Pappa E[1], Rotsiamis N[1], Halkiopoulos G[1], Papadopoulos A[2], Niakas D[1]
[1]*Hellenic Open University, Patras, Greece,* [2]*ATTIKON University Hospital, Athens, Greece*

OBJECTIVES: Roma people compose a vulnerable minority with poor health which has been the subject of discrimination. The aim was to provide a valid estimate of the health status of Roma people in Greece, by using the validated instrument of the SF-36 questionnaire, which has been widely used in previous surveys of general and clinical populations, and also to determine whether SF-36 is a valid and reliable instrument in assessing self-assessed health status of Roma population **METHODS:** The study was carried out in 2009 in two geographically dispersed Roma settlements in Greece. A sample of 433 Roma people was face to face interviewed. The survey included the SF-36, questions on socio-demographic and health related characteristics, health service use and factors associated with material deprivation. Construct validity was investigated with "known group" validity testing and reliability with chronbach alpha coefficient. Statistical significance was accepted at the 5% level. All statistical analyses were undertaken using SPSS v.17. **RESULTS:** Roma responders are young with mean age of 33.5 years old. However they rate their health very low with highest score in PF (66.1%) and the lowest score in MH (41.5%). RP and RE scales had high ceiling and floor effects. Cronbach's alpha coefficient met the criterion (>0.70) for all eight scales with two exceptions. SF-36 scale scores distinguished well, and in the expected manner, between groups of respondents providing evidence of construct validity. Significant statistical differences in mean scores were observed in relation to demographic characteristics, socio-economic status, existence of chronic disease, health services utilization and variables related to material deprivation. **CONCLUSIONS:** The findings support the validity and reliability of the SF-36 when used in assessing Roma's health. On the other hand, Roma experience social exclusion and deprivation which profoundly affect their health. Tackling the poor health of Roma acquires certain public health interventions and health promotion programs.

PRM38

ESTIMATING SF-6D HEALTH STATE UTILITY VALUES FOR COMORID HEALTH CONDITIONS

Ara R, Brazier J
University of Sheffield, Sheffield, UK

OBJECTIVES: The objective of the current study was to compare the accuracy of different methods to estimate health state utility values (HSUVs) for comorbid health conditions. **METHODS:** Data collected during five rounds of the Welsh Health Survey (n=64,437) were used to generate mean SF-6D scores for cohorts with specific health conditions. These data were then used to estimate mean SF-6D scores for cohorts with comorbid health conditions. **RESULTS:** The mean SF-6D scores for the subgroups with comorbidities ranged from 0.465 to 0.607. The minimum and additive methods overestimated and underestimated the majority of actual SF-6D scores, had mean absolute errors (MAE) of 0.056 and 0.121 and just 15% and 3% of estimated values were within the mimimum important difference (MID) for the SF-6D (0.041) respectively. While the multiplicative method also tended to underestimate the actual SF-6D scores (MAE 0.075) it performed better when estimating scores below 0.50 and 47% of estimated values were within the MID. A linear model obtained by mapping the disutilities associated with the mean SF-6D scores for two subgroups with single conditions (plus the interaction between the two) onto the mean SF-6D scores for subgroups with comorbidities gave the most accurate results overall. The predicted SF-6D scores had a mean absolute error of 0.0191 and 88% of predicted SF-6D scores accurate to within the MID. **CONCLUSIONS:** While in our data the linear model gave the most accurate results, additional research is required to validate our results.

PRM39

IDENTIFICATION OF DISEASES FOR EQ-5D BOLT-ON ITEM DEVELOPMENT: AN EMPIRICAL APPROACH

Solem CT[1], Gu NY[1], Pickard AS[2]
[1]Pharmerit North America, LLC, Bethesda, MD, USA, [2]University of Illinois at Chicago, Chicago, IL, USA

OBJECTIVES: A perceived limitation of generic utility measures is lack of ability to capture change relevant to disease-specific areas or interventions. To test whether core EQ-5D items sufficiently measure variability in patients' self-reported quality of life scores, we aimed to identify whether the presence of a series of conditions explained residual variability in EQ-5D visual analog scale (VAS) scores, beyond EQ-5D items. **METHODS:** We utilized generalized linear models (GLM) with a gamma distribution and log link to predict VAS by the 5 EQ-5D items and the presence/absence of 10 conditions (cancer, diabetes, anxiety disorder, hypertension, coronary heart disease, stroke, asthma, COPD/other respiratory, depression, glaucoma), controlling for age, gender, race/ethnicity and number of chronic conditions (i.e., as a proxy for co-morbidities) using the 2000-2003 Medical Expenditure Panel Survey (MEPS) data. Coefficients for disease that were statistically significant (p-value$<$0.01) and showed minimally important difference (MID: coefficient $\geq$0.03) served as criteria to support further investigation of condition-specific "bolt-on" items that extend the content of EQ-5D. **RESULTS:** Of 24,830 respondents, 45.7% were male, 77.2% were white non-Hispanic and had a mean age of 45.9 years (SD 17.1). Overall mean EQ-VAS was 79.75 at first measurement. Diabetes, stroke and depression significantly predicted VAS scores alongside the EQ-5D items and demographic characteristics (p$<$0.001) and met MID criteria. When concurrently controlling for all other conditions, cancer, CHD and COPD also met criteria. **CONCLUSIONS:** Findings suggest respondents with diabetes, stroke, and depression, potentially with cancer, CHD and COPD, had significant heterogeneity in their VAS valuation of their own health that was not explained alone by EQ-5D items or demographics. This study provides one approach to identifying potential chronic conditions where disease-specific "bolt-on" items may be considered for EQ-5D.

PRM40

IMPROVING THE MEASUREMENT OF QUALITY OF LIFE BASED ON FUZZY SCALE

Chen PY[1], Yao G[2]
[1]National Taiwan University, Taipei, Taiwan, [2]National Taiwan University (Dept. of Psychology), Taipei, Taiwan

OBJECTIVES: In past two decades, researchers have proposed to combine fuzzy theory into measurement in various areas. According to their studies, combining fuzzy theory could reduce the properties differences between measurement methods and human cognition, and the results collected by fuzzy scale(FS) were also superior to those by traditional measurement in both validity and reliability. Therefore, the purpose of this study tries to measure the quality of life(QOL) by FS, and examine its own psychometrical properties and comparability with Likert scale(LS). **METHODS:** WHOQOL-BREF Taiwan version was used to compare the results collected by FS and LS, with a set of data from 404 subjects in repeated experiment design. Cronbach's alpha and hypothesis test of reliability coefficient were utilized to compare the reliability of WHOQOL-BREF in both two measurement. Confirmatory factor analysis(CFA) was used to examine the construct validity and measurement invariance (ME/I) between LS and FS at domain level. **RESULTS:** The results indicated that Cronbach's alpha coefficients of FS were significant higher than that of LS in most domains. Moreover, CFA analysis showed that the equal intercept invariance model between FS and LS measurement were supported, all fit index performed well under the factor model at domain level, CFI, RMSEA and SRMR increased very slightly after imposing the equal intercept constrain proposed by Meredith in 1993. **CONCLUSIONS:** According to the above results, FS did improve QOL measurement in reducing the measurement error, and its construct validity was supported by CFA analysis. Besides, the ME/I analysis indicated that FS was still comparable with traditional LS in the lower measurement error of QOL. In future studies, researchers may use previous studies which incorporating fuzzy scale in helping them diagnose and differentiate psychiatric diseases as reference, and look into how the fuzzy scale QOL could be used in other medical fields.

PRM41

ARE GENERAL POPULATION DATA SUITABLE FOR APPROXIMATING BASELINE UTILITY VALUES IN ECONOMIC MODELS?

Ara R, Brazier J
University of Sheffield, Sheffield, UK

OBJECTIVES: Economic models require a baseline utility profile to assess the number of quality adjusted life years (QALY) gained from an intervention. The baseline needed could be obtained from individuals without a specific health condition, depending on the definition of the health condition in the model. We explored whether utilities from the general population are suitable as proxy measures when condition specific data are not available. **METHODS:** Pooling data from four consecutive rounds of the Health Survey for England (n=41,000) and using sub-groups stratified by self-reported health conditions, we compared mean utility scores (EQ-5D) for groups without specific conditions (i.e. the preferred baseline profile) with the mean scores from similar aged cohorts of the general population (i.e. the proxy baseline profile). **RESULTS:** We found the average utility scores from the general population were good approximations for some conditions (e.g. cancer) but not all (e.g. complaints of teeth/mouth). For cohorts who have just one single condition, data from the general population who report they do not have any of the prevalent conditions could be used to approximate the baseline. **CONCLUSIONS:** We present a number of health condition and age-stratified preference-based utility values that could be used to assess the QALY gain compared to the average person who does not have that condition. We also provide age stratified data from the general population that could be used to approximate baseline preference-based utility scores when condition specific data are not available.

PRM42

VALUATION OF HR-QOL UTILITIES BY THE EQ-5D IN A GROUP OF CHRONICALLY ILL PATIENTS

Vanhaute OA[1], Peleman R[1], Annemans L[2]
[1]University Hospital, Ghent, Belgium, [2]Ghent University, Ghent, Belgium

OBJECTIVES: In order to estimate the benefits of health interventions, health related quality of life (HR-QoL) measures are traditionally mapped into utilities based on a valuation by a representative sample of the general population. However, in order to apply such valuations in cost-effectiveness studies of programs addressed to patients, it needs to be ascertained that the values of these patients are not different than these of the population. Therefore we compared the valuation of chronic patients with the already published valuation of the general population. **METHODS:** Between December 2009 and March 2010 the EQ-5D questionnaire was distributed in 15 outpatient services, treating adult (age $>$ 18 yrs) chronically ill patients in the University Hospital Ghent, Belgium. In Belgium the EQ-5D was mapped previously to the Visual Analogue Score (VAS), hence patients in our study were also asked to indicate their actual perception of HR-QoL on a VAS scale. Only EQ-5D profiles which were scored at least 10 times by different patients were considered for further evaluation. All profiles were mapped into VAS by multivariate regression. **RESULTS:** A total of 1348 questionnaires were distributed, of which 768 (57%) were completed. Male/female ratio was 41%/59%, with a mean age of 53.6. Eighteen EQ-5D profiles were scored at least 10 times, with a mean VAS of 0.64 (95% C.I. 0.63-0.66). The complete set of utilities obtained by multivariate regression was significantly different compared to the valuation by the Belgian population sample (p$<$0.0001). Especially in the profiles in which the patient indicates complete dependency or major problems, the HR-QoL value was perceived much higher by patients as compared to the general population. **CONCLUSIONS:** Chronically ill patients perceive their HR-QoL higher than estimated by the population sample. In order to evaluate health programs consequences of these findings should be considered.

PRM43

DIRECT FROM THE PATIENTS – RESEARCH INTO WHAT PATIENTS WOULD LIKE TO IMPROVE IN THEIR ELECTRONIC DIARY EXPERIENCE

O'Gorman HJ[1], Ross J[2]
[1]Almac Group, Craigavon, UK, [2]Almac Clinical Technologies, Souderton, PA, USA

OBJECTIVES: To illustrate patient needs and preferences for patient diaries in support of clinical trials and to identify what can be done to improve the electronic patient diary experience based on the patients' recommendations. **METHODS:** Three hundred seven participants (45% female and 55% male) completed a 10-minute internet survey, fielded in December 2010. The age range of the patients was 19-77 years. This internet survey focused on patients' perceived benefits and experience with current patient diaries and asked where improvements could be made **RESULTS:** From the survey positive experiences reported by patients were ease of use (66%) and simple questions (60%). 48% found no unfavorable aspects in diary keeping but 38% said that diary entries were too frequent. Patients were asked about the use of reminders and 80% stated that they would like to receive reminders via email and 55% via SMS text. With regard to the patient suggested improvements, 59% stated multiple options and more flexibility in keeping the diary would improve their experience and 58% said to shorten the time needed to make a diary entry. Further results will be presented. **CONCLUSIONS:** Simplicity came out as a key factor in patients' use of electronic diaries and should be first priority when designing them. Patients would like to feel involved in the trial and the use of reminders when they need to complete an action was a patient preference. These factors should be considered when designing an ePRO system to be used in a clinical trial.

PRM44

THE FIRST RESEARCH: ASSESSMENT OF THE WTP THRESHOLD FOR QALY BY CONTINGENT VALUATION METHOD IN RUSSIA

Zelenova O
Federal Research Institute for Health Care Organization and Information of the Ministry of Health and Social Development of Ru, Moscow, Russia

OBJECTIVES: To assess the WTP threshold for QALY in Russia. **METHODS:** We have held the opinion poll to define WTP for QALY of the 980 respondents. Questionnaire consists of demographic part: gender, age, education, hospitalization (within the last 5 years), hospitalization of any member of household (within the last 5 years) and occupation. The special part is a detailed 4categories of WTP: WTPsel for the respondent's additional QALY; WTP5sel for the respondent's additional QALY 5 years later were used to establish decision making rules; WTPfam for an additional QALY for a family member; WTPsoc: the cost that the respondent thought society should pay for someone's additional QALY were used to evaluate monetary value of other people's QALY for comparison with respondents' own QALY. **RESULTS:** Average WTPsel and WTP5sel are rather equal 69,000 and 72,000 rubles (the rub/$ rate in Russia is 30 rub for 1 $). The average WTPfam is 16% more than WTPsel.The fact that WTPfam was higher than WTPsel. Average WTPsoc is 146 000 rubles, which is more than twice as much as WTP5sel (72 000 rubles). WTP value is increasing sequentially from WTPsel toWTPsoc in each category. The main factors which influenced WTP the most are occupation, age and education. Whereas factors such as gender, hospitalization (within the last 5 years) and hospitalization of any member of household (within the last 5 years) didn't play an important role. We have compared our figures with International Survey (Takeru Shiroiwa, Japan) and have

obtained the similar results. **CONCLUSIONS:** The WTP for QALY in Russia is 63,000 rubles or $2,300 that is much lower than in other countries but WTP/AAI ratio is nearly the same as in the UK.There are WTP5sel≤WTPsel≤WTPfam≤WTPsocin Russia just like in Australia, the UK and the US.

PRM45

IMPORTANCE OF COLLABORATION WITH DEVELOPERS IN THE CLARIFICATION OF CONCEPTS: A CASE STUDY WITH THE UNIVERSITY OF CALIFORNIA, SAN DIEGO (UCSD) SHORTNESS OF BREATH QUESTIONNAIRE (SOBQ)

Ries AL[1], Kaschinski D[2], Montigny C[3]
[1]*University of California, San Diego, CA, USA,* [2]*Boehringer Ingelheim GmbH, Ingelheim am Rhein, Germany,* [3]*MAPI Institute, Lyon, France*

OBJECTIVES: The UCSD SOBQ, a 24-item instrument developed in US English, assesses self-reported shortness of breath while performing a variety of daily living activities. The objective of this report is to underline the importance of collaboration with the developers to clarify concepts and ensure their correct interpretation while translating the original version into other languages. **METHODS:** Interactive discussion with the developers of the SOBQ was undertaken to formalize a concept list that would: 1) Explain and clarify the conceptual notions underlying each item in simple language so they would be accurately reflected in each language version produced, and 2) Provide acceptable approved translation alternatives. **RESULTS:** The concept list was revised five times and widely expanded with definitions and alternate translations validated by the developers. Through questions raised during the linguistic validation process, collaboration with the developers highlighted items initially considered as unambiguous but which required additional information to be faithfully rendered in all languages. Among the 24 items of the SOBQ, four items proved to be unclear (e.g., "dressing" was clarified as "putting on and taking off clothes" and "picking up and straightening" as "picking things up and tidying them up"). Three other items appeared as culturally inappropriate and, therefore, needed to be adapted to be suitable to the countries for which these activities were not relevant (e.g., "washing car or any other vehicle" was one of the accepted alternatives for "washing car" and "watering flowers" for "watering the lawn"). **CONCLUSIONS:** It is essential to involve the developers in the clarification of the concepts underlying each item in a questionnaire to allow their correct interpretation in other languages and cultures. This step is crucial to ensure comparable content validity between different language versions. This example with the SOBQ shows that the involvement of developers is a dynamic and necessary process.

PRM46

LINGUISTIC VALIDATION AND EPRO – VALUE OF COLLABORATION

Zarzar KM[1], Dawsey R[2]
[1]*TransPerfect, Durham, NC, USA,* [2]*TransPerfect, Atlanta, GA, USA*

OBJECTIVES: As the use of clinical outcomes assessments in global studies continues to rise, and electronic modes of administration proliferate, collaboration between ePRO and linguistic validation providers becomes critical to the success of global initiatives. This cooperation enables the incorporation of the electronic mode of administration into the cognitive interviewing stage of linguistic validation, allowing respondents to view the content in context. Collaboration between ePRO and linguistic validation providers also yields time and cost efficiencies to the sponsor. **METHODS:** A review of prior collaboration with four ePRO providers was conducted to provide insight into key areas for efficiency prior to initiation of a large-scale linguistic validation project involving ePRO. Prior to project initiation, a detailed workflow was outlined, a review of relevant ePRO file formats was conducted, and processes and milestones were developed with input from the linguistic validation provider, the ePRO provider, and the sponsor to ensure deadlines were met. **RESULTS:** Reviews of prior projects revealed early collaboration was commonly impeded as the development of the ePRO platform often initiates on different timelines than linguistic validation process. Common reasons include differing contracting timelines from the sponsor for each service, and addition of countries or languages after ePRO contract execution. By building a collaborative project workflow ahead of project initiation, the ePRO and linguistic validation partners can identify cost and timeline efficiencies in 1) the source content, 2) uploading the translated language directly into ePRO platforms, 3) use of ePRO mode in cognitive interviews, 4) post-localization testing of fonts and characters, and 5) proofreading of the final screenshots. **CONCLUSIONS:** Timeline restrictions resulting from study deadlines and contracting processes can limit the benefit to be achieved by collaboration between ePRO and linguistic validation partners. Early planning, and contracting of each provider with the expectation of collaboration will enable cost and timeline efficiencies, and process improvements.

PRM47

REVIEW OF CLINICIAN AND OBSERVER REPORTED OUTCOMES MEASURES TRANSLATION METHODOLOGIES

Zarzar KM
TransPerfect, Durham, NC, USA

OBJECTIVES: Since the publication of the FDA PRO Guidance in 2009, focus has largely been dedicated to patient-reported outcomes measures. Other commonly used clinical outcomes assessments including clinician-reported outcomes (Clin-RO) and observer-reported outcomes (Obs-RO) warrant attention, as the expectation is that all clinical outcomes assessments will be expected to follow the properties of the PRO guidelines. It can be inferred that the same expectations for translation and cultural adaptation of these measures will also apply, and discussion surrounding translation methodologies for these outcomes measures is necessary. **METHODS:** A review of past Clin-RO and Obs-RO measure translation methodologies was conducted. Linguistic feedback resulting from each stage was reviewed for relevance and impact on language changes. **RESULTS:** Past translation methodologies involved concept definition, dual forward translation, reconciliation of forward translations, back translation, resolution of back translation and forward translation, and clinician or expert review for all clinical outcomes assessments. An additional stage specific to observer-reported outcomes assessments included cognitive interviewing with the relevant respondent population, such as caregivers, parents, etc. Clin-RO measures involve review by native-speaking clinicians in the relevant area of interest. Cognitive interviews with clinicians were not found to be a common practice. **CONCLUSIONS:** The results of this review and feedback analysis suggest observer-reported outcomes measures are best suited to follow the same methodology as PRO measures, with the cognitive interviews conducted with the relevant observer population. Clinician-reported outcomes measures should also follow the same guidelines as PRO measures for translation, however further research into the methodology for execution of the review stage is required to assess if clinician reviews, focus groups with clinicians, cognitive interviews with clinicians, or an alternative will yield the best results for this particular clinical outcomes assessment.

Research On Methods – Statistical Methods

PRM48

A MODEL FOR PATIENTS ACCRUAL IN MULTI-SITE OBSERVATIONAL STUDIES: A SURVIVAL ANALYSIS APPROACH

Longagnani C[1], Bagnardi V[2], Zanoli L[1], Simoni L[1]
[1]*Medidata srl, Modena, Italy,* [2]*University of Milano-Bicocca, Milano, Italy*

OBJECTIVES: The allocation of sufficient time for participant recruitment is one of the fundamental aspects in planning a clinical trial (Carter, 2004): the study of patient accrual is of great interest not only in clinical trials but also in observational studies. In this work we developed a time-to-event (i.e. survival) model aimed to explain the course of patients, according to site and study characteristics. **METHODS:** Nineteen observational non-retrospective studies (663 sites and 22,123 patients) managed by Medidata from 2002 to 2009 were included in the analysis. Time to patient enrolment was calculated as the percentage of time elapsed from the first-patient-in to the enrolment of the patient out of the study planned duration. Individuals enrolled after this period were considered as censored. Site and study characteristics were included in a Cox Proportional Hazard regression model; Hazard Ratios were estimated. **RESULTS:** The course of patients was significantly associated with year of the study (≥2008 vs. <2008: Hazard Ratio 2.37), number of planned sites (≥25 vs. <25: 0.63), study design (cross- sectional vs. longitudinal: 0.33), electronic vs. paper data capture (2.87), start-up and investigator meeting execution (yes vs. no: 2.27 and 0.45 respectively), single patient fee vs. other (1.78), top-enroller list communication (yes vs no: 0.71), competitive enrolment (yes vs. no: 0.47), site initiation visit (yes vs. no: 0.38), protocol amendment with possible effects on enrolment (yes vs. no: 4.21), type of site (academic private hospital/university/private out-patient clinic vs community hospital: 0.86) and median monthly number of phone calls/site (1.15). **CONCLUSIONS:** In our analysis, the most interesting factors influencing patient accrual in the setting of observational studies managed by an Italian CRO appeared to be the number of planned sites, cross- sectional study design, electronic data capture, start-up and investigator meeting execution, top-enroller list communication and competitive enrolment. Further analyses are ongoing as regards a predictive model.

PRM49

EVALUATION OF BIVARIATE META-ANALYSIS METHODS TO SYNTHESISE RESULTS OF SEVERAL STUDIES WITH TWO CORRELATED ENDPOINTS

Aballea S[1], Vataire AL[2], Neine ME[3], Le coroller G[4], Toumi M[5]
[1]*Creativ Ceutical, Paris, Ile de France, France,* [2]*CREATIV-CEUTICAL, Paris, France,* [3]*Pierre & Marie Curie University, Paris, France,* [4]*Creativ-Ceutical, Luxembourg, Luxembourg,* [5]*University Claude Bernard Lyon1, Lyon, France*

OBJECTIVES: Clinical studies generally include several endpoints to compare the effects of alternative interventions. Meta-analyses are usually performed on different endpoints separately. We investigated advantages of bivariate meta-analysis models, accounting for the correlation between endpoints, compared to univariate meta-analyses. **METHODS:** Alternative meta-analysis approaches were applied and compared using simulated datasets of logarithms of odds ratios (OR) for two endpoints. Several datasets of 20 studies were simulated, with different correlations between endpoints, and with or without missing values. Simulations were based on a bivariate normal distribution with mean log ORs of -0.5, corresponding to ORs of 0.61, and variances of 0.25 for both endpoints. The models used were: 1) random-effects univariate models for each endpoint separately; 2) two-stage approach using univariate model for studies with one endpoint and bivariate model for studies with two endpoints; and 3) bivariate model with prior imputation of the variance of second endpoint for studies with one endpoint only, based on the correlation between variances for the two endpoints. All the models were estimated in a Bayesian framework, using WinBugs. **RESULTS:** Results of different models were fairly similar in absence of missing data. In a situation with one endpoint missing at random for 10 studies, and a correlation of 0.8, the bias around estimated OR for that endpoint was 0.12, 0.03, and 0.04 with models 1, 2 and 3 respectively, when an informative prior was used for the correlation. The bias was not reduced with uninformative prior. Variance estimates also differed between models, and were very large with model 2 for some simulations. **CONCLUSIONS:** Bivariate meta-analysis can improve treatment effect estimates when information is collected for two correlated endpoints, especially for an endpoint which is not

included in all studies. Furthermore, the model with prior imputation of the variance appeared to be more stable than two-stage model.

PRM50

SAMPLE SIZE AND ETHICAL CONSIDERATIONS IN RANDOMIZED CLUSTER SAMPLING VERSUS INDIVIDUAL PATIENT RECRUITMENT FORMULAS IN PROSPECTIVE OBSERVATIONAL STUDIES

Chiappinelli R, Stanley S, Criscola R, Wasser T
HealthCore, Wilmington, DE, USA

OBJECTIVES: Differences in computational sample size formulas indicate that randomized cluster samples require more patients to demonstrate the same effect as studies that use Individual Patient Recruitment (IPR) formulas. We compared the differences in randomized cluster sampling and IPR formulas through a simulation study by varying the cluster size and Intra-Cluster Correlation Coefficient (ICC) to determine the magnitude of sample size differences. **METHODS:** The sample size formula for cluster sampling included two terms: 1) estimate of cluster size, and 2) estimate of ICC. Four Mean/Standard Deviation ratios were used reflecting the effect size, three ICC values, and three cluster sizes. Sample size was calculated for non-cluster and cluster formulas for 80% and 90% power. Sample size calculation results between cluster and IPR formulas were compared. **RESULTS:** Differences between cluster and IPR designs found that under sampling in IPR formulas vary from 5-15% and are largest when effect sizes are smallest. The IPR samples were smaller than cluster samples for the same effect size and power. Sample size using the cluster formula was smallest when ICC was small (0.15), at 80 percent power and cluster size of 5 patients per group. Cluster sample size was largest when ICC was large (0.25), at 90 percent power and cluster size of 20. **CONCLUSIONS:** In the research environment where prospective observational methods are used to gather "real world" data, studies that are conducted using cluster sampling, but powered with IPR formulas, are underpowered by as much as 15%. Ethical implications must be considered in prospective studies that require patient informed consent if the study is underpowered. If the prospective study involves risk the equipoise argument may be violated and place patients at risk (assuming there is a study treatment regimen), as the study may not be conclusive because of low power.

PRM51

NONPARAMETRIC REGRESSION ANALYSIS CONTROLS COST ANALYSIS IN DATA WITH OUTLIERS

Eisenberg D, Wasser T
HealthCore, Inc., Wilmington, DE, USA

OBJECTIVES: Cost analysis is often complicated to analyze because of skewed data caused by outliers in the upper tail of the distribution. Some of these outlier expenses are a result of extreme expenses before an observation period starts or during an episode of illness. Theil regression is a non-parametric linear regression method that provides accurate estimates of slope and intercept when outliers are present by calculating values based on the median. **METHODS:** In a study intended to measure the length of time it took for patient costs to return to normal pre-episode costs after pneumonia, the Theil method was used and compared to Ordinary Least Squares (OLS) results on the same data. The baseline cost was computed as the mean cost for the six months prior to diagnosis, the study allowed for a three month episode period and the OLS and Theil regression methods were computed on the monthly costs for the six months after the episode. **RESULTS:** High cost outliers during the three month episode led to elevated costs for the first post episode period. This caused an underestimate of cost using the OLS method. Theil regression correctly estimated the increased time to return to normal in 11 of the 21 variables tracked. These differences ranged from 15 to 370 days. OLS found extended time over Theil for 5 of 21 comparisons. These differences ranged from 2 to 26 days. Agreement between OLS and Theil was found for 5 of 21 comparisons. **CONCLUSIONS:** Outliers in regression analysis frequently occur when the variable of interest is cost. Theil regression offers considerable advantages over OLS regression when the outlier is in one of the tails of the distribution. The advantages include more accurate results as well being able to use all the data without exclusion of any data elements.

PRM52

SOCIOECONOMIC PATTERNS AMONG INTERNATIONAL IMMIGRANTS IN CHILE: THE USE OF CLUSTERS

Cabieses B, Tunstall H, Pickett K, Espinoza M
University of York, York, Yorkshire, England

OBJECTIVES: International immigration to Chile has increased in the past decade. Preliminary analysis found the immigrants were a very heterogeneous and polarized group in their SES which makes it difficult to identify particular needs of vulnerable subgroups within the total immigrant population. This analysis aims to describe their SES patterns. **METHODS:** Cross-sectional Chilean survey (CASEN-2006). From 268,873 participants, one percent were immigrants (n=1.877). Cluster analysis identifies subsets of a data set that contain similar points. Replacing these subsets by their aggregate properties, it creates a compact representation of the data set as a group of clusters. Hierarchical clustering is a step-wise process that merges the two closest or furthest data points or groups of data points at each step. Among the different types of hierarchical cluster analyses available, complete-linkage method was chosen as it creates clusters from the most distant values of the selected attributes (income, education and employment-status). Each SES-cluster was analysed in its demographic (age/sex/marital-status), geographical (urban-rural/region), SES variables (income/education/occupation), material-standards (overcrowding/sanitary-conditions/housing-quality). Analysis in STATA 10.0. **RESULTS:** After conducting complete-linkage hierarchical cluster analysis, three groups were identified: High-SES (n=398), Medium-SES (n=889), Low-SES (n=587). Key patterns are: High-SES: mean 35 years-old, 90% of working age, most married, technical or university level, only 2.7% with ethnic background. Medium-SES: mean 33 years-old, >60% technical education, mixed cluster. Low-SES: mean 25 years-old, >60% women, 8% ethnic background, up to high-school only, 2 poorest income quintiles. **CONCLUSIONS:** Immigrants in Chile are a very heterogeneous group, polarized by their SES. Hierarchical cluster analysis provided an appropriate method to group immigrants according to their socio-economic characteristics and, consequently, to provide clear patterns of SES vulnerability within the total immigrant population. Immigrants living in the Low-SES cluster are a vulnerable group that needs further attention in Chile.

PRM53

COMPARING MULTIPLE PROPENSITY SCORE ADJUSTMENT AND TRADITIONAL REGRESSION ANALYSIS TO ASSESS THE EXPOSURE-OUTCOME ASSOCIATION USING RETROSPECTIVE CLAIMS DATA

Chatterjee S, Aparasu RR, Chen H, Johnson M
University of Houston, Houston, TX, USA

OBJECTIVES: Researchers have suggested that, propensity score (PS) adjustment provides similar results as traditional regression analysis in observational studies. This has been attributed to the inappropriate implementation of PS, like inclusion of both PS and baseline covariates, and absence of covariate balance verification after PS adjustment. The present study employed a multiple PS adjustment model to evaluate the risk of falls/fractures in older adults using atypical antipsychotics, performed a balance check of covariates after PS adjustment and compared the results from multiple PS analysis with traditional regression model. **METHODS:** The study used IMS LifeLink Health Plan Claims Database and included older adults (aged ≥ 50 years) who initiated risperidone, olanzapine or quetiapine anytime during July 1, 2000 to June 30, 2008. Patients were followed until hospitalization/emergency room (ER) visit for falls/fractures, or end of the study period, whichever occurred earlier. Cox proportional hazard regression model was used to evaluate the relative risk of falls/fractures. The traditional model included over 80 baseline covariates which were also used to calculate the PS. The PS model included the two PS and their interaction terms. The covariate balance after PS adjustment was checked using logistic regression. **RESULTS:** After PS adjustment, there was no difference in any of the baseline covariates among the treatment groups. Both traditional regression and PS analyses had similar findings. There was no statistically significant difference with use of risperidone (Traditional: Hazard Ratio, HR, 1.10, 95% CI, 0.86-1.39; PS: HR, 1.09, 0.86-1.38) or quetiapine (Traditional: HR, 1.10, 0.84-1.44; PS: HR, 1.12, 0.86-1.46) compared to olanzapine in the risk of falls/fractures. **CONCLUSIONS:** The study findings suggest that, a PS adjustment model with well-balanced covariates across treatment groups gives similar results as traditional regression model.

PRM54

MODEL AND COVARIATE VISUALIZATION AIDS FOR ENHANCING THE INTERPRETATION OF STEPS IN THE HIGH DIMENSIONAL PROPENSITY SCORING ADJUSTMENT PROCEDURE

Juneau P[1], Huse DM[2]
[1]*Thomson Reuters Healthcare, Boyds, MD, USA,* [2]*Thomson Reuters, Cambridge, MA, USA*

OBJECTIVES: Currently, the work of Schneeweiss, et al. (2009) for propensity score adjustment is considered the standard approach for accounting for confounding in large claims data sets and is endorsed by such bodies as the Observational Medical Outcomes Partnership (OMOP) in the United States. The procedure appears to perform well and has many attractive features for the practitioner; however, examination of the selection of a set of potential effects for adjustment typically involves the perusal of large tables of summary statistics. For large data sets with potentially hundreds of covariates, this display does not afford the practitioner an easy, intuitive view of the relationships amongst the cofounders and with the desired outcome under study. **METHODS:** Modification of simple categorical data visualizations suggested by Cleveland (1993), Keller and Keller (1993), Harris (1999), Friendly (2001) and others were developed in common statistical software packages (e.g. SAS). **RESULTS:** The individual and joint behavior of the contribution of various confounders could be identified quickly and enhanced the user's understanding of their role in the procedure. **CONCLUSIONS:** In a setting with a large number of confounders, the procedure suggested by Schneeweiss, et al. reduces the number of confounders to a more manageable and practical level. Graphical techniques help the practitioner achieve a better understanding of the role of these confounders and the rationale for their inclusion in the adjustment procedure.

Research On Methods – Conceptual Papers

PRM55

A NEW APPROACH TO MODELING CANCER RECURRENCE AND FOLLOW-UP

Rose J[1], Augestad KM[2], Cooper G[1], Meropol NJ[1]
[1]*University Hospitals Case Medical Center, Cleveland, OH, USA,* [2]*University Hospital North Norway, Tromsoe, Norway*

OBJECTIVES: The ability to model cancer recurrence could assist in the optimization of surveillance strategies. However, capturing the dynamics of cancer recurrence in order to simulate follow-up surveillance after initial extirpative surgery presents a significant methodological challenge. The difficulty of modeling recurrence patterns is that relevant experimental and observational data is collected in the context of heterogeneous protocols for follow-up. Using the example of colorectal cancer, we propose a method of controlling for choice of follow-up regimen in order to infer the value of key natural history parameters. Once these values are inferred, any hypothetical follow-up regimen can be superimposed upon the nat-

ural history model to project clinical and/or economic outcomes. **METHODS:** The subset of stage I-III colon cancer patients who will experience recurrence face a constant rate rd of transition from undetectable to theoretically detectable recurrence during a given interval. These same patients face a constant rate ru of transition from resectable (i.e. potentially curable) to unresectable metastatic disease with a minimum interval xdu between the point of detectability and the point of unresectability. A third constant rate parameter rs will determine when, on average, individuals develop recurrence-related symptoms prompting them to seek medical advice before the next scheduled evaluation. The mean point of symptom development will follow the point at which a recurrence becomes detectable by a span of at least xds. However, a normally distributed error term Eds will mean that, for a given simulated patient, symptoms may initiate before or after the patient reaches unresectability. **RESULTS:** A best-fitting set of these natural history parameters can be selected by calibrating to targets of time-to-detection of recurrence, time-to-death, and proportion of patients who present with recurrence-related symptoms prior to scheduled assessments. **CONCLUSIONS:** The data sources for these targets can be existing experimental, observational, or registry data where follow-up schedule and compliance levels are known.

PRM56

DIFFERENTIAL DISCOUNTING: QUESTIONING THE ASSUMPTION OF HEALTHCARE RESOURCE FUNGIBILITY OVER TIME

O'Mahony J
Erasmus University Medical Center, Rotterdam, AL, The Netherlands

OBJECTIVES: Recent work on differential discounting of cost and health effects has reached a degree of consensus in a previously strongly divided debate. Put simply, it holds that the discount rate applied to health effects should equal the discount rate for costs, less the growth rate of either the cost-effectiveness threshold or the consumption value of health, depending on the objectives of the health system. Assuming positive growth in the threshold or the value of health, this implies the cost-effectiveness of preventative interventions improves relative to the situation under equal discounting. **METHODS:** We show how recent analyses of differential discounting implicitly assume healthcare funds to be completely fungible over time. This assumption is difficult to justify in the context of publically funded healthcare systems that exhaust budgets annually. Assuming funds are not fungible results in alternative differential discount rates: in this case, the discount rate on costs should be adjusted upwards by either the growth rate of the threshold or the consumption value of health. **RESULTS:** Under these discount rates, interventions that impose costs in future periods become more cost-effective relative to the situation under equal discounting, rather than those which yield health gains in the future. Indeed, the cost-effectiveness of preventative interventions that reduce future healthcare costs will deteriorate under such alternative differential discounting. Consequently, interventions' cost-effectiveness may differ greatly between the two differential discounting schemes. CONCLUSION: Cost-effectiveness estimates can be highly sensitive to discounting; therefore the theory underpinning discount rates needs to be robust. This analysis shows that the current understanding of differential discounting needs to be re-examined. CEA authorities in countries currently employing differential discounting such as Belgium and The Netherlands and those contemplating it such as England and Wales should consider these issues carefully.

PRM57

REVISITING HPV VACCINATION: WHY EXISTING CEAS UNDERESTIMATE THE VACCINE'S COST-EFFECTIVENESS AND INCORRECTLY ESTIMATE ITS THRESHOLD PRICE

O'Mahony J
Erasmus University Medical Center, Rotterdam, The Netherlands

OBJECTIVES: Existing cost-effectiveness analyses (CEAs) of Human Papillomavirus (HPV) vaccination assume cervical screening remains unchanged. However, current screening intensities are unlikely to be cost-effective due to the likely reduction in disease incidence in vaccinated women. Therefore, reductions in screening intensity are probable. The cost-effectiveness attributable to vaccination varies with screening intensity. The assumption of unaltered screening leads to an underestimation of vaccine cost-effectiveness relative to when screening intensity is reduced. Furthermore, failure to consider other screening intensities yields an incomplete efficient frontier in the cost-effectiveness plane. This can lead to an incorrect estimate of the price at which vaccination becomes marginally cost-effective for a given cost-effectiveness threshold. **METHODS:** We review cost-effectiveness estimates for a wide range of screening only and vaccination plus screening strategies from a model used to estimate vaccine cost-effectiveness in the The Netherlands. We indicate what comparison was used to estimate vaccine cost-effectiveness in previous studies, show what comparisons would be more appropriate and explain how these differ. **RESULTS:** We then show why the cost-effectiveness of adding vaccination to a given screening strategy is not the appropriate basis to determine if the vaccine is cost-effective or the threshold price. Rather, both should be determined by the ICER between the most costly efficient screening only strategy and the least costly vaccination plus screening strategy, even where this least costly vaccination plus screening strategy is not the optimal strategy for a given threshold. **CONCLUSIONS:** CEAs of HPV vaccination may no longer be policy or research priorities following widespread reimbursement and precipitous price reductions. However, the methodological issues raised here are pertinent to both any future CEA of an enhanced vaccine with protection against more HPV types and more generally to cases in which the cost-effectiveness of complementary interventions are not independent.

PRM58

METHODOLOGICAL REVIEWS OF ECONOMIC EVALUATIONS IN HEALTH CARE: ARE THEY USEFUL?

Hutter MF, Antonanzas F
University of La Rioja, Logrono, La Rioja, Spain

INTRODUCTION AND OBJECTIVES: The increasing amount of economic evaluations in health technologies published during the last decades have generated the concern about their methodological features. The aim of this study is, firstly, to explore methodological reviews and to detect their main research topics and, secondly, to appraise their usefulness for economic evaluation practice. **METHODS:** We performed systematic searches in electronic databases (Scopus, Medline and Pubmed) of methodological reviews published in English, period 1990- 2010. We selected those articles whose main purpose was to review and assess the applied methodology. Then we classified data according to study objectives, period of the review, number of reviewed studies, methodological items assessed and their main conclusions. Additionally, we checked how generalizability issues were considered in the reviews. **RESULTS:** A total of 58 methodological reviews were identified, 42 were published during the period 1990 - 2001 and 16 during 2002-10. Items most frequently assessed (by 70% of the reviews) were: perspective, uncertainty and discounting. The type of intervention and disease, funding sources, country in which the evaluation took place, type of journal and author's characteristics were also described in the literature. Generalizability issues were only checked in 14 studies, mainly by those published after 2000. **CONCLUSIONS:** there is an increasing activity of reviewing economic evaluation studies aiming to analyse the application of methodological principles and to offer summaries of papers classified by either diseases or health technologies. These reviews are useful to detect literature trends, targets of the studies and possible deficiencies in the implementation of the methods to specific health interventions.

PRM59

ESTIMATING THE CONFIDENCE INTERVAL FOR THE COST-EFFECTIVENESS RATIO FROM A FAMILY OF REGRESSIONS ON NET MONETARY BENEFIT

Gagnon DD
Thomson Reuters, Santa Barbara, CA, USA

OBJECTIVES: To demonstrate a novel way of deriving the incremental cost-effectiveness ratio (ICER) and associated 95% confidence interval (CI) from the cost-effectiveness acceptability curve (CEAC) generated from a family of regressions on net monetary benefit (NMB). **METHODS:** Definitions and mathematical properties of the ICER, NMB, and CEAC are explored to construct a technique for deriving 95% CIs around the ICER estimated from the CEAC. **RESULTS:** CEA uses the ICER, a measure with statistical issues that preclude easy derivation of confidence intervals. NMB is defined for any willingness-to-pay (WTP) value as: NMB = (effectiveness X WTP) – cost. Because NMB is statistically well-behaved, regression analysis can estimate incremental net monetary benefit (INMB) as the parameter estimate associated with treatment. INMB = (delta effectiveness X WTP) – delta cost. The CEAC is generated from a family of these regressions where the unique members of the family are identified by unique levels of WTP used to calculate NMB. The ICER is the point on the CEAC where the probability of being cost-effective is 50%, because at that point INMB is zero and WTP equals delta cost/delta effectiveness; i.e., the ICER. That point on the CEAC can be identified numerically by simultaneously solving the two equations for INMB from the two regressions that flank estimated INMB of zero. Knowing estimated INMB and the WTP we have two equations and two unknowns, and we solve for delta effectiveness and delta cost. We use a similar procedure on the 95% confidence intervals for two estimated INMBs to find the 95% CI for the ICER. **CONCLUSIONS:** In the case where we estimate the ICER from a family of regressions on NMB to construct the CEAC we can also find the 95% CI of the ICER.

PRM60

ASSESSING RELATIVE CLINICAL VALUE ACROSS TUMOR TYPES IN METASTATIC DISEASE

Karweit J[1], Nanavati S[1], Van Baardewijk M[2], Wagner S[3], Kotapati S[4]
[1]*IMS Consulting Group, New York, NY, USA,* [2]*Bristol-Myers Squibb, Braine L'Alleud, Belgium,* [3]*Bristol-Myers Squibb, Princeton, NJ, USA,* [4]*Bristol-Myers Squibb, Wallingford, CT, USA*

OBJECTIVES: In the absence of increasing budgets, new therapies and resource constraints have necessitated value trade-offs across tumor types and products. Traditional metrics such as median overall survival (OS) may not fully demonstrate the value of individual products in these comparisons. To highlight this, we assessed the value of different innovative cancer drugs relative to their clinical trial comparator using a variety of OS metrics. **METHODS:** We selected novel oncology products used in the treatment of metastatic disease with documented overall survival benefit over comparator at the time of launch. The selected products were: bevacizumab (colorectal cancer, non squamous non-small cell lung cancer), sunitinib (renal cell carcinoma), sorafenib (hepatocellular carcinoma), lenalidomide (multiple myeloma), ipilimumab (melanoma), trastuzumab (breast cancer). Key survival metrics including median OS, mean OS, and landmark survival rates from each analogue's pivotal trials were used to assess the relative value of each analogue. **RESULTS:** The relative value for each analogue differs depending on the survival metric used, suggesting that median OS does not fully capture the value of oncology agents. For example, lenalidomide's relative value is the highest in terms of median OS improvement; however its relative value is diminished when looking at mean OS. Ipilimumab, conversely, shows the highest value in terms of mean OS (attributing benefit to a proportion of patients achieving prolonged survival benefit). Furthermore, sorafenib (HCC) and ipilimumab (melanoma) demonstrate the highest relative value when evaluating 1 year survival improvement.

CONCLUSIONS: This exploratory analysis suggests that use of a broader range of metrics to assess and benchmark value across tumor types may be needed to appropriately inform decision-makers looking to maximize clinical benefit to patients while managing constrained resources.

PRM61

SAMPLE SIZE ESTIMATION FOR PROSPECTIVE OBSERVATIONAL STUDIES

Cox TA[1], Gemmen E[1], Nixon M[2], Doyle J[3], Burgess AJ[2], Jo H[1], Kamble S[1]
[1]*Quintiles, Rockville, MD, USA,* [2]*Quintiles, Bracknell, Berkshire, UK,* [3]*Quintiles, Hawthorne, NY, USA*

OBJECTIVES: Unlike randomized clinical trials (RCTs), prospective observational studies typically address objectives rather than test specific hypotheses. Nevertheless, a minimum sample size is required to allow for adequate exploration of the objectives, and estimation of sample size is an important part of the planning process for these studies. Sample size estimation for observational studies is more complex than sample size calculation for RCTs; subgroup analyses and modeling are to be expected in observational studies, and these analysis methods may require more assumptions and larger sample sizes. At the same time, sample sizes must not be so large as to raise concern that the study includes an unnecessarily high number of sites and patients. This is particularly true for product registries where a specific product is being observed. **METHODS:** This poster will provide examples/case studies of sample size estimations performed for a variety of prospective observational studies and objectives. These case studies will focus on the following **METHODS:** 1) Incorporation of planned propensity score matching to support comparisons of cohorts or subgroups; 2) Investigation of factors that influence outcomes within subgroups; 3) Estimation expressed as number of person-years rather than persons; and 4) Re-estimation of sample size based on interim results. RESULTS AND **CONCLUSIONS:** These methods illustrate the difference between sample size estimation in prospective observational studies and sample size calculation in randomized clinical trials.

PRM62

THE IMPACT OF CENTRE SELECTION ON THE GENERALISABILITY OF ECONOMIC EVALUATION RESULTS FROM MULTI-CENTRE RANDOMISED CONTROLLED TRIALS

Gheorghe A, Roberts TE, Calvert M, Wilson S
University of Birmingham, Birmingham, UK

OBJECTIVES: Economic evaluation (EE) estimates for individual centres in multi-centre randomized controlled trials (RCTs) can differ significantly from the trial-wide result. The existing methods addressing the generalisability of EE results from RCTs (e.g. bivariate hierarchical modelling) assume that the recruiting centres are representative for their jurisdictions, but this assumption has not been generally verified. No explicit method of selecting centres and their recommended sample sizes has been described, despite having been suggested in the literature. **METHODS:** The working hypothesis is that transparent centre selection is a crucial step in assessing the generalisability of EE results from RCTs. Two questions arise: 1) What criteria underpin the current practice of selecting centres for RCT-based EEs? and 2) Can a valid quantitative algorithm be formulated to assist the centre selection process at the trial design stage? **RESULTS:** First, the use of modelling-based methods addressing generalisability has to be supported by evidence that centres are representative for the jurisdiction under scrutiny. There is, thus, a need to assess the current practice of selecting centres for RCT-based EEs. Second, a quantitative methodology for purposively selecting centres for RCTs coupled with EEs has to be devised in order to underpin an objective centre selection process. The proposed operational measure is a generalisability index (GIx) which aggregates relevant generic and intervention-specific covariates and can be formulated at both jurisdiction and centre-level. The GIx can be validated against centre-level cost-effectiveness estimates. **CONCLUSIONS:** A successfully validated GIx will provide evidence towards the legitimate use of existing generalisability techniques. The GIx will allow an objective generalisability assessment for centres that did not participate in the RCT. Describing the rationale for centre selection must become a standalone item in reporting checklists for RCTs and EEs. Furthermore, such a methodology will bridge policy and research by correlating jurisdictional interests with RCT design.

PRM63

MULTIPLE CHOICES - HOW TO MAKE RATIONAL DECISIONS ACROSS SEVERAL INTERVENTIONS WHEN FACED WITH DIFFERENT OUTCOMES AND PERSPECTIVES?

Topachevskyi O[1], Emerson R[2], Standaert B[1]
[1]*GlaxoSmithKline Biologicals, Wavre, Belgium,* [2]*Emerson Consulting, Tervuren, Belgium*

OBJECTIVES: In any assessment to facilitate decision making to allocate limited funding across multiple innovations, the relative value of clinical outcomes or cost containment depends upon preferences. In the case of allocating funds across a portfolio of interventions, one could maximise cases-, hospitalizations-, or deaths-avoided; and/or minimize costs from a health care payer or societal perspective. The optimal mix of innovations to reach the preferred target can be investigated by applying operational research modelling. However, a composite outcome is required in order to maximise multiple endpoints consecutively depending upon preferences for different endpoints. **METHODS:** An optimization model was developed in Microsoft Excel® using the solver function to evaluate the optimal mix of vaccines to implement within a portfolio, in order to avoid specific clinical outcomes (GP-visits, hospitalisations, deaths) or maximise QALYs gained within specific constraints including budget. A composite endpoint was developed to take into account different endpoints, clinical and cost, weighted according to preferences defined by the assessor. The composite endpoint was used as the objective function. **RESULTS:** Depending upon the preference weights defined when determining the composite endpoint, the allocation of resources across a portfolio of several vaccines resulted in different recommendations. If deaths-avoided was weighted highest then the model would optimize on elderly influenza vaccination, adolescent HPV and infant pneumococcal vaccines. If cases-avoided was the highest preference then varicella, rotavirus and pertussis vaccines were recommended. If cost-offsets from a payer perspective were maximised then the recommendation would be to first implement adolescent HPV, elderly influenza and rotavirus vaccination. The combination of preferences to avoid mortality and/or morbidity and/or maximize cost offsets resulted in the recommendation to implement different vaccines from the portfolio. **CONCLUSIONS:** The use of a composite measure and operational research modelling provides a tool to facilitate resource allocation across a portfolio of interventions depending upon decision-maker preferences.

PRM64

THE ROLE OF THE INSTRUMENT DEVELOPER IN THE TRANSLATION OF PATIENT REPORTED OUTCOME MEASURES

Clayson D, Verjee-Lorenz A, Miller F, Two R
PharmaQuest Ltd, Banbury, Oxfordshire, UK

OBJECTIVES: Developers of patient reported outcome (PRO) measures are often involved in the translation of their measures into other languages, and they provide valuable guidance by reviewing concept elaboration and back translation review documents and participating in harmonisation meetings. **METHODS:** However, many of the translation problems that they help resolve are due to difficulties in translating concepts in the measure that are either culturally bound or idiomatic to the source language, and these are features that might be addressed more effectively at an earlier stage. **RESULTS:** The developer can have a positive impact on future translations right from the onset by considering the 'translatability' of concepts when they are developing their conceptual model and generating their item pool, thereby aiming to create a measure which can be translated more accurately. **CONCLUSIONS:** We will examine common linguistic and cultural features which may make measures difficult to translate, and how developers can avoid these to help create global PRO measures that can be applied to all cultures and be administered in global clinical trials and health research.

PRM65

SHOULD WE AGGREGATE COST-EFFECTIVENESS OVER AN INTERVENTION'S ENTIRE IMPLEMENTATION LIFETIME?

O'Mahony J
Erasmus University Medical Center, Rotterdam, The Netherlands

OBJECTIVES: Recent work has suggested that interventions' cost-effectiveness should be assessed over their entire lifetime of implementation, not just over the period of use for a single cohort as typically modelled (Hoyle and Anderson, Medical Decision Making, 2010; Hoyle, PharmacoEconomics, 2011). Such lifetime modelling can capture changes in costs and effects over time. These changes in costs and effects can result from price changes, disease dynamics or the application of differential discounting of costs and health effects. **METHODS:** Suggesting cost-effectiveness be assessed over an intervention's complete lifetime carries assumptions regarding the nature of the decision problem in healthcare resource allocation. In particular, it suggests resources be allocated on the basis of the total cost-effectiveness over all periods in which it is implemented. This lifetime perspective can conflict with the alternative perspective that resources be allocated on the basis of relative cost-effectiveness within each given period. We discuss a number of simple theoretical examples in which the rank ordering of cost-effectiveness of two interventions is different under the two perspectives. The examples include when the prices of interventions trend and have different expected lifetimes, when differential discounting is applied in certain circumstances, or simply when the price of only one intervention falls following patent expiry. **RESULTS:** These examples prompt us to consider which perspective is more appropriate. We argue that as health care resource allocation is an ongoing, repeated resource allocation problem, not one over a finite horizon, that the lifetime perspective is not appropriate. CONCLUSION: Advances in decision analytic modelling need to carefully reflect the actual nature of policy choices. The per-period perspective appears more appropriate to healthcare resource allocation problems than the total implementation lifetime perspective. However, the actual resource allocation process is likely to more complex than either perspective alone might suggest.

PRM66

COMPARISON OF RECONCILIATION AND REVIEW METHODOLOGIES FOR THE TRANSLATION OF PATIENT REPORTED OUTCOME (PRO) MEASURES

Verjee-Lorenz A, Two R, Clayson D, Miller F
PharmaQuest Ltd, Banbury, Oxfordshire, UK **Objective:** *The translation of patient reported outcome (PRO) measures typically involves two key stages where the translation is created and refined.*

METHODS: The first is the reconciliation of two independent translations by an in-country investigator (a lead translator). The second is the back translation review - the reconciled translation is translated back into English and the project manager reviews the English translation(s) against the source text, then the translation is refined through discussion between the project manager and the investigator. Both stages are conducted via email, and the back translation review report is usually reviewed by the instrument developer once all issues have been addressed. We will present an alternative methodology whereby the reconciliation and back translation review are conducted through live conversations (in teleconferences or otherwise) involving forward translators and the instrument developer. **RESULTS:** We will compare these two processes in terms of the types of discussion

and communication they enable. We will also look at the practicalities of each method, and their relative merits and drawbacks and how these can be addressed to maximise their usefulness in refining and improving the translation. **CONCLUSIONS:** We will argue that both methods are beneficial in particular circumstances, and will explore the situations in which each one would be the most appropriate.

PRM67

WHAT EPRO MODALITY IS APPROPRIATE FOR YOUR STUDY?

O'Gorman HJ[1], Ross J[2], Peck R[2], Ross E[2]
[1]*Almac Group, Craigavon, UK,* [2]*Almac Clinical Technologies, Souderton, PA, USA*

OBJECTIVES: To help clarify which ePRO modality (IVR, IWR, Handheld) is appropriate for specific studies through providing three examples of diary requirements and appropriate modalities. Emphasize making this decision early in the planning process. **METHODS:** Examples for three scenarios requiring patients to record their PRO data electronically were drawn up based on experience to illustrate how making appropriate modality choices can minimize patient burden and reduce costs. Scenario One - 10,000 patient global vaccine study. Scenario Two – 500 patient global study, daily diary having 40 questions with more than 5 response options. Scenario Three – 50 GI patients to record their PRO data episodically using a VAS scale daily for over a year. **RESULTS:** Scenario One – Appropriate Choice = IVR: It is expensive and logistically challenging for Sponsors to deploy 10,000 PDAs. Using the IVR global network in place would reduce cost and logistics for the Sponsor and sites. Scenario Two – Appropriate Choice = IWR: When patients are provided more than 5 response options in a lengthy questionnaire, an IWR would be better since response options are visual. IWR would be better than PDA given the sample size and logistics. Scenario Three- Appropriate Choice = PDA: A PDA would be most convenient for the patient since they are providing data daily for over a year. PDA is best for VAS scales since the size of the screen can be controlled. **CONCLUSIONS:** There is overlap in deciding which ePRO modality to use for a particular clinical study. It is critical to decide on the modality early when assembling the protocol, so all points can be considered. Looking at the diary requirements (frequency, length, access) for the study will help the Sponsor to decide which modality is best. Reducing patient and site burden will allow for greater compliance.

PRM68

OUTCOME MEASURES HIERARCHY FOR ATTENTION-DEFICIT HYPERACTIVITY DISORDER

Hormaechea-Beldarrain JA[1], Prieto L[2]
[1]*Hospital Quiron Bizkaia, Erandio, Spain,* [2]*London School of Hygiene and Tropical Medicine, London, UK*

OBJECTIVES: Attaining good patient health outcomes is the underlying purpose of any health care intervention, including drug therapy. **METHODS:** The outcome measure is the basis for evaluating the quality of health services, and a key element in determining the value of health interventions since the value of health care is defined as outcomes relative to cost. According to Porter (2010), value improvement starts with defining and measuring the total set of outcomes for a medical condition and determining the major risk factors. Porter has provided a challenging framework for identifying the full set of outcomes for any medical condition: the outcome measures hierarchy (OMH). **RESULTS:** According to the OMH the full set of outcomes for any medical condition, and its treatment, can be conveyed in a three-tiered hierarchy. Each tier of the hierarchy contains two broad levels, each of which involves one or more distinct outcome dimensions. Each medical condition should have its own outcome measures. Measurement efforts should begin with at least one outcome dimension at each tier, and ideally at each level. Possible outcome dimensions for Attention-Deficit Hyperactivity Disorder (ADHD) are explored and discussed according to Porter's OMH. ADHD is a frequent neurobehavioral disorder that is characterised by inattention, hyperactivity and impulsivity. ADHD is associated with considerable social, family, behavioural and cognitive dysfunction, and is comorbid to depression, bipolar disorder, anxiety, and drug use. Specific dimensions proposed are aimed at capturing particular aspects of patients affected by ADHD. For each dimension, success is measured with several clinical and patient reported metrics. Tier 1 of the OMH is the patient's health status achieved or retained after a health intervention (clinical or drug therapy). **CONCLUSIONS:** Tier 2 regards the process of recovery and the eventual disutility of the treatment process. Tier 3 concerns the sustainability of health.

PRM69

MEASURING RELATIVE EFFECTIVENESS IN EUROPE: AS IN THE USA, HERE TOO, IT IS TIME TO TURN THE QALY PAGE

Prieto L
European Medicines Agency, London, UK

OBJECTIVES: The recently enacted Patient Protection and Affordable Care Act in the United States of America (USA) has created a Patient-Centered Outcomes Research Institute to conduct comparative effectiveness research, but has prohibited this institute from developing or using cost-per-QALY thresholds. **METHODS:** In reaction to this new legislation some authors, from both continents, have insisted that QALYs provide a convenient yardstick for measuring and comparing health outcomes of varied interventions across diverse diseases and conditions. Such arguments in defense of QALYs are erroneous. While it is true that QALYs are internationally recognized as the standard metric of the value of health outcomes, this acknowledgement is, unfortunately, not deserved. **RESULTS:** The problem lies in the QALY calculation (i.e. Utility x Time). While Time is expressed in a ratio scale with a non-arbitrary zero value, Utility is defined as an interval scale with an arbitrary zero point (i.e. death). Permissible arithmetic operations on interval scales are limited: addition and subtraction are allowed, but multiplication and division are not permitted because the absence of an absolute zero. Consequently, the resulting QALY values are not expressed in the same units as the Time scale, preventing any meaningful conclusion on its application to comparative clinical effectiveness research. **CONCLUSIONS:** Although we do not know the exact reasons why the Patient Protection and Affordable Care Act bans the use of cost per QALY in the USA, the initiative should be celebrated, not criticized, and certainly copied in Europe as well.

Cancer – Clinical Outcomes Studies

PCN1

BURDEN OF HOSPITALIZATION IN PATIENTS WITH ADVANCED LUNG CANCER IN FRANCE AND GERMANY

Lobosco S[1], Taylor-Stokes G[1], Iyer S[2]
[1]*Adelphi Real World, Cheshire, UK,* [2]*Pfizer, New York, NY, USA*

OBJECTIVES: To assess the burden of hospitalization in advanced lung cancer patients in France and Germany. **METHODS:** Oncologists (N=80) and pulmonologists (N=40) actively involved in management of Non small cell lung cancer (NSCLC) in France and Germany were invited to participate in a lung cancer disease specific program. Each consenting physician was asked to complete patient record forms for the next 10 advanced (stage IIIB/IV) lung cancer patients seen in their practice. The study period extended from July to October 2010. Data on hospitalization over the past year was provided by the physicians using the patient chart records. The primary reason of hospitalization and the length of stay (LOS) were reported. **RESULTS:** Majority of the patients (N=1213) were male (68%), Caucasian (92%), Stage IV (89%), currently on first line therapy (51%) with an average age of 63 years. Hospitalization records were obtained for 93% (n=1133) of the patients among which 30% (n=341) of the patients had one or more hospitalization events in the previous year with an average (SD) LOS of 10 (8) days. The primary cause reported for the 449 hospitalization events were disease symptoms (44%), surgery (20%) and therapy side effects (17%). The LOS for surgery related hospitalization (n=89) ranged from 1-20 days (mean: 8 days). Among patients hospitalized for disease symptoms (n=197) the most frequently reported primary causes were dyspnea (23%), cough (10%) and pain (11%) with average LOS of 13, 12 and 8 days respectively. Among patients hospitalized for side effects (n=75), anemia (24%), febrile neutropenia (8%), febrile aplasia (8%) were most frequently reported with average LOS of 4 days. **CONCLUSIONS:** Burden of hospitalization due to disease symptoms and treatment related side effects is significant in France and Germany. Innovative therapies effective in alleviation of symptoms and side effects could help significantly in decreasing hospitalization costs.

PCN2

A RETROSPECTIVE LONGITUDINAL STUDY OF TREATMENT PATTERNS AND OUTCOMES AMONG PATIENTS WITH UNRESECTABLE STAGE IIIC/IV MELANOMA IN CANADA (MELODY)

Osenenko K[1], Szabo SM[1], Schultz M[2], Mihalcioiu C[3], Lane S[1], Levy AR[1]
[1]*Oxford Outcomes Ltd., Vancouver, BC, Canada,* [2]*Bristol-Myers Squibb Canada, Montreal, QC, Canada,* [3]*McGill University, Montreal, QC, Canada*

OBJECTIVES: Unresectable metastatic melanoma patients (stages IIIc/IV) have a poor prognosis. Recent improvements in survival have been attributed in part to earlier detection and investigational therapies, however melanoma is considered incurable if it becomes metastatic. No information about treatment patterns for unresectable melanoma in Canada has been published. Objectives of this study were to describe disease characteristics, treatment patterns, health outcomes, and resource utilization for Canadian unresectable melanoma patients treated outside randomized clinical trials [RCT]. **METHODS:** Charts of melanoma patients at seven Canadian centres were screened for eligibility. Unresectable melanoma charts then selected consecutively in reverse chronological order from January 2009 until target number (n=250) exceeded. Data on patient and disease characteristics, treatments (across three lines), adverse event management, health outcomes and resource utilization were then extracted from charts of patients with at least two months of follow-up, from diagnosis until censoring (June 2010 or death). **RESULTS:** Of 1426 melanoma patient charts reviewed, 262 (18%) were for unresectable melanoma patients, 16% (43/262) of which were first diagnosed in an advanced stage. Overall, 10% (26/262) participated in an RCT during the follow-up period and 60% (156/262) received systemic therapy outside an RCT. In the latter group, responsiveness to therapy was low; only 20% (26/132) on first-line and 16% (9/58) on second-line therapy experienced complete or partial response. On first-line therapy, 40% (53/132) experienced adverse events requiring medical management and 18% (24/132) were hospitalized during treatment; corresponding figures for second-line were 38% (22/58) and 24% (14/58) respectively. **CONCLUSIONS:** This study characterizes treatment patterns and provides quantitative estimates of resource utilization for unresectable melanoma patients across Canada. Extant systemic treatments are associated with poor response and considerable resource utilization. This study quantifies the grim prognosis faced by advanced melanoma patients in Canada receiving currently available treatments.

PCN3

CETUXIMAB FOR THE FIRST-LINE TREATMENT OF METASTATIC COLORECTAL CANCER

Ubago R[1], Castillo MA[1], Flores S[2], Rodriguez R[1], Beltran C[1]
[1]*Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, Seville, Andalucia, Spain,* [2]*Andalusian Agency for Health and Technology Assessment, Seville, Andalucia, Spain*

OBJECTIVES: To evaluate the efficacy and safety of cetuximab in combination with chemotherapy vs. chemotherapy alone for the first-line treatment of metastatic colorectal cancer (mCRC), in patients with KRAS wild-type tumours. **METHODS:**

Two systematic reviews of literature have been conducted. One focused on the efficacy, identifying health technology agencies reports, meta-analysis, systematic reviews, and randomized controlled trials (RCTs). The safety systematic review included the previous designs plus observational studies. In the latter review, studies in subsequent lines of treatment were considered. Searches were done in MEDLINE, EMBASE, CRD, and the Cochrane Library until the 8th of June. The quality assessment of the studies was done with the SIGN and CASPe tools. Two authors independently selected the studies, assessed the quality, and performed the data extraction, with disagreements resolved by a third reviewer until consensus was obtained. **RESULTS:** In the efficacy systematic review, three RCTs were included. The chemotherapy in one of these trials was FOLFIRI, in another trial FOLFOX-4, and in the other one was oxaliplatin and fluoropyrimidine chemotherapy. In the safety systematic review, five RCTs (3 studies in first-line, one study in second-line and another with cetuximab in monotherapy in subsequent lines), and an observational study were considered. Cetuximab in combination with FOLFIRI improved overall survival (OS), resection rate, progression free survival (PFS) and overall tumour response rate (RR). Whereas, an increase in terms of OS was not observed with cetuximab in combination with oxaliplatin based regimen, and different results were obtained in PFS. The only benefit observed with the later regimen was in the RR. In terms of safety, cetuximab increased grade 3 or 4 skin toxicity. **CONCLUSIONS:** The benefit of the addition of cetuximab to standard therapy for previously untreated mCRC, KRAS wild-type patients differs depending on the chemotherapy associated, with an improvement in all the outcomes when FOLFIRI is used.

PCN4

EFFECT OF ANTIEMETIC PROPHYLAXIS AGAINST CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING WITH 5-HT3 RECEPTOR ANTAGONISTS IN PATIENTS WITH LYMPHOMA

Lin SJ[1], Hatoum HT[2], Balu S[3]
[1]*University of Illinois at Chicago, College of Pharmacy, Chicago, IL, USA,* [2]*Hind T. Hatoum & Company, Chicago, IL, USA,* [3]*Eisai, Inc., Woodcliff Lake, NJ, USA*

OBJECTIVES: 5-hydroxytryptamine3 receptor antagonists (5-HT3 RAs) are used for prophylaxis of chemotherapy-induced nausea and vomiting (CINV). This study compared the risk of severe CINV associated with hospitalization or emergency room admission among patients with lymphoma initiated and maintained on palonosetron versus the other 5-HT3 RAs (granisetron, ondansetron, and dolasetron). **METHODS:** Adult patients diagnosed with lymphoma and treated with cyclophosphamide were selected from PharMetrics claims data (2005-2009). Other inclusion criteria were continuous patient enrollment for at least ≥6 months before the initial diagnosis and receipt of 5-HT3 RA for CINV prevention on the day of cyclophosphamide treatment (index date). CINV was identified by ICD-9-CM claims for nausea, vomiting, and/or dehydration. Risk of CINV during the follow-up period of 6 months from index date was assessed using multiple regression models, controlling for age, gender, Charlson Comorbidity Index (CCI), and total dose of cyclophosphamide. **RESULTS:** A total of 2609 patients were studied. Palonosetron patients (n=979; 37.5%) were older than the other 5-HT3 RAs (62.1 ± 13.6 vs. 59.0 ± 14.1 years, p<0.0001), with similar CCI and gender. During follow-up, palonosetron patients received more cyclophosphamide dose in significantly fewer CT days (+586 mg; p=0.0005 and -0.73 days, both p<0.0001), and had fewer patients experiencing unadjusted severe CINV (7.3% vs. 10.4%, p=0.007) as compared to the other 5-HT3 RA patients. Multiple regressions found that palonosetron group (versus the other 5-HT3 RA group) experienced fewer CINV claims (0.47 less; p=0.0253), fewer CINV days (48% less; p=0.0006), and a 34% lower severe CINV risk (Odds Ratio=0.66; p=0.006). **CONCLUSIONS:** Patients in palonosetron group received higher CT dose within fewer CT days and experienced significantly lower risk for potentially costly CINV events than patients on other 5-HT3-RA-based antiemetic prophylaxis. Further studies on the clinical and economic impact of the choice of 5-HT3-RA for CINV prophylaxis in patients with lymphoma are needed.

PCN5

REDUCED RISK OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING IN PATIENTS WITH CANCER TREATED WITH HIGHLY EMETOGENIC CHEMOTHERAPY AND ANTIEMETIC PROPHYLAXIS WITH PALONOSETRON

Schwartzberg L[1], Jackson J[2], Jain G[2], Balu S[3]
[1]*Accelerated Community Oncology Research Network, Memphis, TN, USA,* [2]*Xcenda, LLC., Palm Harbor, FL, USA,* [3]*Eisai, Inc., Woodcliff Lake, NJ, USA*

OBJECTIVES: Palonosetron, dolasetron, granisetron, and ondansetron [5-HT3 receptor antagonists (5-HT3-RAs)] are indicated to prevent chemotherapy-induced nausea and vomiting (CINV). This study assessed the risk of uncontrolled CINV following antiemetic prophylaxis with palonosetron + dexamethasone (group 1) versus any of the other 5-HT3-RAs + dexamethasone (group 2) among single-day HEC cycles in cancer diagnosed patients. **METHODS:** Single-day HEC cycles (a gap of at least 5 days between 2 administrations) among patients with a cancer diagnosis and initiating antiemetic prophylaxis with group 1 versus group 2 between June 1, 2006 to June 30, 2010 were identified from the IMS LifeLink claims database. Uncontrolled CINV events were defined as nausea, vomiting, or dehydration ICD-9-CM codes, hydration CPT codes, rescue medications, and/or use of antiemetic therapy from days 2-5 post-HEC administration. Risk for an uncontrolled CINV event was analyzed at cycle level using a logistic multivariate regression model controlling for key variables. **RESULTS:** A total of 67,873 group 1 and 26,540 group 2 cycles (17,272 and 7,365 patients, respectively) were analyzed. Groups 1 and 2 were similar in age [mean (sd): 55.0 (12.3) vs. 55.3 (12.6) years; p=0.1502], Charlson comorbidity score [6.2 (3.2) vs. 6.2 (3.2); p=0.7949], and female distribution (74.7% vs. 73.7%; p=0.0893). Versus group 2, group 1 patients had a higher percent of breast cancer (45.0% vs. 42.2%; p<0.0001) and a lower percent of lymph/hematologic malignancies (11.6% vs. 13.4%; p=0.0002). Group 1 cycles had a significantly lower unadjusted risk of an uncontrolled CINV event (14.1% vs. 15.4%; p<0.0001), while the regression analysis predicted a 10% lower risk for group 1 cycles [Odds Ratio: 0.90 (95% CI: 0.86 – 0.93); p<0.0001]. **CONCLUSIONS:** In this retrospective claims data analysis, patients with cancer receiving single-day HEC cycles and group 1 prophylaxis for CINV had a lower risk for an uncontrolled CINV event versus group 2 prophylaxis.

PCN6

IMPACT OF 5-HT3 RECEPTOR ANTAGONIST SELECTION WITHIN TRIPLE ANTIEMETIC REGIMENS ON THE RISK OF UNCONTROLLED CHEMOTHERAPY-INDUCED NAUSEA IN PATIENTS WITH CANCER TREATED WITH HIGHLY EMETOGENIC CHEMOTHERAPY

Schwartzberg L[1], Jackson J[2], Jain G[2], Balu S[3]
[1]*Accelerated Community Oncology Research Network, Memphis, TN, USA,* [2]*Xcenda, LLC., Palm Harbor, FL, USA,* [3]*Eisai, Inc., Woodcliff Lake, NJ, USA*

OBJECTIVES: Palonosetron, dolasetron, granisetron, and ondansetron [5-HT3 receptor antagonists (5-HT3-RAs)] are indicated to prevent chemotherapy-induced nausea and vomiting (CINV). This study assessed the risk of uncontrolled CINV following antiemetic prophylaxis with palonosetron + dexamethasone (group 1) versus any of the other 5-HT3-RAs + dexamethasone (group 2) among single-day HEC cycles in cancer diagnosed patients. **METHODS:** Single-day HEC cycles (a gap of at least 5 days between 2 administrations) among patients with a cancer diagnosis and initiating antiemetic prophylaxis with group 1 versus group 2 between June 1, 2006 to June 30, 2010 were identified from the IMS LifeLink claims database. Uncontrolled CINV events were defined as nausea, vomiting, or dehydration ICD-9-CM codes, hydration CPT codes, rescue medications, and/or use of antiemetic therapy from days 2-5 post-HEC administration. Risk for an uncontrolled CINV event was analyzed at cycle level using a logistic multivariate regression model controlling for key variables. **RESULTS:** A total of 67,873 group 1 and 26,540 group 2 cycles (17,272 and 7,365 patients, respectively) were analyzed. Groups 1 and 2 were similar in age [mean (sd): 55.0 (12.3) vs. 55.3 (12.6) years; p=0.1502], Charlson comorbidity score [6.2 (3.2) vs. 6.2 (3.2); p=0.7949], and female distribution (74.7% vs. 73.7%; p=0.0893). Versus group 2, group 1 patients had a higher percent of breast cancer (45.0% vs. 42.2%; p<0.0001) and a lower percent of lymph/hematologic malignancies (11.6% vs. 13.4%; p=0.0002). Group 1 cycles had a significantly lower unadjusted risk of an uncontrolled CINV event (14.1% vs. 15.4%; p<0.0001), while the regression analysis predicted a 10% lower risk for group 1 cycles [Odds Ratio: 0.90 (95% CI: 0.86 – 0.93); p<0.0001]. **CONCLUSIONS:** In this retrospective claims data analysis, patients with cancer receiving single-day HEC cycles and group 1 prophylaxis for CINV had a lower risk for an uncontrolled CINV event versus group 2 prophylaxis.

PCN7

THE INCIDENCE AND OUTCOME OF FEBRILE NEUTROPENIA IN DIFFERENT CHEMOTHERAPY REGIMENS FOR CANCER PATIENTS IN BELGIUM

Chevalier P[1], Lamotte M[2], Malfait M[3], Marciniak A[4]
[1]*IMS Health, Vilvoorde, Belgium,* [2]*IMS Consulting Group, Vilvoorde, Belgium,* [3]*AmGen sa/nv, Brussels, Belgium,* [4]*Amgen Ltd, Uxbridge, UK*

OBJECTIVES: The incidence of febrile neutropenia (FN) depends on the cancer type and the chemotherapy regimen used. In Belgium, reimbursement of granulocyte-colony stimulating factors (G-CSF) in primary prophylaxis against FN is limited to 4 indications. This study aimed to provide real-life information on the incidence and impact of FN in chemotherapy-cancer combinations excluded from G-CSF primary prophylaxis reimbursement. **METHODS:** Based on ICD-9 code and drug name all chemotherapy-cancer combinations with at least one patient having an ICD-9 code corresponding to neutropenia (288.0) and/or fever (780.6) and where G-CSF primary prophylaxis was not reimbursed, were retrieved from the IMS Hospital Disease database for the period 2005-2008. This database includes longitudinal (per calendar year) information on diagnoses and drugs prescribed in about 34% of all Belgian hospital beds. Incidence of FN (cases of FN with chemo-cancer combination divided by total number of patients with this chemo-cancer combination), mortality in patients with and without FN and impact of FN on subsequent chemotherapy treatment decisions were assessed. **RESULTS:** Among the 25,544 patients at risk, 3,191 (13%) had at least one FN episode. Highest incidence rates were found in combinations of cisplatin-containing regimens with head and neck (71/287, 25%), stomach (24/110, 22%) and esophagus (36/202, 18%) cancers, lung cancers treated with cisplatin-etoposide (52/292, 18%) or carboplatin-etoposide (102/659, 16%) regimen and multiple myeloma treated with doxorubicin-vincristine regimen (26/152, 17%). Overall, 50% of first FN episodes occurred during cycle 1. Of the 3191 FN patients 11% died, 24% switched chemotherapy regimen and 22% stopped treatment during the cycle with FN. FN occurred subsequently in 27% of 1367 patients continuing the same regimen. **CONCLUSIONS:** This study suggests clinically significant FN-incidence is associated with chemotherapy regimens where G-CSF primary prophylaxis is not reimbursed in Belgium, which may lead to negative outcomes in terms of mortality and treatment disruption.

PCN8

INCIDENCE, PREDICTIVE FACTORS, AND INFECTION COMPLICATIONS OF PROLONGED NEUTROPENIA IN R-CHOP/CHOP TREATED DIFFUSE LARGE B-CELL LYMPHOMA PATIENTS

Zhou KR[1], Kei KM[1], Ng HM[1], Wong RS[2]
[1]*The Chinese University of Hong Kong, Shatin, N.T., Hong Kong,* [2]*Prince of Wales Hospital, Shatin, N.T., Hong Kong*

OBJECTIVES: This is a retrospective cohort study examining the development of prolonged neutropenia as a result of the induction chemotherapy R-CHOP/CHOP in diffuse large B-cell lymphoma (DLBCL) patients. It aims to 1) identify the incidence and predictive factors of the prolonged neutropenia, and 2) evaluate the infection complications and clinical outcomes of prolonged neutropenia in this patient group. **METHODS:** Medical records of 43 DLBCL patients who received R-CHOP/CHOP induction treatment between the year 2000 and 2010 at Prince of Wales Hospital (PWH) were reviewed. Information including basic demographic information, disease-related characteristics, and laboratory values were recorded. Incidence of prolonged neutropenia, duration of neutropenic episodes, and infection complication and outcomes were also collected. Correlations between possible predictive/risk factors and the occurance of prolonged neutropenia were examined using univariate analysis and multivariate logistic regression analysis. **RESULTS:** Inpatient status (OR: 12.000, p-value = 0.006), Ann Arbor stage III or IV (OR: 3.886, p-value = 0.049) and International Prognostic Index (IPI) high risk group (OR: 5.257, p-value = 0.020) were identified as predictive factors of prolonged neutropenia. Prolonged neutropenia has been shown to cause significant longer duration of hospitalization, increased ICU admission, dose reduction and delay in chemotherapy or even early termination of treatment. The use of prophylactic G-CSF and/or antibiotics has also been shown to reduce the occurrence of prolonged neutropenia. **CONCLUSIONS:** Several predictive factors were demonstrated to have association with the occurrence of prolonged neutropenia in DLBCL patients after receiving R-CHOP/CHOP. Preventive measures, including prophylactic G-CSF and/or antibiotics, should be considered as part of the treatment for the patients at risk.

PCN9

ADVERSE EVENTS AMONG PATIENTS WITH METASTATIC COLORECTAL CANCER TREATED WITH MONOCLONAL ANTIBODIES IN CLINICAL PRACTICE

Emons MF[1], Dean B[1], Yu HT[1], Barber B[2], Malin J[3], Zhao Z[2]
[1]*Cerner LifeSciences, Beverly Hills, CA, USA,* [2]*Amgen, Inc., Thousand Oaks, CA, USA,* [3]*Greater Los Angeles Healthcare System and Jonsson Comprehensive Cancer Center at UCLA, Los Angeles, CA, USA*

OBJECTIVES: The monoclonal antibodies (mAbs) bevacizumab (Bmab), cetuximab (Cmab), and panitumumab (Pmab) have been indicated for the treatment of patients with metastatic colorectal cancer (mCRC). The objective of this study was to describe the incidence of adverse events (AEs) among patients with mCRC treated in clinical practice. **METHODS:** Medical chart review was conducted for patients treated at three US cancer centers from January 2004 to March 2009. Qualifying cases were adults with: a diagnosis of colorectal cancer AND evidence of metastasis AND receiving mAb therapy. AEs that were listed in mAb package inserts were examined in the medical records. Grade 3/4 AEs occurring during mAb treatment that were due to or possibly due to the mAb were identified. The Incidence of AEs is reported across all patients and with each specific mAb. **RESULTS:** Among 103 patients with mCRC, 54 experienced 139 AEs that met study criteria. The overall study sample was predominately Caucasian (99%), average age 57.6 years, 51.5% female, and located in the Northeast (28.2%) and Midwest (70.9%). The majority of patients (87%) were on chemotherapy. Grade 3/4 AEs that occurred with a frequency >5% were: rash (24%) (Bmab 11%, Cmab 33%, Pmab 25%), diarrhea (18%) (Bmab 14%, Cmab 17%, Pmab 15%), neutropenia (15%) (11% for Bmab and Cmab, 0% for Pmab), vomiting/nausea (9%) (Bmab 5%, Cmab 7%, Pmab 5%), infusion reaction (8%) (Bmab 3%, Cmab 13%, Pmab 0%), and venous thrombosis (7%) (8% for Bmab, 0% for Cmab and Pmab). **CONCLUSIONS:** In this study of patients treated in community practices, the incidences of AEs with mAb therapies in patients with mCRC had similar patterns as those reported in the individual FDA labels. The findings could be confounded by differences in time on therapy among mAbs. Additional research with larger sample sizes is needed to more thoroughly examine these AEs in clinical practice.

PCN10

COMORBID CARDIOVASCULAR DISEASES IN PATIENTS WITH METASTATIC COLORECTAL CANCER

Overbeek JA[1], Zhao Z[2], van Herk-Sukel MPP[1], Barber B[2], Gao SK[2], Herings RMC[3]
[1]*PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands,* [2]*Amgen, Inc., Thousand Oaks, CA, USA,* [3]*Erasmus Medical Centre, Rotterdam, Zuid-Holland, The Netherlands*

OBJECTIVES: Currently, data regarding the prevalence of cardiovascular comorbidities in patients with metastatic colorectal cancer (mCRC) are limited. This study determined the rate of comorbid cardiovascular diseases in patients with mCRC, as comorbidities may impact treatment decisions, prognoses, and quality of care. **METHODS:** From the PHARMO Record Linkage System (RLS), including among other things, drug dispensing and hospitalization records of approximately 3.2 million residents in the The Netherlands, all patients with a primary or secondary hospital discharge code for CRC and distant metastasis between 2000 and 2008 were selected and defined as patients with mCRC. The first discharge diagnosis defining metastases served as the index date. Prevalent cardiovascular comorbidities were assessed during the 12 months prior to the index date and patients were required to be registered in the PHARMO RLS during this period to be included in the study cohort. Cardiovascular comorbidities were captured using both cardiovascular drug use and hospital admission data. **RESULTS:** A total of 2,964 patients with mCRC were included in the analysis. Mean (± standard deviation) age at diagnosis was 68 (± 12) years and 53% were male. Overall, cardiovascular comorbidities were observed in 52% of the patients. Of all patients identified by drug use (n=1,479), the most commonly used agents were antithrombotic agents (54%), followed by beta blocking agents (46%), and agents acting on the renin-angiotensin system (45%). Of the patients who were hospitalized for cardiovascular comorbidities during the year prior to index date (n=297), about one-third was hospitalized for cardiac dysrhythmia (39%), followed by congestive heart failure (19%) and hypertension (18%). **CONCLUSIONS:** Cardiovascular comorbidities are commonly seen in patients with mCRC, which might be explained by the high mean age at diagnosis. Consideration of these conditions should be an integral part of the treatment strategy in individual patients with mCRC.

PCN11

BEVACIZUMAB IN COMBINATION WITH CHEMOTHERAPY FOR THE FIRST-LINE TREATMENT OF METASTATIC COLORECTAL CANCER

Ubago R[1], Castillo MA[1], Flores S[2], Beltrán C[1]
[1]*Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, Seville, Andalucia, Spain,* [2]*Andalusian Agency for Health and Technology Assessment, Seville, Andalucia, Spain*
Ubago R[1], Castillo MA[1], Flores S[2], Beltrán C[11]*Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, Seville, Andalucia, Spain,* [2]*Andalusian Agency for Health and Technology Assessment, Seville, Andalucia, Spain*

OBJECTIVES: To assess the efficacy of bevacizumab plus chemotherapy compared with chemotherapy alone in previously untreated metastatic colorectal cancer (mCRC) patients, who are appropriated for intensive therapy. **METHODS:** A systematic review of the literature was conducted. The selection criteria of the studies for this review were: health technology agencies reports, meta-analysis, systematic reviews and randomized controlled trials (RCTs), in mCRC comparing chemotherapy plus bevacizumab with chemotherapy alone. Searches were realized in MEDLINE, EMBASE, the Cochrane Library, and CRD databases until the 8th of June 2011. The end points evaluated were overall survival (OS), progression-free survival (PFS), overall tumour response rate (RR), and quality of life (HRQoL). The selection of the studies, quality assessment, data extraction and data analysis were done independently by two authors. Disagreements were resolved by a third reviewer until consensus was obtained. **RESULTS:** Two RCTs comparing chemotherapy plus bevacizumab with chemotherapy alone for first-line treatment of mCRC were included in the efficacy assessment. The chemotherapy in one of these trials was the IFL regimen and in the other trial was XELOX/FOLFOX-4. The addition of bevacizumab to IFL showed an increase in terms of OS (Hazard Ratio (HR): 0.66, p<0.001), PFS [HR: 0.54, p<0.001], and RR. IFL is not current standard chemotherapy and it is not an adequate comparator. The addition of bevacizumab to XELOX/FOLFOX-4 resulted in statistically significant difference in terms of PFS (HR: 0.83; Confidence Interval 97.5%: 0.72-0.95). The median OS was not statistically significant, and the RR was similar in both arms. No RCTs comparing bevacizumab with FOLFIRI vs. FOLFIRI were found. None of the studies reported the impact of bevacizumab treatment on HRQoL. **CONCLUSIONS:** The combination of bevacizumab with chemotherapy increases PFS in untreated mCRC, in patients who tolerate intensive therapy. The improvement in terms of OS remains uncertain. **OBJECTIVES:** To assess the efficacy of bevacizumab plus chemotherapy compared with chemotherapy alone in previously untreated metastatic colorectal cancer (mCRC) patients, who are appropriated for intensive therapy. **METHODS:** A systematic review of the literature was conducted. The selection criteria of the studies for this review were: health technology agencies reports, meta-analysis, systematic reviews and randomized controlled trials (RCTs), in mCRC comparing chemotherapy plus bevacizumab with chemotherapy alone. Searches were realized in MEDLINE, EMBASE, the Cochrane Library, and CRD databases until the 8th of June 2011. The end points evaluated were overall survival (OS), progression-free survival (PFS), overall tumour response rate (RR), and quality of life (HRQoL). The selection of the studies, quality assessment, data extraction and data analysis were done independently by two authors. Disagreements were resolved by a third reviewer until consensus was obtained. **RESULTS:** Two RCTs comparing chemotherapy plus bevacizumab with chemotherapy alone for first-line treatment of mCRC were included in the efficacy assessment. The chemotherapy in one of these trials was the IFL regimen and in the other trial was XELOX/FOLFOX-4. The addition of bevacizumab to IFL showed an increase in terms of OS (Hazard Ratio (HR): 0.66, p<0.001), PFS [HR: 0.54, p<0.001], and RR. IFL is not current standard chemotherapy and it is not an adequate comparator. The addition of bevacizumab to XELOX/FOLFOX-4 resulted in statistically significant difference in terms of PFS (HR: 0.83; Confidence Interval 97.5%: 0.72-0.95). The median OS was not statistically significant, and the RR was similar in both arms. No RCTs comparing bevacizumab with FOLFIRI vs. FOLFIRI were found. None of the studies reported the impact of bevacizumab treatment on HRQoL. **CONCLUSIONS:** The combination of bevacizumab with chemotherapy increases PFS in untreated mCRC, in patients who tolerate intensive therapy. The improvement in terms of OS remains uncertain.

PCN12

DASATINIB OR IMATINIB IN NEWLY DIAGNOSED CHRONIC MYELOID LEUKEMIA PATIENTES IN THE CHRONIC PHASE: FIVE-YEARS FOLLOW-UP SIMULATED COHORT

Darba J[1], Perez-Alvarez N[2], Kaskens L[2], Martin P[3]
[1]*Universitat de Barcelona, Barcelona, Spain,* [2]*BCN Health, Barcelona, Spain,* [3]*Bristol-Myers Squibb Iberia, Madrid, Spain*

OBJECTIVES: Chronic myeloid leukemia (CML) is a progressive disease consisting of three phases: chronic, accelerated and blast crisis. Imatinib achieves high response rates and improves prognosis. Dasatinib is a BCR-ABL kinase inhibitor approved for treating CML across all phases of disease. The present study modeled the time to response, time to accelerated phase, blast crisis and death of newly diagnosed patients with CML receiving first line therapy with dasatinib 100 mg/day or imatinib 400 mg/day in the chronic phase. **METHODS:** A Markov simulation model was developed using two cohorts of 200,000 CML patients treated with dasatinib 100 mg/day or imatinib 400 mg/day. Health states included were complete cytogenetic response (CCyR), major cytogenetic response (MCyR), no-response,

transformation to accelerated phase or blast crisis and death. A 5-year time horizon was considered. Each 3 months the patient faces a probability of staying in the same health state or moving to a next state. Transition to death is possible from all health states. This model was populated with efficacy data from clinical trials and different times to events were modeled using Weibull regression techniques. **RESULTS:** The Weibull model for the time to response and time to transformation to accelerated phase and blast crisis showed significant differences between treatment groups. The model coefficient indicated that the chance of response was higher in dasatinib patients with a difference of 12.54% versus imatinib. Patients receiving imatinib had 1.57% higher chance of moving to the accelerated phase and blast crisis earlier. Time to death did not differ significantly between treatments. **CONCLUSIONS:** The analysis showed earlier responses and a lower chance of reaching the accelerated phase and blast crisis faster with dasatinib 100 mg/day over imatinib 400 mg/day. Results were obtained according to the assumptions used but will need to be validated by future patient level data.

PCN13

TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA (TLN-REGISTRY): A "REAL LIFE" OVERVIEW OF TREATMENT BY OFFICE-BASED ONCOLOGISTS IN GERMANY

Hartmann H[1], Knauf W[2], Abenhardt W[3], Aldaoud A[4], Lerchenmüller C[5], Koska M[1]
[1]*iOMEDICO AG, Freib urg, Germany,* [2]*Oncology Group Practice, Frankfurt, Germany,* [3]*Munich Oncology Outpatient Centre Elisenhof, München, Germany,* [4]*Oncology Group Practice, Leipzig, Germany,* [5]*Haematology-Oncology Group Practice, Münster, Germany*

OBJECTIVES: The treatment of patients with Multiple Myeloma (MM) has changed significantly over the last years. The clinical registry on Multiple Myeloma (TLN Registry) conducted by the iOMEDICO AG in collaboration with the Arbeitskreis Klinische Studien (AKS) and the Kompetenznetz Maligne Lymphome was established to follow the implementation of new standards into daily practice. Here, we present data regarding the therapy reality of MM patients treated by office-based oncologists in Germany. **METHODS:** With a target population of 500 MM patients, the registry prospectively collects data on the treatment of MM patients, including patient characteristics. In addition, data on tumour history, response rates, adverse drug reactions and concomitant diseases are documented. MM patients older than 18 years receiving a 1st- or 2nd-line therapy which has started no longer than 4 weeks before patient enrolment can be recruited into the registry if informed written consent is present. Currently, 114 sites in Germany are participating. **RESULTS:** The registry started in May 2009. By February 2011, 353 patients with MM have been enrolled. Mean age of MM registry population is 70 years at the onset of the systemic 1st-line therapy. Bortezomib/Melphalan/Prednisone is most often used as 1st-line treatment (28%), whereas the Bortezomib/Dexamethasone combination (16%), the Lenalidomide/Dexamethasone combination (14%) or the Bortezomib monotherapy (13%) is most often used as 2nd-line treatment, regardless if stem cell transplantation was reported. On average, MM patients receiving Bortezomib/Melphalan/Prednisone are older than patients who are treated with Bortezomib/Dexamethasone in both 1st- and 2nd-line treatment. **CONCLUSIONS:** The registry provides an overview of the current treatment of patients with MM treated by office-based oncologists in Germany. Furthermore, the registry shows how fast research results concerning the treatment of MM patients are transferred into current medical practice.

PCN14

SYSTEMATIC REVIEW OF CLINICAL EFFICACY AND SAFETY OUTCOMES OF ANTI-ANGIOGENIC THERAPIES FOR METASTATIC COLORECTAL CANCER

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Anti-angiogenic therapy has become an integral component of treatment for metastatic colorectal cancer patients. During last 10 years several studies were conducted to test the safety and efficacy of anti-angiogenic therapies in mCRC patients. This study reviewed the results of randomized controlled trials published in peer-reviewed journals. **METHODS:** We searched the MEDLINE, and abstracts from ECCO, ESMO and ASCO until May 2011. Studies were selected for randomized controlled trials on targeted anti-angiogenic drugs in mCRC. Primary endpoints reviewed were progression-free (PFS) and overall survival (OS). Response rates, toxicity and secondary resectability were secondary endpoints. Aggregated data were further analyzed to understand comparative safety and efficacy. **RESULTS:** Until May 2011, eligible mCRC randomized clinical trials for this review were available for bevacizumab (5 trials including 3101 patients) and vatalanib (2 trial including 2033 patients). Overall, anti-angiogensis therapy for mCRC shows significant OS and PFS benefit versus comparators. The median OS and PFS benefit for regimens containing Bevacizumab were 3 and 3.15 months, versus background chemotherapy. The median OS and PFS benefit for vatalanib containing regimens were statistically insignificant versus background chemotherapy. **CONCLUSIONS:** Anti-angiogensis therapy with Bevacizumab for mCRC shows significant OS and PFS benefit versus comparators.

PCN15

DANCE AS PHYSIOTHERAPY IN THE REHABILITATION OF WOMEN SUFFERING FROM TUMOUR

Szalai M[1], Szirmai A[2], Fuchs N[1], Boncz I[1], Szalai T[1], Kriszbacher I[1]
[1]*University of Pécs, Pécs, Hungary,* [2]*ELTE PPK, Budapest, Hungary*

OBJECTIVES: In Hungary annually 35,000 people die because of malignant cancer. The main characteristics of the treatment of cancer are multidisciplinary and complex approach. The aim of our examination was to measure the effectiveness of dance rehabilitation group of female patients suffering from malignant tumours, and the changes of lifestyle and social support of patients. **METHODS:** Our examination is descriptive, prospective and quantitative. Female patients suffering from malignant cancer illnesses were examined with random sampling method between 2005- 2009. Follow-up was implemented a year later. Data was collected with standardised (F-SoZu, EORTC-QLQ-C30, Campbell) and own-designed questionnaires. Data of 175 patients were processed. Statistical analysis was made with SPSS 17. **RESULTS:** The average age of patients in the dance group was 48.87 years (SD:8,87) and 51,13 in the control group (SD:11,06). The degree of social support in the dance group was 65,22 at the first, 67,55 at second time. In case of the control group the rate was firstly 57,41 then 53,88. The change in the degree of social support was significant in both groups between the two measures ($p<0.01$). Patients attending in the dance group had less corporal and psychic symptoms at both measures than the members of the control group. In case of the questionnaire of Campbell the scores in the dance group was higher in both measures than in the control group. The two groups differ in the degree of change: the dance group had more significant change in case of complacency with life compared to the other group. **CONCLUSIONS:** Dance as a rehabilitation method need less investment form the state and it does not charge the Social Insurance Fund. These arguments cannot be neglected in the current economic status. Care system would get a rehabilitation which may help women to return actively to society.

PCN16

DISEASE BURDEN AND TREATMENT OUTCOMES IN SECOND-LINE THERAPY OF PATIENTS WITH ESTROGEN-RECEPTOR POSITIVE (ER+) ADVANCED BREAST CANCER: A REVIEW OF THE LITERATURE

Boswell KA[1], Wang X[2], Shah MV[1], Aapro MS[3]
[1]*Xcenda, Palm Harbor, FL, USA,* [2]*Novartis Pharmaceuticals Corporation, Florham Park, NJ, USA,* [3]*Multidisciplinary Oncology Institute, Genolier, Switzerland*

OBJECTIVES: To determine the variable burden of disease of patients with advanced ER+ breast cancer and assess the current treatment landscape after failure of ER+ first-line therapy. **METHODS:** A comprehensive literature review was performed (2000–2011) by searching Medline via PubMed and Embase and Cochrane databases to assess disease burden (ie, societal, humanistic and/or economic burden) and treatment landscape for second-line therapy of ER+ advanced breast cancer in postmenopausal women. **RESULTS:** Only 1 study was identified that evaluated burden of disease based on ER status (ER+, ER-, or ER-unknown), which was a subgroup analysis assessing the impact of recurrence over 10 years. The investigators reported that only minor differences in survival and medical costs were noted according to ER status. Regardless of ER status, patients with breast cancer recurrence consumed more health care resources and were associated with more costly care than those without recurrence. A total of 7 studies were identified related to treatment outcomes of ER+ second-line therapy. A combined international population totaled >3,800 patients who had progressed on prior hormonal therapy, including tamoxifen and aromatase inhibitors. Three trials performed a comparative efficacy/safety assessment of ER antagonist vs aromatase inhibitor and 1 trial each for aromatase inhibitor versus megestrol acetate and aromatase inhibitor versus aromatase inhibitor. Among each of the studies evaluated, no significant differences were observed in the primary efficacy endpoint, and the safety profiles were similar. Two additional studies, both dosing evaluations, demonstrated that lower doses had a similar or better efficacy and safety profile. **CONCLUSIONS:** Currently, there is insufficient evidence on the economic and humanistic burden associated with ER status, and this gap warrants further research. With increasing drug resistance and greater economic burden associated with breast cancer recurrence, there is an unmet medical need for improved treatment in this patient population.

PCN17

CORRELATIONS BETWEEN SURROGATE END POINTS AND OVERALL SURVIVAL IN ADVANCED OR METASTATIC BREAST CANCER

Abdel-kader L[1], Castillo MA[1], Lacalle JR[2], Flores S[1]
[1]*Andalusian Agency for Health and Technology Assessment, Seville, Andalucia, Spain,* [2]*Seville University, Seville, Andalucia, Spain*

OBJECTIVES: To determine whether surrogate end points [progression free survival (PFS), time to progression (TTP) and response rate (RR)] are correlated with overall survival (OS) in the first-line treatment of advanced or metastatic breast cancer (BC). **METHODS:** A systematic review of the literature was conducted to indentify randomized clinical trials (RCTs) that evaluate the efficacy of chemotherapy in first-line treatment of advanced or metastatic BC. Searches were realized in MEDLINE and EMBASE databases from 1995 to April 2010. The nonparametric Spearman rank correlation coefficient (rs) was used as a measure of correlation between the difference (Δ) in surrogate outcomes (ΔPFS, ΔTTP and ΔRR) and the difference in OS (ΔOS). Correlation coefficients were compared using the normal approximation to the z-transformation of rs and its standard deviation. Linear regression analysis, through the origin of the plot, evaluating ΔOS as a function of differences in each surrogate outcomes was used to determine the proportion of variability explained (R2). Statistical analyses were performed using STATA software v.10. **RESULTS:** Thirty-four RCTs were included in the analysis, with a total of 11,398 patients evaluated. In the first-line therapy of advanced or metastatic BC, there was a weak significant association between ΔPFS and ΔOS [rs: 0.43 (Confidence Interval (CI) 95%: 0.04-0.71)]. When the analysis was performed including only RCTs in the metastatic stage, the rs data between ΔPFS and ΔOS increased statistically significant to 0.59 (CI95% 0.17 to 0.83). The surrogate outcomes that correlated better with the ΔOS, were ΔTTP [rs: 0,79 (CI95%: 0,43-0,94); R2:62%], and ΔRR [rs: 0,73 (CI95%: 0,55-0,85); R2: 53%]. **CONCLUSIONS:** In the first-line treatment of advanced or metastatic BC, TTP and RR may be appropriate surrogate end points for OS, although it is important to consider the magnitude of their variations.

PCN18

INTERMITTENT VERSUS CONTINUOUS CHEMOTHERAPY FOR FIRST-LINE TREATMENT OF UNRESECTABLE METASTATIC COLORECTAL CANCER (CCRM): SYSTEMATIC REVIEW AND META-ANALYSIS

Botrel TEA[1], Paladini L[2], Clark O[1], Clark LGO[1]
[1]*Evidências, Campinas, Brazil,* [2]*Evidências, São Paulo, São Paulo, Brazil*

OBJECTIVES: To perform a systematic review and meta-analysis of all randomized controlled trials comparing efficacy of Intermittent versus continuous chemotherapy (CT) for first-line treatment of unresectable Metastatic Colorectal Cancer (CCRm). **METHODS:** Several databases were searched, including MEDLINE, EMBASE, LILACS, and CENTRAL. The primary endpoint was overall survival (OS). The data extracted from the studies were combined by using Hazard Ratio (HR) with their corresponding 95% confidence intervals (CI95%). **RESULTS:** Overall, 733 references were identified and screened. The final analysis included 4 trials comprising 1,827 patients analyzed. There was no statistically significant difference between the groups (Intermittent vs continuous chemotherapy) on the analysis of overall survival (fixed effect: HR=1.03, CI95%=0.92 to 1.16; p=0.56). No heterogeneity was detected on this analysis (Chi2 = 2.88, df = 3 (P=0.41); I2 = 0%). **CONCLUSIONS:** Overall survival was similar between groups. The intermittent chemotherapy regimen provides better quality of life that the scheme is continued and probably cost saving.

PCN19

THE BROADER BURDEN OF HPV-RELATED DISEASE IN ENGLAND: A PRELIMINARY ANALYSIS

Khalid JM[1], Amelio JM[1], Carroll SM[2], Charman F[2], Maguire A[1]
[1]*United Biosource Corporation, London, UK,* [2]*Sanofi Pasteur MSD, Maidenhead, UK*

OBJECTIVES: The Human Papillomavirus (HPV) is a known cause of cervical cancer and genital warts, and causes a proportion of vaginal, vulval, penile, anal, and head and neck (H+N) cancers. Quantifying the broader burden of HPV-related cancers is important as this group represents approximately 5.2% of all cancers. **METHODS:** Using cancer registry data covering the population of England (2003-2008), we examined incidence of HPV-related cancers. HPV-associated sites were identified (cervix, vulva, vagina, anus, penis and H+N) and grouped according to ICD-O-3 site. Incidence rates were age-adjusted (ASR) to the European standard population by the direct method and 95% Confidence intervals (95% CI) calculated using STATA SE11.0. A literature review was conducted to ascertain the percentage attributable to HPV for each cancer type. Over 300 articles were reviewed and graded by relevance, sample size, and date. **RESULTS:** ASRs for HPV-related cancers were: vagina/vulval cancers: 0.33(95% CI 0.3-0.4) and 1.4(95% CI: 1.3-1.4) per 100,000 females. Penile cancer: 0.8(95% CI: 0.7-0.8) per 100,000 males. Anal cancers: 10.8(95% CI:10.7-11.1) males and 6.0(95% CI:5.8-6.0) females per 100,000. Base of tongue and lingual tonsil: 0.06(95% CI:0.06-0.07) males and 0.02(95% CI:0.01-0.02) females per 100,000; tonsil: 0.11(95% CI:0.10-0.12) males and 0.03(95% CI:0.03-0.04) females per 100,000; oropharynx: 0.05(95% CI:0.05-0.06) males and 0.02(95% CI:0.01-0.02) females per 100,000. Estimates reported in literature for percentage of HPV-attributable cases ranged from 70-100% for cervical, 27-76% vulval, 70-90% vaginal, 40-54% penile, 76-90% anal, and 11-72% for HPV-associated H+N cancers. The most commonly reported strains were HPV 16, 18, 31, and 33. **CONCLUSIONS:** The incidence of HPV-related cancers represents a significant burden. Recent incidence estimates are similar to 2002 estimates, apart from an increase in anal cancers. Estimates of the HPV-attributable percentage for each cancer and projected prevalence will be used to assess the impact of implementing a quadrivalent HPV vaccination programme in England.

PCN20

SYSTEMATIC REVIEW OF SKELETAL RELATED EVENTS IN BREAST CANCER

Broder M[1], Gutierrez B[2], Linhares Y[1], Cherepanov D[1]
[1]*Partnership for Health Analytic Research, LLC, Beverly Hills, CA, USA,* [2]*Bristol-Myers Squibb, Lawrenceville, NJ, USA*

OBJECTIVES: Metastatic bone lesions lead to an increase in the risk for skeletal related events (SREs), including pathologic fracture, spinal cord compression, hypercalcemia of malignancy, and severe bone pain requiring palliative radiotherapy or surgery to bone. Twenty-nine percent of breast cancer patients with bone metastases develop SREs. Our objective was to systematically review the literature on the impact of SREs on pain, quality of life (QOL), morbidity, survival and cost in breast cancer patients. **METHODS:** We searched PubMed, limiting to peer-reviewed English-language human studies published in 2000-2010. The search was based on a SRE definition accepted by the U.S. Food and Drug Administration and European Medicines Agency. Articles were included if they were randomized-controlled trials, clinical trials with appropriate control group, systematic reviews, meta-analyses, case-series or economic analyses, and were excluded if they did not provide interpretable results on outcomes of interest. **RESULTS:** A total of 209 articles were screened, of which 131 were excluded, and 78 were abstracted. No studies, outside of bisphosphonate trials, were identified that examined the impact of SREs as a group on clinical outcomes. Bisphosphonate treatment reduced SREs, and hence improved pain and QOL. Literature indicated that presence of pathologic bone fractures is correlated with increased risk of death. Spinal cord compression significantly impaired ambulatory function and shortened survival of these patients compared to historical controls. Radiation therapy improved pain and QOL while bone surgery was shown to improve pain and function with vertebrectomy. Limited evidence suggested treatment cost of SREs is $14,000 (95% CI: $11,000-$17,000) per patient. **CONCLUSIONS:** Presence of clinical SREs is associated with worse morbidity and survival, while their treatment is associated with improved pain, QOL and morbidity among breast cancer patients. SREs appear to increase cost of treatment substantially.

PCN21

SYSTEMATIC REVIEW OF SKELETAL RELATED EVENTS IN PROSTATE CANCER

Broder M[1], Gutierrez B[2], Linhares Y[1], Cherepanov D[1]
[1]*Partnership for Health Analytic Research, LLC, Beverly Hills, CA, USA,* [2]*Bristol-Myers Squibb, Lawrenceville, NJ, USA*

OBJECTIVES: Between 65-75% of patients with prostate cancer experience metastatic bone disease. Metastatic bone lesions increase risk for skeletal related events (SREs), which include clinical SREs (pathologic fracture, spinal cord compression, hypercalcemia of malignancy) and treatments of clinical SREs (radiotherapy or surgery to bone) resulting from severe bone pain. Our objective was to systematically review the literature on the impact of SREs on pain, quality of life (QOL), morbidity, survival and cost in prostate cancer patients. **METHODS:** We searched PubMed, limiting to peer-reviewed English-language human studies published in 2000-2010. The search was based on SRE definition accepted by the US Food and Drug Administration and European Medicines Agency. Articles were included if they were randomized-controlled trials, clinical trials with appropriate control group, systematic reviews, meta-analyses, case-series or economic analyses, and were excluded if they did not provide interpretable results on outcomes of interest. **RESULTS:** A total of 209 articles were screened, of which 131 were excluded, and 78 were abstracted. No studies, outside of bisphosphonate trials, were identified that examined the impact of SREs as a group on clinical outcomes. In bisphosphonate trials, patients with SREs had significantly more pain and worse 1-year survival compared with no SREs. Pathologic bone fractures significantly decreased QOL and were associated with increased risk of death. Although spinal cord compression (SCC) has a significant impact on pain, improvement in morbidity may be achieved if SCC is treated. SCC is associated with significant decreases in patient survival. Radiation therapy improved pain and possibly QOL while bone surgery improved pain. Limited evidence suggested SREs increased cost by approximately €7,000 (Euros) and $12,000 (USD). **CONCLUSIONS:** Clinical SREs are associated with worse clinical outcomes, including pain, QOL, morbidity and survival, while treatment of clinical SREs is associated with improved pain and QOL among prostate cancer patients. SREs appear to increase cost substantially.

PCN22

SAFETY PROFILE OF BEVACIZUMAB IN METASTATIC COLORECTAL CANCER

Castillo MA, Ubago R, Flores S, Rodríguez R, Beltrán C
Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, Seville, Andalucia, Spain
Castillo MA, Ubago R, Flores S, Rodríguez R, Beltrán C*Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, Seville, Andalucia, Spain*

OBJECTIVES: To assess the overall risk of bevacizumab related adverse events in patients with metastatic colorectal cancer (mCRC). **METHODS:** A systematic review of the literature was conducted. The selection criteria of the studies for this review were: health technology agencies reports, meta-analysis, systematic reviews, randomized controlled trials (RCTs) and observational studies in patients treated with bevacizumab for mCRC. MEDLINE, EMBASE, the Cochrane Library, and CRD databases were searched until June 8, 2011. The selection of the studies, quality assessment, data extraction and data analysis were done independently by two authors. Disagreements were resolved by a third reviewer until consensus was obtained. **RESULTS:** To evaluate the safety profile of bevacizumab, two systematic reviews with meta-analysis and two observational studies were included (the BEAT and the BRiTE studies). A total of 3271 patients were included in one meta-analysis, which evaluated the risk of fatal adverse events (FAE) and 3,385 patients were included in the other meta-analysis, which evaluated any grade of toxicity. An increased risk of FAE was not observed between patients with mCRC receiving bevacizumab in combination with chemotherapy and patients receiving chemotherapy alone [Relative Risk (RR):1.21 Confidence Interval (CI) 95%: 0.65-2.24]. Patients treated with bevacizumab had an increased risk of developing grade 3-4 hypertension (RR: 4.27; CI95%: 2.80–6.51), any grade gastrointestinal perforation (RR: 5.04; CI95%: 1.72–14.79), grade 3-4 arterial thromboembolic events (RR: 1.23; CI95%: 0.93–1.62), and discontinuation because of grade 3-4 adverse events (RR: 1.21; CI95%: 1.03–1.43). The results from the observational studies were consistent with the data reported in the meta-analysis. **CONCLUSIONS:** Although the risk of FAE was not increased with bevacizumab in patients with mCRC, grade 3-4 hypertension, any grade gastrointestinal perforation, grade 3-4 arterial thromboembolic events, and discontinuation due to grade 3-4 adverse events were higher in the bevacizumab group.

PCN23

SURVIVAL ANALYSES ADJUSTED FOR CROSSOVER IN RELAPSED MULTIPLE MYELOMA: RESULTS OF THE APEX TRIAL

Pacou M[1], Gauthier A[1], Abrams K[2], Spencer M[3]
[1]*Amaris Consulting UK, London, UK,* [2]*University of Leicester, Leicester, UK,* [3]*Janssen-Cilag Limited, High Wycombe, UK*

OBJECTIVES: An interim analysis of APEX, a phase III randomized, open-label clinical trial, demonstrated superiority of bortezomib over high-dose dexamethasone in terms of time to disease progression (TTP). According to the original study protocol, patients were allowed to cross over on disease progression. Following interim analysis, patients could cross over regardless of the disease status. The ITT analysis of overall survival (OS) may therefore result in a biased estimate of the treatment effect. This study aimed to adjust the analysis for crossover. **METHODS:** The Iterative Parameter Estimation (IPE) algorithm using a Weibull distribution was selected as the primary analysis based on the findings from a simulation study (Morden et al). The IPE algorithm using a Gompertz distribution and the Rank

Preserving Survival Time (RPSFT) model were used as secondary analyses. The Inverse Probability of Censoring Weights (IPCW) method and the Cox model using treatment as a time-dependent covariate were used as sensitivity analyses. **RESULTS:** Overall, 71% of patients randomized to dexamethasone crossed over to bortezomib. The primary analysis led to a hazard ratio of 0.59 (95%CI: [0.32,0.86]) for bortezomib versus dexamethasone, compared to 0.77 (95%CI: [0.61,0.97]) using the ITT approach. The results of the secondary analyses were consistent with the primary analysis. The IPCW provided results, which were very sensitive to the choice of the time interval. Lastly, the Cox model with treatment as a time-dependent variable resulted in a counter-intuitive higher hazard ratio than the ITT analysis, consistent with results from simulation studies indicating this approach is biased. **CONCLUSIONS:** Adjusting for crossover led to a decrease of the hazard ratio from 0.77 to 0.59, and resulted in wider confidence intervals than the ITT analysis. Additional analyses are required to assess the performance of the IPCW method compared to the IPE algorithm and the RPSFT model under different scenarios.

Cancer – Cost Studies

PCN24

BUDGET IMPACT MODEL FOR RARE CANCER TREATMENT: CASE IN POINT CUTANEOUS T-CELL LYMPHOMA

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Develop budget impact model to forecast total cost of treatment for cutaneous T-cell lymphoma (CTCL) for US public and private payer. **METHODS:** The clinical efficacy and safety data were obtained from the published pivotal study results. Costs of adverse events were estimated based on claims database analysis, AHRQ's HCUP and CMS Medicare 2009 databases. Drug cost was estimated based on 2011 AWP price. Epidemiology data were obtained from NCI-SEER and CDC databases. A budget impact model was implemented over a period of five years, based on a stable population and on different penetration and substitution rates of newly approved therapy. Model was developed in excel based format. Blinded Model design and outputs were tested with payers and KOLs. **RESULTS:** For rare cancers such as CTCL, the budget impact of treatment with targeted cancer therapies is in the range of $460,000-$530,000 per 1 million covered lives. The per patient per member (PPPM) budget impact of this treatment is 46-53 cents. Medical cost offsets were estimated but were insignificant compared to total cost of treatment. US payers rated PPPM output as the one of the most important relevant outputs of model. **CONCLUSIONS:** This budget impact model shows that new treatments for rare forms of cancer are likely to have minimal budget impact on payers. PPPM based outputs are more relevant to payers, than per patient treatment costs. However, an emerging concern is the total budget impact of all therapies indicated for ultra-orphan disorders, which might be an important consideration for future models.

PCN25

BUDGET IMPACT ANALYSIS OF SWITCHING TO DIGITAL MAMMOGRAPHY IN A BREAST CANCER POPULATION-BASED SCREENING PROGRAM

Arrospide A[1], Comas M[2], Mar J[1], Sala M[2], Hernandez C[3], Roman R[2], Castells X[2]
[1]*Hospital Alto Deba, Mondragon, Spain,* [2]*Hospital del Mar-IMIM, CIBER de Epidemiología y Salud Pública (CIBERESP), Barcelona, Spain,* [3]*Hospital del Mar-IMIM, Barcelona, Spain*

OBJECTIVES: Digital mammography is costlier than screen film mammography but presents benefits at the technological and logistic level. The aim of this study was to analyze the budget impact and the health benefits of the introduction of digital mammography in a population-based breast cancer screening program. **METHODS:** A discrete-event simulation model was implemented including the processes under a breast cancer screening program and the natural history of breast cancer. The screening events included: invitation (biennial) of the target population (women aged 50-69 years), participation, screening test, confirmatory tests after a positive mammography result, cancer diagnosis and treatment. Natural history of breast cancer included the following health states: no cancer, preclinical (non symptomatic) cancer, clinical (or symptomatic) cancer and death. Digital and analogical mammography had the same sensitivity, but different specificities were applied according to type of mammography and also initial or successive screening. Results were collected during a 20-year screening scenario. **RESULTS:** A total of 90,575 women were screened under both techniques during the simulated 20 years. This population resulted in more than 262,500 screening mammograms. The recall rate was 5.9% under digital mammography and 6.4% under analogical mammography, while the numbers of confirmatory tests needed were 23,728 and 32,697, respectively. The cancer detection rate was 0.7% for both techniques. Digital mammography saved 1.909.167 euros in additional tests, while it was 1.026.807 euros more expensive in screening mammograms and presented similar costs of treatments. **CONCLUSIONS:** Results suggest that, although population-based breast cancer screening with digital mammography is costlier in terms of screening mammographies, it saves money in terms of additional tests needed. The health benefits are similar to those of conventional analogical mammography, but it reduces the number of additional tests needed, which represent a clear benefit to participating women.

PCN26

LONG-TERM FISCAL IMPLICATIONS OF MEPACT IN THE TREATMENT OF HIGH-GRADE NON-METASTATIC OSTEOSARCOMA: A BUDGET IMPACT MODEL AND A LIFETIME TAX PERSPECTIVE

Johal S[1], Knight C[2], Bell MJ[3], Ralston S[4]
[1]*RTI Health Solutions, Sheffield, UK,* [2]*RTI Health Solutions, Sheffield, UK, UK,* [3]*RTI Health Solutions, Manchester, UK,* [4]*Takeda Global Research & Development Centre (Europe) Ltd, London, UK*

OBJECTIVES: The addition of MEPACT as an add-on treatment to adjuvant chemotherapy in the treatment of high-grade non-metastatic osteosarcoma after macroscopically complete surgical resection has been shown to significantly increase overall survival of young patients. This study assessed the costs (drug and administration) and the long-term financial impact on the UK (UK) government of introducing MEPACT. **METHODS:** Based on the cost of MEPACT and using survival rates derived from a clinical trial, we projected the net budgetary impact of MEPACT compared to no MEPACT. Further, we modelled the net tax contribution to the state of a surviving patient over a lifetime by subtracting direct government transfers that are made to the individual (child benefit, education etc) from the individual's gross tax contribution based on average anticipated earnings. **RESULTS:** Using UK incidence rates of osteosarcoma the model estimated approximately 54 newly diagnosed non-metastatic cases per year. Assuming that 38 doses of MEPACT (calculated from trial data) are added to the treatment regimen of 50% of patients at a cost of £91,189 , the expected 1-year cost would be UK £3,972k compared with £1,450k had all patients been treated without MEPACT. Administration costs accounted for 3% of total costs. The lifetime discounted value of net taxes from a 14 year old patient treated with MEPACT is £79,000. The breakeven age, defined as the point at which the net tax contribution becomes greater than zero, is approximately 41 years. **CONCLUSIONS:** The additional budget impact due to MEPACT is mainly due to the cost of the drug. From the tax calculations, we conclude that investment in MEPACT does not negatively impact the long run fiscal budget of the UK government. Conversely, by taking a broader government perspective over an average lifetime, a surviving patient returns a positive net value to the State.

PCN27

BUDGET IMPACT ANALYSIS FOR CHRONIC MIELOID LEUKEMIA THERAPY IN BULGARIA

Savova A[1], Petrova G[2]
[1]*Medical University Sofia, Faculty of Pharmacy, Sofia, Bulgaria,* [2]*Medical University, Faculty of Pharmacy, Sofia, Bulgaria*

OBJECTIVES: To evaluate the budget impact of nilotinib for newly diagnosed patients with chronic myeloid leukemia (CML) for the health care system in Bulgaria. **METHODS:** Current standard of therapy (imatinib) is compared with the newly authorized for sale nilotinib and dasatinib used as a first line therapy. Cost of yearly pharmacotherapy and adverse drug reactions management have been calculated for 3 years for different proportions of newly diagnosed patients with CML in chronic phase. The exchange rate is 1 BGN = 0.51 EUR. **RESULTS:** Clinical studies shows significant benefits from nilotinib but the question remains if it is worth the cost of therapy. Calculation of the yearly pharmacotherapy cost per 100 patients arranges the medicines in monetary value order as follows: 5,398,092 BGN for imatinib, 6,564,681 BGN for nilotinib, and 8,365,872 BGN for dasatinib. Weighed cost by the probability of appearing of the ADR is 733.26 BGN for imatinib, 509.75 for nilotininb, and 1,010.29 BGN for dasatinib. The relative share of patients treated with nilotinib in first line is 12% for the first year, 32% for the second, and 38% for the third year. The introduction of nilotinib will change the budget for all patients with CML to 6,895,316 in comparison with 6,725,246 BGN before the introduction, to 7,177,671 BGN in the second year, and to 7,262,378 BGN in the third year. Thus the over all increase for the observed 3 years will be within 179,044 BGN. **CONCLUSIONS:** The introduction of nilotinib as first line therapy for patients with newly diagnosed CML will lead to relatively small increase in the health care budget in Bulgaria compared to the clinical benefit in terms of achievement of deeper response, improvement of overall survival and less disease progression.

PCN28

CAPECITABINE FOR THE TREATMENT OF BREAST CANCER IN PRIVATE HEALTH SYSTEM IN BRAZIL: COST ANALYSIS BASED ON REAL WORLD DATA

Clark O[1], Clark LGO[1], Botrel TEA[1], Rosa B[2], Medina P[1], Paladini L[3], Fiol E[2], Rodrigues N[2], Faleiros E[1], Castro AP[2], Fortes AF[2]
[1]*Evidências, Campinas, Brazil,* [2]*Evidências, Campinas, SP, Brazil,* [3]*Evidências, São Paulo, São Paulo, Brazil*

OBJECTIVES: Capecitabine (C) is approved in Brazil for the treatment of breast cancer (BC), 2nd or subsequent lines. In the private sector, it's not often used, due to the fact that health insurance plans (HI) do not offer coverage for oral (PO) chemotherapy (CHEMO), only for intravenous (IV). Our aim was to determine if the use of C could spare costs if adopted by HI. **METHODS:** We searched Evidencias Database for BC patients eligible for the use of C, in the year of 2008. This database has information from over 2 million of users of 14 HI. We identified the IV CHEMO actually used and the costs paid. Then, based on the data of each individual patient and in the length of use of CHEMO, we calculated the associated costs in a scenario where C replaced the IV CHEMO used. Also, we performed some sensitivity analysis based on different percentages of substitutions of IV by PO chemo. We considered only the prices of drugs. **RESULTS:** We found 518 BC patients eligible for C use. These patients received 3581 cycles of chemotherapy (Paclitaxel, Docetaxel, Gemcitabine, Vinorelbine, Doxorubicin). The total cost for these treatments were US$ 5 364 000. If C replaced 100% of the IV CHEMO, the total cost would drop to US$2,078,000, 62% smaller than the IV alternative. In a simulation, where 60% of the patients would use the IV option and 40% would use C, the total cost would also be smaller: US$4,050,000, 25% smaller than when IV route is used exclusively. **CONCLUSIONS:** The adoption of C by HI in Brazil is cost-saving for BC patients.

PCN29

BUDGETARY IMPACT OF ADOPTION OF ERLOTINIB FOR LUNG CANCER IN THE PRIVATE HEALTH INSURANCE MARKET IN BRAZIL: A REAL WORLD DATA ANALYSIS

Clark O[1], Clark LGO[1], Botrel TEA[1], Medina P[1], Paladini L[2], Rosa B[3], Rodrigues N[3], Fortes AF[3], Castro AP[3], Faleiros E[1]
[1]*Evidências, Campinas, Brazil,* [2]*Evidências, São Paulo, São Paulo, Brazil,* [3]*Evidências, Campinas, SP, Brazil*

OBJECTIVES: In Brazil, health insurance plans (HI) must pay for anticancer intravenous (IV) chemotherapy (CHEMO) but not for those taken by mouth (PO). Erlotinib (E) is a PO CHEMO used to treat lung cancer 2nd or 3rd line. Our aim was to establish the budgetary impact of the adoption of E, when compared to the IV competitors docetaxel (D) and pemetrexed (P) for the HI in Brazil. **METHODS:** We searched Evidencias Database for patients eligible for the use of E, in the year of 2008. This database has information from 2 million of users of 14 HI. Then, we calculated the costs of the IV chemo actually used. A simulation of the costs if E were adopted was carried out. Many different sensitivity analyses were performed, according to the line of treatment in which E was administered and the proportion changing from IV to the PO option. **RESULTS:** We found 285 records of patients that were suitable for the use of E. The cost of IV CHEMO was US$2,293,000. If E replaced the treatment for all patients, the cost would be reduced to US$1,067,000, resulting in a economy of US$1,222,000 (54%) of the total. If instead of replacing the IV option, E was used as an additional line of treatment, an increase of US$635,000 in total costs would occur. In a sensitivity analysis, that can reflect the practice, where 50% of the patients would receive E instead of P or D in 2nd line, and 30% would receive E in 3rd line, the adoption of E would result in an economy of US$295,000. **CONCLUSIONS:** The adoption of E for the treatment of lung cancer in Brazil can be cost-saving for HI.

PCN30
COMPARATIVE ANALYSIS OF COST AND RESOURCE USE AMONG PATIENTS WITH BRAIN METASTASIS BY INITIAL PRIMARY CANCER

Ganguli A[1], Dacosta Byfield S[2], Teitelbaum A[3], Ray S[1]
[1]*Abbott Laboratories, Abbott Park, IL, USA,* [2]*OptumInsight, Eden Prairie, MN, USA,* [3]*i3 Innovus, Eden Prairie, MN, USA*

OBJECTIVES: To examine variation in real world health care utilization (HCU) and costs associated with management of brain metastasis (BrMts) by primary malignancy type. **METHODS:** A retrospective analysis utilized claims-data from a national health insurer, identifying patients ≥18 yrs with ≥2 claims ≥7 days apart for BrMets (ICD-9 198.3x) from January 2004 to April 2010. The index date was the date of the first BrMets claim. Continuous enrollment (CE) in the health plan for 6 months before (baseline) and 1 month after (follow-up) index date was required; <1 month follow-up was permitted if due to death. Excluding primary brain tumors, baseline CE data (1993 to the index date) was examined to identify the initial primary malignancy. HCU (inpatient stays, office, outpatient and ER visits) and all-cause per-patient per-month (PPPM) costs were examined. **RESULTS:** A total of 1031 lung and 395 breast cancer patients, and 93 with melanoma were included. Baseline Charlson comorbidity score was not significantly different. Mean age at BrRMets diagnosis was highest for lung (60yr) compared to breast cancer (55yr) and melanoma (56yr)[p-value<0.01]. Rates of HCU (events/person-month) were significantly different for melanoma, breast and lung cancer patients: 0.28 versus 0.17 and 0.24 for inpatient stays; 3.16 versus 3.87 and 3.94 for office visits; 2.84 vs. 2.69 and 2.80 for outpatient visits [p-value<0.01]. Total costs PPPM were highest for melanoma ($21,373) compared to breast ($17,933) and lung cancer ($15,199) [p-value=0.001]. Inpatient costs PPPM represented the largest portion of medical costs (44%-50%), but were not significantly different across cohorts: melanoma ($9397), breast ($8781) and lung cancer ($7628). Pharmacy costs PPPM were highest among melanoma ($1555) then breast ($737) and lung cancer ($720) [p-value <0.001]. **CONCLUSIONS:** Variation was observed in HCU and costs among BrMets patients based on initial primary tumor type. Analyses of cost studies on BrMets patients need to take this into consideration.

PCN31
SEQUENTIAL TREATMENT OF METASTATIC RENAL CELL CARCINOMA WITH TARGETED THERAPIES: ADVERSE EVENTS ASSOCIATED COSTS, FROM THE PUBLIC AND PRIVATE PERSPECTIVES IN BRAZIL

Fernandes RA[1], Takemoto MLS[1], Bines J[2], Tolentino ACM[1], Takemoto MMS[1], Santos PML[1], Caldas A[3], Valentin J[3]
[1]*ANOVA - Knowledge Translation, Rio de Janeiro, Brazil,* [2]*Clementino Fraga Filho Hospital, Federal University of Rio de Janeiro, Rio de Janeiro, Brazil,* [3]*Novartis Biociências SA, São Paulo, Brazil*

OBJECTIVES: To estimate direct costs associated to grades 3-4 adverse events (AEs) management treatment of metastatic renal cell carcinoma (mRCC) with targeted therapies (sorafenib, sunitinib, pazopanib, bevacizumab, everolimus and temsirolimus) and to perform a comparative analysis from public and private healthcare perspectives, in Brazil. **METHODS:** A systematic literature review was conducted to identify grades 3-4 AEs related to targeted therapies. To obtain direct costs related to AEs management, procedures were created from national guidelines and expert validation. Total cost for each drug was calculated, considering a six-month time horizon. Only direct medical costs were considered, expressed in 2011 Brazilian reals (BRL). Unit costs were obtained from Brazilian official lists. As no head-to-head trials were found, indirect comparison in second-line targeted therapy was performed according to NCCN guideline for everolimus (grade 1 recommendation) versus sorafenib and sunitinib (grade 2A) and temsirolimus (grade 2B). Bevacizumab (grade 2B) was excluded as data was available only for the association with IFN. In the base case, grades 3-4 incidence rates were obtained from phase III clinical trials and varied in sensitivity analysis based on results obtained in meta-analyses or observational studies. **RESULTS:** When compared to NCCN 2A recommendation grade for second-line targeted therapy, everolimus is cost-saving in base case and sensitivity analysis: versus sorafenib, there are savings ranging from 5BRL to 717BRL and from 96BRL to 5841BRL in public and private perspectives, respectively; versus sunitinib, savings vary from 153BRL to 681BRL and from 1778BRL to 5136BRL in public and private perspectives, respectively. Everolimus was cost-saving due to easily manageable AEs and their frequencies. **CONCLUSIONS:** Considering grades 1 and 2 NCCN recommendation for mRCC second-line targeted therapies, everolimus represents the highest quality of evidence and is also considered the lowest cost option for the management of associated AEs from public and private healthcare perspectives, in Brazil.

PCN32
COST SAVINGS WITH BEVACIZUMAB COMPARED TO SUNITINIB IN THE TREATMENT OF MRCC

Benkovic V[1], Jelec D[2], Antolic S[3], Stevanovic R[4]
[1]*Croatian society for pharmacoeconomics and Health Economics, Zagreb, Croatia,* [2]*Roche Ltd, Croatia, Zagreb, ZAGREB, Croatia,* [3]*ROCHE d.o.o., ZAGREB, Croatia,* [4]*Croatian Society for Pharmacoeconomics and Health Economics, Zagreb, Croatia*

OBJECTIVES: Assessing the adverse events costs of comparable regimens (sunitinib vs bevacizumab) in context of budget impact analysis in Croatian setting. **METHODS:** Authors have assessed costs and outcomes of bevacizumab and sunitinib via systematic review, performed in January 2011. Survival rates, incidence and prevalence was assessed via Croatian National Cancer Registry, and the model was verified with Monte Carlo simulations. Direct drug, adverse events and treatment costs were calculated in kuna/per patient yearly according to price listings of National Institute for Health Insurance. Local data was verified with structured interviews gathered with Croatian oncologists (N=6) involved in this indication in their daily practice. Focus of the analysis was the drug cost and the adverse events treatment cost. **RESULTS:** Sunitinib has showed costly side effects such as neutropenia, trombocitopenia, hypothiroidism and cardiovascular complications. The cost of adverse events (aforementioned) for sunitinib per patient yearly is 3.904 HRK (535 EUR), whereas for bevacizumab is 1.404 HRK (192 EUR). Bevacizumab demonstrated significantly lower adverse events costs than sunitinib. Overall budget impact (from payers perspective) when bevacizumab is introduced equals -29.753,52 HRK (-4075 EUR) of savings yearly per patient. **CONCLUSIONS:** At current costs, head to head drug price comparison demonstrates that bevacizumab is less costly, demonstrating dominant ability to reduce costs due to less frequent and less costly adverse events, whereas in budget impact context introducing bevacizumab brings savings.

PCN33
COST ANALYSIS: TREATMENT OF CHEMOTHERAPY-INDUCED ANAEMIA WITH ERYTHROPOIESIS-STIMULATING AGENTS (ESAS) IN SPAIN

Duran A[1], Spaepen E[2], Lamotte M[3], Brosa M[4], Gutierrez L[5], Restovic G[6], Annemans L[7]
[1]*IMS Health, London, UK,* [2]*SBD Analytics BVBA/SPRL, Bekkevoort, Belgium,* [3]*IMS Consulting Group, Vilvoorde, Belgium,* [4]*Oblikue Consulting, Barcelona, Spain,* [5]*Amgen S.A., Barcelona, Spain,* [6]*Amgen S.A., Barcleona, Spain,* [7]*Ghent University, Ghent, Belgium*

OBJECTIVES: Spaepen et al. (The Oncologist 2008;13:596–607) published a cost analysis comparing darbepoetin-alfa (DARB), epoetin-alfa (EPO-A) and epoetin-beta (EPO-B) in the treatment of chemotherapy-induced anaemia in 2393 patients. Data were derived from the IMS Hospital Disease Database, a longitudinal database in secondary care unique to Belgium. The objectives of this study were to assess the applicability of that analysis in the Spanish setting, and to evaluate differences in cost between ESAs in Spain. **METHODS:** To adapt the Belgian data for Spain, discrepancies in epidemiology and treatment patterns were examined, and costs were replaced with Spanish-specific unit costs. Adjusting for tumour-specific incidence and chemotherapy use, costs were analyzed using a mixed-effects model stratifying for propensity score quintiles as in Spaepen 2008. Data sources included Eurostat, national cancer registries, IMS sales data, treatment guidelines, and reimbursement guidelines and lists. **RESULTS:** The Spanish and Belgian populations were similar in terms of age, gender, ESA use and blood transfusions. Adjusting for chemotherapy use and the relative weight (incidence Spain/ incidence Belgium) of four pre-specified cancer types [haematological (1.2094), lung (0.6716), female breast (0.5654) and female genital (0.9589)], total costs (mean±SE) with DARB were 26% lower compared with EPO-A (p<0.0001) and 20% lower compared with EPO-B (p=0.0019). Anaemia-related costs were 29% and 17% lower in DARB patients than in EPO-A (p<0.0001) and EPO-B (p=0.0226) respectively. The mean duration of treatment was 40.63±2.39 days for DARB; 53.59±1.25 for EPO-A and 52.39±2.54 for EPO-B. **CONCLUSIONS:** By using published epidemiologic and treatment pattern data, it was possible to adapt the Belgian Hospital database to the Spanish population. Total and anaemia-related costs were lowest in patients receiving DARB compared with EPO-A or EPO-B. These findings are consistent with those from the Belgian analysis.

PCN34
COST ANALYSIS OF ANEMIA TREATMENT WITH ERYTHROPOIESIS-STIMULATING AGENTS (ESAS) IN CANCER PATIENTS RECEIVING CHEMOTHERAPY IN ITALY

Duran A[1], Spaepen E[2], Lamotte M[3], Lucioni C[4], Kutikova L[5], Pujol B[5], Gozzo M[6], Annemans L[7]
[1]*IMS Health, London, UK,* [2]*SBD Analytics BVBA/SPRL, Bekkevoort, Belgium,* [3]*IMS Consulting Group, Vilvoorde, Belgium,* [4]*Wolters Kluwer Health Italy Ltd, Milan, Italy,* [5]*Amgen (Europe) GmbH, Zug, Switzerland,* [6]*Amgen Dompe S.p.A., Milan, Italy,* [7]*Ghent University, Ghent, Belgium*

OBJECTIVES: Spaepen et al. (the Oncologist 2008;13:596–607) published a cost-analysis comparing darbepoetin-alfa (DARB), epoetin-alfa (EPO-A) and epoetin-beta (EPO-B) in the treatment of chemotherapy-induced anaemia, using propensity score matching. The study was performed using IMS Hospital Disease Database (2003-2005, a longitudinal database unique to Belgium containing individual patient/admission-level data on diagnoses, procedures, and pharmaceuticals. Given

the limited availability of databases reporting the same information in Italy, the objectives of this study were to assess the applicability of the Belgian analysis, and to estimate cost differences between ESAs in Italy. **METHODS:** To adapt the Belgian data for the Italian setting, costs were replaced with Italian-specific costs, and discrepancies in epidemiology and treatment patterns were examined. Adjusting for country discrepancies, costs were analyzed using a mixed-effects model stratifying for propensity score quintiles as in Spaepen et al. Sources included Eurostat, national cancer registries, IMS sales data, treatment and reimbursement guidelines, and reimbursement public tariffs. **RESULTS:** The Italian and Belgian populations were similar in terms of age, gender, ESA use and blood transfusions. The Belgian dataset was adjusted to reflect the incidence of haematological, lung, female breast and female genital cancers. No major differences between countries were found regarding the use of ESAs or blood transfusions. In Italy, total costs (mean±SE) were €10,546±873 for DARB versus €14,063±745 and €13,274±910 for EPO-A ($p<0.0001$) and EPO-B ($p=0.0008$), respectively. Anaemia-related costs were €3,144±211 for DARB versus €5,049±119 and €3,656±230 for EPO-A ($p<0.0001$) and EPO-B ($p=0.0935$). ESA costs were €2,475±187 for DARB versus €4,241±115 and €3,115±203 for EPO-A ($p<0.0001$) and EPO-B ($p=0.0139$). **CONCLUSIONS:** Total and anaemia-related costs were lowest in patients receiving DARB compared with EPO-A and EPO-B in Italy. These findings are consistent with those from the Belgian analysis. Adapting Belgian data to Italy is feasible when accounting for patient and treatment characteristics and costs.

PCN35

CAPECITABINE FOR THE TREATMENT OF COLORECTAL CANCER IN PRIVATE HEALTH SYSTEM IN BRAZIL: A BUDGETARY IMPACT ANALYSIS BASED ON REAL WORLD DATA

Clark O[1], Clark LGO[1], Botrel TEA[1], Paladini L[1], Medina P[1], Rosa B[2], Fiol E[2], Fortes AF[2], Castro AP[2], Faleiros E[1], Rodrigues N[2]
[1]*Evidências, Campinas, Brazil,* [2]*Evidências, Campinas, SP, Brazil*

OBJECTIVES: Capecitabine (C) is approved in Brazil to treat colorectal cancer CRC, and can replace the combination of 5fluorouracl (5FU) and folinic acid (FA) in many chemotherapy (CHEMO) combination. There are restrictions to their use in the private sector in Brazil, as oral (PO) CHEMO is not covered by health insurance plans (HI). For many patients and physicians, a PO option is preferred over the intravenous (IV) . Our aim was to study the budgetary impact linked to the use of C for the treatment of CRC in HI. **METHODS:** We searched Evidencias Database for CRC patients eligible for the use of C, in the year of 2008. This database has information from over 2 million of users of 14 HI. We calculated the costs of the IV chemo actually used (mainly combinations of 5FU-FA with oxaliplatin and irinotecan). We calculated the costs of the drug used and, when appropriate, the infusion pump to deliver 5FU by continuous infusion. Then, based on the real data of each individual patient, we calculated the costs if C replaced 5FU-FA in the CHEMO. We assumed both treatments would have the same efficacy, as reported in the literature. **RESULTS:** We found 315 records of CRC patients that used IV Chemo and could replace it by C. These patients received 2706 cycles of treatment and had an actual total cost of US$7,237,000 (85% of them refers to the CHEMO drugs only). If C replace 5FU-FA in the IV CHEMO, the total cost would drop 9.5%, to US$6,804,000, mainly due to the exclusion of the need of an infusion pump. **CONCLUSIONS:** The use of C to treat CRC is linked to a smaller cost than the IV alternative in the private health plans in Brazil.

PCN36

THE ECONOMIC IMPACT OF TREATING EARLY LUNG CANCER: A SYSTEMATIC REVIEW

Mahar AL, Fong R, Johnson A
Queen's University, Kingston, ON, Canada

OBJECTIVES: Lung cancer is one of the most common cancers in the world. Standard curative therapy includes surgical resection of the primary tumour. Understanding how to combine best clinical outcomes for the most efficient use of resources is important. We undertook a systematic review of the costs related to managing early stage lung cancer to summarize the body of literature from the global community. **METHODS:** An electronic literature search of EMBASE, MEDLINE and HEALTHSTAR was performed (January 2000-August 1, 2010). The search terms "Lung Cancer" and "Costs and Cost Analysis" or "Economics" were used. Two reviewers independently evaluated articles and consensus was achieved for all discordant evaluations. Data were abstracted using a standardized abstraction form. Costs are reported in 2010 Canadian dollars. **RESULTS:** The literature search identified 3654 abstracts; 25 articles were included and the research spanned 13 countries. The majority (15/25) of the studies performed cost identification studies; the remainder included 9 cost-effectiveness and 1 cost-utility analyses. Prospective research was performed in only one study. Just over 50% (13/25) of the studies reported a perspective, while 14/25 specified a time horizon for cost and health outcome collection. Overall costs for treating early NSCLC ranged from $24,040 (no recurrence) to $97,774 (persistent recurrence). The mean costs per patient for surgery ranged from $88 (lobectomy chest drain equipment) to $92,967 (thoracotomy lobectomy). **CONCLUSIONS:** The literature varies in adherence to optimal assessment methodology, and room for improvement is evident. Costs vary by treatment modality, yet few comparisons of available options exist for this population. Further comparisons of population-based clinical and economic outcomes are necessary in order to understand the burden of early lung cancer. This systematic review of the costs of early lung cancer may help to inform the methodologies and costs for future cost-effectiveness evaluations.

PCN37

COST-MINIMIZATION ANALYSIS OF SECOND-LINE CHEMOTHERAPY FOR NON-SMALL-CELL LUNG CANCER (NSCLC)

Laurendeau C[1], Chouaid C[2], Florentin V[3], Duchon D'engenières V[3], Detournay B[1]
[1]*Cemka, Bourg la Reine, France,* [2]*Service of Pneumology, Paris, France,* [3]*Roche SAS, Neuilly-sur-Seine Cedex, France*

OBJECTIVES: To compare the costs associated to second-line chemotherapies for adNSCLC in France. Three therapies, docetaxel, pemetrexed and erlotinib are currently marketed in France for second-line management of advanced non-small-cell lung cancer (adNSCLC). Published studies showed no statistically differences between these treatments in term of efficacy (median progression-free survival or survival), but there are few data on the costs of these therapies. **METHODS:** A cost-minimization analysis was based on an indirect comparison of the results of two prospective randomized French clinical trials (GFPC05-06 and CYTAR) in second-line setting. Costs were estimated in the perspective of the French National Sickness Fund and included direct treatments costs (excluding transports) and in-patients costs both for treatment administration and potential adverse events. All costs were estimated on a 100 days period. **RESULTS:** Studied population included 145 patients treated with erlotinib, 75 patients treated with docetaxel and 75 with pemetrexed. Characteristics of patients were assumed to be similar. Overall, the median direct costs of the second line chemotherapies/100 management days were: 9,009€ (IQR: 8,403-12,291) for docetaxel, 14,229€ (IQR: 12,718-20,099) for pemetrexed and 7,134€ (IQR: 6,752-8669) for erlotinib. Two by two, total costs differences between compared chemotherapies were all statistically significant ($p<0.001$). The cost breakdowns among drug costs, in-patient stays for drug delivery, tests and supportive care and adverse events were respectively 85%, 0%, 0%, 15% (erlotinib), 73%, 6%, 6%, 15% (pemetrexed), and 59%, 20%, 7%, 14% (docetaxel). **CONCLUSIONS:** Costs of second-line therapies for adNSCLC appeared to be slightly lower using erlotinib as compared with docetaxel and pemetrexed due to lower administration costs. However, this study was based only on an indirect comparison and head to head trials are required to confirm such a conclusion.

PCN38

ECONOMIC EVALUATION OF DARBEPOETIN ALPHA IN THE MANAGEMENT OF PATIENTS WITH CHEMOTHERAPY INDUCED ANEMIA (CIA) IN GREECE

Fragoulakis V, Maniadakis N
National School of Public Health, Athens, Greece

OBJECTIVES: An economic evaluation was undertaken to compare the treatment cost of patients on darbepoetin alfa (DA) 500 mcg once every 3 weeks (Q3W) and 150 mcg weekly (QW), epoetin-alfa (EA) 40,000 IU QW, epoetin-beta (EB) 30,000 IU QW and 3-times weekly (TIW) in the management of chemotherapy-induced anaemia (CIA) in Greece. **METHODS:** : The analysis was based on a decision tree model reflecting the local management of patients, driven primarily by their response to therapy (measured in terms of an increase in haemoglobin concentration ≥2 g/Dl). As therapies are assumed to be of similar efficacy, a cost-minimisation analysis was undertaken considering National Health Services and patient transportation costs. Different data on the dose and cost of drugs, and frequency of therapy and response rates, were obtained from the published literature, expert opinions and registries. The model was probabilistic and was used to run Monte Carlo simulations to compensate for uncertainty. Results correspond to 2011 costs. **RESULTS:** The mean total cost per patient treated with DA-Q3W was €2951 (95% Uncertainty Interval (UI): €2912-2992), DA-QW €3192 (95%UI: €3075-3308), EA-QW €3781 (95%UI: €3646-3914), EB-TIW €4908 (95%UI: €4563-5251), and EB-QW €3956 (95%UI: €3821-4089). Cost-savings associated with DA-Q3W were: 8% relative to DA-QW; 22% to EA-QW; 40% to EB-QW; and 25% to EB-TIW. The mean cost per response to DA-Q3W was €3999 (95%UI: €3760-€4241); to DA-QW €4326 (95%UI: €4036-4639); to EA-QW €5560 (95%UI: €5322-5790); to EB-TIW €7219 (95%UI: €6699-7734) and to EB-QW €5818 (95%UI: €5575-6051). **CONCLUSIONS:** The present economic analysis indicates that DA-Q3W and DA-QW may be associated with lower cost in comparison with other options for the treatment of patients with CIA in Greece. Of the two DA-based schemes, DA-Q3W appears to be associated with lower therapy cost. Research funded by Genesis Pharma.

PCN39

BURDEN OF BRAIN METASTASIS IN AN METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) POPULATION

Ganguli A[1], Henk H[2], Teitelbaum A[3], Ray S[1]
[1]*Abbott Laboratories, Abbott Park, IL, USA,* [2]*OptumInsight, Eden Prairie, MN, USA,* [3]*i3 Innovus, Eden Prairie, MN, USA*

OBJECTIVES: To assess the impact of brain metastasis (BrMets) on health care costs and survival among metastatic NSCLC patients in a geographically diverse commercially insured US population. **METHODS:** Retrospective analyses were conducted using a US commercial administrative claims database linking data from a lung cancer registry and mortality records from the Social Security Administration Death Master File (2005-2010). Two cohorts were formed – a) with BrMets, and b) without BrMets. Healthcare cost (hospitalization, ambulatory and pharmacy) and resource use (hospitalization, emergency {ER} and ambulatory visits) were compared using a generalized linear model (diagnosis →end of follow-up); a Cox proportional hazard model estimated impact on survival. All models adjusted for stage at diagnosis, pre-diagnosis comorbidity, age, and gender. **RESULTS:** A total of 584 metastatic NSCLC patients were included (mean 60.5 years/56.3% male): 247 (42.3%) had claims-based evidence of BrMets and were more likely to have been diagnosed with stage IV disease (62.8% vs. 52.2% without BrMets). Overall survival was shorter among patients with evidence of BrMets (median = 13.5 vs. 17.0 months; HR=1.29, $p<001$); health plan enrollment duration was similar (median = 11.7 months). With similar lengths of follow-up, average health care costs following diagnosis of

BrMets was 23% higher ($184,872 vs. $150,931; p=0.010) after adjustment for other factors. The difference was consistent across resources: 25% higher hospitalization costs $46,871 vs. $37,504; p=.082); 23% higher ambulatory costs, ($121,224 vs. $98,276; p=0.033); 23% higher retail pharmacy costs, ($13,282 vs. $10,774; p=0.118). Patients with BrMets averaged more hospitalizations (2.4 vs. 1.9; p=0.005), ER visits (2.7 vs. 2.2; p=0.067), and ambulatory encounters (111 vs. 92; p=0.005) from initial NSCLC diagnosis to end of follow-up. **CONCLUSIONS:** Intensity of resource use and costs were higher in metastatic NSCLC, especially in BrMets patients. Treatment that improves disease control could reduce the intensity of cost and resource use among NSCLC BrMets patients.

PCN40

HEALTH CARE RESOURCES UTILIZATION AND COSTS IN METASTATIC MELANOMA

Wang S, Zhao Z, Barber B, Gao SK, Wagner V
Amgen, Inc., Thousand Oaks, CA, USA

OBJECTIVES: To assess health care resource utilization and costs among patients with metastatic melanoma in real world practice setting. **METHODS:** Using a large US medical claims database, patients were identified between 2005 and 2010 using ≥2melanoma diagnoses (ICD-9-CM: 172.xx, V10.82) and ≥2 diagnoses for metastasis (ICD-9-CM: 197.xx, 198.xx). The index date was the first date of metastasis diagnosis. Patients who had other primary malignant tumors prior to the melanoma diagnosis, were younger than 18 years old at the index, or had a pre-index period of less than 6 months, were excluded from the analysis. Patients were followed from the index date to death, disenrollment, or end of the study period (June 30, 2010), whichever occurred first. Health care utilization and health care costs (adjusted to 2010 dollars) were examined per patient-year for office visits, outpatient visits, emergency room (ER) visits and inpatient hospitalization. **RESULTS:** A total of 2,546 patients with metastatic melanoma were identified. Mean (± standard deviation) age at the index was 60.6 (± 14.0) years and 36.5% were female. Overall, 87.3% of the patients had at least one physician office visit with a mean of 24.0 visits per person-year, 64.7% had an ER visit with a mean of 12.9 visits per person-year, 90.6% had an outpatient visit with a mean of 8.3 visits per person-year, and 82.2% had been hospitalized with a mean of 12.4 hospitalizations per person-year. The mean total costs per patient-year were $117,610, which was driven mainly by inpatient costs ($60,355/patient-year) and outpatient costs ($34,540/patient-year). **CONCLUSIONS:** Inpatient and outpatient care are key cost drivers in the medical management of patients with advanced melanoma.

PCN41

HOSPITAL HEALTH CARE COSTS FOR THE MANAGEMENT OF HER2-POSITIVE BREAST CANCER WITH BRAIN METASTASES

Baffert S[1], Cottu P[1], Kirova Y[1], Bachelot T[2], Mercier F[3], Le Rhun E[4], Lévy C[5], Gutierrez M[6], Madranges N[7], Moldovan C[8], Coudert B[9], Spaëth D[10], Serin D[11], Cotté FE[12], Benjamin L[12], Simondi C[1], Maillard C[13], Laulhère-Vigneau S[13], Durand-Zaleski I[14]
[1]*Institut Curie, Paris, France,* [2]*Centre Léon Bérard, Lyon , France,* [3]*StatProcess, Port-Mort, France,* [4]*CLCC Oscar Lambret, Lille, France,* [5]*CLCC François Baclesse, Caen, France,* [6]*Centre René Huguenin, Saint Cloud, France,* [7]*Institut Bergonié, Bordeaux, France,* [8]*CRLCC Henri Becquerel, Rouen, France,* [9]*Centre Georges-François Leclerc, Dijon, France,* [10]*Centre d'Oncologie de Gentilly, Nancy, France,* [11]*Clinique Sainte Catherine, Avignon, France,* [12]*GlaxoSmithKline, Marly le Roi, France,* [13]*Céri Médical, Garches, France,* [14]*Hôpital Henri Mondor, Créteil, France*

OBJECTIVES: Incidence of breast cancer (BC) with brain metastases (BM) is increasing especially among patients with HER2-positive status. Their management is based on diversified and expensive treatments for which costs data are scarce. We estimated hospital costs of BCBM and their evolution within a period of two years following BM diagnosis. **METHODS:** An observational retrospective multicenter study was conducted on 207 HER2+ breast cancer (BC) patients, newly diagnosed with brain metastases (BM) as first site of relapse or secondary metastases between January 2006 and December 2008. Data on patient profile, treatments (neurosurgery, radiotherapy, chemotherapy), complications leading to rehospitalisation and hospitalisation stays were collected. Direct medical costs were estimated from the Health Insurance perspective using Diagnosis Related Groups (DRGs) official tariffs and expensive drugs tariffs (2007). Censored treatment cost data were analyzed using the Bang and Tsiasis method. **RESULTS:** Patients were treated by radiation therapy (91.8%), chemotherapy (84.5%) and neurosurgery (12.6%). The mean cost of management of HER2-positive BCBMs was 18,480€/patient from 0-6 months, 16,306€ from 7-12 months, 15,844€ from 13-18 months and 15,225€ from 19-24 months. The mean cost of the first year following diagnosis was 33,847€/patient. The proportion of costs attributed to inpatient hospitalizations stay was equal to the one attributed to expensive drugs whatever the time period of follow-up (17,153€/patient for hospitalizations vs 16,693€/patient for expensive drugs after one year of follow-up). Patients with BM as first site of relapse induced more health care resources compared to patients with secondary BM. **CONCLUSIONS:** The management of BCBM generates important health care resources mainly concentrated within the first months. Health care costs decrease during the follow-up period while the variability of costs is increasing. These results illustrate the personalized disease management at the advanced stage of disease. Observational studies are an interesting opportunity to estimate health care resources and associated costs more precisely.

PCN42

TREATMENT COSTS OF BONE METASTASES IN PATIENTS WITH LUNG CANCER: RESULTS FROM A FRENCH PROSPECTIVE, OBSERVATIONAL, MULTICENTER STUDY (GFPC 0601)

Borget I[1], Decroisette C[2], David P[3], Fournel P[4], Locher C[5], Grangeon V[6], Thomas P[7], Barlesi F[8], Bombaron P[9], Chouaid C[10]
[1]*Health Economic service, Biostatistic and Epidemiology Department, Villejuif, France,* [2]*Centre Hospitalier de la Région d'Annecy, Pringy, France,* [3]*Service of Pneumology, Elbeuf, France,* [4]*Hôpital Nord,, Saint-Etienne, France,* [5]*Service of Pneumology, Meaux, France,* [6]*Service of Pneumology, Roanne, France,* [7]*Centre Hospitalier, GAP, France,* [8]*Département des Maladies Respiratoires, Marseille, France,* [9]*Service of Pneumology, Mulhouse, France,* [10]*Service of Pneumology, Paris, France*

OBJECTIVES: The aim of this prospective, observational, multicenter study was to estimate the management costs of bone metastatic disease (BMD) in patients with lung cancer. **METHODS:** Consecutive patients presenting BMD from lung cancer diagnosed between May 2006 and May 2007 in 40 centers were enrolled. The natural course of bone metastatic disease was modeled using a Markov model with 4 health states (asymptomatic patient, symptomatic patient, skeletal-related event (SRE) and death) and a cycle length of one month, until death or a 5-year period. Direct medical costs induced by BMD (including symptomatic or therapeutic treatment and hospitalizations) were prospectively collected from the health care provider's perspective. **RESULTS:** Among the 554 patients enrolled (mean age 62 years, 77% of males), 26.7% presented a SRE at diagnosis and 39% during follow-up. The median survival time was 5.8 months, and the 1- and 2-year survival rates were 22% and 7%, respectively. The main BMD treatments were opiate therapy (78%), biphosphonates (52%), radiotherapy (42%), and surgery (9%). The mean monthly BMD treatment costs were 190 €, 374 €, and 4 672 € for asymptomatic patients, symptomatic patients, and patients with SRE, respectively. The average first-year BMD management cost was 3 999 € ± 4 135 (IC95%: 374-15 886), and 49.5% of this cost was attributable to patients with SRE. **CONCLUSIONS:** This analysis underlines the burden of bone metastatic disease, and particularly of skeletal-related event in overall treatment costs.

PCN43

COST OF HPV ASSOCIATED DISEASES IN SAINT-PETERSBURG

Lyalina LV[1], Tolkushin A[2], Akhmetzyanov IM[3], Nikolaevich MS[4]
[1]*Pasteur Scientific-Research Institute of Epidemiology and Microbiology, Saint-Petersburg, Russia,* [2]*MSD, Moscow, Moscow, Russia,* [3]*Edicia innovation center, Saint-Petersburg, Russia,* [4]*Ramzaev Scientific-Research Institute of Radiation Hygiene, Saint-Petersburg, Russia*

OBJECTIVES: To assess an economical burden of HPV associated diseases in Saint-Petersburg. **METHODS:** Total lifetime costs (direct and indirect) of HPV-associated diseases (cervical cancer, cervical dysplasia – CIN I-III, and condylomatosis - genital warts) in one cohort (13 years old girls in 2010; life expectancy - 74 years; cohort amount - 16 thousands) were estimated. Epidemiologic forecast was prepared based on mathematical-statistical modeling with least-square method of regression analysis on parent observation matrix. Raw epidemiologic data on morbidity and mortality were derived from official statistics. Cost of treatment was calculated using current out-patient and hospital tariffs (in obligatory medical insurance program) and standards of treatment (as of 2009). Indirect costs (gross output underproduction, disability pension, sick-pay etc.) were assessed based on existing legislation (Federal and Saint-Petersburg's regional). No discounting was applied in the analysis. **RESULTS:** Rates (per 100 000 female population) of dysplasia, genital warts, and cervical cancer incidence, and death were 16.5, 38.7-59,7, and 13.1-17.3, and 7.1-9.6, respectively. 10 years' growth of cervical cancer incidence and mortality was expected to be 12-15% and 8-15% (in different age groups), respectively. Total annual economic burden due to HPV diseases was 822 mln. Rub which includes: 72 mln. Rub – treatment of cervical cancer, 637 mln. Rub – indirect costs due to cervical cancer; 89 mln. Rub – dysplasia, 20 mln. Rub – genital warts. Sum of total cost in one cohort was 1.1 billion Rub. **CONCLUSIONS:** Economic burden of HPV-associated diseases in Saint-Petersburg in one cohort expected to be 1.1 billon Rub.

PCN44

COST-OF-ILLNESS STUDY OF HUMAN PAPILLOMAVIRUS CANCERS IN ENGLAND

Tempest MJ[1], Thurston S[1], Carroll S[2], Charman F[2], Rajoriya F[2]
[1]*Pharmerit Ltd, York, UK,* [2]*Sanofi Pasteur MSD, Maidenhead, UK*

BACKGROUND: Human papillomavirus (HPV) is the most common sexually transmitted infection and is a well-established cause of anogenital cancers (responsible for over 70% of cervical cancers). Vaccines that target the HPV strains responsible for such cancers elicit virus-neutralising antibody responses, thus preventing the initial infection and some re-infections associated with the same HPV types. Research also suggests that HPV is a risk factor in cancers originating in the upper aero-digestive tract, known as head and neck (H+N) cancers. **OBJECTIVES:** To estimate the prevalence, incidence and associated costs of HPV-related anogenital and H+N cancers in England. **METHODS:** The Hospital Episode Statistics (HES) database was used to estimate the prevalence and incidence of anogenital and head and neck cancers in England from 2002 to 2011. An in-house epidemiologic study and published sources were used to estimate the proportions of these cancers attributable to HPV . Cost estimates using Healthcare Resource Groups (HRGs) in combination with the most recent UK National Tariff will be applied to the data. Estimates for costs outside the scope of the National Tariff (such as rehabilitation costs which, for example, are a key component of H+N cancer treatment pathways) will be derived from expert opinion using resource use surveys. Results will be validated by clinical experts in each cancer included in the analysis. **RESULTS:** The analyses will highlight key areas of the broader burden of HPV-related cancers and quantify the associated healthcare costs falling on the NHS in England. A proportion of HPV-related cancers can be prevented through vaccination, as such, the analysis aims to capture overall costs and, in turn, the potential for cost offsets through the implementation of preventative healthcare pathways. **CONCLUSIONS:** The use of HPV vaccines has the potential to reduce the incidence of a proportion of HPV-related cancers, improving patient quality of life in a cost-effective manner.

PCN45

PROJECTION OF THE PATIENTS' POPULATION TREATED FOR CHRONIC MYELOID LEUKEMIA IN CHRONIC PHASE IN FRANCE: AN EPIDEMIOLOGICAL MODEL AT THE HORIZON 2015

Fagnani F[1], Sartre J[2], Rota C[2], Bregman B[2], Gaudin AF[2]
[1]Cemka, Bourg la Reine, France, [2]Bristol-Myers-Squibb, Rueil Malmaison, France

OBJECTIVES: Chronic Myeloid Leukemia (CML) is a myeloproliferative disease associated with a chromosomal translocation (Philadelphia chromosome). Since 2003 life-long treatment by Tyrosine Kinase Inhibitors (TKIs) have dramatically improved survival. The objective of this study was to predict the characteristics of the population under TKI treatment at the horizon 2015. **METHODS:** An epidemiological model was developed over the period 2003-2015 on first and following line therapies, combining demographic, incidence, prevalence, survival data and probability of resistance or intolerance in each line. Data were derived from published randomized clinical studies. The model was tested over the period 2003-2009 by comparison with retrospective market data and then extrapolated to the period 2010-2015. **RESULTS:** At the time of the first TKI launch (imatinib) in 2003, a prevalent group of 1,878 patients started treatment. Second-generation TKIs dasatinib and nilotinib were then made available in France between November 2007 and May 2008 as second line therapy, and potentially in mid-2011 as first line. Despite a stable annual number of 600 incident cases (1.25 x10-5) of CML eligible for a TKI first line treatment, the total number of patients under treatment increased to 7260 in 2010 (a 3.9-fold increase since 2003) of which 1083 were in second line (15%). The extrapolation model predicted a total of 10,069 treated patients in 2015 of which 1,618 in second line (16%) representing a 39% 5-year increase. **CONCLUSIONS:** The dramatic overall survival benefit associated with TKIs was a key factor for explaining the growth of the CML treated population aside from the emergence of second line therapies.

PCN46

COST OF METASTATIC PROSTATE CANCER TREATMENT IN THE 12 MONTHS FOLLOWING DIAGNOSIS PER PATIENT IN RUSSIAN FEDERATION

Yagudina R[1], Kulikov A[1], Kogon L[2]
[1]I.M. Sechenov First Moscow State Medical University, Moscow, Russia, [2]FGBU NCESMP Minzdravsocrazvitiya RF, Moscow, Russia

OBJECTIVES: With 75,880 patients under medical supervision in 2007, prostate cancer is the fourth most frequent cancer in Russia and the first in terms of increase of mortality (+21,6%) with ,8909 deaths/year. Moreover metastatic prostate cancer (MPCa) holds more than 60% of these patients at the same time being the leading expenditure driver. The purpose of this study was to evaluate the burden of illness and total per patient costs, associated with managing patients with (MPCa) in the 12 months following diagnosis in Russia from perspective of public healthcare system. **METHODS:** A costing model combined the data of official algorithms (standard of treatment approved by Ministry of Health) and guidelines of MPCa management, as well as local experts opinion and published data on resource use and unit costs from published sources to calculate total per patient direct costs of MPCa treatment. Direct costs of MPCa include expenses on medical services and pharmacotherapy (cytostatics, hormones and antihormones, accompanying and other drugs). As initial treatment following diagnosis radiotherapy was used most frequently. Use of chemotherapy was low. Relapse and mortality were not factored into the model. Total direct medical costs of initial treatments following diagnosis per patient were calculated for MPCa in 12 months timeframe. **RESULTS:** Total per patient direct costs following diagnosis was 810,529 roubles. Analysis of the costs structure showed that hormone therapy represents a significant higher cost to surgery, while radiotherapy had the highest cost proportion. Pharmacotherapy was the major driver of MPCa treatment cost (more than 50% share from all expenditures). **CONCLUSIONS:** In this study quantifying the cost of MPCa treatment in Russia was found a significant resource utilization and healthcare costs, along with the major cost drivers. Given the number of new cases diagnosed in Russian Federation, these estimates suggest a large total spending on the disease.

PCN47

CLINICAL AND ECONOMIC BURDEN OF BREAST CANCER IN JAPAN: A DIAGNOSIS PROCEDURE COMBINATION–BASED CLAIMS DATABASE SURVEY

Arakawa I[1], Ohta K[2], Matsubayashi D[2], Nakamura M[2], Shiragami M[3]
[1]Teikyo Heisei University, Ichihara, Chiba, Japan, [2]Medical Data Vision Co., Ltd., Chiyoda ku, Tokyo, Japan, [3]Nihon University, Funabashi, Chiba, Japan

OBJECTIVES: In 2008, the annual medical expenditure on cancer treatment in Japan was approximately 16 trillion yen. In the past decade, a few molecular-targeted drugs (MTDs) were developed for the treatment of HER2+ metastatic breast cancer (HER2-MBC). The number of MTD-treated patients increases every year, which is a concern with regard to the economic impact of cancer therapy. Trastuzumab is the most popular alternative to HER2-MBC therapy in Japan, but it has a high national health insurance price of approximately 220,000 yen per month for women weighing 50 kg. To estimate the clinical and economic burden of breast cancer (BC) and HER2-MBC therapies, we commenced a large clinical database survey, by examining the diagnosis procedure combination (DPC)–based claims, which included flat payment schemes. **METHODS:** The database, which consists of 15 DPC-targeted institutions that had contracted with Medical Data Vision Ltd., includes approximately 400,000 patients. To extract the pertinent population and estimate the clinical and economic burden of MTDs, a target population consisting of individuals diagnosed with BC on or before March 31, 2010, aged more than 20 years, and treated with MTDs for HER2-MBC was chosen. The observation period was April 1, 2008 to March 31, 2010. **RESULTS:** During the observation period, 2,419 individuals were diagnosed with BC. Of these, 98 were receiving or had received MTDs. The observed estimated economic cost of BC treatment was 994,000 yen, with an observation duration of approximately 14.0 person-months. The cost of HER2-MBC treatment with MTDs was estimated at 4,455,000 yen with a duration of 17.4 person-months. CONCLUSION: HER2-MBC therapy seriously impacted the annual medical expenditure in Japan and had a rare survival duration. The database was useful for conducting an economic analysis of cancer treatment in Japan.

PCN48

COSTS OF TUBEROUS SCLEROSIS COMPLEX (TSC) NEUROLOGICAL AND DEVELOPMENTAL MANIFESTATIONS IN BRAZIL

Mussolino F[1], Saba da Silva N[2], Valentim J[3]
[1]NEW BD - Business Developers, São Paulo, SP, Brazil, [2]IOP-GRAACC/UNIFESP, São Paulo, SP, Brazil, [3]Novartis Biociências SA, Sao Paulo, SP, Brazil

OBJECTIVES: To estimate direct medical costs of Tuberous Sclerosis Complex with neurological and developmental manifestations under the Brazilian public health care system perspective (SUS). **METHODS:** A retrospective database analysis was developed from ICD-10 search from January/2008 (revision of table of procedures by SUS Information Technology Department/DATASUS) to February/2011. Neurological and developmental manifestations of TSC included in the study were subependymal giant cell astrocytoma (SEGA), epilepsy, epileptic syndromes/infantile spasm, mental disability and autism, based on prevalences and expected costs to SUS. Direct medical costs per patient per year for each manifestation were estimated based on DATASUS ambulatory (high complexity) and hospital settings, whose databases included 2,016,188 and 9,236,360 persons, respectively. Epidemiologic literature was applied to correct misreported data and estimate average cost per patient per year for all manifestations. Sensitivity analysis was performed for the prevalence of manifestations. Costs were reported in 2010 Reals. **RESULTS:** The most prevalent procedure (and respective unit cost) for SEGA, epilepsy/epileptic syndromes/infantile spasm, and mental disability/autism were surgery (R$6302), hospitalization for uncontrolled seizure (R$585) and anti-epileptic drugs (R$1887), and psychiatric ambulatory treatment (R$275/R$892), respectively. The average direct medical costs per patient per year at SUS were R$7672 for SEGA, R$2,570 for epilepsy, R$1,349 for epileptic syndromes/infantile spasm, R$4668 for mental disability and R$2,276 for autism. Average cost per patient per year for all manifestations was R$19,180. This cost varied from R$13,580 to R$22,556 in sensitivity analysis. TSC neurological and developmental manifestation costs are expected to be underestimated due to lack of access and provision of health services, mainly in long-term disorders. **CONCLUSIONS:** TSC neurological and developmental manifestations impose significant economic burden to the Brazilian public health care system. However, the real economic burden is potentially higher as the diagnosis and treatment of the disease and its manifestations are underestimated considering restrictions of access and health service provision.

PCN49

INCIDENCE RATE AND BURDEN OF ILLNESS ASSOCIATED WITH HUMAN PAPILLOMAVIRUS RELATED GENITAL CANCERS IN SPANISH WOMEN

Rana C, Mann K, Wadhwa A, Pathak P
Heron Health Private Ltd, Chandigarh, Chandigarh, India

OBJECTIVES: To review incidence rate and burden of illness associated with Human Papillomavirus (HPV) related female genital (cervical, vulvar and vaginal) cancers in Spain. **METHODS:** Databases and registries searched for data retrieval included EMBASE, PUBMED, Cochrane, Globocan, WHO, SEER and relevant grey literature. Studies reporting epidemiology and costs associated with HPV-related genital cancers in females were of interest. **RESULTS:** In 2008, age standardized incidence rate of cervical cancer per 100,000 females was 6.3 in Spain compared to 5.7, 7.2, 10.6 and 15.3 in US, UK, Europe and worldwide, respectively (Globocan 2008). The incidence of cervical cancer was highest among Spanish women aged 45-54 years. Incidence rate of vulvar and vaginal cancers ranged from 1.6-4.0 and 0.3-0.7 per 100,000 females, respectively. Additionally, vulvar and vaginal cancers were most common among older women (≥70 and ≥65 years, respectively). In the same year (2008), mortality rate due to cervical cancer was 1.9 per 100,000 females (WHO 2010). Mortality rate for vulvar-vaginal cancer was 9.34% from 1997-2008 (Gil-prieto 2011). Annually, 7.6 million pap smear tests were performed in Spain at the cost of €622 million (Castellsague 2009). Average number of hospitalizations per year was 4151 due to cervical cancer and 17,883 due to vulvar-vaginal cancers. Mean (SD) length of hospital stay due to cervical cancer was 8.7 (15.2) days and 8 (10) days due to vulvar-vaginal cancer (Gil 2007, Gil-prieto 2011). Estimated annual cost of hospitalization due to cervical cancer and carcinoma in situ was €19 million (Gil 2007). Indirect costs (productivity loss) associated with mortality related to cervical cancer were €1.1 million (Oliva 2006). **CONCLUSIONS:** HPV-related genital cancers have significant incidence and mortality rate in Spanish women with higher risk in elderly female population. The direct and indirect costs incurred due to genital cancers are substantial and reflect considerable economic burden.

PCN50

FIRST AND SECOND LINE LUNG CANCER TREATMENT UTILIZATION PATTERNS AND ASSOCIATED COSTS IN A UNITED STATES HEALTH CARE CLAIMS DATABASE

Ramsey S[1], Henk H[2], Sullivan J[3], Teitelbaum A[3], Akhras K[4], Sollano J[4], Smith G[4], Chen C[4]
[1]Fred Hutchinson Cancer Research Center, Seattle, WA, USA, [2]OptumInsight, Eden Prairie, MN, USA, [3]OptumInsight, Eden Prairie, MN, USA, [4]Pfizer, New York, NY, USA

OBJECTIVES: Because treatment options for lung cancer are changing rapidly, it is important to understand current treatment patterns and cost implications. We conducted a retrospective claims analysis to identify common lung cancer regimens and direct medical costs in a large US commercial health insurance and Medicare Advantage database. **METHODS:** We identified patients with lung cancer receiving 1st or 2nd line chemotherapy between January 2006 to December 2010

using an algorithm utilizing enrolment records and ICD-9 codes. A patient flow algorithm was constructed to define treatment cohorts. Patients were stratified based on the lung cancer drug treatment received following diagnosis and first line therapy. Total costs are report for the 1 year follow up period after initiation of drug treatment. **RESULTS:** A total of 2739 lung cancer patients were included in the analysis; 53% >65 yr. Paclitaxel or docetaxel plus platinum were the most commonly utilized 1st line regimens. Pemetrexed plus docetaxel was the most common 2nd line treatment. Among patients receiving 1st line treatment and remaining enrolled in the health plan, only 16.7% received 2nd line treatment. Total costs (average +/− SD) in the year following chemotherapy initiation was $70,205 ± 66,956 (range $50,000-$120,000) for those with 1 line of therapy versus $93,432± $66,208 (range $62,000-$169,000) with two or more lines. For all patients, average ambulatory care costs (which included IV administration costs) were $34,449±40,847, intravenous drug costs ($17,246± 27,488), and inpatient hospital costs (14,180 ±$31,409) comprised the largest proportion of costs in the year following chemotherapy initiation. **CONCLUSIONS:** In this analysis, few lung cancer patients received 2nd line treatment.. For those patients who received 2nd line treatment and beyond, direct medical care costs are over $23,000 higher over years 2006-10 compared to those receiving only one line. Ambulatory costs comprised the greatest proportion of total costs (50%).

PCN51

HEALTH CARE RESOURCES AND COSTS ACROSS LINES OF THERAPIES IN INSURED PATIENTS WITH METASTATIC BREAST CANCER IN THE UNITED STATES

Bonthapally V[1], Ganguli A[2], Landsman-Blumberg P[3], Mcmorrow D[4], Ray S[2]
[1]*Abbott Laboratories, abbott park, IL, USA,* [2]*Abbott Laboratories, Abbott Park, IL, USA,* [3]*Thomson Reuters, Ann Arbor, MI, USA,* [4]*Thomson Reuters, Cambridge, MA, USA*

OBJECTIVES: To compare health care resource utilization (HRU) and costs by line of therapy (LOT) among patients with metastatic breast cancer (MBC). **METHODS:** MarketScan® databases, January 1, 2005 to December 31, 2009, were used to identify women aged ≥18 with breast cancer (ICD-9-CM of 174.xx). The index date was the first prescription fill or administration of anti-neoplastic agents. Either a 90-day gap in treatment or initiation of a new regimen ended each LOT. Per patient per month (PPPM) expenditures for utilizers of inpatient (IP), outpatient (OP), emergency department visits (ED), MBC-drugs (oral and infused), hormonal, radiology, and supportive therapies across four LOTs (1L-first line, 2L-second, 3L-third, 4L-fourth) were statistically compared. HRU rates (Visits per patient with ≥1 Visit) were also compared. **RESULTS:** A total of 8494 MBC patients (1L:7,765; 2L:4,077; 3L:2,033, 4L:1,059) were included. Bone metastases were most common (43.9%) at index followed by liver (17.7%) and lung (12.8%). PPPM expenditures for IP (1L: $1,183, 2L:$1,318, 3L: $1,401, 4L:$1,670; p=0.660), OP (1L:$1,751, 2L:$1,624; 3L: $1,626; 4L:$1,626, p=0.413), and ED (1L:$64, 2L:$67, 3L: $73, 4L:$57 p=0.997) were not stastically siginificantly different across the four LOTs. PPPM expenditures for MBC oral-drugs (1L:$460, 2L:$530, 3L:$589, 4L:$743,p=0.37), hormonal (1L:$87 , 2L:$65, 3L: $70, and 4L:$55,p=0.388), and radiology therapies (1L:$290,2L:$280,3L: $280,and 4L: $271, p=0.999) were also not statistically different across LOTs. MBC infused-drugs (1L:$4096,2L:$4,607,3L:$4,841, 4L:$4,521,p=0.001) did differ. Within supportives, PPPM across LOTs were stastically different for anti-emetics (1L:$283,2L:$321;3L: $320;4L:$311,p=0.007) and pain medications (1L:$42,2L:$50;3L:$62;4L:$71,p=0.002) but not for IV-bisphosphonates (1L:$406,2L:$412;3L:$419;4L:$410,p=0.964). The mean HRU rates for IP (range1.4-1.4), ED (1.7-1.8), OP hospial (8.4-9.4) office-visit (11.2-12.6), and Other outpatient visits (18.9-20.5,) were similar across LOTs. **CONCLUSIONS:** No significant variation in the PPPM costs of (IP, OP, ED, MBC oral drugs, hormonal, radiology, or IV bisphosphonates) was oberved across four LOTs. LOT costs differed for infused drugs, anti-emetics, and pain medication within this MBC population. Further research is required to explore these variations.

PCN52

ECONOMIC IMPACT OF HEALTHCARE RESOURCE UTILISATION PATTERNS AMONG PATIENTS DIAGNOSED WITH ADVANCED MELANOMA IN THE UK, ITALY, AND FRANCE: RESULTS FROM A RETROSPECTIVE, LONGITUDINAL SURVEY (MELODY STUDY)

Johnston K[1], Levy A[2], Lorigan P[3], Maio M[4], Lebbé C[5], Middleton M[6], Testori A[7], Bédane C[8], Konto C[9], Dueymes A[10], Van Baardewijk M[11]
[1]*Oxford Outcomes Ltd, Vancouver, BC, Canada,* [2]*Dalhousie University, Halifax, NS, Canada,* [3]*The Christie NHS Foundation Trust,, Manchester, Cheshire, UK,* [4]*University Hospital of Siena, Siena, Italy,* [5]*Hôpital St-Louis, Paris, France,* [6]*Churchill Hospital, Oxford, , UK,* [7]*Istituto Europeo di Oncologia, Milan, Italy,* [8]*Hopital Dupuytren, Limoges , France,* [9]*Bristol-Myers Squibb, Paris , France,* [10]*PAREXEL International, Semoy, France,* [11]*Bristol-Myers Squibb, Braine L'Alleud, Belgium*

OBJECTIVES: To describe patterns of health care resource utilisation and associated costs for patients with advanced melanoma in the UK, Italy, and France. **METHODS:** For patients receiving systemic treatment, or supportive care, hospitalisation, hospice care, and outpatient data were retrieved retrospectively from advanced disease diagnosis until 1 May 2008 as part of a multicountry observational study (MELODY; Lorigan et al., ISPOR 2010). Costs were estimated by multiplying the utilisation level by unit cost. In an exploratory analysis, costs were compared between individuals who died within one year of initiating first-line treatment (short-term survivors) and those with ≥1 year follow-up (long-term survivors). **RESULTS:** Hospitalisation costs were highest in France (€6262 per-person compared with €3225 in the UK and €2486 in Italy), reflecting higher rates of hospitalisation. In contrast, outpatient costs were highest in the UK (€782 per-person, compared with €115 in France and €72 in Italy), reflecting both the highest rate and frequency of outpatient visits and the highest cost per visit. While daily hospice costs were lowest in the UK, frequency and duration of hospice care were notably higher than in Italy or France, resulting in the highest total hospice costs per-person. Hospitalisation rates were consistently higher during supportive care compared with systemic therapy. It should be noted that roughly a third of patients entered clinical trials and therefore could not be included in the analysis. In exploratory analysis, total costs were generally higher for long-term survivors, but monthly per-patient costs were generally lower for long-term survivors, consistent with a hypothesis that resource utilisation and costs do not necessarily increase proportionally with extended survival. **CONCLUSIONS:** Total costs associated with resource utilisation for advanced melanoma patients varied across countries. Overall cost differences were due to differences in frequency and intensity of utilisation patterns and variation in unit costs of health resources.

PCN53

ECONOMIC BURDEN OF HPV-RELATED HEAD & NECK AND ANAL CANCERS IN GERMANY

Remy V[1], Heitland W[2], Klussmann J[3], Schaedlich P[4], Chen X[4], Moro L[1]
[1]*Sanofi Pasteur MSD, Lyon, France,* [2]*Munich Municipal Hospital, Munich, Germany,* [3]*University of Giessen, Giessen, Germany,* [4]*IGES, Berlin, Germany*

OBJECTIVES: Data on economic burden of head & neck (H&N) and anal cancers in Germany is scarce. Human papillomavirus (HPV) infection is likely to be responsible for 16% to 72% of H&N cancer, and 84% of anal cancer. This study aimed to assess the annual management costs (hospitalisations, inpatient rehabilitations, sick leaves) associated with these HPV-related cancers from the German Statutory Health Insurance (SHI) perspective. **METHODS:** This study was based on the retrospective analysis of five German databases, which cover hospitalisations (German Federal Statistical Office-Destatis), major categories of treatment such as surgery, radiotherapy and medical (Institute for the Hospital Remuneration System-InEK), inpatient rehabilitations (German Public Pension Insurance-DRV) and sick leaves (Local-SHI-funds, Federal Ministry of Health). Associated number of cancers, health care resource use, and costs were identified and extracted using ICD-10 codes (H&N cancer: C01-C06, C09-C14, C32; anal cancer: C21). The HPV-related cancers total cost was estimated based on the percentage of each cancer and anatomical site likely to be attributable to HPV. **RESULTS:** In 2008, 69,631 hospitalisations for H&N and anal cancers were reported (92% due to H&N cancer), whereas the number of inpatient rehabilitations and sick leaves were 5,415 and 18,391, respectively. The estimated total cost associated with HPV-related H&N and anal cancers was €111 million, mainly represented by H&N cancer (74%). Hospitalisations, inpatient rehabilitations, and sick leaves, accounted for 82%, 4%, and 15% of total HPV-related cost, respectively. **CONCLUSIONS:** The estimated annual cost of HPV-related H&N and anal cancers contribute to a significant economic burden in Germany, appearing to be as important as cost of HPV-related cervical cancer, and should be considered when assessing health and economic benefits of HPV vaccination in both genders. Furthermore, this cost is likely to be underestimated since outpatient management cost is not included, and may be significant for these cancers.

PCN54

HOSPITAL COSTS RELATED TO HEPATITIS C VIRUS INFECTION: FIRST ANALYSIS OF THE FRENCH HOSPITAL NATIONAL DATA BASE

Rotily M[1], Vainchtock A[2], Lannuzel X[3], Jouaneton B[4], Wartelle-bladou C[5], Anceau A[3]
[1]*Heva, LYON, France,* [2]*HEVA, LYON, France,* [3]*Janssen, Issy-les-Moulineaux, France,* [4]*HEVA, Lyon, France,* [5]*Hopital Saint Luc, Montreal, QC, Canada*

OBJECTIVES: There are approximately 4 million of Hepatitis C Virus (HCV) carriers in Europe. HCV infection is a leading cause of liver cirrhosis (LC), transplantation (LT), and hepatocellular carcinoma (HCC). On the brink of new antiviral treatments in France, we aimed at evaluating the 2009 hospital costs related to chronic hepatitis C. **METHODS:** All hospital stays with a B18.2 ICD-code were extracted from the 2009 hospital database and distributed in five groups: uncomplicated chronic hepatitis C, LC, HCC, LT, and unclassifiable. Costs were calculated using the French medical information system (PMSI). **RESULTS:** A total of 27,258 stays were identified (15,482 patients): uncomplicated hepatitis C (42%), LC (41%), HCC (13%), LT (2%), unclassifiable (2%). Mean length of stay was 6.1 and 28.7 days in medical and surgical units respectively; 8,214 medical procedures for baseline/follow-up assessments were carried out in patients with uncomplicated hepatitis, including 1,970 liver biopsies. Annual cost was estimated at 65,652,651€, including 47% for LC, 18% for HCC, and 19% for LT. The mean annual cost per patient increased from 1,049€ (uncomplicated hepatitis) to 4,748€ for LC, 6,513€ for HCC, and 40,152€ for LT (expensive drugs excluded). Expensive drugs accounted for 7% of total costs in public sector (95% of all stays), including 30% for cancer therapies, 33% for erythropoietins, 12% for anti-infection drugs and 11% for hemostasis. **CONCLUSIONS:** This first analysis devoted to HCV infection of the French hospital national database brings new and essential information. It shows that 84% of HCV-related hospital costs are attributable to advanced liver diseases, and 19% to the 2% of patients' recipients of a liver transplant. Together with more efficient therapies, enhancing screening and access to treatment policy could substantially relieve the social burden of HCV.

PCN55

THE ECONOMIC BURDEN OF ADJUVANT CHEMOTHERAPY IN GERMANY

Eiermann W[1], Rezai M[2], Kuemmel S[3], Kühn T[4], Benkow A[5], Hogberg D[6], Schweikert B[7], Blohmer JU[5]
[1]*Rotkreuzklinikum München gGmbH, München, Germany,* [2]*Luisenkrankenhaus, Düsseldorf, Germany,* [3]*Kliniken Essen-Mitte, Essen, Germany,* [4]*Klinikum Esslingen, Esslingen, Germany,* [5]*Sankt Gertrauden Krankenhaus, Berlin, Germany,* [6]*OptumInsight, Stockholm, Sweden,* [7]*OptumInsight, München, Germany*

OBJECTIVES: In Germany, breast cancer is the most frequent cancer. In 2007, 7.2% of total German health care expenditure was spent on breast cancer. Despite, its

important epidemiological and economic burden, literature on cost of chemotherapy in breast cancer is rather scarce in Germany. The objective of this study was to estimate the cost of adjuvant chemotherapy in early stage breast cancer in Germany, using two different perspectives: the sick funds and the society. **METHODS:** A semi-systematic search of the literature was conducted to identify relevant articles describing the cost of adjuvant chemotherapy in Germany. The electronic database Pubmed and a selection of congress databases were searched using combinations of search terms designed to identify publications describing cost of adjuvant chemotherapy in early stage breast cancer patients. Searches were limited to those published in the English and German language between January 2000 and April 2011. A retrospective multicentre study was conducted to collect chemotherapy-related resources used. Unit costs were collected from public sources (EBM catalogue, Rote list, DRG list). Cost items collected included: chemotherapy drugs, monitoring and administration, prevention and management of adverse events, transportation to the treatment centre, and when using the societal perspective, also sick leaves. **RESULTS:** A total of 51 patients were included the study. The following adjuvant chemotherapy regimens were given to the patients: TAC (22%), FEC (20%), FEC+DOC (20%), TC (20%), EC+DOC/PAC (12%) and others (8%). The average total costs for an adjuvant chemotherapy treatment were estimated to be €11,036 in a sick fund perspective and €16,199 in a broader societal perspective. The direct costs were €5722 for chemotherapy drugs, €982 for chemotherapy administration and monitoring, €4228 for supportive drugs and management of adverse events. The indirect costs of sick leaves were €5163. **CONCLUSIONS:** Adjuvant chemotherapy represents a significant economic burden to the health care system and the society.

PCN56

ARE OUT-OF-POCKET PAYMENTS FOR ORAL ONCOLOGIC THERAPIES TOO HIGH? UPDATED RESULTS FROM A U.S. CLAIMS DATA ANALYSIS

Raborn ML[1], Pelletier EM[2], Smith DB[2], Reyes CM[1]
[1]*Genentech Inc., South San Francisco, CA, USA,* [2]*IMS Consulting Group, Watertown, MA, USA*

OBJECTIVES: Oral oncologic therapies increasingly are becoming part of treatment options for cancer. These agents often fall within the pharmacy benefit, with the potential for increased out-of-pocket payments (OOPP) for patients. This study evaluated patient OOPP for oral oncologic therapies in US managed care plans. **METHODS:** Patients aged 18+ years with 1 of 22 oral oncologics (altretamine, bexarotene, capecitabine, cyclophosphamide, dasatinib, erlotinib, etoposide, everolimus, gefitinib, imatinib, isotretinoin, lapatinib, lenalidomide, leucovorin, nilotinib, sorafenib, sunitinib, temozolomide, thalidomide, topotecan, tretinoin, vorinostat) were identified in 2009 from a nationally-representative medical and pharmacy claims database of over 100 US health plans. OOPP were calculated as the allowed amount (dollars a health plan allows for a therapy, including member liability) minus the paid amount (dollars paid by a health plan for a therapy). Mean/median per-claim OOPP were reported for each oral therapy and stratified by geographic region, health plan type, and payer type. **RESULTS:** A total of17,483 patients with at least 1 oral oncologic were identified in 2009. Mean age was 38 years, 44% were male, and 82% had a commercial payer. Per-claim OOPP for the 22 oral oncologics varied. Median OOPP ranged from $0 (altretamine) to $42 (bexarotene); average OOPP were $9 (leucovorin) to $523 (dasatinib). Overall, 79% of patients were paying $50 or less per claim; 13% were paying >$100 per claim. Among the majority of therapies, the highest average OOPP were found in the Northeast and South. PPO and indemnity plans had the largest OOPP for almost two-thirds of the therapies. Medicare Risk (private Medicare) and self-insured patients had higher OOPP for most therapies compared to commercial payers and Medicaid. **CONCLUSIONS:** OOPP in the United States differ among oral oncologic options and confirm previous findings. As costs for therapy become a greater part of treatment decisions, an understanding of the cost burden to patients will be critical in informing choices.

PCN57

COST OF TREATMENT OF MULTIPLE MYELOMA IN UKRAINE

Mandrik O[1], Zalis'ka O[2], Severens JL[3]
[1]*Danylo Halytsky Lviv national medical university, Lviv, Ukraine,* [2]*Danylo Halytsky Lviv National Medical University, Lviv, Ukraine,* [3]*Erasmus University Rotterdam, Rotterdam, The Netherlands*

OBJECTIVES: The major aims of the current research are to learn the average costs of treatment of multiple myeloma (MM) in Ukraine. According to the world statistics 30 new cases are registered annually per 1 million of population. In Ukraine there are 4,434 cases of MM registered; these patients receive compensation by the government for only limited amounts of necessary medicines, with most medicines being paid for by patients themselves. **METHODS:** A database containing records from hospital cards (2006-2010) for patients with MM was analyzed retrospectively. The sample was composed of 98 patients, aged 29 to 81 (mean age 62.5, s.d. 9,6; 35.6% males). Drug costs related to direct diagnosis and associated MM diseases (e.g., anemia, bone damage) were calculated. **RESULTS:** The average annual cost of pharmaceutical treatment for patients with MM was 518.27EUR (1EUR=11,371UAH on 20.06.2011). Accounting for the prevalence of MM in Ukraine (4,434 cases), the total cost of treatment of MM in Ukraine is 2,297,984EUR. A significant amount of these costs covers treatment of MM-associated bone disease, resulting in an average annual cost of 70.76EUR for treatment of these disorders of MM patients. From basic therapy the most expensive were treatment schemes with bortezomib (6 patients). If patients who were treated with bortezomib are excluded from the general pool, the total costs of drug treatment will be 107.68EUR from which 64.08EUR will take treatment of bone disorders with biphosphonates. No correlations were found between sex, age, date of diagnosis and costs of treatment. **CONCLUSIONS:** Analysis of the treatment practice and costs for MM patients has shown that treatment of MM with bortezomib, even though involving only a small number of patients, and treatment of MM-related conditions within the majority of patients takes the major part of total costs.

PCN58

THE COST OF STRONG OPIOID TREATMENT OF ONCOLOGICAL PAIN IN THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM

Paloni EDMP[1], Bonachela Alves. F[2], Morais AD[3], Pereira ML[3], Bahmdouni L[3]
[1]*ORIZON - Companhia Brasileira de Gestão de Serviços, Sao Paulo, Sao Paulo, Brazil,* [2]*ORIZON - Companhia Brasileira de Gestão de Serviços, São Paulo, Brasil., Sao Paulo, Sao Paulo, Brazil,* [3]*Janssen Cilag Farmaceutica, São Paulo, SP, Brazil*

OBJECTIVES: To estimate the cost of treatment of oncological pain with four strong opioids (methadone, morphine, oxycodone, fentanyl) in the Brazilian private healthcare system between January and December 2010. **METHODS:** A claims database of over 57 HMOs was analyzed to recover combined use of strong opioids and oncological treatments between January and December 2010. Records showed expenditure with medications, materials, hospitalization, and procedures and diagnostics. **RESULTS:** Over the one-year study period, 293,918 patients made use of at least one of the four opioids. The total healthcare expenditure with these patients was R$ 3,243,890,302.91 (R$ 11,036.72/patient/year). Around 53% of these patients (157,104) made concomitant use of oncology treatments, representing around 74% of the total costs (R$ 2,424,503,643.76), with an average cost of R$ 15,432.48/patient/year. The remaining patients (136,814) had an average cost of R$ 5.989,06 per patient/year. Within the oncology patient population, the total healthcare expenditure with the four opioids alone was R$ 5,203,001.81. Fentanyl was the most commonly used opioid in about 66% of patients, followed by morphine (33%), methadone (1%) and oxicodone (0,8%). Around 17% of the oncology patient population made use of two or more opioids during the study period. **CONCLUSIONS:** Pain treatment of oncology patients is more costly for private payers in Brazil when compared with patients not receiving oncological treatment. Although 47% of patients were considered non-oncological, this is not certain as they could have received oncological treatment outside the study period or in a provider not covered by the database (e.g. public hospital). With about 17% of oncological patients receiving two or more opioid treatments with the 12 month period suggests opioid rotation is common.

PCN59

ECONOMICS OF PRIMARY PROPHYLACTIC G-CSF USE IN PREVENTING NEUTROPENIA IN ELDERLY BREAST CANCER PATIENTS RECEIVING CHEMOTHERAPY: ARE SHORT-TERM INCREASE IN COSTS NECESSARILY BAD?

Rajan SS[1], Lyman GH[2]
[1]*University of Houston, Houston, TX, USA,* [2]*Duke University, Durham, NC, USA*

OBJECTIVES: Chemotherapy is vital for breast cancer treatment, but early-onset toxicities like neutropenia hinder chemotherapy administration, especially in the elderly. Neutropenia also increases costs due to hospitalizations and aggressive systemic antibiotics administration. Primary prophylactic (PP) use of granulocyte-colony stimulating factors (G-CSF) helps prevent neutropenia. However, evidence supporting the cost-effectiveness of PPG-CSF is not conclusive and ASCO guidelines state the need for establishing cost-savings in high-risk groups like the elderly. This study examined the effect of PPG-CSF administration at the start of first-course chemotherapy on Medicare costs during the year following the start of chemotherapy. **METHODS:** A retrospective observational study of patients newly diagnosed with breast cancer, between 1994 to 2002, was conducted using the SEER-Medicare. To account for non-random nature of observational data, a covariate genetic matching technique was used to pre-process the data before performing parametric regression analysis to estimate the effect of PPG-CSF on costs. Logarithm of cost was used as the dependent variable. **RESULTS:** Administration of PPG-CSF during the first-course of chemotherapy was associated with 57% increase in costs during the study period, despite an 11% drop in neutropenia hospitalization costs. Forty-one percent of the increase in costs is due to increase in chemotherapy costs during the year after the start of chemotherapy. **CONCLUSIONS:** A significant part of increase in immediate medical costs in breast cancer patients receiving PPG-CSF is due to the improvement in chemotherapy administration. Thus, increase in short-term costs are not necessarily bad in patients receiving PPG-CSF. Adequate chemotherapy administration during the first year of breast cancer therapy has long been established to prevent future recurrences, reduce mortality and reduce long-term breast cancer care costs. Accounting for long-term savings due to recurrence and metastasis prevention, indirect patient-care costs, and quality of life aspects, is extremely vital for cost-analyses in chronic diseases like breast cancer.

PCN60

ECONOMIC EVALUATION OF VACCINATION AGAINST CERVICAL CANCER IN THE MOSCOW REGION

Shakhanina I[1], Namazova-baranova L[2], Krasnopolskiy VI[3], Zarochentseva NV[3], Kozachenko VP[4], Demarteau N[5], Shchurov D[6]
[1]*Central SRI of epidemiology of Rospotrebnadzor, Moscow, Russia,* [2]*State Institution Scientific Centre for Children's Health under jurisdiction of the RAMS, Moscow, Russia,* [3]*MRSRIOG (Moscow Region Scientific Research Institute of Obstetrics and Gynecology), Moscow, Russia,* [4]*Russian Oncological Center n.a. N.N. Blokhin, Moscow, Russia,* [5]*GlaxoSmithKline Biologicals, Wavre, Belgium,* [6]*GlaxoSmithKline, Moscow, Russia*

OBJECTIVES: To estimate clinical outcomes and cost-offset (cost-benefit) from a societal perspective expected from human papilloma virus (HPV) vaccination in the Moscow region (MR). **METHODS:** A static population model developed in MS Excel was adapted to the MR setting. The model estimated the annual number of abnormal Papanicolaou smear test (abnormal PAP), precancerous lesions (cervical intraepithelial neoplasia (CIN)) and cervical cancer (CC) as well as costs (RUB) as-

sociated with treatment and productivity loss over a one year period at vaccine steady state (i.e. when all women are vaccinated), current vs. future burden assuming 95% vaccine coverage. The MR incidence data on abnormal PAP and CINs were extrapolated from the relative proportion of abnormal PAP, precancerous lesions and CC previously published. Vaccination effectiveness was based on clinical trial data and HPV distribution for Russia and Eastern Europe. Medical costs were estimated from resources used and listed Russian price. Indirect costs include unpaid taxes, illness allowance and regional GDP foregone. No discount was applied. Sensitivity analyses were conducted on main parameters (number of lesions, vaccine effectiveness, costs). **RESULTS:** Vaccination with the bivalent HPV vaccine in the MR was estimated to prevent 13,737 abnormal PAP (112.6 m.rub.), 11,750 CIN1 (296.1 m.rub.), 4,222 CIN2/3 (259.3 m.rub.), 504 CC (98.9 m.rub.), 199 cases of lifelong disability (44.6 m.rub.) and 276 cases of CC deaths annually. Total cost offsets could amount to 811.6 m.rub. (664.8 m.rub. treatment cost only) representing 2.5x annual cost of vaccinating one cohort of 12 year-old girls (328.9 m.rub.) (2.0x vs. treatment cost only). The benefit-to-cost ratio (cost offset/vaccination cost) ranged from 1.8 to 3.1 over the sensitivity analyses. **CONCLUSIONS:** Implementation of HPV vaccination in the MR could significantly decrease cervical HPV-infection disease-related burden. The cost of vaccination, at steady state, could be fully compensated by the cost offset.

PCN61

IMPACT OF APPROPRIATE TREATMENT INFORMED BY EGFR MUTATION STATUS ON PATIENT OUTCOMES FROM DIAGNOSIS TO DEATH IN ADVANCED NON-SMALL CELL LUNG CANCER

Teale C[1], Parasuraman B[2], van der Scheer F[3], Langenfeld M[4], Ruff L[5], Hanmore E[6]
[1]*AstraZeneca, Macclesfield, UK,* [2]*AstraZeneca, Glen Mills, PA, USA,* [3]*AstraZenca, Zoetermeer, The Netherlands, The Netherlands,* [4]*AstraZeneca BV, Zoetermeer, The Netherlands,* [5]*Medaxial, London, UK,* [6]*Medaxial group, London, London, UK*

OBJECTIVES: To investigate the extent to which using the most efficacious first-line therapy to manage advanced non-small cell lung cancer (NSCLC) based on patients' EGFR mutation status has clinical, economic, and quality of life (QoL) benefits from diagnosis to death. **METHODS:** A deterministic cost-consequence model was developed to investigate alternative diagnostic and treatment strategies across multiple treatment lines in advanced NSCLC. Cost (drug and other treatment-related), resource use, clinical, and QoL data were included. Cost and resource use data were derived from the Dutch National Formulary, market research studies and expert opinion. Clinical and QoL data – including progression-free survival (PFS) – were derived from published studies and expert opinion. **RESULTS:** Different testing and treatment strategies were modelled in a hypothetical population of 1,000,000 individuals. 498 patients presented with stage III/IV NSCLC. In the base-case (no EGFR mutation testing) all patients received first-line doublet chemotherapy followed by second-line docetaxel (50%) or best supportive care (50%). Total median PFS in the population was 246.00 years (5.93 months per patient). Total healthcare costs, including adverse event (AE) management, were €11,801,371 (€23,698 per patient). EGFR mutation testing all patients identified 60 patients as EGFR mutation-positive. First-line treatments were assigned based on mutation status (EGFR mutation-positive patients received gefitinib followed by second-line docetaxel, all others were treated as in the base-case strategy). Compared with the base-case strategy there was an 11.8% increase in total PFS (0.70 months per patient). Second-line PFS increased 12.0%. Additionally, fewer AEs (anaemia, diarrhoea, dyspnoea, febrile neutropenia, neurotoxicity and vomiting) and improved QoL were seen. Excluding testing costs, total healthcare costs increased 17.4%. **CONCLUSIONS:** Strategies where patients were appropriately treated based on EGFR mutation status increased clinical and QoL benefits at relatively low incremental cost, compared to strategies where patients were not tested or were treated sub-optimally. Benefits extended beyond first-line treatment.

PCN62

COSTS AND CONSEQUENCES OF HPV VACCINATION IN THAILAND: RESULTS OF A PREVALENCE BASED MODEL

Van Enckevort P[1], Kongngamkam K[2], Van Kriekinge G[3]
[1]*GlaxoSmithKline Pte Ltd, Singapore,* [2]*GlaxoSmithKline (Thailand) Limited, Bangkok, Thailand,* [3]*GlaxoSmithKline Biologicals, Wavre, Belgium*

OBJECTIVES: Two human papillomavirus (HPV) vaccines are available worldwide: a bivalent vaccine (BV) targeting oncogenic high-risk HPV-16/18 and a quadrivalent vaccine (QV) targeting both high-risk HPV-16/18 and low-risk HPV-6/11. Based on data in their respective trials, BV is likely to have higher efficacy against non-vaccine oncogenic HPV-types (cross protection). QV has an effect against genital warts (GW). The potential effect of both vaccines in Thailand on cervical intraepithelial neoplasia grade 1-3 (CIN1-3), GW, cervical cancer (CC) and related treatment costs was investigated. **METHODS:** A static model estimated the above outcomes over a one-year period at steady state versus the current situation. Costs were assessed from a health care payer's perspective. Epidemiological and cost data were obtained from published sources; efficacy figures were based on the latest clinical trial results from each vaccine and region-specific HPV distribution among lesions (local data was used where possible). Sensitivity analyses were conducted on all input data, such as with scenarios where the incidence and costs of treating GW were varied. **RESULTS:** BV was projected to avert 9394 cases of CC annually. BV potentially would result in an additional reduction of 5470 CIN1, 5177 CIN2/3 and 1113 CC cases annually compared with QV, while QV potentially would prevent an additional 125,957 GW cases annually. The additional cost saved with BV was estimated at THB 356 million annually compared with QV. Sensitivity analyses report additional cost-savings for the BV compared with QV under all scenarios. **CONCLUSIONS:** The level of cross protection of BV potentially would allow for an additional reduction in CC and HPV-related morbidity compared to QV; under our model, this resulted in cost averted that offset the economic benefit QV will have in preventing GW in Thailand.

PCN63

COST-EFFECTIVENESS OF SUNITINIB IN PATIENTS WITH ADVANCED OR METASTATIC PANCREATIC NEUROENDOCRINE TUMORS IN PORTUGAL

Soares M[1], Inês M[2], Contente M[3]
[1]*York University, York, Yorkshire, UK,* [2]*Pfizer Portugal, Porto Salvo, Oeiras, Portugal,* [3]*Pfizer Portugal, Porto Salvo, Portugal*

OBJECTIVES: Sunitinib is an oral multitargeted tyrosine kinase inhibitor approved in Europe in 2010 for use in well-differentiated pancreatic neuroendocrine tumors (pNET) that have spread or cannot be removed with surgery. This study evaluated the cost-effectiveness of sunitinib + best supportive/palliative care (BSC) compared to placebo + BSC in Portuguese patients. **METHODS:** A Markov model was adapted to predict life-years (LY) and associated costs (€) of pNET patients' treatment over lifetime in Portugal. The model tracks transitions of patients between three health states: progression free, post-progression and death. Transition probabilities between health states and adverse events probabilities were based on published results from the phase III pNET trial of sunitinib. BSC overall survival (OS) probabilities were adjusted for crossover with a rank preserving structural failure time (RPSFT) statistical analysis. Resource use was elicited through a panel of five Portuguese experts with extensive clinical experience. Subsequent treatments are not included given the lack of efficacy evidence. Adverse events treatment costs and unit costs were extracted from Portuguese literature and official sources. A National Health Service perspective was adopted and both costs and effectiveness were discounted at 5%. **RESULTS:** Average cost per patient for sunitinib + BSC and placebo + BSC treatment were 54,215€ and 10,239€ respectively, while the average effectiveness gained with sunitinib was 1.83LY. This resulted in an incremental cost-effectiveness ratio (ICER) of 24,035€/LY. While the application of the RPSFT method may have some limitations and therefore provide uncertainty regarding the true OS benefit, the intent-to-treat classic analysis that does not correct for the confounding effect of crossover generated an ICER of 34,387€/LY. **CONCLUSIONS:** Compared with BSC, sunitinib treatment in patients with advanced or metastatic unresectable pNET improve effectiveness in terms of life-years gained and is cost-effective by the commonly used threshold in Portugal for assessment of new health technologies.

PCN64

EVALUATING THE COST-EFFECTIVENESS OF THE ADDITION OF RITUXIMAB TO CHEMOTHERAPY IN THE FIRST LINE TREATMENT OF FOLLICULAR LYMPHOMA PATIENTS IN THE UK

Rafia R[1], Papaioannou D[2], Stevenson M[1], Rathbone J[1], Woods HB[3]
[1]*University of Sheffield, Sheffield, South Yorkshire, England,* [2]*University of Sheffield, Sheffield, South Yorkshire, UK,* [3]*The University of Sheffield, Sheffield, South Yorkshire, UK*

OBJECTIVES: To assess, from a UK NHS perspective, the cost-effectiveness of the addition of rituximab (R) to selected chemotherapies: CVP (cyclophosphamide, vincristine and prednisolone); CHOP (cyclophosphamide, doxorubicin, vincristine and prednisolone) and MCP (mitoxantrone, chlorambucil and prednisolone) in the first-line treatment of follicular lymphoma. **METHODS:** A patient level simulation model was developed with four mutually exclusive and exhaustive health states: progression free survival on first line treatment (the starting state); progression free survival on second line treatment (PFS2); progression; and death (an absorbing state). First-line treatment consisted of chemotherapy or R-chemotherapy. Patients relapsing before death move into PFS2 and are assumed to receive second-line treatment dependent on initial treatment and time of relapse. After progression, patients enter the progression state where they reside until death. The model horizon was 25 years with costs and benefits discounted at 3.5%. Separate analyses were undertaken assuming rituximab maintenance for patients who responded to R-chemotherapy in first-line induction. Evidence from phase III trial were used when possible, however due to data limitations, assumptions were necessary which increases the uncertainty in the results. **RESULTS:** The estimated Incremental Cost-Effectiveness Ratios (ICERs) for the addition of rituximab to CVP, CHOP and MCP were £7,720, £10,834 and £9,316 per QALY gained respectively assuming no first-line rituximab maintenance. The ICERs increased to £14,959, £21,687 and £20,493 per QALY gained respectively when maintenance treatment was assumed. The ICER was sensitive to assumptions regarding the choice of parametric distribution to model the effectiveness of first-line treatment, the maximum time a patient can remain progression-free and potential resistance to rituximab, with the most favourable (unfavourable) ICER being approximately £4,000 (£61,000) per QALY gained. **CONCLUSIONS:** The addition of rituximab to CVP, CHOP and MCP is expected to fall below a cost per QALY gained of £25,000 regardless of the assumption on maintenance.

PCN65

COST-EFFECTIVENESS OF TREATING METASTATIC RENAL CELL CARCINOMA (MRCC) PATIENTS WHOSE DISEASE FAILED ON ONE PRIOR VEGF-TKI THERAPY WITH EVEROLIMUS COMPARED TO TREATING WITH BEST SUPPORTIVE CARE (BSC) ALONE IN CANADA

Casciano R[1], Chulikavit M[1], El Ouagari K[2], Wang X[3]
[1]*Analytica International Inc., New York, NY, USA,* [2]*Novartis Pharmaceuticals Corporation, Dorval, QC, Canada,* [3]*Novartis Pharmaceuticals Corporation, Florham Park, NJ, USA*

OBJECTIVES: The analysis of the sub-group of patients who received one prior VEGF-TKI-based therapy in the RECORD-1 clinical trial reported a median progression-free survival of 5.42 months and 1.87 months for the everolimus and BSC-alone arms, respectively. A Markov model was developed to assess the cost-effectiveness of treating mRCC patients whose disease had failed on one prior VEGF-TKI

therapy with everolimus versus BSC alone from the Canadian societal perspective. **METHODS:** A Markov model simulated 2 hypothetical patient cohorts (everolimus versus BSC alone) from the time of initial treatment throughout the 6-year time horizon. The cost-effectiveness of everolimus was calculated in terms of cost per life-years gained (LYG) as well as cost per quality-adjusted life year (QALY) gained. Health state transition probabilities were derived directly from the RECORD-1 subgroup analysis; costs and health state utility values were obtained from literature. The analysis was performed from a societal perspective; as such, direct medical costs and indirect costs associated with productivity loss due to morbidity or future income loss attributed to early mortality were included. A sensitivity analysis from the payer's perspective was additionally performed. Outcomes and costs were discounted at a 5% annual rate. **RESULTS:** Treatment with everolimus produced an estimated gain over BSC alone of 0.643 LYG (0.455 QALYs) at an incremental cost of $22,074. The deterministic analysis resulted in incremental cost-effectiveness ratios (ICERs) of $34,326/LYG and $48,507/QALY. The payer's perspective sensitivity analysis resulted in ICERs of $48,670/LYG and $68,777/QALY. According to the probabilistic sensitivity analysis, given a threshold of $100,000/QALY, the probability that everolimus was cost-effective, from a societal perspective, was 100%. **CONCLUSIONS:** Results of this analysis suggest that, from a Canadian societal perspective, everolimus is a cost-effective alternative to BSC alone when treating mRCC patients whose disease fails on one prior VEGF-TKI treatment.

PCN66

A COST AND OUTCOMES ANALYSIS OF BEVACIZUMAB PLUS FOLFIRI VERSUS CETUXIMAB PLUS FOLFIRI FOR THE TREATMENT OF FIRST-LINE METASTATIC COLORRECTAL CANCER PATIENTS FROM THE BRAZILIAN PRIVATE PAYER PERSPECTIVE

Caponero R[1], Santos EAV[2], Buschinelli CT[2], Ferracini M[2], Ngoh CA[3]
[1]*Hospital Brigadeiro, São Paulo, Brazil,* [2]*Roche Brazil, São Paulo, Brazil,* [3]*Roche, Basel, Switzerland*

OBJECTIVES: Colorectal cancer (CRC) is the third most frequent worldwide and about 28,110 new cases were expect for Brazil in 2010. Two biologic agents are approved for treatment of mCRC in Brazil: cetuximab, exclusively for K-RAS wild-type patients and bevacizumab, for both K-RAS types. We aimed to compare costs and outcomes of bevacizumab versus cetuximab in first-line treatment of mCRC, both in combination with FOLFIRI from a private payer perspective in Brazil. **METHODS:** In the absence of head-to-head trials comparing Bev+FOLFIRI and Cet+FOLFIRI, an adjusted indirect comparison was conducted using Bucher-method. Hazard ratios (HRs) from 3 studies: BICC-C(part II) comparing Bev+FOLFIRI vs Bev+IFL; AVF2107g comparing Bev+IFL vs IFL; and CRYSTAL comparing Cet+FOLFIR versus FOLFIRI; were utilized. An illness-death Markov model was enhanced. Risks for progression and mortality were derived from Weibull regression model (assuming deaths conditional upon prior progression). Natural mortality rates were applied according to IBGE life table. Only direct costs were considered for patients with 1,78m2 and 70Kg. Ex-factory prices were obtained from official public sources. Time-horizon was two years according to natural history of the disease. Utilities were derived from international sources; discounting was 5% for costs and outcomes, according to local guidelines. A probabilistic sensitivity analysis (PSA) was conducted in order to evaluate the robustness of results. Non-statistically significant HR 95%-CIs were exploited in PSA. **RESULTS:** Results of the analysis suggest Bev+FOLFIRI combination is less costly compared to Cet+FOLFIRI ($Brz216,838.38 vs. $Brz276,770.15) and a trend towards improved effectiveness with Bev+FOLFIRI (OS 20.1 vs. 16.60 months; QALYs 1.1 vs. 0.9) in first-line treatment of mCRC. PSA portends that Bev+FOLFIRI is dominant over Cet+FOLFIRI (93,44% of iterations Bev+FOLFIRI prolonged OS, being less costly). **CONCLUSIONS:** Based on current available data, analysis suggest Bev+FOLFIRI presents lower costs and better efficacy than Cet+FOLFIRI for treatment of first-line mCRC from a private payer perspective in Brazil.

PCN67

ERLOTINIB AS SECOND LINE TREATMENT FOR ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC): ECONOMIC MODELING (EM) RESULTS

Santos EAV[1], Buschinelli CT[1], Ferracini M[1], Pepe C[2], Estanislao M[2]
[1]*Roche Brazil, São Paulo, Brazil,* [2]*MedInsight, São Paulo, São Paulo, Brazil*

OBJECTIVES: To determine the cost-effectiveness of erlotinib compared with docetaxel every 3 weeks (D3W) or weekly (DW) or pemetrexed in second line treatment for patients with advanced or metastatic NSCLC, from the Brazilian Private Healthcare System perspective. **METHODS:** The analysis is based on a three stage Markov model to estimate costs and consequences of treatments over 2 years. Epidemiological and efficacy data were derived from a systematic literature search. Indirect network meta-analysis assessed the relative efficacy of the compared treatments. The survival curves were modeled by fitting a Weibull distribution. Only direct medical costs were considered: Drug costs, daily hospital admission rates, procedures and laboratory test unit cost were obtain from Brazilian official databases of private healthcare system fees. Costs and benefits were discounted at 5% yearly and reported in 2010 Brazilian currency (BRL). Outcomes were expressed as progression-free survival (PFS; months), overall survival (OS; months) and quality adjusted life years (QALY). Probabilistic sensitivity analysis (PSA) was conducted to assess model robustness. **RESULTS:** Through the systematic literature review we identified a network meta-analysis performed by Hawkins et al comparing BR21, JMEI, TAX 317, ISEL, INTEREST and SIGN trials that formed the body of clinical data for the analysis. The analysis showed higher clinical benefits and lower average costs for erlotinib (9.73 OS; 4.24 PFS; 0.25 QALY; R$40,471) than D3W (8.49 OS; 3.21 PFS; 0.21 QALY; R$47,180) or DW (8.49 OS; 3.21 PFS; 0.21 QALY; R$56,549) or pemetrexed (8.49 OS; 3.31 PFS; 0.21 QALY; R$60,151), showing the dominance of erlotinib related to compared treatments. PSA demonstrated that in 86%, 98% and 97% of the simulations erlotinib was dominant compared to D3W, DW and pemetrexed. **CONCLUSIONS:** This analysis portends that Erlotinib could be considered as a dominant treatment strategy in 2nd line mNSCLC compared to docetaxel or pemetrexed under the Brazilian Private Healthcare System perspective.

PCN68

COST-EFFECTIVENESS AND QUALITY OF LIFE ANALYSIS OF THE MULTICENTER ITAC02-01 STUDY: PROSPECTIVE RANDOMIZED COMPARISON OF REDUCED INTENSITY VERSUS NON-MYELOABLATIVE CONDITIONING REGIMEN FOR MATCHED RELATED ALLOGENEIC STEM CELL TRANSPLANTATION

Le Corroller Soriano AG[1], Siani C[2], Tabrizi R[3], Michallet M[4], Bay JO[5], Fabre R[6], Boher JM[7], Blaise D[8]
[1]*INSERM UMR912, Marseilles, France,* [2]*University Claude Bernard Lyon1, Lyon, France,* [3]*CHU Haut Lévèque, Pessac, France,* [4]*Hopital Edouard Herriot, Lyon, France,* [5]*CHU Estaing, Clermont-Ferrand, France,* [6]*INSERM, Marseille, France,* [7]*Institut Paoli-Calmettes, Marseille, France,* [8]*Institut Paoli Calmettes, Marseilles, France*

OBJECTIVES: The optimal intensity of conditioning prior to allogeneic hematopoietic stem cell transplants (HSCT) remains uncertain. We present the result of the prospective socio-economic evaluation associated with a randomized study comparing two levels of intensity reduction. **METHODS:** We compare reduced intensity conditioning regimen (RIC= Fludarabine, oral myleran and anti-thymocyte-globulin) and non myeloablative conditioning regimen (NMAC= Fludarabine and total body irradiation). Direct medical transplant costs were estimated by micro-costing on the basis of patients' CRF until 18 months after transplant. Costs of treatment of progression were estimated within five years after transplant. Cost-effectiveness analysis was performed using overall survival (OS) and disease free survival (DFS) as endpoint. Health-related quality of life (HRQL) was measured prospectively by the EORTC QLQ-C30 questionnaire administered seven days before transplant and on days +30 +80 +180 and +360. Linear mixed model analysis was performed to test whether there were differences in HRQL outcomes within and between the two groups over time. GVHD occurrence was included in the model. **RESULTS:** A total of 139 patients with hematological malignancies were treated (RIC: N=69; NMAC: N=70). Survival and DFS at one and five years were identical after RIC and NMAC. The mean total cost per patient was not different between groups (83,656€ for RIC vs. 72,592€ for NMAC, NS). This is related to decreased post graft costs for NMAC (-22,815€, p=0.002) being offset by increased costs of disease progression (+11,750€, p=0.008). Using DFS as endpoint, the RIC is cost-effective: incremental cost-effectiveness ratio=978.64 [95%IC=313.23-2447.91]. Using OS no differences were found between the two groups. RIC had a stronger negative impact on patients' HRQL independently of GVHD. **CONCLUSIONS:** The results confirmed the relapse/toxicity arbitrage associated with the choice of the allo-HSCT conditioning regimen. Moreover, the importance of the choice of endpoints and follow-up times in the economic evaluation of cancer treatment is highlighted.

PCN69

COST-EFFECTIVENESS ANALYSIS OF RITUXIMAB MAINTENANCE TREATMENT OF FOLLICULAR LYMPHOMA IN PATIENTS RESPONDING TO FIRST-LINE INMUNOCHEMOTHERAPY INDUCTION

Castro-gomez AJ[1], Lopez-Guillermo A[2], Rueda A[3], Salar A[4], Rubio-Terrés C[5]
[1]*Roche Farma S.A., Madrid, Spain,* [2]*Hospital Clinico, Barcelona, Spain,* [3]*Hospital Costa del Sol, Marbella, Andalucia, Spain,* [4]*Hospital del Mar, Barcelona, Spain,* [5]*HealthValue, Madrid, Spain*

OBJECTIVES: Maintenance treatment with Rituximab of follicular lymphoma (FL) patients responding to first-line induction therapy with R-CHOP, R-CVP or R-FCM, increases progression-free survival (hazard ratio 0.55; 95% CI 0.44 to 0.68, P <0.0001) compared with observation. We performed a cost-effectiveness analysis of maintenance therapy in first line of the FL with rituximab, compared with the option of "wait and watch" strategy. **METHODS:** We developed a Markov model of the FL, with four health states (progression free survival in first or second line, progression and death). The transition probabilities between states were obtained from clinical trials PRIMA and EORTC 20981. Health state utilities were obtained from literature. The use of health resources, from the perspective of the National Health System was estimated by a panel of Spanish onco-hematologist experts. Unitary costs (€ in 2010) were obtained from Spanish sources. Deterministic and probabilistic analyses were performed. **RESULTS:** In the deterministic base case analysis, for a time horizon of 30 years, the incremental cost per life year gained (LYG) and quality-adjusted life-years (QALYs) gained, was €5663 and €6253 respectively. The sensitivity analyses confirmed the stability of the base case for time horizons of 10 and 20 years and various statistical distributions (Weibull, exponential, log-logistic, log-normal, Gompertz, and gamma) ranging between €4222 and €8766. **CONCLUSIONS:** Compared with observation, rituximab maintenance treatment of the FL that responds to inmunochemotherapy induction in first line, is a cost-effective strategy.

PCN70

COST-EFFECTIVENESS OF CETUXIMAB AND BEVACIZUMAB IN THE FIRST-LINE TREATMENT OF METASTATIC COLORECTAL CANCER (MCRC) FOR PATIENTS WITH KRAS WILD-TYPE TUMOURS IN THE UNITED KINGDOM

Samyshkin Y[1], Hertel N[1], Griebsch I[2]
[1]*IMS Health, London, UK,* [2]*Merck KGaA, Darmstadt, Germany*

OBJECTIVES: Combinations of chemotherapy and monoclonal antibodies (MAbs) against the vascular endothelial growth factor (bevacizumab) and the epidermal growth factor receptor (cetuximab) have been shown to improve the clinical outcome of patients with mCRC. Little is known about the economic implications of their use. The aim of this analysis was to evaluate the cost, clinical- and cost-

effectiveness of adding the MAbs cetuximab or bevacizumab to chemotherapy in the first-line treatment of mCRC patients with KRAS wild-type tumours, from the UK (UK) NHS perspective. **METHODS:** A semi-Markov model was developed to simulate patient outcomes and costs for first and subsequent lines of treatment including long-term survival after a curative resection of liver metastases. Data for progression-free survival, resection rates and other model parameters were mainly derived from the CRYSTAL and NO16966 phase 3 studies. The long-term benefits of surgery were estimated from a consecutive series of 1439 patients. Resource use included drugs, physician visits, scans, hospitalizations and treatment of adverse events. Extensive sensitivity analyses were undertaken to explore the robustness of the results. **RESULTS:** In the base case, the estimated mean life expectancy for cetuximab- and bevacizumab-containing regimens was 3.22 and 2.31 years (all undiscounted) respectively. The incremental cost-effectiveness ratio (ICER) for FOLFIRI+cetuximab compared with FOLFIRI alone was £30,665 per quality-adjusted life year (QALY) and £17,626 per QALY compared with FOLFOX+bevacizumab. The ICER is mainly driven by the number of patients becoming resectable and the acquisition cost for each antibody. **CONCLUSIONS:** This analysis suggests that cetuximab in combination with FOLFIRI is the most effective treatment regimen compared with FOLFOX+bevacizumab or chemotherapy alone for patients with KRAS wild-type tumours. The incremental cost-effectiveness ratios of cetuximab in combination with chemotherapy compared with chemotherapy alone, and bevacizumab-containing regimens are within the commonly accepted threshold for cost-effectiveness in the UK.

PCN71

VALUE OF PROGRESSION-FREE SURVIVAL (PFS) IN REFRACTORY NON-SMALL CELL LUNG CANCER (NSCLC): AN EXPLORATORY MODELING ANALYSIS

Ferrufino CP[1], Foley D[2], Trochlil K[1], Munakata J[3]
[1]*IMS Consulting Group, Alexandria, VA, USA,* [2]*Boehringer Ingelheim, Ridgefield, CT, USA,* [3]*IMS Consulting Group, Redwood City, CA, USA*

OBJECTIVES: PFS is an important endpoint in advanced NSCLC as it permits earlier assessment of treatment benefit compared to overall survival (OS) and is not influenced by subsequent treatment lines. Multiple treatment strategies have demonstrated PFS benefits in solid tumor oncology, but the economic and humanistic value of improved PFS remains unclear. **METHODS:** We developed a literature-based, 3-state (progression-free, disease-progression, death) Markov model designed to estimate clinical and economic outcomes associated with 2nd-line treatment from a US-payer perspective. Modeled treatments included a commonly used FDA-approved epidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI) and an equivalent hypothetical intervention with theoretical improvements applied to quantify value of PFS gains. In base-case, we assumed 20% PFS improvement for intervention and no differences in OS and tolerability profiles or costs between comparators. Model parameters were pulled from published sources and included OS, PFS, adverse event rates, health-state utilities, dosing, and costs. Costs (2010 USD) and effects were discounted 3%. **RESULTS:** In base-case, projected total lifetime discounted costs, PFLYs and QALYs were higher for intervention ($30,791; 0.53 PFLY; 0.32 QALY) vs. EGFR-TKI ($26,705; 0.43 PFLY, 0.30 QALY). Scenario analyses identified two major determinants of costs-effectiveness in our model: PFS improvements accompanied by quality of life (QoL) improvements and post-progression treatment cost savings. Applying a range of QoL improvements (10%-30%) resulted in increased lifetime QALYs for intervention (0.35-0.39) such that ICER was <$50,000/QALY with >25% QoL improvements. For QoL improvements <25%, cost-effectiveness can be achieved with post-progression cost savings. **CONCLUSIONS:** An intervention conferring PFS improvements may be cost-effective if modest treatment-related QoL improvements and/or post-progression cost savings are realized. New and emerging treatments for NSCLC therapies that demonstrate improvement in one or both of these measures and/or OS and safety benefits will probably be competitive as payers start to weigh cost-effectiveness measures in coverage decisions.

PCN72

COST - EFFECTIVENESS ANALYSIS OF CERVICAL CANCER VACCINATION STRATEGIES IN SPAIN

García-Jurado L[1], Morano R[2], Torné A[3], Malvar A[4], Bayas JM[3], Casado MA[1]
[1]*Pharmacoeconomics & Outcomes Research Iberia, Madrid, Spain,* [2]*GlaxoSmithKline, Tres Cantos, Madrid, Spain,* [3]*Hospital Clinic, Barcelona, Spain,* [4]*Conselleria Sanidade, A Conuña, Spain*

OBJECTIVES: Assess clinical and economic outcomes of vaccination (Va) with human papillomavirus (HPV) 16/18 AS04-adjuvanted vaccine (16/18Vac) added to screening programmes (Scr) in cervical cancer (CC) prevention, from the National Healthcare System perspective. **METHODS:** A lifetime Markov cohort model with yearly cycles was populated using national epidemiological, cost and treatment data to simulate the natural history of HPV and assess the effect of Va+Scr strategies versus Scr alone. Base case considers vaccinating a cohort of 206.788 girls aged 11, 80% of vaccine coverage and screening each 3 years from age 25 to 65. Efficacy of 16/18Vac was 95% against HPV-16/18 and cross-protection against 5 oncogenic non-vaccine types of 68%. Outcomes measured were number of CC cases, CC deaths, quality adjusted life years (QALYs), costs and incremental cost-effectiveness ratio (ICER) between both strategies. The model also tested a broader campaign vaccinating both 11 & 18 years old during 7 years (100,000 individuals per cohort and year) versus vaccination girls aged 11 only. A discount rate of 3% over costs and outcomes was applied. Sensitivity analyses were performed to assess influence of different parameters. **RESULTS:** Base case scenario would avoid 817 CC cases and 188 deaths (undiscounted) versus Scr alone and generate 1,018 additional QALYs, resulting in an ICER of € 29.295/QALY (discounted). Vaccination of the cohorts aged 11 & 18 would avoid 2,448 CC cases and 602 CC deaths (undiscounted) compared with vaccination only of the 11 years cohort, and represents an ICER of 28,931€/QALY (discounted). Sensitivity analysis shows more favourable cost-effectiveness with higher coverage. **CONCLUSIONS:** HPV vaccination with 16/18Vac added to current screening programmes in Spain is a cost-effective strategy. More favourable cost-effectiveness results may be obtained by expanding vaccination to 18 years old women and increasing vaccination coverage. Results are in accordance with other studies published at national level.

PCN73

COST EFFECTIVENESS OF ZOLEDRONIC ACID VS. PAMIDRONATE OR NO THERAPY FOR THE TREATMENT OF BONE METASTASES SECONDARY TO PROSTATE CANCER

Carter JA[1], Bains M[2], Chandiwana D[2], Kaura S[3], Botteman MF[1]
[1]*Pharmerit North America, LLC, Bethesda, MD, USA,* [2]*Novartis Pharmaceuticals UK Limited, Camberley, Surrey, UK,* [3]*Novartis Pharmaceuticals Corporation, Florham Park, NJ, USA*

OBJECTIVES: Zoledronic acid (ZOL) is the only approved bisphosphonate for SRE prevention in hormone-refractory prostate cancer (mHRPC). However, in the UK (UK), 19% and 4% of metastatic, mHRPC patients, do not receive bisphosphonates or receive non-approved/unproven bisphosphonates (i.e., pamidronate [PAM]), respectively for the prevention of skeletal-related events (SREs). This analysis sought to estimate, from a UK payer perspective, the cost effectiveness of providing ZOL to those mHRPC patients not receiving ZOL. **METHODS:** This analysis was based on the results of a published randomized phase III clinical trial wherein mHRPC patients received ≤15 months of ZOL or placebo (PBO) (Saad et al, 2002). Since PAM has been shown to be no different than PBO in mHRPC in a pooled analysis of two trials (Small et al 2003) (i.e., 25% of subjects experienced an SRE at 6 months), the PBO cohort data from the ZOL trial was as a surrogate for PAM data in the absence of a direct comparison of ZOL versus PAM (or other bisphosphonates). Costs were estimated using hospital tariffs and published/internet sources. Quality adjusted life years (QALYs) gained were based on a previously published analysis of the Saad et al (2002) data. Survival was assumed to be identical for both groups. **RESULTS:** Compared with the use of PAM/PBO, treatment with ZOL (at list price of £174.14/infusion vs £80/infusion with PAM) resulted in increased QALYs (+0.03566/pt), fewer SREs (-0.8314/pt, i.e., 0.8315 vs 1.6629), and fewer SRE-related costs (-£1,639/pt, i.e., £2,004 vs. £3,643). Total costs were higher with ZOL (+£702/pt). ZOL cost £19,689/QALY. **CONCLUSIONS:** The use of ZOL for the prevention of SREs in UK patients with bone metastases secondary to mHRPC is cost effective relative to providing no or unapproved bisphosphonates.

PCN74

COST-EFFECTIVENESS ANALYSIS OF CHEMOPREVENTION FOR COLORECTAL CANCER BY LOW DOSE ASPIRIN IN SOUTH KOREA

Lee JY[1], Lee EK[2]
[1]*Sookmyung Womens' University, Seoul, South Korea,* [2]*Sookmyung Women's University, Seoul, South Korea*

OBJECTIVES: This study aims to identify whether it is desirable to recommend low-dose aspirin as chemoprevention therapy for colorectal cancer in addition to routine screening through cost-effectiveness review for general population in Korea. **METHODS:** A Markov model was constructed to simulate the disease natural history of colorectal cancer with routine screening and additional chemoprevention by low dose aspirin. The model evaluated hypothetical cohorts of each 100,000 men and women aged from 50 to 70 years old stratified as 5-years interval. The analysis adopted a social perspective and all costs and outcomes were discounted at 5% for 30 years. The result was presented as the incremental cost per QALY gained. Uncertainty was explored with deterministic and probabilistic sensitivity analysis. **RESULTS:** The analysis showed that the use of low dose aspirin in addition to routine screening comparing to the screening alone is likely to result in a incremental cost per QALY of around 3,000,000 KRW/QALY to 8,700,000 KRW/QALY for men over than 50 years old and of around 4,700,000 KRW/QALY to 12,000,000 KRW/QALY for women over than 55 years old. The deterministic sensitivity analysis for uncertain parameters demonstrated that this analysis results were robust. Assuming a willingness-to-pay threshold of 15,000,000 KRW per QALY gained, the probabilistic sensitivity analysis suggested that low dose aspirin chemoprevention is more net benefit than screening alone for both men over than 50 years old and women over than 55 years old. However, there was considerable uncertainty in the current evidence available. **CONCLUSIONS:** Low dose aspirin appears to be cost-effective regardless of the wide distribution of ICER as chemoprevention of colorectal cancer coupled with screening comparing to the screening alone for the men over than 50 years old and women over than 55 years old. Therefore, low dose aspirin can be recommended as chemoprevention therapy in Korean population.

PCN75

EPIDEMIOLOGIC AND ECONOMIC IMPACT OF HPV (6/11/16/18) VACCINATION IN TURKEY

Bakir M[1], Levent A[2], Nagy L[3], Brandtmüller A[3], Singhal P[4], Pillsbury M[4], Dasbach E[5]
[1]*Marmara University Medical School, Istanbul, Turkey,* [2]*Hacettepe University Medical School, Ankara, Sihhiye, Turkey,* [3]*Merck Sharp and Dohme, Budapest, Hungary,* [4]*Merck & Co., Inc., West Point, PA, USA,* [5]*Merck Research Laboratories, North Wales, PA, USA*

OBJECTIVES: to assess the epidemiological and economic impact of a quadrivalent human papillomavirus (HPV) types 6/11/16/18 vaccination in Turkey. **METHODS:** a published mathematical model of the transmission dynamics of HPV infection and disease was adapted for Turkey. The model captured direct protective effects of vaccination and indirect effects (herd immunity). Model inputs were used from Turkey when available; otherwise, the default values in the original model were used. The vaccination strategy included HPV vaccination of 12-year-old girls com-

bined with current cervical cancer screening and HPV disease treatment practices in Turkey. For the vaccination strategy 85% coverage rate was assumed in the frame of a mandatory school-based program. Reference strategy was current cervical cancer screening and HPV disease treatment practices in Turkey. Costs were estimated from the perspective of the Turkish healthcare system, using direct medical costs associated with the diagnosis and treatment of cervical diseases. **RESULTS:** Over 100 years, cumulative % (absolute) reduction in the incidence of 6/11/16/18-related cases of CIN1, CIN2/3, cervical cancer, cervical cancer deaths, genital warts-female, and genital-warts-male was 78% (4,894), 72% (32,537), 57% (73,277), 54% (40,513), 86% (404,674), and 86% (409,029), respectively, in the vaccination group compared to the reference group. Number of 6/11/16/18-related CIN1, CIN2/3, cervical cancer, cervical cancer deaths, and genital warts (both in female and male population) was halved in the vaccination strategy group compared to the reference strategy group by year 19, 24, 41, 44, and 14, respectively. The incremental cost-effectiveness ratio for routine vaccination of 12-year-old girls was 18,251 TRY/QALY over 100 years. **CONCLUSIONS:** A quadrivalent HPV vaccination program can reduce the incidence of cervical cancer, CINs and genital warts in Turkey at a cost-per-QALY ratio within the range defined as cost effective.

PCN76

COST-EFFECTIVENESS ANALYSIS OF COMPLIANCE WITH CLINICAL PRACTICE GUIDELINES IN SARCOMA TREATMENT: AN ECONOMIC EVALUATION IN TWO EUROPEAN REGIONS

Perrier L[1], Buja A[2], Mastrangelo G[2], Sandona P[2], Ducimetière F[1], Blay JY[1], Gilly FN[3], Siani C[4], Biron P[1], Ranchère-Vince D[1], Decouvelaere AV[1], Thiesse P[1], Bergeron C[5], Rossi CR[2], Ray-coquard I[1]
[1]*Cancer Centre Léon Bérard, Lyon, France,* [2]*University of Padova, Padova, Veneto, Italy,* [3]*University hospital Lyon Sud, Pierre Bénite, France,* [4]*University Claude Bernard Lyon1, Lyon, France,* [5]*Institut d'Hémato-Oncologie Pédiatrique, Lyon, France*

OBJECTIVES: Sarcomas are rare tumours (1-2% of all cancers) with high discordance in diagnosis and low compliance with clinical practice guidelines (CPG). The objective was then to perform a cost-effectiveness analysis (CEA) of compliance with CPG compared to non compliance in the treatment of sarcoma. **METHODS:** The study included patients aged >15 years with histological diagnosis of sarcoma treated at the University hospital of Lyon and/or Léon Bérard Cancer centre (Rhône-Alpes region, France) in 2005/2006 or in public hospitals of Veneto (Italy) in 2007. The time horizon was three years post diagnosis. The hospital's perspective was adopted, based on a microcosting approach. All costs were expressed in euros 2009. A 4% annual discount rate was applied to both costs and effects. Incremental Cost Effectiveness Ratios (ICER) were expressed as costs per life year gained, per disease-free year gained, and per relapse-free year gained when treatments were compliant with CPG compared to not compliant. Probabilistic sensitivity analyses were performed based on 10000 bootstrap replications both with and without adjusting data to grade. **RESULTS:** A total of 219 patients were included in the study. Compliance with CPG was observed for 118 patients (54%). Average total costs reached €23,571 when treatment was in accordance with CPG and €27,313 otherwise. Compliance with CPG strictly dominates for disease-free and relapse-free survivals. When handling uncertainty, probabilities that compliance with CPG still strictly dominates were 33%, 63% and 88% for overall, disease-free, and relapse-free survivals, respectively. When costs and effects were adjusted to grade, probabilities reached 17%, 48% and 75%, respectively. **CONCLUSIONS:** Given that few cost-effectiveness analyses have examined compliance with CPG in rare tumours, these results are promising and should encourage physicians' efforts to increase their compliance to CPG.

PCN77

COST-EFFECTIVENESS OF GRANULOCYTE COLONY STIMULATING FACTOR (G-CSF) IN PRIMARY (PP) AND SECONDARY PROPHYLAXIS (SP) OF FEBRILE NEUTROPENIA (FN) IN PATIENTS WITH STAGES 2 AND 3 BREAST CANCER (BC) UNDERGOING CYTOTOXIC CHEMOTHERAPY IN FRANCE

Perrier L[1], Bachelot T[2], Leon N[3], Maurel F[4], Cohen-Nizard S[5], De Liège F[5]De Liège F[5]
[1]*Cancer Centre Léon Bérard, Lyon, France,* [2]*Centre Léon Bérard - Inserm U□□, Lyon Cedex08, France,* [3]*IMS Health, Puteaux, France,* [4]*IMS Health, Puteaux, France, France,* [5]*Amgen France SAS, Neuilly-sur-Seine, France*

OBJECTIVES: To estimate the cost-effectiveness of G-CSF PP strategies versus pegfilgrastim SP and G-CSF SP strategies versus no prophylaxis for decreasing FN incidence in patients treated with cytotoxic chemotherapy for stages 2 and 3 breast cancer. **METHODS:** A Markov model was designed to track health outcomes (FN events) and medical direct costs (G-CSF, administration and FN episode costs, calculated with French Sickness Fund perspective). The model compared 9 prophylaxis strategies for three frequent BC chemotherapies (TAC [docetaxel, doxorubicin, cyclophosphamide], TC [docetaxel, cyclophosphamide] and AC-T [doxorubicin, cyclophosphamide—docetaxel]): pegfilgrastim (Neulasta®), 6-day filgrastim (Neupogen®), 11-day filgrastim, 6-day lenograstim, as either PP (initiated from first cycle) or SP (initiated after FN event), or no prophylaxis. Inputs included transition probabilities (relative FN risks depending on the chemotherapy, determined from expert opinion and published studies: TAC, 25%; TC, 10% and AC-T 7% for AC and 21% for T), FN history and chemotherapy cycle), as well as unit costs for prophylaxis resources and overall cost associated with FN. Incremental cost-effectiveness ratios (ICERs) were expressed per FN event avoided. PP strategies were compared to SP with pegfilgrastim and SP strategies were compared to no prophylaxis. **RESULTS:** In the high risk population (chemotherapy FN risk ≥20%), PP-pegfilgrastim was the most cost-effective PP-G-CSF versus SP-pegfilgrastim. With TAC, ICER was €8,383 per FN avoided. In less cytotoxic regimens without considering patient risk factors, after an FN event, SP-pegfilgrastim was the most cost-effective SP-G-CSF compared to no prophylaxis, with ICERS ranging from €4614 with TC to €4795 with AC-T. **CONCLUSIONS:** According to our model based on French cost data, pegfilgrastim in PP and SP is more cost-effective than PP and SP with filgrastim and lenograstim in BC. PP-pegfilgrastim is the most cost-effective PP strategy in case of high risk of FN.

PCN78

REVIEW OF THE RECENT PHARMACEUTICAL ADDITIONS TO THE TREATMENT OF COLORECTAL CANCER

Van rooijen EM[1], Van Gils C[2], Bazargani YT[3], Coupe VM[4], Punt CJA[5], Uyl-De Groot CA[6]
[1]*institute for Medical Technology Assessment (iMTA), Rotterdam, The Netherlands,* [2]*Erasmus University, Rotterdam, The Netherlands,* [3]*Insitute for Medical Technology Assessment, Rotterdam, The Netherlands,* [4]*VU University Medical Center, Amsterdam, Noord-Holland, The Netherlands,* [5]*Radboud University MC, Nijmegen, The Netherlands,* [6]*Institute for Medical Techonology Assessment (iMTA), Rotterdam, The Netherlands*

OBJECTIVES: Colorectal cancer (CRC) is one of the most prevalent forms of cancer worldwide. This review aims to report on the most recent clinical and cost-effectiveness data available for five of the most often used drugs in the treatment of advanced (ACRC) and non-advanced CRC; oxaliplatin, irinotecan, bevacizumab, panitumumab and cetuximab. **METHODS:** A systematic review of the literature was performed for the clinical effectiveness. Articles were divided on type of CRC, ACRC or non-advanced CRC , and for ACRC on time point of treatment (1st, 2nd or 3rd line). If possible, data on overall survival (OS) and progression free survival (PFS) were extracted. An additional systematic review was performed to identify cost-effectiveness analyses performed for non-advanced CRC and ACRC, from which total costs, total gains (LYG or QALYs) and ICERs were extracted. **RESULTS:** Regarding clinical effectiveness, our search identified seven articles for oxaliplatin, six for irinotecan, four for bevacizumab five for cetuximab and four for panitumumab. The cost-effectiveness search yielded 6 articles for non-advanced CRC and 17 articles for ACRC. Clinical effectiveness has been demonstrated in the literature for oxaliplatin, irinotecan and bevacizumab, with on average approximately two to three months additional survival. Effectivness of panitumumab and cetuximab has mainly been demonstrated on PFS, where on average 2 months is gained. The ICERs of oxaliplatin for non-advanced CRC were between £2,970 and $24,104/QALY. ICERs reported oxaliplatin and irinotecan combination therapy vs monotherapy with 5-FUin ACRC are between $10,137/LYG and £58.400/progression free LYG. ICERs for bevacizumab, cetuximab and panitumub in addition to combination chemotherapy in advanced CRC, when reported, are between €17.000/LYG and $299,613/QALY **CONCLUSIONS:** Clinical effectiveness of oxaliplatin, irinotecan, bevacizumab, cetuximab and panitumab has been established. However, it is not clear whether the use of these drugs is also cost-effective, especially not for bevacizumab, cetuximab and panitumumab.

PCN79

COST EFFECTIVENESS OF ERLOTINIB IN FIRST LINE TREATMENT OF ADVANCED NON SMALL CELL LUNG CANCER (NSCLC) IN VULNERABLE ELDERLY PATIENTS: AN ECONOMICAL ANALYSIS OF A PROSPECTIVE PHASE 2 STUDY (GFPC 0505)

Chouaid C[1], Le Caer H[2], Corre R[3], Crequit J[4], Jullian H[5], Falchero L[6], Dujon C[7], Vergnenegre A[8]
[1]*Service of Pneumology, Paris, France,* [2]*Hôpital de draguignan, Draguignan, France,* [3]*CHU Rennes, rennes, France,* [4]*Service de Pneumologie Centre Hospitalier., BEAUVAIS, France,* [5]*Service de Pneumologie-Allergologie, MARTIGUES CEDEX , France,* [6]*Service de Pneumologie, VILLEFRANCHE sur SAONE, France,* [7]*Hôpital De Versailles, versailles, France,* [8]*Hôpital du Cluzeau Service de Pathologie Respiratoire, LIMOGES, France*

OBJECTIVES: Weekly gemcitabin and erlotinib are both active in elderly patients treated for NSCLC. The aim of the GFPC0505 randomized phase II trial was to compare the efficacy and the cost of weekly gemcitabin (G) followed by erlotinib after progression (arm A) versus erlotinib followed by G after progression (arm B) in frail elderly patients with advanced non small-cell lung cancer (NSCLC), selected on the basis of a comprehensive geriatric assessment (CGA). **METHODS:** Frail elderly chemotherapy-naive patients with stage IIIB/IV NSCLC were selected after a CGA. Main clinical outcome was time to second progression (TTP2). Costs were limited to direct medical costs and were prospectively collected until progression, from the third party payer perspective. Health utilities (based on disease states and grade 3-4 toxicities) and costs after progression were derived from the literature. Sensitivity analyses were performed. **RESULTS:** Median age of the 94 enrolled patients was 78.2 years, and 76 (80%) were male. There is no significantly difference between the 44 and 50 patients respectively randomized in arm A and B, in terms of efficacy (TTP2: 4.3 and 3.5 months: overall survival: 4.4 and 3.9 months, mean QALY:0.347 and 0.325) and in terms of mean direct costs (15,363 and 15,233€). **CONCLUSIONS:** In this population, the 2 strategies appeared equivalent in terms of efficacy and costs. Supported by an unrestricted educational grant from Roche

PCN80

COMPARATIVE ANALYSIS OF COST-EFFECTIVENESS BEVACIZUMAB + PACLITAXEL VERSUS USING ONLY VERSUS PACLITAXEL AS FIRST LINE TREATMENT OF PATIENTS WITH METASTATIC BREAST CANCER IN MEXICO PUBLIC INSURANCE (SEGURO POPULAR)

Arreola Ornelas H[1], Rosado Buzzo A[2], García L[2], Camacho LM[2], Lechuga D[3]
[1]*OikoSalud y Fundación Mexicana para la Salud, Mexico City, Mexico, Mexico,* [2]*OikoSalud, Mexico City, Mexico, Mexico,* [3]*Roche Mexico, Mexico, Mexico, Mexico*

OBJECTIVES: To evaluate whether the use of bevacizumab + paclitaxel offers best cost-effective results regarding the use of paclitaxel for patients with metastatic breast cancer mBC **METHODS:** The treatment was evaluated up to the progression of the disease, rescue management and palliative up to to death in a Markov model, operating 65 cycles of 28 days. An incremental cost effectiveness analysis and sensitivity analysis was performed considering as an outcome measure progres-

sion-free survival (PFS), on the cohort of 2000 patients with Her2 Ne mBC negative and a subanalysis of the populations of patients with triple negative of patients with Her2 Neu Negative, taking into account direct medical costs and social costs due to premature death, in a horizon of 5 years (discount rate 5%). **RESULTS:** The 40.35% of patients survived after 12 months using bevacizumab + paclitaxel, while only 35.20% did so with only administered paclitaxel. 59.6% of these patients were PFS with combination therapy, while 37.71% did with monotherapy. Combined therapy provides more effectiveness than monotherapy in terms of overall survival, progression-free survival (PFS) and therapeutic response. The incremental cost of bevacizumab + paclitaxel is $9,639 USD obeying the PFS difference in time between the two cohorts, and higher consumption on the combination versus monotherapy. For triple negative subpopulation, the ICER is $2295 USD while for the sub-population of HER 2 is $1854 USD. The ICER is compared against a threshold of 3 times GDP per capita in Mexico. The ICER is lower than the threshold, so it is cost-effective **CONCLUSIONS:** The combination of bevacizumab + paclitaxel, for all cases studied, represents a better alternative cost effective versus paclitaxel monotherapy.

PCN81

A COST-EFFECTIVENESS ANALYSIS OF ADJUVANT TRASTUZUMAB REGIMENS IN EARLY HER2/NEU-POSITIVE BREAST CANCER IN COLOMBIA

Buendia rodriguez JA[1], Vallejos C[2]
[1]*Universidad de Buenos Aires, Buenos Aires, Buenos Aires, Argentina,* [2]*Universidad de La Frontera, Temuco, Chile*

OBJECTIVES: : One-year adjuvant trastuzumab therapy increases disease-free and overall survival in the adjuvant treatment of early HER2-positive breast cancer. This study aims to assess the long-term cost-effectiveness of adjuvant trastuzumab treatment in Colombia **METHODS:** A Markov health-state transition model was constructed to simulate the natural development of breast cancer in women with HER2/neu-positive after 12 months of after trastuzumab adjuvant chemotherapy over a lifetime perspective with annual transition cycles. The model incorporated five broad health states (disease-free, local recurrence [LCR], distant recurrence [DCR], cardiac failure, death). Baseline event rates and 3-year relative risk (RR= 0.75) were derived from the HERA trial. Costs and utility weights were from the literature and were discounted by 3% annually **RESULTS:** On the basis of HERA data, the model results showed that the utilization of adjuvant trastuzumab treatment in early breast cancer can prolong 8.23 quality-adjusted life-years, compared with 7, 78 quality-adjusted life-years in the standard chemotherapy group. The incremental cost-effectiveness ratio was US$134,581. Results are moderately sensitive to variation of relative risk, cost and number of cycles of trastuzumab and less sensitive to breast cancer survival rates and variations in cardiac toxicity **CONCLUSIONS:** The results suggest that the 1-year adjuvant trastuzumab treatment is not cost-effective in Colombia. Both clinical and economic benefits were not superior for the 1-year adjuvant trastuzumab treatment group compared with the standard adjuvant chemotherapy group

PCN82

COST-EFFECTIVENESS ANALYSIS OF TRASTUZUMAB + DOCETAXEL VERSUS DOCETAXEL ALONE IN THE TREATMENT OF HER2+ METASTATIC BREAST CANCER

Athanasakis K, Golna C, Kyriopoulos J
National School of Public Health, Athens, Greece

OBJECTIVES: To investigate the cost-effectiveness of the addition of trastuzumab in a docetaxel monotherapy for women with HER2+ metastatic breast cancer (MBC) in the Greek healthcare setting. **METHODS:** A 3-state model was constructed to simulate progression of the disease and overall quality adjusted survival for patients receiving trastuzumab and docetaxel (T+D) or docetaxel alone (D). The model ran on 1-month cycles and simulated the progress of patients over a total period of 12 years. Data on effectiveness were derived from a randomized controlled trial comparing the outcomes of six cycles of docetaxel 100 mg/m2 every 3 weeks, with or without trastuzumab 4 mg/kg loading dose followed by 2 mg/kg weekly until disease progression in women with an average age of 53 years, and an average body surface area of 1.7148m2. Costs were estimated from a third-party payer perspective (2011 Euros), discounted at 3%/annum. **RESULTS:** Patients in the T+D arm had a mean incremental gain of 0.729 years (95% CI: 0.10, 1.36) in overall survival and 0.449 (95% CI: 0.14 0.76) QALYs in quality-adjusted survival than those in the D arm (1.992 vs. 1.542). Taking into account the average incremental cost of 30,474.62€ (95% CI: 23,592.04, 38,195.93) in the T+D arm, the analysis reveals that the Incremental Cost Effectiveness Ratios (ICERs) are estimated at 41,811.13€ and 67,824.92 for every life year or QALY, respectively, gained with trastuzumab. The probabilistic sensitivity analysis showed that the ICERs produced by T+D were favourable at 17.1% of the Monte Carlo simulations at the 50,000€ and 35.7% at the 60,000€ threshold. **CONCLUSIONS:** The addition of trastuzumab to a first line treatment of HER2+ MBC with docetaxel represents an intervention with a high probability of being cost-effective from a third party-payer perspective

PCN83

COST-EFFECTIVENESS ANALYSIS OF COMBINATION THERAPIES INCLUDING CLASS II ANTICANCER DRUG FOR ADVANCED OR METASTATIC GASTRIC CANCER

Oh JY[1], Lee EK[2]
[1]*Sookmyung Women's University, Seoul , South Korea,* [2]*Sookmyung Women's University, Seoul, South Korea*

OBJECTIVES: This study was performed to evaluate the cost-effectiveness of three kinds of combination therapies including class II anti-cancer drugs in patients with advanced or metastatic gastric cancer. **METHODS:** A Markov model was simulated to assess the clinical and economic impact over 5 years from societal perspective. Life Years Gained(LYG) were measured as a clinical outcome. In the model, Docetaxel+cisplatin+5-FU(DCF), S-1+cisplatin(SP), Capecitabine+cisplatin(XP) were selected as 1st line chemotherapies. When the disease progressed in the second line therapy, Leucovorin + 5-FU + Irinotecan (FOLFIRI), it was assumed that best supportive care was performed. Transition probabilities and mortality were calculated by using adjusted parameter of "time to progression(TTP) or progression free survival(PFS), overall survival(OS)", which were obtained by indirect comparison (control group: 5-FU + Cisplatin). Both direct medical costs and direct non-medical costs were calculated. Costs and outcomes were discounted at an annual rate of 5% and sensitivity analysis was performed to evaluate uncertainty in the results. **RESULTS:** SP was dominated by XP because the total LYG per patient was higher and cost was lower for XP compared with SP. When DCF was compared with XP, incremental LYG was 0.045. However, incremental cost of DCF was also 10,719,975 KRW. Incremental cost-effectiveness ratio for DCF compared to XP was calculated over 200 million per LYG. The results of the sensitivity analysis showed no significant difference. **CONCLUSIONS:** Although a threshold of ICER is not fixed in Korea, GDP per capita is usually used for reference. In that case, it is considered that XP is cost-effective compared with DCF. Therefore, XP is the more cost-effective than DCF and SP. Further research should be carried out about cost-utility by using utility weight according to the state of gastric cancer.

PCN84

POPULATION VACCINATION PROGRAM FOR HUMAN PAPILLOMAVIRUS IN SPANISH GIRLS: AN EFFICIENCY STUDY

Lorente MR[1], Antonanzas F[2]
[1]*University of La Rioja, Logrono, la Rioja, Spain,* [2]*University of La Rioja, Logrono, La Rioja, Spain*

OBJECTIVES: The incidence of cervical cancer in Spain is about 10/100,000 women per year, one of the lowest in Europe. Screening programs and the population vaccination against HPV are the two health care interventions aiming to reduce cancer development.The objective of this study is to analyse the efficiency of the population vaccination program in Spanish girls aged 11-14. **METHODS:** A simulation discrete event model with a horizon of 20 years, under the perspective of the National Health System, applied to the context of a high level of coverage Spanish region (La Rioja) was developed. The cytological results of the population screening program (14,760 women) and a review of literature on Spanish papers as well as official statistics were used in the model. Finally, the model took also into account the impact of some progression co-factors and the decrease on the immunity along time. **RESULTS:** According to the model outputs, from the 2725 girls of the first vaccination camping, 38.2% will not get infected by the HPV, 56.1% will clear the virus in a spontaneous way, 3.8% will either not progress or do not confirm the diagnoses, and, consequently, 1.9% would confirm a cervical lesion (29 LSIL and 23 HSIL), without considering the vaccination effect.A population vaccination program (that reached a 97.5% coverage) vs no vaccination at all will have an Incremental Cost Effectiveness Ratio of 43,657.8 euros per avoided pre-cancer cervical lesion. **CONCLUSIONS:** Although some primary preventative measures are convenient from a public health perspective, their final health and economic outcomes should be analysed. According to the results of this study, targeting only some risk populations should be considered as a way of increasing the low efficiency of the general population vaccination program.

PCN85

COST-EFFECTIVENESS OF A HUMAN PAPILLOMAVIRUS VACCINATION OF BOYS

Hren R
University of Ljubljana, Ljubljana, Slovenia

OBJECTIVES: To analyze cost-effectiveness of a human papillomavirus (HPV) vaccination of boys at age 12 against oropharyngeal carcinoma and anogenital warts. **METHODS:** We developed Markov decision model for a population of boys of age 12. We assessed the following outcomes: costs, gains in quality adjusted life years (QALYs), incremental cost-effectiveness ratio (ICER) for two options: vaccination with quadrivalent vaccine and no vaccination, and for the two currently-available vaccination choices: one with quadrivalent vaccine and one with bivalent vaccine. We employed Monte Carlo microsimulation in the analysis of results. **RESULTS:** Comparison of HPV vaccination of boys at age 12 vs. no vaccination resulted in ICER of 109,384 GBP per QALY. The outcome was sensitive to the vaccination costs, the probability of developing oropharyngeal carcinoma and anogenital warts, and proportion of oropharyngeal carcinoma attributable to infection with types HPV-16 and HPV-18. When comparing quadrivalent and bivalent vaccines, resulting ICER was 5,205 GPB per QALY. **CONCLUSIONS:** Our results indicate that HPV vaccination of boys with quadrivalent vaccine is at present deemed not cost-effective, i.e., ICER exceeds willingness-to-pay threshold of 30,000 GBP per QALY. Comparison of quadrivalent and bivalent vaccines revealed that the additional benefits of protection against anogenital warts would favour quadrivalent vaccine as the vaccination choice. An increase in incidence of HPV-positive oropharyngeal carcinoma and anogenital warts, and reduction of vaccination costs could substantially reduce ICER. Results of our study have potential healthcare policy implications for HPV national immunisation programs in the UK and other jurisdictions of developed countries.

PCN86

COST-EFFECTIVENESS OF RITUXIMAB IN FOLLICULAR LYMPHOMA FIRST LINE MAINTENANCE TREATMENT FROM PUBLIC PAYER PERSPECTIVE IN POLAND

Gadaj A[1], Kalinowska A[1], Hawrylecka D[2], Holojda J[3], Krawcewicz A[4], Spychalowicz W[5], Russel-Szymczyk M[6], Szkultecka-debek M[6]
[1]*MAHTA Sp. z o.o., Warsaw, Poland,* [2]*Podkarpacie Oncology Center, Brzozow, Poland,* [3]*District Specialist Hospital, Legnica, Poland,* [4]*Institute of Hematology and Transfusion Medicine,*

Warsaw, Poland, [5]Silesian Medical Academy, Katowice, Poland, [6]Roche Polska Sp. z o.o., Warsaw, Poland

OBJECTIVES: To assess cost-effectiveness of rituximab (RTX) 1st line maintenance treatment compared to observation (O) in patients with follicular lymphoma (FL) from the Polish public payer perspective. **METHODS:** Efficacy and safety of rituximab 1st line maintenance therapy was assessed based on the results of systematic review and the PRIMA clinical trial. Direct medical costs were assessed based on the data regarding clinical practice of FL treatment and medical resources use gathered in 5 oncology centers. The following costs were calculated and included: drugs, drug administration, treatment-related adverse events, lymphoma relapse treatment, patient health monitoring. A life-time horizon (25 years) and public payer perspective were assumed. Costs were discounted at 5% and effects at 3.5%. A four health state Markov model (progression-free 1st line, progression-free subsequent line, progression and death) was used. Sensitivity analysis was performed testing the influence of various critical parameters such as utilities values, different costs categories, length of time horizon and patient's body surface. **RESULTS:** Introduction of 1st line maintenance therapy with RTX resulted in gain of 1.4 life years and 1.3 quality adjusted life years compared to observation. The total incremental costs were 60,707 PLN (1 EURO=3.96 PLN) which corresponded to an incremental cost-effectiveness ratio (ICER) of 43,348 PLN and an incremental cost-utility ratio (ICUR) of 47,357 PLN. Both values were below 110 000 PLN cost-effectiveness threshold assumed by the Polish public payer. The results were sensitive to discount rates, utilities values applied to the specific health states, length of time horizon. None of the tested scenarios resulted in values of ICUR and ICER exceeding the 110,000PLN threshold, providing evidence that rituximab treatment is cost-effective from public payer perspective. **CONCLUSIONS:** Rituximab in 1st line maintenance treatment of FL is an effective, safe and cost -effective therapeutic option.

PCN87

THE COST EFFECTIVENESS OF CETUXIMAB (ERBITUX) IN THE THIRD LINE TREATMENT OF METASTATIC COLORECTAL CANCER IN THE UK

Perard R[1], Samyshkin Y[2], Guillermin ALG[3]
[1]*Merck Serono Limited, Feltham, UK,* [2]*IMS Health, London, UK,* [3]*IMS Health, London , UK*

OBJECTIVES: To estimate the cost-effectiveness of cetuximab plus best supportive care (BSC) or cetuximab plus chemotherapy in patients with EGFR-expressing KRAS wild-type metastatic colorectal cancer who have failed at least two previous chemotherapeutic regimens in the metastatic setting from the UK NHS perspective. **METHODS:** A Markov model was developed to inform the cost-effectiveness (CE) of cetuximab plus BSC and cetuximab plus chemotherapy both versus BSC, and additionally the CE of cetuximab plus BSC and cetuximab plus chemotherapy both versus panitumumab plus BSC. Progression-free survival and overall survival data were collected from the following clinical trials: Karapetis et al. 2008, De Roock et al. 2007 and 2010, and Amado et al. 2008. These three clinical studies were relevant to perform indirect treatment comparisons. **RESULTS:** In the base-case analysis, treatments with cetuximab resulted in additional QALY as follows: cetuximab plus BSC versus BSC (0.303), cetuximab plus chemotherapy versus BSC (0.668), cetuximab plus BSC versus panitumumab plus BSC (0.193), and cetuximab plus chemotherapy versus panitumumab plus BSC (0.616). The base-case incremental cost effectiveness ratios (ICER) for cetuximab plus BSC and cetuximab plus chemotherapy, both compared to BSC are in the region of £50,000 per QALY. Compared to panitumumab plus BSC, the ICERs are below the NICE's £30,000 willingness-to-pay threshold. **CONCLUSIONS:** Weighting the QALYs gained with the NICE supplementary advice, suggests that cetuximab plus BSC or cetuximab plus chemotherapy is potentially a cost-effective use of NHS resources in this setting.

PCN88

ECONOMIC MODEL OF GRANULOCYTE-COLONY STIMULATING FACTOR (G-CSF) IN PRIMARY (PP) AND SECONDARY PROPHYLAXIS (SP) OF FEBRILE NEUTROPENIA (FN) IN NON-HODGKIN'S LYMPHOMA (NHL) PATIENTS UNDERGOING CHEMOTHERAPY IN FRANCE

Perrier L[1], Sebban C[2], Leon N[3], Maurel F[4], Cohen-Nizard S[5], De Liège F[5]
[1]*Cancer Centre Léon Bérard, Lyon, France,* [2]*Cancer Centre Leon Berard, Lyon, France,* [3]*IMS Health, Puteaux, France,* [4]*IMS Health, Puteaux, France, France,* [5]*Amgen France SAS, Neuilly-sur-Seine, France*

OBJECTIVES: To assess the cost-effectiveness in France of current G-CSF strategies as PP (from first cycle and before an FN event) and SP (after an FN event) for NHL patients receiving cytotoxic chemotherapy. **METHODS:** A Markov model was developed to calculate cost per FN events avoided, life-year saved (LYS), and quality adjusted life year (QALY); results were expressed as incremental cost-effectiveness ratios (ICERs). ICERs for 9 prophylaxis strategies were evaluated for three NHL chemotherapies (CHOP, CHOP-R and ACVBP): PP or SP with pegfilgrastim (Neulasta®), 6-day filgrastim (Neupogen®), 11-day filgrastim, 6-day lenograstim; and no prophylaxis. All strategies were compared to no prophylaxis. FN-related outcomes including FN-hospitalizations, FN-mortality and RDI were assessed using epidemiologic data, utility and chemotherapy-related FN-risk (21% for CHOP-21, 19% for RCHOP-21, 52% for ACVBP). Direct healthcare costs (G-CSF, administration, and FN-related events) were calculated from French Health insurance perspective. Costs and outcomes were discounted (4%/year). Based on international guidelines, PP should be given to high-risk patients (FN risk320%). **RESULTS:** In the high chemotherapy FN-risk population, pegfilgrastim was the most cost-effective G-CSF compared to SP-pegfilgratim. For instance, in patients undergoing ACVBP chemotherapy, ICERs with PP-pegfilgrastim were €2,019 per FN avoided, €10,194 per QALY gained and €8,632 per LYS versus SP-pegfilgrastim. In RCHOP-21 and without considering patient risk factors, if SP was considered instead of no prophylaxis, pegfilgrastim was the dominant G-CSF with ICERs of €2,112 per FN avoided, €14,703 per QALY gained and €11,940 per LYS versus no prophylaxis. **CONCLUSIONS:** With French settings, pegfilgrastim is the most cost-effective PP-G-CSF in high chemotherapy FN-risk patients versus SP-pegfilgrastim. After an FN event, pegfilgrastim is the most cost-effective SP-G-CSF versus no prophylaxis.

PCN89

PUBLIC HEALTH IMPACT OF QUADRIVALENT HPV TYPES 6, 11, 16, 18 VACCINE IN SAO PAULO, BRAZIL USING A TRANSMISSION DYNAMIC MODEL

Singhal P[1], Tannus G[2], Pillsbury M[3], Dasbach E[4]
[1]*Merck & Co., Inc., West Point, PA, USA,* [2]*Axia.Bio, São Paulo, Brazil,* [3]*Merck & Co., Inc., west point, PA, USA,* [4]*Merck Research Laboratories, North Wales, PA, USA*

OBJECTIVES: To assess the public health impact of the quadrivalent (6,11,16,18) HPV vaccination program for São Paulo, Brazil. **METHODS:** A published mathematical model of the transmission dynamics of HPV infection and disease was adapted for São Paulo, Brazil. The model captured direct protective effects of vaccination and indirect effects (herd immunity). Model inputs were used from Brazil or the Latin/America region when available; otherwise, the default values in the original model were used. Maintaining current cervical cancer screening practices in Brazil, we evaluated two strategies: routine vaccination of females by age 12 (S1), and S1 combined with a temporary (5 years) female catch-up program for age 12–24 years (S2). The vaccine coverage rates were 85% for the routine and 95% by age 26 years for the catch-up vaccination programs. **RESULTS:** Comparing S1 to no vaccination, we estimated the cumulative percent (absolute cases) reduction in HPV 6/11/16/18-related incident genital warts-female, genital warts-male, cervical intraepithelial neoplasia (CIN) grade 1, CIN 2/3, cervical cancer cases, and cervical cancer deaths would be 78% (2,488,240), 67% (2,166,770), 68% (360,235), 65% (1,154,566), 47% (135,810), and 44% (39,147), respectively, over 100 years. Compared to S1, S2 provided additional cumulative percent (absolute cases) reduction of 9% (273,866), 11% (357,728), 7% (39,455), 7% (131,861), 7% (19,620), and 7% (6,009) in HPV 6/11/16/18-related incident genital warts-female, genital warts-male, CIN 1, CIN 2/3, cervical cancer cases, cervical cancer deaths. **CONCLUSIONS:** A prophylactic quadrivalent HPV vaccination program for females in Sao Paulo, Brazil can substantially reduce the incidence of cervical cancer, CIN, and genital warts. Female catch up vaccination may provide greater reductions in HPV-related diseases.

PCN90

COST-EFFECTIVENESS ANALYSIS OF ERLOTINIB VERSUS DOCETAXEL, PEMETREXED FOR SECOND-LINE TREATMENT OF ADVANCED NON-SMALL-CELL LUNG CANCER IN RUSSIA

Nguyen TTT[1], Yagudina R[2], Kulikov A[2]
[1]*I.M Sechenov First Moscow State Medical University, Moscow, Russia,* [2]*I.M. Sechenov First Moscow State Medical University, Moscow, Russia*

OBJECTIVES: Evaluate the cost-effectiveness analysis of erlotinib compared with docetaxel and pemetrexed in the second-line treatment of advanced non-small-cell-lung cancer (NSCLC) from a societal perspective in a Russian setting. **METHODS:** A Markov state transition model, based on two randomized phase III studies of erlotinib versus pemetrexed (HORTC) and pemetrexed versus docetaxel (Nasse H. et al 2005), was used to estimate total direct costs and quality-adjusted life years (QALYs). Data about cost of medical services and drugs are received from the price-list of out-patient medical aid in clinic MMA of I.M.Sechenov 01.02.2011, site minzdravsoc.ru//medicine and other accessible electronic resources. Costs, effectivenesses, utilities were discounted at 3%. Sensitivity analysis for key parameters in the model was conducted. **RESULTS:** Erlotinib was associated with a reduction in total costs (1 179 452 roubles versus 1 260 607 roubles and 1 769 367 roubles) and improved outcomes (total QALYs of 0.299 versus 0.248 and 0.271) in comparison with docetaxel and pemetrexed, respectively. Sensitivity analysis showed that major factors influencing cost-effectiveness and cost-utility ratios are survival gain, price of drugs, discount rates. **CONCLUSIONS:** In summary erlotinib is more cost-effective in comparison with docetaxel and pemetrexed for second-line treatment of advanced NSCLC due to lower adverse event and drug administration costs.

PCN91

PHARMACOECONOMIC ANALYSIS OF MCRC THERAPY WITH XELOX/FOLFOX4 REGIMES WITH BEVACIZUMAB OR CETUXIMAB AS THE FIRST LINE TREATMENT IN RUSSIA

Tikhomirova AV[1], Yagudina RI[2], Kulikov AU[2]
[1]*FGBU NCESMP Minzdravsocrazvitiya of Russia, Moscow, Russia,* [2]*Moscow Medical Academy, Moscow, Russia*

OBJECTIVES: This study is devoted on a comparative pharmacoeconomic analysis regimes XELOX + BV (bevacizumab) versus XELOX + CET (cetuximab) treatment (q3w); FOLFOX4 + BV and FOLFOX4 + CET (q2w) in the treatment of mCRC. The efficacy and safety of combined treatment regimens based on the data of international clinical trials. **METHODS:** Medical services were taken from the standards of medical care for patients with ÑRC and their costs were based on the price-list of Cancer Research Center. The cost analysis of anticancer and related drugs were based on the information about limit selling/import prices of vital and essential drugs. The main characteristics for Markov's model were: the Markov states (without progression, progression, death); a Markov's cycle (1 month); the time horizon (5 years). **RESULTS:** The cost of diagnosis was 16757 rubles, the medical services – 222802 rubles. The mCRC therapy as a first line by XELOX in combination with BV was 1029694 rubles or with CET–1899867 ruble; FOLFOX4 in combination with BV–1109402 rubles or with CET–2026917 rubles. The highest CER was for mode XELOX+CET-263870 rubles. The Markov's model shows that the COST/QALY and COST/LYG will above with each year, but in comparing groups with BV or CET therapy in the next 5 years, it was shown a tendency of the increase in cost per

QALY and per LYG for XELOX/FOLFOX4+CET. **CONCLUSIONS:** As a result of cost analysis it was identified anticancer schemes, requiring the lowest and highest costs. The account of CER, Markov's model construction have demonstrated the benefits of using XELOX/FOLFOX4+BV regimes in patients with mCRC.

PCN92

THE COST-EFFECTIVENESS OF NANOPARTICLE ALBUMIN-BOUND PACLITAXEL COMPARED TO SOLVENT-BASED PACLITAXEL IN WOMEN WITH METASTATIC BREAST CANCER

Vandewalle B[1], Almeida J[1], Félix J[1], Silva MJ[1], Luz R[2]
[1]*Exigo, Alhos Vedros, Setúbal, Portugal,* [2]*Centro Hospitalar Lisboa Central, Lisboa, Lisboa, Portugal*

OBJECTIVES: To perform a cost-effectiveness analysis comparing nanoparticle albumin bound (nab) paclitaxel (N-P, 260 mg/m2) with solvent-based paclitaxel (S-P, 175 mg/m2) given every 3 weeks as second-line treatment for metastatic breast cancer (MBC) from the perspective of the Portuguese National Health System (PNHS). **METHODS:** A Markov type stochastic process including disease states progression-free, progressive disease and death was designed to model long-term effectiveness and costs. Patient level data from a randomized, open-label, phase III study (n=460) was used to estimate parametric survival models (weibull) for time to treatment discontinuation, time to progression and time to death. Effectiveness was measured in life years (LY). Only direct costs were considered (drugs, medical visits, hospitalization, adverse events (grade 3/4) treatment and monitoring, terminal care). The source for unit costs was the PNHS price list. Time horizon was fixed at 4 years. Probabilistic sensitivity analysis was conducted with Monte Carlo simulations. Discount rates of 5%/year were applied to costs and effectiveness. **RESULTS:** A mean gain of 25 LY (95%CI: [2; 46]) was estimated for each 100 patients treated with N-P. This would represent an average 22% life expectancy increment. The estimated mean incremental cost of N-P treated patients was 7370 € (95%CI: [6762; 7945]). Corresponding average incremental cost-effectiveness ratio was 29,535€/LY. Probabilistic sensitivity analysis revealed an 83% probability of N-P to be cost-effective in comparison with S-P, at the commonly accepted threshold of 50,000€. **CONCLUSIONS:** nab-Paclitaxel may be considered a cost-effective drug as it adds a substantial relative increment in the overall survival over second-line solvent -based paclitaxel monotherapy in women with metastatic breast cancer. The estimation of long-term benefits of nab-Paclitaxel beyond the clinical trial follow-up period by Markov based modelling can provide valuable support to decision making in the context of scarce resources.

PCN93

COST-EFFECTIVENESS OF TREATMENT WITH NEW AGENTS IN ADVANCED NON-SMALL-CELL LUNG CANCER: A SYSTEMATIC REVIEW

Bongers ML[1], Coupe VM[1], Jansma EP[2], Smit EF[1], Uyl-de Groot C[3]
[1]*VU University Medical Center, Amsterdam, Noord-Holland, The Netherlands,* [2]*VU Amsterdam University Library, Amsterdam, Noord-Holland, The Netherlands,* [3]*The Institute for Medical Technology Assessment, Erasmus University, Rotterdam, The Netherlands*

OBJECTIVES: Over the past decades, research focusing on new chemotherapeutic agents for patients with inoperable NSCLC have reported only modest gains in survival. These health gains are achieved at considerable costs, but economic evidence on superiority of one of the agents in terms of cost-effectiveness is lacking. The objective of this systematic review is to assess fully published cost-effectiveness studies comparing the new agents docetaxel, paclitaxel, vinorelbine, gemcitabine and pemetrexed, and the targeted therapies erlotinib and gefitinib among each other. **METHODS:** PubMed, EMBASE.com and Economic Evaluations (via the Cochrane Library, Wiley) were systematically searched for fully published studies from the past 10 years. Studies were screened by two independent reviewers according to a priori inclusion criteria. The methodological quality of the included studies was evaluated by two independent reviewers using standardized assessment tools. **RESULTS:** A total of 222 potential studies were identified. Eleven cost-effectiveness or cost-utility studies were included. The methodological quality of the full economic evaluations was fairly good. Transparency in costs and resource use, details on statistical tests and sensitivity analysis were points for improvement. In first-line treatment, one study indicated that gemcitabine-cisplatin was cost-effective compared to paclitaxel-based regimens, and another study indicated that gemcitabine-cisplatin was cost-effective compared to platinum-based regimens containing either paclitaxel, vinorelbine or docetaxel in terms of progression-free survival. In a third study, pemetrexed-cisplatin was cost-effective compared to gemcitabine-cisplatin in patients with nonsquamous cell carcinoma. In second-line treatment, docetaxel was cost-effective compared to BSC (range of ICERs per LYG: US$22,190-US$32,133). Erlotinib was cost-effective compared to placebo in one study (ICER per LYG: US$33,728). Docetaxel and pemetrexed were dominated by erlotinib in one study and in two studies, respectively. **CONCLUSIONS:** We found indications for superiority in terms of cost-effectiveness of gemcitabine-cisplatin in a first-line setting and for erlotinib in second-line setting.

PCN94

COMPARATIVE ANALYSIS OF COST-EFFECTIVENESS BEVACIZUMAB + PACLITAXEL VERSUS USING ONLY VERSUS PACLITAXEL AS FIRST LINE TREATMENT OF PATIENTS WITH METASTATIC BREAST CANCER IN THE IMSS (MEXICAN INSTITUTE OF SOCIAL SECURITY)

Arreola Ornelas H[1], Rosado Buzzo A[2], García L[2], Camacho LM[2], Lechuga D[3]
[1]*OikoSalud y Fundación Mexicana para la Salud, Mexico City, Mexico, Mexico,* [2]*OikoSalud, Mexico City, Mexico, Mexico,* [3]*Roche Mexico, Mexico, Mexico, Mexico*

OBJECTIVES: To evaluate whether the use of bevacizumab + paclitaxel offers best cost-effective results regarding the use of paclitaxel for patients with metastatic breast cancer mBC **METHODS:** The treatment was evaluated up to the progression of the disease, rescue management and palliative up to to death in a Markov model, operating 65 cycles of 28 days. An incremental cost effectiveness analysis and sensitivity analysis was performed considering as an outcome measure progression-free survival (PFS), on the cohort of 2000 patients with Her2 Ne mBC negative and a subanalysis of the populations of patients with triple negative of patients with Her2 Neu Negative, taking into account direct medical costs and social costs due to premature death, in a horizon of 5 years (discount rate 5%). **RESULTS:** The 40.35% of patients survived after 12 months using bevacizumab + paclitaxel, while only 35.20% did so with only administered paclitaxel. 59.6% of these patients were PFS with combination therapy, while 37.71% did with monotherapy. Combined therapy provides more effectiveness than monotherapy in terms of overall survival, progression-free survival (PFS) and therapeutic response The incremental cost of bevacizumab + paclitaxel is $7529 USD obeying the PFS difference in time between the two cohorts, and higher consumption on the combination versus monotherapy. For triple negative subpopulation, the ICER is $1793 USD while for the sub-population of HER 2 is $1448 USD. The ICER is compared against a threshold of 3 times GDP per capita in Mexico. The ICER is lower than the threshold, so it is cost-effective **CONCLUSIONS:** The combination of bevacizumab + paclitaxel, for all cases studied, represents a better alternative cost effective versus paclitaxel monotherapy.

PCN95

THE COST-EFFECTIVENESS OF APREPITANT FOR THE PREVENTION OF NAUSEA AND VOMITING INDUCED BY MODERATELY EMETOGENIC CHEMOTHERAPY IN BREAST CANCER PATIENTS COMPARED TO CURRENT CLINICAL PRACTICE IN SCOTLAND

Nikoglou E[1], Humphreys S[1], Pellissier J[2], O' Regan C[1]
[1]*Merck Sharp and Dohme, Hertfordshire, UK,* [2]*Merck & Co, St. Charles, IL, USA*

OBJECTIVES: Chemotherapy induced nausea and vomiting (CINV) is a common and distressing adverse effect of cancer chemotherapy. Despite the widespread use of prophylactic anti-emetic agents, control of CINV induced by moderately emetogenic chemotherapy (MEC) remains sub-optimal, with breast cancer patients representing a sub-population at increased risk. The aim of this analysis was to evaluate the cost-effectiveness of an aprepitant regimen compared to current clinical practice in Scotland for the prevention of CINV in breast cancer patients receiving MEC. **METHODS:** A decision-analytic model was developed to estimate the costs and health outcomes associated with the prevention of CINV over a single chemotherapy cycle with a time horizon of 5 days post-chemotherapy. The analysis compared an aprepitant regimen (aprepitant, ondansetron and dexamethasone pre-chemotherapy, and aprepitant for 2 days following chemotherapy) to a commonly used regimen in Scottish clinical practice (dexamethasone and ondansetron pre-chemotherapy, and dexamethasone and domperidone for 2 days following chemotherapy). The health outcomes in the model were: complete protection (no emesis, no rescue therapy and maximum nausea <25mm on VAS); complete response (no emesis and no rescue therapy, but maximum nausea ≥25 mm); incomplete response (some emesis or rescue therapy). Transition probabilities were based on a randomised clinical trial comparing aprepitant and standard of care regimens, which included 438 breast cancer patients. Chemotherapy among breast cancer patients was comprised of anthracycline plus cyclophosphamide (AC) regimens (87.2%) and non-AC regimens (12.8%). **RESULTS:** An aprepitant regimen when compared to Scottish clinical practice for preventing CINV in breast cancer patients receiving MEC is cost-effective with an incremental cost effectiveness ratio (ICER) of £14,610 per QALY. **CONCLUSIONS:** Aprepitant is a cost-effective option for the prevention of acute and delayed nausea and vomiting induced by MEC for the treatment of breast cancer in Scottish clinical practice.

PCN96

COSTS OF ADJUVANT CHEMOTHERAPY WITH OXALIPLATIN IN STAGE III COLON CANCER: COMPARING THE THREE SCHEMES STANDARDS: FOLFOX-4, FLOX AND XELOX

Calderillo G, Melchor J, Ruiz E, Meneses A, Albarran A
National Cancer Institute of Mexico, Mexico City, Mexico, Mexico

OBJECTIVES: The adjuvant chemotherapy for stage III Colon Cancer is based in oxaliplatin for 6 months. FOLFOX-4, FLOX and XELOX were very similar results in efficacy and safety. There are some differences in total doses and form of the application. We present the differences in direct and indirect costs of the 3 schemes in the National Cancer Institute (NCI) of Mexico. **METHODS:** We analyzed 130 patients with stage III Colon Cancer treated in the NCI of Mexico, from January 2004 to August 2010. The body surface mean was 1.62 and the costs were calculated based on current prices-government in November 2010. We considered the following costs: 1) Chemotherapy / BS , 2) Prophylactic anti-emetics, 3) Use of central catheter (patients with XELOX, not used catheter), 4) Medical offices, 5) Laboratory tests, 6) Adverse events grade 3-4 (used the frequency of reports of Andre T 2004/ FOLFOX, Kuebrer JP 2007/FLOX and Schomll HJ 2007/XELOX) and 7) Number of visits to the Hospital and indirect costs at each visit (cost for visit was $ 39.68 US). All costs was report in US dollars ($ 12.50 Mexican pesos = 1 dollar US) **RESULTS:** The estimated costs incurred by adjuvant chemotherapy regimen are reported as follows (FLOX, FOLFOX-4, XELOX): Chemotherapy ($13,349, $13,685, $15,365), Anti-emetics ($326, $433, $288), Subclavian catéter-maintenance ($237, $237, $0), QT – application ($764 $1,433, $352), Blood tests ($422, $563, $376), Medical offices ($405, $527, $365), Adverse events grade 3-4 ($726, $568, $371), Hospital visits (number) (40, 61, 17). Indirects costs for visit $1,587, $2,420, $675). The total cost of the treatment is ($17,817, $19,866, $ 17,790). **CONCLUSIONS:** The FOLFOX scheme was more expensive with the highest number of hospital visits. The scheme XELOX is more practice, less expensive, less visit at the hospital and with less impact on lifestyle.

PCN97

ECONOMIC EVALUATION OF PROPHYLACTIC PEGFILGRASTIM AND FILGRASTIM IN PATIENTS WITH MYELOABLATIVE CHEMOTHERAPY TO AVOID NEUTROPENIA IN THE IMSS (MEXICAN INSTITUTE OF SOCIAL SECURITY)

Nambo-Lucio M
CMN Siglo XXI, Mexico City, Mexico, Mexico

OBJECTIVES: To assess whether prophylactic use of pegfilgastrim offers better results in terms of health and expense associated with the incidence of febrile neutropenia (FN) associated with myelosuppressive chemotherapy compared to filgrastim in the IMSS **METHODS:** The measure of effectiveness was considered by the incidence of NF in patients receiving myeloablative chemotherapy (Qt) and received prophylaxis. According to literature, the prophylactic use of pegfilgrastim reduced by 90% the incidence of FN and the prophylactic use of filgrastim reduces by 39%. We constructed a decision tree, which considered the costs of treatment and complications, including, costs of drugs, consultations, laboratory studies, hospitalization and procedures. The incidence of FN is 20% when is used Qt. **RESULTS:** If used as a prophylactic filgrastim, average cost of prophylactic treatment over the complications of FN would be US$1982. However, if used as prophylactic pegfilgrastim, based on their efficiency, the cost would be US$1421. If we use as a prophylactic pegfilgrastim we will have savings of 28% compared with using filgrastim. Following the trend of consumption of filgrastim in IMSS published by the Federal Institute of Access to Public Information (IFAI) and assuming that 30% of this consumption was used for prophylaxis for patients who received Qt, then we can estimate that the number of prophylaxis given was about 15,000 cycles in 2009. This represents average savings of treatment (including complications of NF) of 10 million USD, however if they had been treated with pegfilgrastim savings had been for 18 million USD or 8 million USD more savings (+86%) that using filgrastim as prophylaxis. **CONCLUSIONS:** The prophylactic use of pegfilgatrim reduces costs of care for cancer patients that are in Qt in the IMSS and provides a benefit to patients.

PCN98

ESTIMATING THE POTENTIAL COST-EFFECTIVENESS OF HUMAN PAPILLOMAVIRUS (HPV) VACCINATION IN GERMANY USING A DYNAMIC TRANSMISSION MODEL

Damm O[1], Horn J[2], Kretzschmar M[3], Deleré Y[4], Kaufmann AM[5], Wichmann O[4], Krämer A[1], Greiner W[1], Mikolajczyk R[2]
[1]*School of Public Health, University of Bielefeld, Bielefeld, Germany,* [2]*Bremen Institute for Prevention Research and Social Medicine, Bremen, Germany,* [3]*University Medical Centre Utrecht, Utrecht, The Netherlands,* [4]*Robert Koch Institute, Berlin, Germany,* [5]*Charite-Universitaetsmedizin Berlin, Berlin, Germany*

OBJECTIVES: In clinical studies, prophylactic HPV vaccines have demonstrated high efficacy in the prevention of HPV infections, cervical intraepithelial neoplasia (CIN) and genital warts. In Germany, routine HPV vaccination is recommended for females aged 12 to 17 years. No transmission model reflecting the German healthcare setting which evaluates the cost-effectiveness of both the bivalent and quadrivalent HPV vaccines has been published yet. Hence, the objective of this study was to determine the long-term impact of both available vaccines in addition to the existing cervical cancer screening programme in Germany. **METHODS:** A mathematical model simulating the transmission dynamics and the natural history of HPV infection was developed. The age-structured model takes account of the occurrence of CIN, cervical cancer and genital warts and was calibrated using German data on HPV prevalence and cancer statistics. Epidemiological and economic parameter estimates were obtained from published literature and supplemented by expert interviews. The base-case analysis was conducted from a third-party payer perspective and assumed a vaccination coverage of 50%, 10 years of sustained vaccine protection followed by a period of waning immunity, costs of €474 for the initial immunisation series and a 3% discount rate on future costs and health effects. **RESULTS:** Compared with current screening practice, vaccination of 12-year-old girls prevented additional 97,822 cervical cancer cases and 23,462 deaths over a time horizon of 100 years. Under base-case assumptions, the discounted ICERs were €57,413 per life-year gained and €37,198 per QALY gained for the bivalent vaccine, and €36,700 per life-year gained and €15,229 per QALY gained for the quadrivalent vaccine. **CONCLUSIONS:** Considering the commonly accepted threshold of €50,000 per QALY gained, routine HPV-vaccination of 12-year-old girls is likely to be cost-effective in Germany. Additional protection against genital warts in females and males by the quadrivalent vaccine improves the cost-effectiveness ratio substantially.

PCN99

COST-EFFECTIVENESS OF DASATINIB VERSUS HIGH-DOSE IMATINIB AND NILOTINIB IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA RESISTANT TO STANDARD-DOSE IMATINIB IN PORTUGAL

Darba J[1], Kaskens L[2], Abecasis M[3], Vitorino R[4], Carrasco J[5]
[1]*Universitat de Barcelona, Barcelona, Spain,* [2]*BCN Health, Barcelona, Spain,* [3]*Inst Portogues Oncologica, Lisboa, Portugal,* [4]*Bristol-Myers Squibb, Paço de Arcos , Portugal,* [5]*Bristol-Myers Squibb, Paço de Arcos, Portugal*

OBJECTIVES: To assess the cost-effectiveness of dasatinib 100 mg/day vs. imatinib 600 mg/day, imatinib 800 mg/day and versus nilotinib 800 mg/day in patients with chronic myeloid leukaemia (CML) in the chronic phase of the disease, resistant to prior therapy with imatinib 400 mg/day from the perspective of the Portuguese National Health Service (NHS). **METHODS:** A cost-utility Markov model was developed by BMS for NICE appraisal and has been adapted to the Portuguese treatment practice. Four health states were considered, three represented CML phases (chronic, accelerate and blast) and the death state with one-month cycles. The model was populated with efficacy data from clinical trials, resource utilization by expert opinion, published quality of life data for CML laypersons in the UK and unit prices from official 2010 price lists. A life-long, NHS perspective was used and deterministic results were determined. A deterministic sensitivity analysis was performed to test the robustness of the results. **RESULTS:** The results showed that chronic phase CML patients resistant to standard dose imatinib gain on average 2.72 life-years, or 2.38 quality adjusted life-years, when treated with dasatinib 100 mg/day compared with imatinib 600 mg/day or compared to imatinib 800 mg/day and on average 0.53 life-years, or 0.47 quality adjusted life-years compared to nilotinib 800 mg/day. The incremental cost per quality adjusted life year gained (QALY) amounts to €39,941 when dasatinib 100 mg/day is compared with imatinib 600 mg/day, and to €14,470 when compared to imatinib 800 mg/day and to €29,422 when compared to nilotinib during a lifetime period. **CONCLUSIONS:** The results indicate that dasatinib is a cost-effective option in CML patients resistant to standard-dose imatinib in Portugal in comparison with high-dose imatinib and nilotinib.

PCN100

A COST–UTILITY ANALYSIS OF DEGARELIX IN THE TREATMENT OF ADVANCED HORMONE-DEPENDENT PROSTATE CANCER IN SCOTLAND

Fisher D[1], Brereton NJ[1], Kildegaard nielsen S[2], Tate E[3]
[1]*BresMed Health Solutions, Sheffield, South Yorkshire, UK,* [2]*Ferring International Center S.A., St. Prex, Switzerland,* [3]*Hayward Medical Communications, Newmarket, Suffolk, UK*

OBJECTIVES: Degarelix is the first gonadotrophin-releasing hormone (GnRH) antagonist to be launched in the UK for first-line treatment of advanced prostate cancer. The aim of this evaluation was to predict long-term clinical and economic outcomes from treatment with degarelix compared to treatment with goserelin, standard current practice, from the perspective of NHS Scotland. **METHODS:** Analyses were conducted using a 20 year semi-Markov (cohort health-state transition) cost-utility model which was recently submitted to and accepted by the Scottish Medical Consortium (SMC). The model considers two patient groups – the intention-to-treat population (ITT) of patients with hormone-responsive prostate cancer in whom treatment with androgen-deprivation therapy is indicated and who would be prescribed a LHRH agonist and a high-risk population with a baseline PSA level >20ng/ml. Probabilistic and deterministic sensitivity analyses were conducted to assess uncertainty in the model. **RESULTS:** The key benefit of treatment with degarelix comes from keeping patients in the first-line treatment state for longer, incurring less time and costs in the later more costly and lower utility non-hormonal therapy state. At NHS list-price degarelix is estimated to dominate treatment with goserelin within both populations with a saving of £271 and QALY gain of 0.46 in the ITT population. Probabilistic sensitivity analyses show that degarelix is likely to be cost-effective (at a willingness-to-pay of £500 per QALY) in 100% of cases. **CONCLUSIONS:** The economic analysis shows that degarelix not only provides a better patient outcome but is also less costly than goserelin over a lifetime of treatment. It is rare for a new treatment to predict dominance over existing therapies – only 18% of SMC submissions up to 2011 have predicted dominance. In addition degarelix shows a large gain in quality of life (almost half a year in full health) even when a conservative assumption of no increase in survival is applied.

PCN101

A COST-EFFECTIVENESS ANALYSIS FOR SECOND-LINE TREATMENT OF RELAPSED/REFRACTORY (RR) MULTIPLE MYELOMA (MM) IN THE UNITED KINGDOM

Jiang Y[1], Spencer M[2], Gauthier A[1], Pacou M[1]
[1]*Amaris Consulting UK, London, UK,* [2]*Janssen-Cilag Ltd, High Wycombe, UK*

OBJECTIVES: MM is the second most common haematological malignancy. With the recent introduction of new agents, survival has greatly improved. This study aimed to assess the cost-effectiveness of bortezomib (BOR) vs. dexamethasone (DEX) as second-line treatment of RRMM. Lenalidomide in combination with dexamethasone (LEN+DEX) was also considered in a secondary analysis. **METHODS:** An area under the curve decision-analytic model was developed, containing three health states: "pre-progression", "post-progression" and "dead". Survival analyses of the APEX trial (BOR vs. DEX) were used to estimate the transition probabilities by line of treatment. As 71% of patients randomised to DEX crossed over to BOR, the hazard ratios (HR) were adjusted for crossovers (progression-free survival [PFS]: 0.56; overall survival [OS]: 0.59). HRs for LEN+DEX vs. DEX (PFS: 0.35; OS: 0.71) were retrieved from the MM-09/10 trials (not adjusted for 47.6% cross-over or line of treatment). Treatment schedule, compliance rate and adverse events (AEs) rates were retrieved from the above clinical trials, while utility weights were retrieved from the published literature. The model runs over patients' lifetime, and discount rate of 3.5% was applied to costs and QALYs and assumptions around level of vial sharing for bortezomib were investigated. **RESULTS:** BOR was associated with an incremental effectiveness of 1.56 life years gained (LYG) and 0.86 QALYs per patient compared to DEX, while LEN+DEX was found to be less effective (-0.64 LYG, -0.28 QALYs) than BOR. Scenario analyses showed BOR is cost-effective in most cases when compared to DEX, while LEN+DEX was dominated by BOR. The results were sensitive to treatment effect on survival. **CONCLUSIONS:** The model suggests that BOR is a cost-effective option for treating RRMM in the UK.

PCN102

ECONOMIC EVALUATION OF THREE FORMULATIONS OF LEUPROLIDE ACETATE WITH ATRIGEL® IN ANDROGEN DEPRIVATION THERAPY FOR ADVANCED PROSTATE CANCER IN NINE EUROPEAN COUNTRIES

Retsa P[1], Sidhu M[1], Odeyemi I[1], Tombal B[2], Wex J[3]
[1]*Astellas Pharma Europe, Staines, UK,* [2]*Cliniques Universitaires Saint-Luc, Brussel, Belgium,* [3]*PharmArchitecture Limited, London, UK*

OBJECTIVES: Three formulations of leuprolide, an established LH-RH agonist are used in the management of advanced prostate cancer. In order to inform clinical practice, the economic impact of the different formulations and dosing schedules were evaluated for Austria, Belgium, Czech Republic, Hungary, Italy, Latvia, The Netherlands, Poland and Portugal. **METHODS:** Database searches identified 10 clinical trials of leuprolide 1-monthly (1M), 3-monthly (3M) and 6-monthly (6M) with Atrigel®, requiring 6, 4 and 2 hospital treatment visits respectively. Due to reported comparable efficacy, safety and adherence, cost-minimisation analysis was conducted. Costs of the product, specialist consultations and diagnostics (converted to 2010 euros) were considered during up to 12 months follow-up. The perspective was that of public payers. **RESULTS:** The review showed that with the use of leuprolide 1M, 3M and 6M the respective percentage of patients achieving testosterone suppression of ≤50ng/dl was 93.3%, 98.3% and 97.3% ($p>0.05$). However, 6M was the least cost treatment option, with average total annual costs from 788€ (Poland) to 1839€ (Portugal). The 3M option was 2.5% (Hungary) to 37.6% (Belgium) higher than 6M cost; while 1M formulation had the highest cost: 15.6% and 151.6% more than 6M for those countries, respectively. The 3M option was 11.2% to 45.3% less expensive than 1M. The cost drivers were the frequency of visits for injection and monitoring. The study showed that up to 50% additional visits could be funded with the savings resulting from switching eligible patients from 1M and 3M to 6M. Results were robust in one-way sensitivity analyses, as well as probabilistic sensitivity analysis. **CONCLUSIONS:** Leuprolide acetate with Atrigel® 1M, 3M and 6M formulations offer comparable efficacy and safety. However, driven by the frequency of visits, the 6-monthly formulation offers the greatest cost-savings for prostate cancer patients in the European countries studied.

PCN103

THE ADJUVANT TREATMENT OF STAGE 3 COLON CANCER (ACC): AN INDIRECT COST-MINIMISATION AND POPULATION NET HEALTH BENEFIT ANALYSIS OF CAPECITABINE + OXALIPLATIN (XELOX) VS. IV 5-FU + FA + OXALIPLATIN (FOLFOX)

Garside J, McNamara S, Millar D
Roche Products Limited, Welwyn Garden City, UK

OBJECTIVES: XELOX is the most utilised therapy for aCC in the UK. The aim of this analysis was to assess and compare the population net health benefit (pNHB) of all patients with aCC switching from the FOLFOX regimen to XELOX, from a UK National Health Service (NHS) perspective. **METHODS:** An indirect comparison of the NO16968 (XELOX) and MOSAIC (FOLFOX-4) trials was undertaken (where both regimens were compared to i.v. 5-FU plus FA) showing XELOX to be non-inferior. A cost minimisation approach was therefore taken. Drug costs were based on UK list prices taken from the British National Formulary (BNF 61), and additional costs such as administration costs, adverse event costs and pharmacy costs were taken from NHS reference costs, the literature and previous technology appraisals. A £20,000/QALY assumed displacement threshold was utilised to estimate the pNHB provided. Uncertainty was explored via one-way sensitivity analyses. **RESULTS:** Replacing FOLFOX-6 and FOLFOX-4 with XELOX saved £6490 and £9778 per patient respectively, of which £2434 and £1534 came from drug acquisition costs. Over 60% of the total savings were realised from reductions in the frequency of pharmacy use and administration resource use. The savings realised from full implementation of the XELOX regimen could be used by the NHS to generate more than 1000 QALYs over the next 5 years. The costs of AEs were similar across all three regimens. XELOX achieved savings of £3,400 per patient even when all parameters in the sensitivity analysis were simultaneously set to the worse case scenarios. **CONCLUSIONS:** XELOX has been demonstrated to be cost-effective and significantly cost-saving versus FOLFOX-4 and FOLFOX-6 in aCC from an NHS perspective. Full conversion of all aCC patients to XELOX could offer the NHS substantial financial savings and a significant pNHB of over 1000 QALYs over a 5 year period.

PCN104

COST MINIMIZATION ANALYSIS (CMA) OF CAPECITABINE/CISPLATIN (XP) VS. 5-FU/CISPLATIN (FP) REGIMENS IN ADVANCED GASTRIC CANCER (AGC) TREATMENT IN THE ROMANIAN SETTING

Curescu S[1], Stanculeanu DL[2], Croitoru A[3], Radu CP[4]
[1]*Timisoara Clinical Hospital Romania, Timisoara, Romania,* [2]*Bucharest Oncologic Institute, Bucharest, Romania,* [3]*Fundeni Clincal Institute, Bucharest, Romania,* [4]*Roche Romania, Bucharest, Romania*

OBJECTIVES: The objective was to compare the first-line therapy costs of capecitabine+cisplatin(XP) and 5-FU+cisplatin (FP) in patients with AGC in the Romanian health care system. **METHODS:** Due to similar efficacy as shown in the study ML 17 032 (Kang et al.) a cost minimization analysis was performed (CMA). Direct costs of the two alternative therapies were estimated based on the trial results on actual dose and the number of administrations, and unit costs in Romanian hospitals from payer perspective (National Health Insurance House). Adverse event (AE) profiles were used to calculate costs of treating AEs. An expert panel estimated typical treatment patterns and costs of treating major AEs. **RESULTS:** XP arm patients received 5.2 cycles vs. 4.6 cycles in FP arm. The substitution of oral capecitabine for infusional 5-FU reduced the number of hospital clinic visits by 17.6 (22.8 for FP versus 5.2 for XP). Drug costs were estimated to be ROL 5,230 greater in the XP arm, but drug administration costs were ROL 5,904 lower, yielding a net cost saving of ROL 674 per patient (1Euro=4,2 ROL). Adverse event profiles were almost similar: associated costs to treat AEs were less than ROL 270 per patient and were lower in the XP arm by ROL 67. Total incremental cost was - ROL 741 in favor of XP regimen. **CONCLUSIONS:** Oral capecitabine treatment is a cost-saving regimen for AGC from Romanian public payer's perspective.

PCN105

ECONOMIC EVALUATION OF PANITUMUMAB AND CETUXIMAB IN THE TREATMENT OF PATIENTS WITH EGFR EXPRESSING MCRC WITH NON-MUTATED (WILD-TYPE) KRAS IN GREECE: A COST MINIMIZATION ANALYSIS

Fragoulakis V[1], Papagiannopoulou V[2], Kourlaba G[1], Ducournau P[3], Maniadakis N[1]
[1]*National School of Public Health, Athens, Greece,* [2]*Amgen Hellas, Athens, Greece,* [3]*Amgen (Europe) GmbH, Zug, Switzerland*

OBJECTIVES: Metastatic colorectal cancer (mCRC) accounts for a substantial economic and clinical burden worldwide. The aim of the present study was to conduct an economic evaluation in Greece comparing panitumumab with cetuximab in the monotherapy treatment of patients with non-mutated (wild-type) KRAS, epidermal growth factor receptor (EGFR)-expressing mCRC. **METHODS:** Based on literature search, panitumumab and cetuximab are assumed to have similar efficacy, hence a cost-minimization analysis was carried out from the third-payer-party (Sickness Fund) and the National Health Service (NHS) perspective. A probabilistic model was constructed to estimate the resource utilization and costs associated with the management of patients receiving either therapy. Due to known differences in various settings regarding drug use, two type of analysis were undertaken: one reporting "cost per mg" and another reporting "cost per vial". Treatment cost accounted for administration of second line chemotherapy, laboratory and biochemical examinations and for hospitalization due to toxicity. Data on resource utilization were collected from two oncology units in Greece and prices refer to 2011. Non parametric bootstrapping was employed to deal with uncertainty and to estimate variability measures. **RESULTS:** From a third-payer-party perspective, it was found that the mean 20-week total cost per patient for panitumumab and cetuximab in the "per mg analysis" was €16,349 (95%CI: 16,036.7-16,637.8) and €18,242 (95%CI: 17,902.4-18,597.9), respectively. The corresponding mean total costs obtained in "per vial analysis" was €18,808 (95%CI: 18,437.7-19,161.7) and €19,701 (95%CI: 19,358.6-20,053.1), respectively. From the NHS perspective, while the mean total costs per patient were higher than for third party payers, versus cetuximab, panitumumab was still associated with a 12.40% and 17.7% cost reduction in per-vial and per-mg analysis, respectively. **CONCLUSIONS:** In the Greek NHS and Sickness Fund setting, panitimumab may represent a cost-saving option compared with cetuximab in the management of patients with non-mutated (wild-type) KRAS, epidermal growth factor receptor (EGFR)-expressing mCRC.

PCN106

CAPECITABINE PLUS OXALIPLATIN (CAPOX) VERSUS FLUOROURACIL/LEUCOVORIN PLUS OXALIPLATIN (FOLFOX) IN STAGE III COLON CANCER: A COST-MINIMIZATION ANALYSIS BASED ON REAL WORLD COSTS IN THE NETHERLANDS

van Gils CWM, de Groot S, Redekop WK, Uyl-De Groot CA
Institute for Medical Techonology Assessment (iMTA), Rotterdam, The Netherlands

OBJECTIVES: Recent publications have demonstrated equal efficacy of capecitabine and fluorouracil/leucovorin in combination with oxaliplatin in the adjuvant treatment of stage III colon cancer. It is stated that CAPOX and FOLFOX can be used interchangeably. **METHODS:** A cost-minimization analysis was performed using a Markov model, a two-year time horizon and a hospital perspective. Assuming equal efficacy of CAPOX and FOLFOX, transition probabilities were based on the MOSAIC trial (Andre et al., 2004 and 2009). Dutch real-world population-based treatment and follow-up cost were calculated using a representative sample of 102 patients treated with oxaliplatin for stage III colon cancer in 19 hospitals in the The Netherlands. Resource use was collected from the first administration of adjuvant chemotherapy until disease progression (or end of follow-up). Costs of drug acquisition, drug administration, patient monitoring, and adverse events were considered and reported in euro 2009. **RESULTS:** In Dutch practice, the median time on adjuvant treatment was 24 weeks for both CAPOX and FOLFOX, as recommended in the guidelines. Mean total costs were € 19,373 for CAPOX and € 31,324 for FOLFOX, resulting in a significant overall cost savings of € 11,951 for CAPOX compared with FOLFOX. Main savings resulted from administration costs (€ 8,460), due to increased hospital admissions in the FOLFOX treatment as the administration of fluorouracil involves a 48-hour continuous infusion. Other savings were obtained from acquisition costs (€ 2181) and costs of managing adverse events (€ 1427). Monitoring costs were comparable in CAPOX and FOLFOX. Probabilistic sensitivity analysis confirmed the robustness of the results. **CONCLUSIONS:** CAPOX is cost-saving in comparison with FOLFOX for the adjuvant treatment of stage III colon cancer in a real-world setting in the The Netherlands. Considering the high incidence of colon cancer in the The Netherlands, substantial overall savings can be realized by routine use of CAPOX in this indication.

PCN107

POTENTIAL BENEFITS OF INTRODUCING A COMPANION DIAGNOSTIC IN ADVANCED NON-SMALL CELL LUNG CANCER

Zaim R, Gaultney J, Redekop W, Uyl-de Groot C
Institute for Medical Technology Assessment, Erasmus University, Rotterdam, The Netherlands

OBJECTIVES: Gefitinib is a promising first-line treatment option in advanced non-small cell lung cancer (NSCLC) patients with positive epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutations. However, some patients with ènsitivé EGFR-TK mutations and primary resistance do not respond to gefitinib treatment. The objective of this early health technology assessment was to quantify the potential health gain and cost consequences that would result with the introduction of a companion diagnostic prior to first-line treatment of advanced NSCLC patients with positive EGFR-TK mutations. **METHODS:** A Markov model was designed to compare a companion diagnostic strategy (gefitinib or gemicitabine-carboplatin) versus treating all patients with gefitinib (gefitinib for all). Model in-

puts were taken from the IPASS trial, literature and publicly available sources. A two-year time horizon (based on the IPASS) was applied to calculate incremental costs, progression-free life years (PFLYs) and quality adjusted life years (QALYs). The perspective of National Health Service (NHS) in England and Wales was used. Sensitivity analyses were performed to assess uncertainty in the results. **RESULTS:** Base-case results revealed that the companion diagnostic strategy was dominant with improvements in effects (0.095 PFLYs, 0.020 QALYs) and reduction in costs (-£774). Small differences in QALY estimates were a consequence of using health utility inputs from second-line advanced NSCLC setting (intravenous treatment only). The results were sensitive to the health utilities, probability of being a responder and sensitivity, specificity and cost of the companion diagnostic. **CONCLUSIONS:** This early health technology assessment suggests that introducing a companion diagnostic prior to first-line advanced NSCLC treatment has the potential to improve effectiveness and reduce costs compared to the gefitinib for all strategy. Further research should aim at eliciting generic utility values to better estimate the potential health benefits of targeted therapies in this setting.

PCN108

ECONOMIC EVALUATION OF SUNITINIB MALATE FOR THE FIRST-LINE TREATMENT OF METASTARIC RENAL CELL CARCINOMA IN THE CHINESE HEALTH CARE SETTING

Wu J[1], Zhang N[1], Dong P[2]
[1]*Tianjin University, Tianjin, China,* [2]*Pfizer China, Beijing, China*

OBJECTIVES: To assess the cost-effectiveness of sunitinib malate as a first-line treatment in metastatic renal cell carcinoma (mRCC) compared with sorafenib and interferon-alfa (IFN-α) in the Chinese healthcare setting. **METHODS:** A Markov model was developed in Microsoft Excel® to simulate disease progression and determine outcomes over 5 years of a hypothetical cohort of 1,000 patients with mRCC receiving first-line treatment (in 6-week cycles, 4 weeks treatment plus 2 weeks off treatment) with sunitinib compared with sorafenib as well as IFN-α. The model parameters were derived from the Pivotal Study A6181034-A3, published literatures, government sources as well as clinical experts' opinions. Only direct costs were considered in terms of drug treatment, routine follow-up, severe adverse events, disease progression, and costs of health care resources involved in the palliative care of terminally-ill patients. Health outcomes were measured in LYs and QALYs. The results were expressed as ICER and ICUR. Time horizon was 5 years and the discount rate of 5%/year was applied to costs and effectiveness. Sensitivity analyses were also performed. **RESULTS:** The results indicated that in terms of total average cost per patient over 5 years, sunitinb was less costly (¥611,054) than sorafenib (¥613,304), and more costly than IFN-α(¥150,159). Concerning health outcomes, the estimated gains for one patient treated with sunitnib over IFN-α were 0.25 LYs and 0.29 QALYs, and over sorafenib were 0.09 LYs and 0.13 QALYs. The ICER and ICUR of sunitinib versus IFN-α were ¥1,837,954 per LY gained and ¥1,585,357 per QALY gained, respectively. **CONCLUSIONS:** Results suggest that sunitinib has better clinical efficacy compared to sorafenib and IFN-α, and is a cost-saving alternative to sorafenib as a first-line treatment for mRCC in China. When compared with IFN, Sutent achieved better clinical outcomes with increased cost.

PCN109

COST EFFECTIVENESS OF FIRST LINE TYROSINE KINASE INHIBITOR TREATMENT IN EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) MUTATED ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC) PATIENTS: A MARKOV MODEL

Borget I[1], Vergnenegre A[2], Chouaid C[3]
[1]*Health Economic service, Biostatistic and Epidemiology Department, Villejuif, France,* [2]*SIME, Limoges, France,* [3]*Service of Pneumology, Paris, France*

OBJECTIVES: EGFR testing and first line tyrosine kinase inhibitor (TKI) for patients with activating mutations is an option for the treatment of advanced non-small cell lung cancer (NSCLC). There is few data's on the cost-effectiveness of this strategy. The objective of this study was to determine the incremental cost-effectiveness ratio of first-line treatment with TKI compared to recommended chemotherapy (cisplatin pemetrexed doublet) in patients with EGFR mutation. **METHODS:** A Markov model was developed. Clinical outcomes were derived from the EURTAC phase III trial comparing TKI to chemotherapy in first-line of NSCLC. Cost data were estimated using individual data from French randomized clinical trial or prospective cohort, whereas utility scores derived from published data's. Costs were limited to direct costs for medications, physician visits, hospitalizations and treatment of adverse events. Analysis was limited to the period between treatment initiation of until first progression. All costs were expressed in 2010 Euro. Sensitivity analyses were performed. **RESULTS:** First line treatment with TKI was more effective than recommended chemotherapy (respectively 0.730 and 0.437 QALY), but also more expensive (respectively 29 702 € and 18 796 € per patient). The incremental cost-effectiveness ratio was then estimated at 37 221 €/QALY. Sensitivity analyses showed the robustness of the results. **CONCLUSIONS:** Based on these data, first line treatment based on TKI appeared as cost effective in EFGR mutated advanced NSCLC patients.

PCN110

ECONOMIC EVALUATION OF GEFITINIB FOR FIRST-LINE TREATMENT OF EGFR MUTATION POSITIVE ADVANCED NON-SMALL CELL LUNG CANCER PATIENTS IN GREECE

Fragoulakis V[1], Pallis A[2], Kourlaba G[1], Georgoulias V[2], Maniadakis N[1]
[1]*National School of Public Health, Athens, Greece,* [2]*University General Hospital of Herakleio, Herakleio, Greece*

OBJECTIVES: To investigate the cost-effectiveness of Gefitinib relative to the other alternatives used for the first line treatment of EGFR mutation positive advanced lung cancer patients, including: gemcitabine/carboplatin, paclitaxel/carboplatin, vinolerbin/cisplatin, gemcitabine/cisplatin and pemetrexed/cisplatin, from a provider and payer perspective in Greece **METHODS:** A probabilistic Markov model was constructed with four health states: treatment response, stable disease, disease progression and death. Objective response rates, hazard ratios and utility decrements for Gefitinib relative to paclitaxel/carboplatin were obtained from a head-to-head trial (IPASS), while meta-analysis was used to estimate corresponding data for remaining comparators. Utilities were applied to estimate Quality Adjusted Life Years (QALYs). The databases of several hospitals were analyzed to estimate resource utilization. Unit prices were obtained from the most up to date official resources and reflect 2011. Outcomes were bootstrapped 5,000 times to deal with uncertainty and to construct uncertainty intervals (UI). A discounting rate of 3.5% was applied for all outcomes. **RESULTS:** Mean QALYs were: 1.10 (95%UI:0.89-1.28), 1.04 (95%UI:0.87-1.19), 0.95 (95%UI:0.80-1.05), 0.91 (95%UI:0.76-1.10), 0.90 (95%UI:0.77-1.00) and 0.87 (95%UI:0.73-0.99) for gefitinib, pemetrexed/cisplatin, gemcitabine/cisplatin, gemcitabine/carboplatin, paclitaxel/carboplatin and vinolerbin/cisplatin respectively. From a provider perspective, total treatment cost per patient was: €61,865 (95%UI:€52,848-€71,444), €72,817 (95%UI:€65,213-€80,014), €59,270 (95%UI:€52,830-€65,530), €60,842 (95%UI:€50,113-€71,343), €58,081 (95%UI:€53,237-€62,628) and €54,468 (95%UI:€46,874-€62,245), respectively. Hence, gefinitib dominates all other options apart from vinolerbin/cisplatin, which is the least costly option. The incremental cost per QALY gained with gefitinib relative to vinolerbin/cisplatin, was limited to €9,662. Similar were the results from a payer perspective. The incremental cost per QALY gained in this case was €27,369. Probabilistic analysis indicated that at a 50,000 willingness to pay threshold gefitinib was cost-effective in 90% of cases in both perspectives of analysis. **CONCLUSIONS:** Gefitinib may represent a cost-effective choice, compared with alternative used in the first line treatment of mutation positive non-small cell lung cancer patients in Greece.

PCN111

COST-EFFECTIVENESS OF HUMAN PAPILLOMAVIRUS VACCINATION FOR PREVENTION OF CERVICAL CANCER IN RORAIMA, A BRAZILIAN AMAZONIC REGION STATE

Balbinotto G[1], Jardim A[2]
[1]*UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL, PORTO ALEGRE, RS, Brazil,* [2]*UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL, PORTO ALEGRE, rs, Brazil*

OBJECTIVES: : To assess cost-utility of the prophylactic HPV vaccination on the prevention of ICC in brazilian amazonic region **METHODS:** : A Markov cohort model was developed as an analytic tool to simulate the natural history of HPV and its progress to ICC, considering the current preventive programs. Transition probabilities assumptions were based mainly on empirical data of local and national studies. The model evaluated the addition of the vaccine to 3 cervical cancer screening scenarios (0, 3 or 10 exams throughout life). **RESULTS:** : The scenario of three Pap tests resulted in satisfactory calibration (base case). The addition of HPV vaccination would reduce by 35% the incidence of ICC, in a setting of 70% vaccination coverage. The incremental ratio of cost-effectiveness (IRCE) was R$1200 for each year of quality-adjusted life (QALY) saved. The sensitivity analysis confirms the robustness of this result, and duration of immunity was the parameter with greater variation in IRCE. **CONCLUSIONS:** : Vaccination has a favorable profile in terms of cost-utility, and its inclusion in the immunization schedule would result in substantial reduction in incidence and mortality of ICC in amazonic region of Brazil

PCN112

COST-UTILITY OF TREATMENT FOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN CHILDHOOD

Rae CS[1], Furlong W[2], Sala A[3], Jankovic M[4], Naqvi A[5], Barr RD[1]
[1]*McMaster University, Hamilton, ON, Canada,* [2]*Health Utilities Inc., Dundas, ON, Canada,* [3]*Azienda Ospedaliera S. Gerardo, Monza, Italy,* [4]*Ospedalo Nuovo S. Gerardo, Monza, Italy,* [5]*The Hospital for Sick Children, Toronto, ON, Canada*

OBJECTIVES: Cost-utility evaluation comparing Dana-Farber Cancer Institute (DFCI) and Berlin-Frankfurt-Munster (BFM) treatment strategies for childhood ALL. **METHODS:** Children treated at 7 centres in Canada, Italy and the USA were eligible for health-related quality of life (HRQL) assessment using the Health Utilities Index Mark 3. Parents completed assessments during 4 active treatment phases and at 2-years following therapy. Mean HRQL scores were used to calculate quality-adjusted life years (QALYs). Costs were calculated from the perspective of the Ontario (Canada) health care system. Patients from 2 Ontario centres were eligible for costing. Service utilization was obtained from Canadian Institute of Health Information Discharge Abstract Database and National Ambulatory Care Reporting System records. Standard costs were used for inpatient, outpatient and physician services. Difference in mean cost was assessed by t-test. The analytical horizon was 5 years after diagnosis. Future costs and QALYs were discounted at 5% per year. Sensitivity analyses used 95% confidence bounds (CB) of mean HRQL scores and discount rates of 0% or 3%. **RESULTS:** A total of 1281 HRQL assessments were collected. Costs were measured for 28 DFCI and 66 BFM patients. Based on mean HRQL scores, BFM had 0.17 (0.16 at 3% and 0.03 at 0%) more QALYs than DFCI. On lower CB for BFM and upper CB of DFCI mean HRQL scores, BFM had 0.16 (0.16 at 3% and 0.03 at 0%) fewer QALYs than DFCI. Mean costs for BFM ($101484) and DFCI ($98760) did not differ significantly (p=0.777). **CONCLUSIONS:** The cost-utility evaluation simplified to a QALY-effectiveness analysis because of no significant difference in mean costs. Sensitivity analysis indicates that mean QALY estimates are imprecise and overlap between the two strategies. Therefore, BFM and DFCI are equally QALY-effective within the range of estimation uncertainty. Future work will focus on diagnostic sub-groups with more precise cost and QALY estimates.

PCN113

COST-UTILITY ANALYSIS OF COMBINATION THERAPY OF PEGYLATED LIPOSOMAL DOXORUBICIN(PLD) AND CARBOPLATIN FOR KOREAN WOMEN WITH PLATINUM-SENSITIVE OVARIAN CANCER

Lee HY[1], Hong JM[1], Yang BM[1], Lee TJ[1], Kim BG[2], Kang SB[3], Kim YT[4], Kim YM[5], Kim JW[1], Yang JM[1], Jung YJ[1]

[1]*Seoul National University, Seoul, South Korea,* [2]*Samsung Medical Center, Seoul, South Korea,* [3]*National Cancer Center, Gyeonggi-Do , South Korea,* [4]*Yon-Sei Severance Hospital, Seoul , South Korea,* [5]*Asan Medical Center, Seoul, South Korea*

OBJECTIVES: Our objective was to perform the cost-utility analysis of comparing the combination therapy of Pegylated Liposomal Doxorubicin(PLD)/ Carboplatin with that of Paclitaxel/Carboplatin as a second-line treatment for women with Platinum-sensitive ovarian cancer among the Koreans. **METHODS:** Model : Markov model was constructed with 10-year time horizon. Treatment sequence was consisted of 1st ~ 6th line chemotherapy and best supportive care before death. Cycle length, time interval for efficacy evaluation of chemotherapy, was 9 weeks. Structure: The model consists of four health states: Responsive, Progressive, Clinical Remission and Death. At any given time, a patient may either remain at the current therapy line or make a transition to the next therapy or death. Effectiveness data: Median time to progression and survival were obtained through a systematic literature review and were pooled using meta-analytical approach. In case the required data was not available, it was elicited from opinions of expert panel. These outcomes were then converted into transition probabilities using formula. Costs and utilities: Direct cost included drug acquisition costs, costs for test, monitoring, BSC, and out-of-pocket cost. Indirect costs included transportation-related expenses. Utilities were obtained from existing literature. **RESULTS:** PLD/Carboplatin combination as the 2nd line therapy in the sequence of treatment turned out to be more effective but with higher costs, showing ICER of Korean Won(KRW) 19,712,349 (equivalent to US$ 18,093). This result was robust in all the deterministic sensitivity analyses, only except when the median TTPs were varied. The probability of cost-effectiveness for PLD/Carboplatin combination therapy was 50.6% at the willingness to pay of KRW 22,000,000 (about US$20,202), which is 2010 Korean GDP per capita. **CONCLUSIONS:** It could be safe to assert that the PLD/Carboplatin combination therapy is an economically valuable option as the 2nd-line chemotherapy for the treatment of Platinum-sensitive ovarian cancer within the Korean context.

PCN114

COST EFFECTIVENESS OF ADJUVANT CYCLOPHOSPHAMIDE IN THE TREATMENT OF BREAST CANCER IN SPAIN

Walter E, Brennig C, Schöllbauer V

Institute for Pharmaeconomic Research, Vienna, Austria

OBJECTIVES: The combination of doxorubicin and Cyclophosphamide (AC) has been a standard adjuvant breast-cancer regimen. The purpose of this analysis was to estimate the cost-effectiveness of AC compared with AT (Doxorubicin and Docetaxel), CMF (Cyclophosphamide, Methotrexate and 5-Fluoruracil) and FEC (5-Fluoruracil, Epirubicin and Cyclophosphamide) administered as adjuvant therapy to women with node-positive early breast-cancer in Spain. **METHODS:** We developed a multi-country Cost-Utility-Model to simulate the long-term consequences from initiation of adjuvant-chemotherpy over 10-years. Markov-modelling technique were used to estimate incidence of complications during chemotherapy (febril-neutropenia, chemotherapy-induced nausea and vomiting, dose-reduction, dose-delay, other grade 3 or 4 adverse-events) and long-term consequences like local or distant-relapse, acute-myelogenous-leukemia, chronic-heart-failure and death. Monte-Carlo-simulation accounted for uncertainty. The model includes twelve health-states. Probabilities were derived from clinical and epidemiological studies; direct costs (2010 Euro) from published sources from the payer's perspective. QALYs, life-years and costs were discounted at 5% p.a. **RESULTS:** Over a 10-year timeframe, costs associated with AC amounts to 13,265.88€ and 5.85 QALYs (6.49 LYs). Costs associated with AT are 15,361.89€. The cost-saving potential associated to AC amounts to 2,096.01€ per patient with comparable outcomes to AT. Costs associated with CMF are 14,144.63€ and QALYs and LYs do not differ from AC. AC dominates both AT and CMF. FEC associated total-costs are 15,138.23€ and 6.02 QALYs (6.81 LYs). Incremental costs vs. AC amounts to 1,872.35€ favorable for AC, the QALY gains are 0.17 QALYs (0.32 LYs). The incremental cost-effectiveness-ratio amounts 46,208.13€. Probabilistic sensitivity-analysis demonstrated the robustness of the model regarding input-data and assumptions. From a cost-minimization viewpoint AC remains the dominant strategy up to a price of 0.13€/mg (current price 0.01€/mg). **CONCLUSIONS:** AC chemotherapy is a cost-effective alternative to AT, CMF and FEC. AC is characterized by a clear cost advantage and comparable quality-of-life and life-years.

PCN115

COST OF SKELETAL-RELATED EVENTS (SRES) IN PATIENTS WITH BONE METASTASES TO SOLID TUMOURS BASED ON THE HEALTH RESOURCE UTILISATION (HRU) COLLECTED IN A PROSPECTIVE EUROPEAN MULTINATIONAL OBSERVATIONAL STUDY

Hechmati G[1], Cure S[2], Gouépo A[3], Hoefeler H[4], Lorusso V[5], Lüftner D[6], Durán I[7], Garzon-rodriguez C[8], Ashcroft J[9], Wei R[10], Ghelani P[11], Bahl A[12]

[1]*Amgen (Europe) GmbH, Zug, Switzerland,* [2]*i3 Innovus, Uxbridge, UK,* [3]*i3 Innovus, Nanterre, France,* [4]*Forschungszentrum Ruhr, Witten, Germany, Witten, Germany,* [5]*Oncology Institute ASL, Leece, Italy,* [6]*Universitätsmedizin Berlin, Berlin , Germany,* [7]*Centro Integral Oncologico Clara Campal (CIOCC), Madrid, Spain,* [8]*Instituto Catalán Oncología ICO-IDIBELL, Barcelona, Spain, Barcelona, Spain,* [9]*Pinderfields General Hospital, Wakefield , UK,* [10]*Amgen Inc, San Francisco, CA, USA,* [11]*Ovatech Solutions, London, UK,* [12]*University Hospitals Bristol, Bristol, UK*

OBJECTIVES: Estimate the cost of SREs in patients with bone metastases secondary to solid tumours (i.e. breast, lung and prostate). **METHODS:** This study assessed county-specific HRU (in Germany, Italy, Spain and the UK [EU4]) as attributed by study investigators to SREs (defined as pathologic fracture [non-vertebral fracture, NVF; vertebral fracture, VF], radiation to bone [RB], spinal cord compression [SCC] and surgery to bone [SB]). Cost-conversion was based on country-specific HRU data (inpatient stays, outpatient visits, emergency room visits, nursing home/long-term care facility stays, home health visits and outpatient procedures) collected retrospectively for 90 days prior to enrolment and prospectively for up to 18-21 months. Unit costs were collected from 2010 national sources. GBP were converted into Euros (£1=1.12867 Euro). **RESULTS:** A total of 478 eligible patients contributed 893 SREs (109 NVF, 48 VF, 585 RB, 61 SCC and 90 SB) during the study period which, were used for cost conversions. Mean cost per NVF across the EU4 ranged from 1720€ (Germany) to 3209€ (Spain). Mean cost per VF was lowest in the UK (1015€), was more than twice as costly in Germany and Italy (2100€) and highest in Spain (6968€). In the UK, mean cost per RB was about 3 times lower and cost per SCC was approximately twice as costly relative to the other European countries. Mean SB cost was 3348€ in Italy and 4263€ in Spain and was twice as costly in Germany and the UK. Cost variation was linked to the type of HRU and differences in local unit costs. **CONCLUSIONS:** All SREs are associated with substantial costs and cost per SRE type varied depending on the type of HRU and local unit costs. Preventing SREs in patients with bone metastases may help to reduce the financial burden to the European healthcare systems.

PCN116

COST-EFFECTIVENESS OF DENOSUMAB VERSUS ZOLEDRONIC ACID (ZA) FOR THE PREVENTION OF SKELETAL-RELATED EVENTS (SRE) IN PATIENTS WITH BONE METASTASES FROM SOLID TUMORS IN THE NETHERLANDS

Lothgren M[1], Bracco A[1], Lucius B[2], Northridge K[3], Halperin M[3], Macarios D[4], Chung K[4], Danese MD[3]

[1]*Amgen (Europe) GmbH, Zug, Switzerland,* [2]*Amgen B.V., Breda, The Netherlands,* [3]*Outcomes Insights, Inc., Westlake Village, CA, USA,* [4]*Amgen Inc., Thousand Oaks, CA, USA*

OBJECTIVES: The objective of this study was to perform a model-based economic evaluation of denosumab vs. ZA in the prevention of SREs in patients with bone metastases from advanced solid tumors based on data from head to head phase III clinical trials in breast cancer (BrCa), prostate cancer (PrCa) and other solid tumors (OST), excluding multiple myeloma. **METHODS:** Three separate three-state Markov models (On Treatment, Off Treatment, and Dead) were developed for each cancer type. Constant SRE incidence rates estimated from the clinical trials were used for denosumab and ZA within each study. Overall survival was not significantly different between treatments, and was estimated using parametric distributions for extrapolation beyond the trial duration. Analyses were based on a lifetime model horizon and trial-based discontinuation. SRE-related utility decrements were derived from trial-based EQ-5D data. SRE-related costs and administration cost were based on local data. Costs were discounted 4% and QALY outcomes at 1.5% according to local guidelines. The models predictions were validated by comparing the SRE predictions against those observed in the clinical trials. **RESULTS:** Denosumab resulted in fewer SREs, higher QALYs, lower SRE-related costs, lower administration cost and higher medication and total cost. The predicted incremental cost-effectiveness ratio (ICER) per SRE avoided was €1,644, €3,475, and €690 and the ICER per QALY gained was €26,524, €44,622, and €11,660 for BrCa, PrCa and OST, respectively. One-way sensitivity analyses were performed including administration cost, SRE and adverse event cost and SRE QALY decrements. Administration costs were important drivers of results. **CONCLUSIONS:** Denosumab provides superior effectiveness vs. ZA with fewer SREs predicted over patients lifetime. The estimated incremental cost/QALY indicates that denosumab is cost-effective vsersus ZA in The Netherlands and represents good value for money in prevention of SREs in patients with bone metastases from all advanced solid tumors based on commonly accepted thresholds.

PCN117

HEALTH RESOURCE UTILISATION (HRU) ASSOCIATED WITH SKELETAL-RELATED EVENTS (SRES) IN PATIENTS WITH BONE METASTASES (BMS): RESULTS FROM A RETROSPECTIVE, MULTINATIONAL EUROPEAN STUDY

Gunther O[1], Body JJ[2], Sleeboom H[3], Hechmati G[4], Pereira J[5], Maniadakis N[6], Terpos E[7], Acklin YP[8], Finek J[9], Mossman T[10], Von Moos R[8]

[1]*Amgen Ltd, Uxbridge, UK,* [2]*Centre Hospitalier Universitaire Brugmann, Brussels, Belgium,* [3]*HAGA Hospital, The Hague, The Netherlands,* [4]*Amgen (Europe) GmbH, Zug, Switzerland,* [5]*Universidade Nova de Lisboa, Lisbon, Portugal,* [6]*National School of Public Health, Athens, Greece,* [7]*University of Athens School of Medicine, Alexandra University Hospital, Athens, Greece,* [8]*Kantonsspital Graubünden, Chur, Switzerland,* [9]*University Hospital, Plzen, Czech Republic,* [10]*Amgen Ltd, Cambridge, UK*

OBJECTIVES: Patients with BMs from advanced cancer experience SREs (radiation/surgery to bone, pathologic fracture or spinal cord compression). Limited data exist on the financial burden of SREs. HRU data will support healthcare resource planning and the assessment of new products that prevent/delay these events. **METHODS:** Eligible patients with BMs from breast/lung/prostate cancer or multiple myeloma were enrolled in centres in Austria, Czech Republic, Finland, Greece, Poland, Portugal, Sweden and Switzerland. HRU extracted from patient charts included inpatient stays, outpatient visits, day care visits, emergency room visits, procedures, etc. We present HRU data for Austria, Czech Republic, Poland, Sweden and Switzerland (collected retrospectively from both 3.5 months prior to the SRE and 3 months after the SRE). **RESULTS:** A total of 658 eligible patients with at least one SRE were enrolled across five countries (36%, 13%, 27% and 25% had breast, lung and prostate cancer and multiple myeloma, respectively). Across all tumour and SRE types, mean increase from baseline in number of inpatient stays per SRE for Austria, Czech Republic, Poland, Sweden and Switzerland, respectively, were 1.0(95%CI:0.7-1.3), 0.8(95%CI:0.6-1.0), 0.9(95%CI:0.7-1.1), 0.8(95%CI:0.6-0.9) and

0.9(95%CI:0.7-1.1), with a mean increase in total length of stays per SRE of 16.4(95%CI:13.1-19.8), 11.4(95%CI:8.0-14.8), 10.9(95%CI:8.8-13.0), 13.4(95%CI:9.3-17.4) and 17.2(95%CI:13.6-20.7) days, respectively. For the same countries, the mean increase in number of outpatient visits per SRE were 3.8(95%CI:2.7-4.9), 4.7(95%CI: 3.5-6.0), 1.1(95%CI:0.7-1.5), 1.3(95%CI:0.7-1.8) and 5.2(95%CI:4.0-6.5). Mean increase in number of procedures per SRE were 10.9(95%CI:9.5-12.2), 6.9(95%CI:5.6-8.2), 4.4(95%CI:3.7-5.0), 4.7(95%CI:3.9-5.6) and 10.1(95%CI:8.8-11.4). Data by SRE type show considerable HRU variation. **CONCLUSIONS:** Data indicate that SREs may result in a mean increase of 0.8–1.0 inpatient stays with a mean total duration of 10.9–17.2 days. SREs are also linked to numerous outpatient visits and procedures. Thus, a further reduction in the number of SREs by new bone-targeted agents should reduce the financial burden on European health care systems.

PCN118

CONSUMPTION OF ANTINEOPLASTIC AGENTS IN SLOVAK REPUBLIC WITHIN PERIOD OF 2006-2010

Gatialova K[1], Bellova K[1], Binder R[1], Foltan V[2], Snopkova M[2]
[1]*Comenius University, Bratislava, Slovak Republic,* [2]*Faculty of Pharmacy, Comenius University, Bratislava, Slovak Republic*

OBJECTIVES: The main objective of this study was to evaluate the utilisation of antineoplastic agents in Slovak Republic during the period of 2006-2010. **METHODS:** Statistical analysed data including the number of medicine packages, DDD and financial expenditures were abstracted from the Slovak Institute of Drug Control. Key data were provided by wholesalers due to their legal obligation towards the SIDC. **RESULTS:** Consumption of antineoplastic agents in terms of DID (DDD/1000 inhabitants/day) reached its highest peak in 2007 with 31,12 and the lowest value of DID was observed in 2009 with 27,30. The total expenditures doubled their volume within period of 2006-2010 from 56,021,412 € to 111,646,240 € respectively. Number of delivered packages showed slight increase from 426,412 in 2009 to 629,782 in 2010 while price per single package was rising from 131,29 € (2006) to 197,68 € (2008) and then decreased to 177,28 € (2010). Resulting from further study the highest consumption in terms of DID was reached by gemcitabine (7,38 in 2006 and 7,21 in 2010), ifosfamide (5,91 in 2006 and 6,94 in 2010) and fourouracil (2,56 in 2006 and 3,26 in 2010). Expressed in financial units the most costly antineoplastic agent in 2006 was imatinibum with 8 569 021 €, followed by rituximab with 4,896,000 € and irinotecan with 4,888,660 €. In 2010 reached paramount financial consumption bevacizumab with 17,771,426 €, trastuzumab with 10,173,699 € and imatinibum with 8,212,353 €. **CONCLUSIONS:** Expenditures for antineoplastic agents are continually rising as a result of biological treatment establishment. There is observed significant increase of their consuption due rheumatic diseases treatment.

PCN119

LACK OF DATA FOR INDIRECT COSTS ASSOCIATED WITH TREATMENT OF EARLY BREAST CANCER

Urspruch A[1], Marlow E[2], Mccormick AL[2], Sibbring GC[2]
[1]*F. Hoffmann-La Roche, Basel, Switzerland,* [2]*Complete Medical Group, Macclesfield, Cheshire, UK*

OBJECTIVES: To review and analyse studies capturing indirect costs of treatment in EBC. Indirect costs can form a substantial part of the treatment cost and have a considerable impact on both the patient and society. **METHODS:** A literature review was conducted to identify publications that included indirect costs of EBC treatment. Indirect costs were defined as various out-of-pocket expenses or productivity losses. Medline, Embase, EmCare, Cochrane, NHSEED, HEED and EconLit databases were searched for published articles (January 2000 to November 2010), using pre-specified terms. A targeted internet search also captured publications from national websites in 10 countries. Indirect cost data were analysed to identify trends and a gap analysis was performed. **RESULTS:** Only 28 studies reported relevant data; they included data from economic models (based on thousands of patients), observational studies (including 22-324 patients), databases and surveys. The majority of studies reported indirect costs per patient; two studies reported cost to society, but rarely as part of total costs of EBC. Data collation and reporting was inconsistent across studies due to a variety of methods, definitions and outcomes, which made cross-comparisons difficult. Productivity losses and out-of-pocket costs were the most frequently reported outcomes (54% and 46% of studies, respectively). Mortality-associated costs were captured in 11% of studies. **CONCLUSIONS:** It was difficult to draw quantitative conclusions from the studies included in this review due to the paucity of studies, lack of standardisation and inconsistency in reporting of data. Reducing indirect costs would ease the financial burden to society, owing to the majority of patients being of working age. Identified cost data will be presented in the forthcoming poster; however, further work is required.

PCN120

THE NATURAL HISTORY OF FLUDARABINE-REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA PATIENTS WHO FAIL ALEMTUZUMAB OR HAVE BULKY LYMPHADENOPATHY – A EUROPEAN PERSPECTIVE

De cock E[1], Haiderali A[2], Wasiak R[3], Lis Y[4], Lévy V[5]
[1]*United BioSource Corporation, Barcelona, Barcelona, Spain,* [2]*GlaxoSmithKline, Collegeville, PA, USA,* [3]*United BioSource Corporation, London, UK,* [4]*Cardiff University, Cardiff, UK,* [5]*Hôpital Avicenne, Paris, France*

OBJECTIVES: To describe the current pattern of care and resource utilisation in Europe for patients with fludarabine-refractory chronic lymphocytic leukaemia (CLL) who are either refractory to alemtuzumab (DR) or ineligible for alemtuzumab due to bulky lymphadenopathy (BFR) **METHODS:** Medical charts were reviewed from nine sites in France, Germany, Italy, Spain and the UK. Patient charts with an index diagnosis of DR or BFR between January 2002 and June 2008 were abstracted, with a pre and post-index review period of 6 and 18 months respectively. **RESULTS:** Data are from an interim analysis of 37 patients, 62% (n=23) DR and 38% (n=14) BFR. Median time between first diagnosis and index refractory diagnosis was 5.2 years. Average age was 62.2 (range 41-77), 76% were male and average number of co-morbidities was 2.2. Many patients (59%) died during the post index period with median survival following diagnosis of refractory disease being 6.2 months. In the pre-index period the average number of pharmacotherapy regimens was 0.9 (range 0-3) and in the post-index period 1.4 (range 1-4). During the 24 month review period the most frequent single agent regimens were alemtuzumab (38% patients) and methylprednisolone (19%). Patients receiving combination therapy most frequently received rituximab (43%), mainly in combination with CHOP (16%), fludarabine/cyclophosphamide (11%), and bendamustine (8%). 89% of patients experienced at least one treatment related adverse event, including infection (76%), anaemia (76%), thrombocytopenia (68%) and neutropenia (62%). Average number of post-index A&E visits was 0.8 and inpatient stays 1.9, the majority (86%) relating to CLL or its treatment. Average inpatient stay was 11.2 days. Most patients (81%) had multiple diagnostic investigations (average 11.5), predominantly CT scans (average 6.1) and X-rays (average 2.0). **CONCLUSIONS:** This study demonstrates the high economic burden and continuing unmet clinical needs of patients with fludarabine-refractory CLL disease in Europe.

PCN121

CHALLENGES IN CONDUCTING PHARMACOECONOMIC ANALYSES IN CENTRAL AND EASTERN EUROPE – CASE STUDY ON BREAST CANCER

Skoupá J[1], Orlewska E[2], Kalo Z[3], Hájek P[4]
[1]*Pharma Projects s.r.o., Prague5, Czech Republic,* [2]*Centre for Pharmacoeconomics, Warsaw, Poland,* [3]*Eötvös Loránd University, Budapest, Hungary,* [4]*Pfizer, Praha , Czech Republic*

OBJECTIVES: Health technology assessment (HTA) is rapidly developing in CEE countries as new technologies are difficult to finance with scare resources. Researchers often struggle with limited local epidemiologic and cost data. Therefore transferability of resource utilization from one to other markets is becoming an interesting topic. Late 2009 we conducted a study of advanced breast cancer in four CEE markets (Poland, Hungary, Slovak and Czech Republics). The project aimed to assess treatment sequence and resource used. **METHODS:** A common questionnaire was distributed to oncologists managing about 30 % of all oncology patients. The assessed periods of advanced breast cancer were: a) treatment initiation; b) routine follow-up on active treatment; c) pre-progression follow-up; and d) progression period. Data were extracted from hospital information systems and patient's charts retrospectively. Final results covered individual treatment/disease periods and total treatment course. **RESULTS:** Similar proportions of breast cancer patients precede to second-line treatment, we found differences in patients proceeding to third line treatment. In Czech about 67 % of treated completed 3 lines chemotherapy, in Poland it was about 30 %. In Czech and Slovakia taxane monotherapy represented the preferred first-line choice, Poland and Hungary favoured combination chemotherapy. We found differences across countries such as cancer care organization, guideline availability, number of oncologists. The above mentioned differences resulted in cost variations per patient from about 6 thousand USD (excluding chemotherapy) in Poland to 12 thousand USD in Hungary. Positions with highest relevance to cost differences were frequency and reimbursement of in-patient management and BS/palliative care. **CONCLUSIONS:** As cancer care organization, treatment algorithms and reimbursement for services differ, there is limited value in transferring cost data across CEE countries. The observed differences are especially relevant for cancer care where market access for new technologies might be un-equal in particular health care systems.

Cancer – Patient-Reported Outcomes & Preference-Based Studies

PCN122

DISCLOSING TRADITIONAL & COMPLEMENTARY MEDICINES (T&CM) USE TO THE HEALTH CARE PROVIDERS: A QUALITATIVE STUDY AMONG CANCER PATIENTS AT A LOCAL HOSPITAL IN MALAYSIA

Farooqui M[1], Hassali A[2], Knight A[3], Akmal A[4], Tan BS[5], Farooqui MA[6]
[1]*Universiti Teknologi MARA, Pulau Pinang, Malaysia,* [2]*Universiti Sains Malaysia, Minden, Pulau Pinang, Malaysia,* [3]*Universiti Sains Malaysia (USM), Penang, Malaysia,* [4]*University Sains Malaysia, Penang, Penang, Malaysia,* [5]*General Hospital Penang, George Town, Pulau Pinang, Malaysia,* [6]*Allianze University College of Medical Sciences, Kepala Batas, Malaysia*

OBJECTIVES: This research study aimed to investigate the cancer patients' beliefs towards disclosing T&CM use to the health care provider. **METHODS:** Qualitative methodology was adapted to collect in-depth information with consented cancer patients. The participants were recruited from the oncology wards at Penang General Hospital from February till July 2010. Patients with different types of cancer and stages were recruited from the three major ethnic groups in Malaysia namely Malay, Chinese and Indians. Upon institutional ethical approval and informed consent from the participants, 20 semi-structured interviews were conducted. All interviews were audiotaped, transcribed verbatim and translated into English for thematic content analysis. **RESULTS:** Mixed beliefs were reported and a total of 4 themes were identified from the interview analysis: fear of termination of therapy by the physicians, fear of interaction with the orthodox medicines, perceived disinterest by the physicians and perception that T&CM are simple and its discussion to the physicians is irrelevant. Most of the patients agree that T&CM disclosure is important to avoid any interaction with the chemotherapy or radiotherapy. On the other hand, patients believe that T&CM discussion is not important due to the lack of physicians' knowledge & interest in discussing T&CM. A common perception regarding the simplicity in nature of some of the non-invasive traditional modalities such as prayers, spiritual & faith healing was reported as reasons of not disclosing T&CM use to the physicians. **CONCLUSIONS:** Understanding the underly-

ing beliefs of patients' reluctance to disclose T&CM usage to healthcare providers especially the physicians is important especially when they are on active cancer treatment. Results from this study can help physicians to initiate open discussions with patients at the time of treatment decision in order to improve patients' compliance towards proven therapies. Further research is required to evaluate physicians' attitude towards cancer patients' use of T&CM.

PCN123

A LITERATURE REVIEW ON UTILITY VALUES ASSOCIATED WITH HPV-RELATED DISEASES

Shupo F[1], Dorey J[2], Remy V[3], Aballea S[4]
[1]Creativ-Ceutical, London, UK, [2]Creativ Ceutical, Paris, France, [3]Sanofi Pasteur MSD, Lyon, France, [4]Creativ Ceutical, Paris, Ile de France, France

OBJECTIVES: Human papillomavirus (HPV) infection is associated with cervical cancer and genital warts as well as other diseases, such as vulvar, vaginal, anal, penile and head and neck (H&N) cancers. Utility values for those other cancers will be needed for more comprehensive cost-effectiveness models of HPV vaccination. This study aims to identify all utility values for HPV-related cancers in elicitation and economic evaluation studies. **METHODS:** Literature searches were implemented using Medline, EMBASE, Tufts University CEA registry, CRD-HTA register databases and completed with recent conference abstracts. No limits were set on time, geography or language for searches. All utility elicitation techniques were considered. **RESULTS:** 109 abstracts satisfied inclusion criteria: 4 genital warts, 75 cervical, 1 vulvar, 4 anal and 25 H&N cancer abstracts. 19 were excluded after review of full publications. Most economic evaluations used utilities from previous models. Two sets of values were identified for cervical cancer: one using time trade-off (TTO) among healthy female volunteers and another based on expert opinion. Utilities for H&N cancers were elicited from one study using EQ-5D in oncology nurses (0.06-0.86 according to treatment status) and one using TTO in 10 physicians (0.68-0.93). Additionally, one study elicited utilities after laryngectomy from patients and health care providers (0.44-0.89). Utilities for oral cancer were measured using standard gamble in healthy volunteers (0.68-0.92 by stage). Utilities for anal cancer were based on gastrointestinal cancer. No values were found for penile, vulvar and vaginal cancers. **CONCLUSIONS:** Although some data exist for cervical cancer and genital warts, there is a paucity of high-quality utility data for other HPV-related diseases. This literature review will be useful for future HPV economic evaluations. New elicitation studies could be performed to fill in some gaps. However, for some rare cancers, using other diseases as proxies could be an acceptable approach.

PCN124

THE IMPACT OF CONDITION LABELLING ON HEALTH STATE VALUES

Brazier J[1], Rowen D[2], Tsuchiya A[1], Young T[1], Ibbotson R[3]
[1]University of Sheffield, Sheffield, UK, [2]University of Sheffield, Sheffield, South Yorkshire, UK, [3]Sheffield Hallam University, Sheffield, UK

OBJECTIVES: Many descriptions of health used in vignettes and condition-specific measures name the medical condition. This paper assesses the impact of referring to the medical condition in the descriptions of health states valued by the general population. **METHODS:** A valuation study was conducted using face-to-face interviews involving the time trade-off valuation technique. All respondents valued the same eight health states but descriptions featured different labels: no label / "irritable bowel syndrome" / "cancer". We analyse responses from 241 members of the UK general population providing 1910 observations, with a response rate of 39% and completion rate of 99%. Random effects generalized least squares regressions were used to estimate the impact of each label and experience of the condition on health state values. **RESULTS:** There is no significant difference between health state values when the health state description contains no label or an IBS label. The inclusion of a cancer label in the health state description affects health state values and the impact is dependent upon the severity of the state, with a significant reduction in values for more severe health states (up to -0.25 for the worst possible state) but no significant difference for mild states. **CONCLUSIONS:** A condition label can affect health state values, but this is dependent upon the specific condition and severity. These differences may reflect greater precision for utility estimates experienced for these conditions or preconceptions such as fear and dread. Further research using qualitative analysis is recommended to enable better understanding of the reasoning used by respondents to determine why the inclusion of different condition labels affects health state values. Until this information is available, we recommend avoiding condition labels in health state descriptions (where possible) to ensure that values are not affected by prior knowledge or preconception of the condition that may distort the health state being valued.

PCN125

ELICITATION OF HEALTH STATE UTILITIES IN NEUROENDOCRINE TUMOURS

Swinburn P[1], Chandiwana D[2], Quadri N[1], Wang X[3], Lloyd AJ[1]
[1]Oxford Outcomes, an ICON plc Company, Oxford, Oxon, UK, [2]Novartis Pharmaceuticals UK Limited, Surrey, UK, [3]Novartis Pharmaceuticals Corporation, Florham Park, NJ, USA

OBJECTIVES: A number of newly developed treatments for advanced Neuroendocrine Tumours (NET) have demonstrated potential for significantly improving outcomes both in terms of disease progression and tolerability. There is however a paucity of available evidence detailing the quality of life impact of such therapies which is suitable for use in supporting economic evaluations. This study was designed to address this unmet need by capturing utility values for receiving NET treatment. **METHODS:** A number of health state descriptions were developed to characterise the typical quality of life challenges faced by NET patients undergoing therapy. These vignettes were developed based upon the findings of a literature review, in-depth interviews with patients (n=5) and discussions with experienced NET specialists (clinicians n=5, oncology nurse n=1). The states described stable and progressive disease with a range of common treatment related grade III/IV toxicities (stomatitis, rash, diarrhoea, nausea/vomiting, hyperglycaemia, thrombocytopenia, hand & foot syndrome and pneumonitis). One hundred members of the UK general public rated each state in a time trade-off (TTO) interview. The TTO exercise explores participants' willingness to trade overall survival against changes in quality of life and therefore provides an indication of its value in that state. **RESULTS:** Values suitable for both pancreatic and carcinoid NET treatment are presented. Stable disease had a reported utility value of 0.77 whilst progressive disease was associated with a marked decline and a value of 0.62. The impact of toxicities was variable ranging from stable disease + hyperglycaemia (0.78) to stable disease + stomatitis (0.56). **CONCLUSIONS:** This study characterises the burden associated with receiving NET treatment, related adverse events and disease progression. It demonstrates the considerable value of therapies offering reduced toxicity and the prospect of delaying progression in terms of preserving quality of life. These values could be used in establishing the cost-effectiveness of future treatments.

PCN126

WHICH FACTORS CAN AFFECT UTILITIES?

Kang E[1], Lee J[2], Jeong H[1]
[1]Soon Chun Hyang University, Asan , Choongnam, South Korea, [2]Kyungwon University, Sungnam, Gyunggi-do, South Korea

OBJECTIVES: Published utilities for the same health condition vary across studies. The purpose of this study was to find the factors that were related to utilities using the case of colorectal cancer. **METHODS:** We did systematic review first to summarize the literature on the utilities of colorectal cancer and ran meta-regression to analyze the factors affecting the utilities of colorectal cancer. We searched the literature published up until December, 2010 in Medline, Science Direct, CINAHL, EMBASE, and KoreaMed using the combinations of keywords, one set of keywords representing colorectal cancer and the other representing utilities. In total, 88 abstracts were retrieved and 57 were excluded after the abstract review and 15 studies were excluded after the full-text review. Finally, 228 utility scores in 16 studies were included in the meta-regression. For each of the 228 utilities, information was recorded on its cancer stage, cancer type, cancer treatment, adverse reaction, remission, definition of the lower bound, definition of the upper bound, respondent, preference elicitation method, source of utility, and survey method. Fixed effect model was used to control for the correlations within the same study. **RESULTS:** Compared to stage 1, stage 3, 4, and best supportive care state had lower utilities. Colorectal cancer had the higher utilities than either colon cancer or rectal cancer. Adverse reaction was related to lower utilities. Other definition of the upper bound than perfect health was related to higher utilities. Compared to TTO, HALex had lower utilities and HUI had higher utilities. On the other hand, the other factors were not significantly related to the level of utilities. **CONCLUSIONS:** In the case of colorectal cancer, utilities were affected by cancer stage, cancer type, adverse reaction, definition of upper bound, and preference elicitation method. In practice, we should mind that characteristics of health condition and utility measurement may affect the level of utilities when we use utilities from the literature.

PCN127

HEALTH STATE UTILITY ASSESSMENT FOR BREAST CANCER

Shih V[1], Chan A[2], Xie F[3], Ko Y[2]
[1]National Cancer Centre Singapore, Singapore, [2]National University of Singapore, Singapore, [3]McMaster University, Hamilton, ON, Canada

OBJECTIVES: 1) To develop both English and Chinese versions of the descriptions of health states describing different stages of breast cancer and different adverse effects related to tamoxifen and aromatase inhibitors for breast cancer, and 2) To elicit individuals' preferences for these health states from a group of oncology nurses. **METHODS:** Twenty hypothetical health states and their descriptions were developed based on literature review and oncology expert panel reviews. Health state utilities were obtained from 20 oncology nurses using the visual analogue scale (VAS) and standard gamble (SG) methods. After recalibration, the adjusted utility scores were on a scale of 0 (death) and 1 (perfect health). **RESULTS:** The health states developed represented different disease stages and the presence and type of treatment side effects in breast cancer. For each health state, various general health-related quality of life domains, such as pain/discomfort and ability to work, were included in the descriptions, along with a state-specific description. The mean utility score of respondents' 'current health' was greater than 0.9 while mean adjusted VAS-derived utility scores ranged from 0.256 to 0.860, and median adjusted SG-derived utility scores ranged from 0.284 to 0.673. Among the side effects evaluated in the 'no recurrence' health state, ischemic cerebrovascular events, pulmonary embolism, and spine fracture had the greatest utility detriment. **CONCLUSIONS:** The study results indicate the value that individuals place on the avoidance of disease progression and the side effects of hormonal therapies in breast cancer. The health state descriptions developed can be used in future research to obtain society's utilities for use in a cost-utility analysis.

PCN128

EQ-5D UTILITY INDEX IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC) WITH PROGRESSION DURING OR AFTER FIRST-LINE DOCETAXEL THERAPY

James N[1], Eisenberger M[2], Fizazi K[3], Heidenreich A[4], Joulain F[5], Laizet C[6]
[1]University of Birmingham, Birmingham, UK, [2]Johns Hopkins University, Baltimore, MD, USA, [3]University of Paris, Paris, France, [4]Universitatsklinikum der RWTH Aachen, Aachen, Germany, [5]Sanofi-aventis, Massy, France, [6]Covance, Rueil-Malmaison, France

OBJECTIVES: Limited information exists on utility in CRPC patients, especially in mCRPC patients who progress after first line therapy. This study is to describe correlates of utility assessments in patients with mCRPC who have progressed during or after docetaxel first-line therapy. **METHODS:** An observational study of mCRPC patients progressing during or after the first-line docetaxel therapy was performed in US, France, Germany and UK. Patient characteristics, first-line treatment details and quality of life using a generic EQ-5D questionnaire were evaluated at the time of second line treatment decision. Descriptive analyses and multivariate analysis for EQ-5D utility index are presented. **RESULTS:** Eighty-two patients were recruited in the study and 74 patients had an evaluable EQ-5D questionnaire. In this subset the median age was 72 years and 81% had a good ECOG performance status (ECOG-PS score 0 or 1). The mean (± SD) utility index was 0.63 (± 0.26). Relationship between utility index and potential correlates was analysed using univariate regressions. Age, ECOG-PS and time since diagnosis were related with the utility score, but stage at diagnosis, time between last dose of treatment and progression, total number of docetaxel cycles and response to first line treatment were not. After multivariate adjustment for these correlates and accounting for country variation, ECOG-PS (0-1 versus 2-3) was the strongest predictor of utility index ($p<.0001$), with a strong utility increment of 0.38 for ECOG-PS 0-1 patients. Age (18-64, 65-74, ^{3} 75 years) and time since diagnosis ($\leq$ 2, 2-4, 4-8, $>$ 8 years) were not statistically significant ($p=0.127$ and 0.072, respectively). There was no difference between countries ($p=0.329$). **CONCLUSIONS:** In metastatic prostate cancer patients who have reached castration-resistant stage and progressed after first-line docetaxel, ECOG-PS is the strongest correlate of utility score measured by EQ-5D. This finding appears equally applicable across several European countries and US.

PCN129

MAPPING THE CANCER-SPECIFIC EORTC QLQ-C30 AND EORTC QLQ-BR23 TO THE GENERIC EQ-5D IN METASTATIC BREAST CANCER PATIENTS

Kang H[1], Ko SK[2], Kim EJ[3]
[1]*Yonsei University, Incheon, South Korea,* [2]*Pfizer Pharmaceuticals Korea Ltd., Seoul, South Korea,* [3]*Seoul National University, Seoul, South Korea*

OBJECTIVES: To develop a mapping algorithm for a conversion of the EORTC QLQ-C30 and EORTC QLQ BR-23 into the EQ-5D derived utilities in metastatic breast cancer (MBC) patients. **METHODS:** We enrolled 199 patients with MBC from the four leading Korean hospitals in 2009. EQ-5D utility, cancer-specific (QLQ-C30) and breast cancer-specific quality of life data (QLQ-BR23), and selected clinical and demographic information were collected from the study participants. Ordinary least squares regression models were used to model the EQ-5D using QLQ-C30 and QLQ-BR23 scale scores. To select the best model specification, six different sets of explanatory variables were compared. **RESULTS:** Regression analysis with the multi-item scale scores of QLQ-C30 was the best-performing model, explaining for 48.7% of the observed EQ-5D variation. Its mean absolute error between the observed and predicted EQ-5D utilities (0.092) and relative prediction error (2.784%) was among the smallest. Also, this mapping model showed the least systematic errors according to disease severity. **CONCLUSIONS:** The mapping algorithms developed have good predictive validity and therefore they enable researchers to translate cancer-specific health-related quality-of-life measures to the preference-adjusted health status of MBC patients.

PCN130

UTILITY WEIGHTS FOR SKELETAL RELATED EVENTS IN CASTRATION RESISTANT PROSTATE CANCER

Fassler P[1], Holmstrom S[2], Van Engen A[1]
[1]*Quintiles, Hoofddorp, The Netherlands,* [2]*Astellas Pharma Global Development, Leiderdorp, The Netherlands*

OBJECTIVES: Skeletal related events (SREs) are a major cause of morbidity for castration resistant prostate cancer (CRPC) patients with bone metastases. SREs can have a debilitating effect on patient's quality of life (QoL), although severity depends on the type of SRE. The purpose of this study is to determine what data are available on utility weights by SRE type for use in a cost-utility analysis of CRPC. **METHODS:** A systematic literature review of PubMed was performed to identify data on SRE utilities. The search was limited to the past 10 years and to metastatic cancer and bone neoplasms. **RESULTS:** The search yielded 82 articles, of these 19 contained SRE and utility information only 8 of which reported utility weights. One article reported a utility decrement for hip fractures (0.03) in CRPC. Another reported utility decrements for pathologic fractures (0.13) and radiation to bone (0.07) in metastatic prostate cancer (mPCa). Two articles contained utility data differentiated per SRE for non-small-cell lung carcinoma (NSCLC) and advanced renal cell carcinoma (aRCC). These decrements were calculated using a multiplier per SRE derived from an earlier study in metastatic breast cancer (mBCa) and ranged from 0.05 for vertebral fractures to 0.50-0.61 for spinal cord compression. The other 4 articles only reported the overall utility, but did not specify per type of SRE. **CONCLUSIONS:** To accurately model the impact of SREs on CRPC, QoL utility weights should be assigned to each SRE type to account for their varying severity. This study found only one article with a utility weight for a specific SRE in CRPC and one for mPCa. However, the use of SRE utility weights derived from a mBCa study for measuring SRE decrements in NSCLC and aRCC suggest SRE utility weights derived from other cancers may be acceptable for a CRPC cost-utility analysis.

PCN131

SYSTEMATIC EVALUATION OF SPECIFIC QUALITY OF LIFE INSTRUMENTS FOR PROSTATE CANCER

Schmidt S, Pardo Y, Vilagut G, Garin O, Pont A, Cunillera O, Becerra V, Ferrer M
IMIM (Institut de Recerca Hospital del Mar), Barcelona, Catalunya, Spain

OBJECTIVES: This study aims to perform a systematic expert evaluation of the measurement properties of specific health-related quality of life instruments for prostate cancer. **METHODS:** We conducted a systematic literature search to identify articles about specific health-related quality of life instruments developed for prostate cancer. Secondly, titles and abstracts were reviewed independently by two experts and, in case of discrepancies, by a third expert to filter the information. Thirdly, for every instrument identified, two experts reviewed the articles about measurement properties and applied the EMPRO tool (Evaluating the Measurement of Patient-Reported Outcomes), which was specifically designed for a standardized evaluation of measurement properties of PRO instruments regarding: conceptual and measurement model, reliability, validity and responsiveness among other. Scores are transformed to a scale from 0 to 100. **RESULTS:** Ten specific questionnaires were indentified with great variability regarding available information on measurement properties (between 2 and 13 articles): DALE questionnaire (2), ES-CAP_CDV (2), TALCOTT questionnaire (2), PCQoL (3), EORTC QLQ PR-25 (3), PORPUS (3), PROSQOLI (4), EPIC (7), FACT-P (11) and UCLA-PCI (13). Only 5 out of 10 questionnaires provided full information regarding their measurement properties. Regarding their conceptual and measurement model, EPIC demonstrated the highest score ($>$90), followed by UCLA-PCI, PROSQOLI, Talcott questionnaire, PCQoL, EORTC PR25, and PORPUS ($>$50). Only three questionnaires presented high reliability scores (EPIC and PCQoL $>$80, UCLA-PCI $>$50). UCLA-PCI showed the highest scores for validity ($>$80), followed by PORPUS and PCQoL ($>$70), PROSQOLI and EPIC ($>$50). Highest responsiveness scores were observed for PCQoL (100), EPIC and PORPUS ($>$80), and PROSQOLI ($>$70). **CONCLUSIONS:** In this systematic evaluation, only 2 out of 10 questionnaires provided information supporting their conceptual and measurement model, as well as good reliability, validity and responsiveness: EPIC and PCQoL. All instruments have a psychometric design except PORPUS, which was designed to perform cost-utility analysis.

PCN132

A DEVELOPMENT OF QUALITY INDICATORS FOR EVALUATING HOME PALLIATIVE CARE AND THEIR RELATION WITH BEREAVED FAMILY SATISFACTION

Saito S[1], Shimozuma K[2], Yamaguchi M[3], Ueda K[4]
[1]*Okayama University, Okayama, Okayama, Japan,* [2]*Ritsumeikan University, Kusatsu, Shiga, Japan,* [3]*Okayama Prefectural University, Soja, Okayama, Japan,* [4]*Japan Red Cross Hiroshima College of Nursing, Hatsukaichi, Hiroshima, Japan*

OBJECTIVES: : To develop QI (Quality Indicator) specialized for evaluating domiciliary palliative care and to explore the relationship of this QI with family satisfaction as a typical outcome of palliative care service at home. **METHODS:** A modified Delphi method was adopted to select potential QIs and rate the appropriateness and feasibility of them by multi-professional specialists engaged at home palliative care. A retrospective study on the medical records to examine relation between the developed QIs and FAMCARE (score of family satisfaction) was conducted on 44 patients with cancer who received home palliative care service between 2001 and 2008 at a regional clinic in Japan. **RESULTS:** Twelve indicators were selected and included some items concerning long-term care insurance, surroundings and rehabilitation. A number compatible with the QIs was 7.5 ± 3.4 and found to have weak relationship with length of the home care (correlation coefficient 0. 298 ($p=0.05$)). It also showed correlation with FAMCARE average scores (correlation coefficient 0. 431 ($p=0.04$)). **CONCLUSIONS:** These QIs seem to be useful for monitoring and evaluating home palliative care but have some problems such as mixture of indicators for evaluating end-of-life care and care in the stable stage. The number of QIs documented on the charts was related with the FAMCARE score, which might be affected by the period of the home care.

PCN133

MEASURING PATIENTS' EXPECTATION AND SATISFACTION WITH INTEGRATIVE CANCER THERAPY

An SM, Kim SH, Kim KS, Chung HS, Lee SK, Cheon S, Lee SH, Park S, Kim EH, Eo WK, Choi WC
Kyung Hee University, Seoul, South Korea

OBJECTIVES: Integrative therapy may focus on the synergic effect of complementary therapies to increase effectiveness of conventional treatment. Korean cancer patients may expect better care with integrative cancer therapy of combining conventional western treatment with traditional Korean medicine (TKM), and eventually determine their satisfaction with the outcomes of treatment. The objective of this study was to investigate patients' expectation and satisfaction with the integrative cancer therapy. **METHODS:** A total of 102 cancer patients were participated. Due to the specialty of Integrative Cancer Center (ICC) for those who received only western treatment received care elsewhere. Based on clinical decision at ICC, patients received either integrative treatment with combining conventional treatment with TKM ($n=55$) or TKM only ($n=43$). At ICC, Rhus verniciflua Stokes Extract which is described in the literature was used as TKM. We use Korean translation of Cancer Therapy Satisfaction Questionnaire (CTSQ) to measure patients' expectation and satisfaction. **RESULTS:** Mean age was 51.9 and most were stage 4 (74.4%). In the integrative therapy group, mean scores of Expectations of Therapy (ET), Feelings about Side Effects (FSE), Satisfaction with Therapy (SWT) domains were 80.7+/−15.0, 74.9+/−23.5, and 73.7+/−14.6, respectively, whereas in the TKM group, mean scores of ET, FSE, SWT were 80.8+/−16.8, 87.5+/−19.3, and 78.1+/−14.5, respectively. Only FSE was statistically different between the two groups ($p=.0054$). Similar results were seen in stage 4 patients. Cronbach's alpha of this Korean CTSQ domains were acceptable (0.74-0.86). **CONCLUSIONS:** Previously treated cancer patients in particular, eventually seek additional care with integrative cancer therapy. Their expectation about integrative cancer therapy, however, was not much different from traditional medicine. This may due to hard experi-

ence from battling cancer such as side effects from conventional western cancer treatment. The findings of this study suggest that cancer patients regardless of stage may expect and satisfy with less toxic treatments with less side effects .

PCN134

PATIENT PREFERENCES FOR NON-SMALL CELL LUNG CANCER (NSCLC) TREATMENTS

Bridges JF[1], Mohamed A[2], Finnern HW[4], Woehl A[3], Hauber AB[2]
[1]*Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA,* [2]*RTI Health Solutions, Research Triangle Park, NC, USA,* [3]*Boehringer Ingelheim, Bracknell , UK,* [4]*Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, CT, USA*

OBJECTIVES: Treatment decisions for patients diagnosed with advanced non-small cell lung cancer (NSCLC) require assessment of the risks and benefits of treatment. We sought to understand the patient perspective when making these choices by estimating utilities (preference weights and relative importance weights) for different hypothetical NSCLC treatment profiles. **METHODS:** One hundred patients with NSCLC were recruited in the UK and completed a self-administered, web-based conjoint analysis questionnaire. The questionnaire presented patients with pair-wise choices of NSCLC treatment profiles which systematically varied the duration of progression-free survival (PFS), severity of disease symptoms, severity of the treatment-related adverse events (diarrhea, fatigue, fever/infection, nausea/vomiting and rash) and mode of treatment administration (intravenous versus oral). Preference weights were estimated using a random-parameters logit. Importance weights were calculated from the model coefficients. **RESULTS:** Eighty-nine patients (73% male) completed all choice tasks appropriately. The highest utility was associated with treatments that increased PFS and improved disease-related symptom severity from severe to mild (10.0; 95% CI: 6.1, 13.9). However, patients preferred a reduction in PFS if disease-related symptoms were severe. Utility was higher for treatments that had no fatigue (5.0; 95% CI: 2.7, 7.3), no diarrhea (2.8; 95% CI: 0.7, 4.9), no fever/infection (2.1; 95% CI: 0.2, 4.1), no nausea/vomiting (2.1; 95% CI: 0.1, 4.1), no rash (2.0; 95% CI: 0.2, 3.9) and for oral administration instead of infusion (1.8; 95% CI: 0.0, 3.6). Patients were found to be indifferent to treatments associated with mild diarrhea and mild nausea/vomiting. Avoiding moderate fatigue was half as important as increasing PFS by seven months with improvement in symptom severity from severe to mild. **CONCLUSIONS:** NSCLC patients attributed the highest utility to treatment efficacy. Treatments that increased PFS with low severity of disease related symptoms, no fatigue and oral administration were preferred.

PCN135

INFLUENCE OF ECONOMIC IMPLICATIONS RELATED TO THE PRESCRIPTION OF ORAL AND INTRAVENOUS CHEMOTHERAPY ON PHYSICIANS' PREFERENCES: A DISCRETE CHOICE EXPERIMENT

Benjamin L[1], Cotté FE[2], Philippe C[3], Mercier F[4], Bachelot T[5], Vidal-Trécan G[6]
[1]*University of Paris Descartes, School for Public Health (EHESP), GlaxoSmithKline, Marly le Roi Cedex, France,* [2]*GlaxoSmithKline, Health Outcome Studies, Marly le Roi Cedex, France,* [3]*Qualees, Poissy Cedex, France,* [4]*StatProcess, Port-Mort, France,* [5]*Centre Léon Bérard - Inserm U590, Lyon Cedex08, France,* [6]*Hôpital Cochin, Unité de Santé publique, Paris, France*

OBJECTIVES: Oral chemotherapy generates for hospitals additional resources for therapeutic education and health care coordination currently not taken into account in reimbursement tariffs. This may influence the prescription of oral chemotherapy. We estimated the relative influence of the route and tariff of administration, efficacy, tolerability and adherence on physician's preferences. **METHODS:** A Discrete Choice Experiment was performed among 203 French physicians qualified in oncology. From an online questionnaire with six fictive scenarios, first presented in curative setting then in palliative setting, respondents had to choose between treatment A or B which differed with respect to efficacy, tolerability, adherence and route of administration. Three of these attributes (efficacy, tolerability, adherence) had two modalities (good vs. moderate) and the later (route of administration) had three modalities: intravenous (€286–379/session in private and public hospital respectively), oral with the current tariff (€28/consultation), oral with a fictive tariff (€31/consultation and €83 for a patient support program). The relative influence of attributes was analyzed using a conditional logistic regression model. **RESULTS:** Efficacy was the predominant criteria in choosing a treatment either in curative setting (β coefficient=2.114, $p<0.0001$) or in palliative setting (β=1.063, $p<0.0001$). Oral route of administration had a positive effect in palliative setting (β=0.612, $p=0.035$ for the current tariff and β=0.506, $p<0.0001$ for the fictive tariff). Removing the efficacy attribute of the model, tolerability (β=1.228, $p<0.0001$) and adherence (β=1.223, $p<0.0001$) were influent, but only in curative setting while the oral route with a fictive tariff remained influential only in palliative setting (β=0.431, $p<0.0001$). **CONCLUSIONS:** The oral route of administration was influential in palliative setting, which is consistent with the priority to preserve quality of life at the advanced stage of disease. Physicians were sensitive to the fictive tariff for a patient support program, but as expected, in curative setting the key criterion remains the efficacy.

PCN136

CANCER PATIENTS' PERCEPTIONS TOWARDS THE INTEGRATION OF TRADITIONAL & COMPLEMENTARY MEDICINES (T&CM) INTO THE CONVENTIONAL CANCER TREATMENT: A QUALITATIVE INSIGHT

Farooqui M[1], Hassali MA[2], Knight AAS[3], Akmal A[4], Seang TB[5], Farooqui MA[6]
[1]*Universiti Teknologi MARA (UiTM), Sebrang Perai, Pulau Pinang, Malaysia,* [2]*Universiti Sains Malaysia, Minden, Pulau Pinang, Malaysia,* [3]*Advanced Medical & Dental Institute, Kepala Batas, Pulau Pinang, Malaysia,* [4]*University Sains Malaysia, Penang, Penang, Malaysia,* [5]*Penang General Hospital, George Town, Pulau Pinang, Malaysia,* [6]*Allianze University College of Medical Sciences, Kepala Batas, Malaysia*

OBJECTIVES: The national health care system encourages and supports the integration of T&CM into the conventional cancer treatment stream. The study aimed to evaluate the perception of cancer patients towards the integration of T&CM into their conventional therapies. **METHODS:** Qualitative methodology was adapted to collect in-depth information from consented patients recruited from one of the local hospitals with integrative medicines unit. After obtaining institutional ethical approval, patients with different types of cancer and stages were approached. Saturation point was reached after conducting 18 interviews as no new themes emerged with subsequent interviews. All interviews were audiotaped, transcribed verbatim and translated into English for thematic content analysis. **RESULTS:** Mixed perceptions were shown towards the integration of traditional medicines into the modern cancer treatment. All patients agreed with integrating traditional therapies into their conventional health care plans only when the oncologists allow it. However, concerns were shown towards an implicit criticism of oncologists regarding traditional medicines. Patients supported the use of traditional therapies to overcome side effects due to conventional therapies provided the therapies are proven for their safety with conventional medicines. For most of the patients, cancer was perceived as a fatal disease and use of traditional therapies is among the ways to put efforts for cure. Since the legitimacy of traditional medicines in the country is among the challenges faced by the lawmakers, patients appreciated that such efforts can prevent patients from being trapped by the quacks. **CONCLUSIONS:** Patients showed signs of approval towards the integration or traditional medicines. However, patients would like their oncologists to provide and supervise such therapies. At the same time, the challenge is to find a common ground for an open discussion with modern health care practitioners towards integration of traditional therapies into the modern cancer treatments.

PCN137

HEALTH STATE UTILITIES IN BREAST CANCER

Färkkilä N[1], Roine R[2], Jahkola T[3], Sintonen H[4], Hänninen J[5], Taari K[3], Saarto T[6]
[1]*University of Helsinki and GlaxoSmithKline Oy, Espoo, Finland,* [2]*Helsinki and Uusimaa Hospital Group, Helsinki, Finland,* [3]*Helsinki University Hospital, Helsinki, Finland,* [4]*University of Helsinki, Helsinki, Finland,* [5]*Terhokoti Palliative Care Unit, Helsinki, Finland,* [6]*Helsinki University Hospital, Helsinki, Other ->, Finland*

OBJECTIVES: Health state utilities are essential for health economic analysis. This study assesses the utilities for different health states in breast cancer (BC), compares different HRQoL instruments and explores factors associated with poor HRQoL. **METHODS:** An observational cross-sectional study among BC patients in the Hospital District of Helsinki and Uusimaa was carried out between September 2009 and April 2011. A total of 778 BC patients (aged 31-90) assessed their HRQoL with the generic 15D and EQ-5D+VAS and the cancer specific EORTC-QLQ C30 HRQoL questionnaires. Patients were divided into five mutually exclusive groups based on disease state: baseline before treatment (n=52), 1st year of remission after diagnosis or recurrence (n=128), 2nd or following years after remission (n=405), metastatic disease (n=177) and terminal care (n=16). Linear stepwise regression analysis was used to evaluate the association between the VAS-score and clinical and demographic factors as well as the EORTC symptom and functioning scale scores. **RESULTS:** The mean (± SD) utility values with 15D were for baseline patients 0.896±0.083, 1st year of remission 0.901±0.80, following years after remission 0.884±0.103, metastatic disease 0.825±0.113 and for palliative patients 0.756±0.110 and with EQ-5D 0.818±0.228, 0.860±0.178, 0.843±0.189, 0.746±0.251, 0.514±0.300, respectively. The difference between the instruments was consistent in all states of the disease. In regression analysis, higher EORTC QLQ-C30 scores for social, role and emotional functioning were associated with improved HRQoL. However, the most important explanatory variable was higher education. **CONCLUSIONS:** The utility scores were highest at 1st year of remission and deteriorated in the more advanced states of the disease. The 15D provided higher utility values than the EQ-5D. The choice of the HRQoL instrument has a significant effect on the utility values. Regression analysis showed that functioning has more impact on HRQoL than symptoms or clinical and demographic parameters except for education.

PCN138

THE IMPACT OF ADVANCED OR METASTASIC NON-SMALL CELL LUNG CANCER (NSCLC) SYMPTOMS ON PATIENT DAILY LIVING AND HEALTH RELATED QUALITY OF LIFE: FINAL RESULTS

Artal A[1], Oramas J[2], Cobo M[3], Domine M[4], Barneto I[5], Rodríguez-Abreu D[6], Menendez-ureña M[7], Andrade J[8], Guillot M[9], Perulero N[10], Castro-Gomez AJ[11]
[1]*Hospital Universitario Miguel Servet, Zaragoza, Spain,* [2]*Hospital Universitario de Canarias, La Laguna, Santa Cruz de Te, Spain,* [3]*Hospital Regional Universitario Carlos Haya, Malaga, Spain,* [4]*Fundación Jiménez-Díaz, Madrid, Spain,* [5]*Hospital Universitario Reina Sofía, Córdoba, Andalucía, Spain,* [6]*Hospital Universitario Insular de Gran Canaria, Las Palmas de Gran Canaria, Spain,* [7]*Hospital Universitario de Móstoles, Mostoles, Madrid, Spain,* [8]*Complejo Hospitalario de Toledo-Hospital Virgen de la Salud, Toledo, Castilla La Manc, Spain,* [9]*Hospital Universitari Son Espases, Palma de Mallorca, Spain,* [10]*IMS Health, Barcelona, Spain,* [11]*Roche Farma S.A., Madrid, Madrid, Spain*

OBJECTIVES: The benefits of systemic treatment NSCLC patients are greater control of the symptoms and improvement of HRQoL. The study aimed to assess the impact on daily living and HRQoL of the symptoms of advanced NSCLC. **METHODS:** Observational study with prospective follow-up (basal and 6-8 week visit). 257 patients with stage IIIB NSCLC, with pleural/pericardial effusion or stage IV NSCLC, about to initiate second-line treatment were included by 32 hospitals in Spain. Demographic and clinical data relating to Lung Cancer Symptom Scale (LCSS) and the lung-specific Functional Assessment of Cancer Therapy questionnaire (FACT-L) were collected. Specific questions evaluating impact of symptoms on patient daily life were included. **RESULTS:** By gender, 79.4% of patients were men, the mean (SD) age was 63.7 (10.0) years. ECOG 1 was presented by 56.4% and 38.9%

of patients at the basal and final visits respectively. 93% (n=240) of patients received chemotherapy in first line and 78.2% received targeted therapies (mainly erlotinib) as second line therapies. Twenty-six percent of patients demonstrated disease progression at the final visit but FACT-L scores showed no difference between visits; 48.8% of patients reported unchanged perceived health status and 28.1% reported an improvement. Patient and physician LCSS scores showed 86.4% of patients reported more symptoms than their physician but that there were no differences between visits. The impact of symptoms on daily life was slightly lower at the final than the basal visit. Statistically significant differences were observed between disease progression and the impact of cough ($p = 0.040$) and pain ($p = 0.02$), and also between the LCSS scale score ($p < 0.01$). **CONCLUSIONS:** Stability and improvement of some symptoms corresponded to lower impact of the same symptoms on patients. The number and type of symptoms were related to HRQoL and the degree to which patient daily life was affected.

PCN139

HUMAN PAPILLOMA VIRUS AND CERVICAL CANCER - KNOWLEDGE AND INTEREST OF MAN AND WOMAN

Vajda R, Szalai M, Boncz I, Kornya L, Radnai Z, Szili R, Szalai T, Kriszbacher I
University of Pécs, Pécs, Hungary

OBJECTIVES: The aim of our research was to determine the degree of knowledge concerning cervical cancer screening and human papilloma virus (HPV) and to find out what information sources would be accepted gladly for these. **METHODS:** Research was based on quantitative cross-sectional study. Interview was made between students, workers from health and other sectors, between 15-55 years, from a South-Transdanubian region. A self-designed questionnaire was used. Analysis was made by Chi square test, data processing by Microsoft Excel and SPSS 19.0. **RESULTS:** Out of 200 people 150 women and 50 men answered the questionnaire. The number of women participating in gynecological screening was relatively high (66.7%). 98-81% of the interviewed population knew the meaning of HPV. In addition, 98% of women with health knowledge as well as 74% of the laywomen knew the connection between HPV and cervical cancer. 80% of qualified women and 49% of laywomen knew the screening method. There was a significant difference between the two groups concerning the meaning of P3 category. 94% of female respondents and 58% of all men have heard of HPV, 68% of them had some knowledge about the connection between HPV and cervical cancer. However, only 14% of male knew that HPV could infect both sexes. 66.5% of the respondents show interest in HPV and/or cervical cancer and 75.5% of them are only partially satisfied with the information provided. **CONCLUSIONS:** In summary, it is necessary to provide proper informative programs. There would be a great chance for citizens to receive enough information with comprehensive collaboration.

PCN140

RURAL - URBAN DIFFERENCES IN FATALISTIC BELIEFS ABOUT CANCER PREVENTION

Mehta HB, Johnson ML
University of Houston, Houston, TX, USA

OBJECTIVES: Prior literature showed that people holding fatalistic beliefs, defined as events are controlled by external forces and humans are powerless to influence them, are less likely to engage in cancer preventive behavior such as smoking and exercising. The study aimed to assess rural-urban difference in fatalistic beliefs about cancer prevention. **METHODS:** The Health Information National Trend Survey (HINTS)–2007 data was used in this study; it is conducted biennially by National Cancer Institute to collect cancer related information from non-institutionalized adult population. Three fatalistic beliefs were captured in the database: 1) it seems like everything causes cancer; 2) there are so many different recommendations about preventing cancer, it is hard to know which ones to follow; and 3) there is not much you can do to lower your chances of getting cancer. All survey participants were included in the cohort. Multivariable logistic regression was used to assess rural-urban differences in three fatalistic beliefs adjusting for age, gender, race, region, education, employment status, income, health insurance, marital status, cancer history and cancer seeking information. All analyses were carried out using jackknife weights to account for survey design enabling us to extrapolate results at national level. **RESULTS:** Of 7674 participants, 54.59% agreed that everything causes cancer, 76.7% agreed that it's hard to know which recommendations to follow and 28.29% agreed that they cannot do much to lower chances of getting cancer. Compared to urban residents, rural residents were 35% (OR: 1.35; 95% CI: 1.12-1.60), 36% (OR: 1.36; 95% CI: 1.10-1.68) and 31% (OR: 1.31; 95% CI: 1.07-1.60) more likely to hold fatalistic beliefs (i), (ii) and (iii), respectively. **CONCLUSIONS:** A substantial proportion of Americans hold fatalistic beliefs about cancer prevention. Programs or interventions should be specifically designed for rural population to reduce fatalistic beliefs that might improve cancer prevention behaviors.

PCN141

QUALITY OF LIFE IN SMALL CELL LUNG CANCER: RESULTS OF AN OPEN-LABEL PHASE III CLINICAL TRIAL

Hudgens S[1], King J[2], Khan ZM[3]
[1]*Mapi Values, Boston, MA, USA,* [2]*Celgene Corporation, Summit, NJ, USA,* [3]*Celgene, Summit, NJ, USA*

OBJECTIVES: Health status, burden of illness and quality of life are considered crucial for clinical decision making in lung cancer. The purpose of this study was to provide the statistical results associated with the patient-reported outcome endpoints at the conclusion of this Phase 3, randomized, open-label, multinational study of Amrubicin compared with Topotecan. **METHODS:** Change in quality of life from Cycle 1 to end-of-study focused on change in lung cancer symptom and domain scores as well as minimally clinical important difference (MCID) as measured by the 9-item Lung Cancer Symptom Scale. Longitudinal Mixed Models were conducted adjusting for Treatment, Disease Stage, Previous Treatment Response, and Time to Drop Out. MCID was calculated as 1 standard error of measurement from baseline to end of study. Additionally, change in individual symptom scores on the LCSS for appetite, cough, dyspnea, fatigue, heomptysis, and pain were evaluated descriptively. **RESULTS:** A total of 607 patients were included in the study at baseline. Follow-up LCSS data was available on 51.7% of Amrubicin and 46.2% of Topotecan patients. Amrubicin showed greater clinical improvements on LCSS total score and symptom burden as measured by the MCID analysis as well as the longitudinal analysis. Specifically, 65% of patients on Amrubicin improved or demonstrated no change on the LCSS Symptom Burden Score compared to 52% of Topotecan patients. On the same scale, 30.25% of Topotecan patients worsened compared to 20.24% of Amrubicin patients (MCID=8.17; Chi-Square = 6.70, $p = 0.0822$). **CONCLUSIONS:** Amrubicin has better symptom control (and QOL vs. Topotecan) on all symptoms (equivalence on hemoptysis). Subgroup analyses are consistent and are all in favor of Amrubicin (survival, previous response, disease stage, and study response). Refractory patients later treated with Amrubicin have greater symptom control and QoL vs. Topotecan.

PCN142

METHODOLOGICAL LIMITATIONS OF PATIENT-REPORTED OUTCOME MEASURES (PROMS) IN ONCOLOGY: A META-REVIEW

Smith AB[1], Taylor M[1], Parry D[2]
[1]*York Health Economics Consortium, York, North Yorkshire, UK,* [2]*AstraZeneca, Macclesfield, UK*

OBJECTIVES: The US Food and Drug Administration (FDA) published guidance (2006, 2009) on the use of patient-reported outcome measures (PROMs) in labelling claims places an emphasis on areas such as psychometric validation and interpretability of PROMs, in addition to statistical issues. Given that the vast majority of oncology PROMs were developed prior to the guidance it is appropriate to re-evaluate these PROMs to determine whether they comply with the new regulatory advice. **METHODS:** A comprehensive meta-review was undertaken of systematic reviews of oncology patient-reported outcome measures (PROMs) used in randomised controlled trials (RCTs). The Cochrane Library, PubMed, Ovid, PsychInfo and EMBASE databases were searched. English language articles published between 2000 and 2011 were identified. **RESULTS:** A final 7 systematic reviews were identified from 435 potential articles involving 443 RCTs in oncology. The reviews covered lung, breast and colorectal and advanced cancers, leukaemia and multiple myeloma. A total of 71,379 patients had completed the PROMs in the RCTs. The most commonly used instruments were the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 (38% of RCTs) and the Functional Assessment of Cancer Therapy – General (FACT-G) questionnaire (18% RCTs). A total of 82% RCTs had used psychometrically validated instruments; 70% trials reported culturally valid instruments and virtually all RCTs reported timing of PROMs assessment (97%). However, only 28% RCTS reported clinical significance, 32% reported missing data and 25% provided a priori hypothesis of expected changes in PROMs scores. **CONCLUSIONS:** Although oncology PROMs currently utilised in RCTs are compliant with certain areas of the FDA guidance, there are critical aspects where these fall short of the requirements, particularly in terms of missing data and clinical interpretation. These methodological limitations will need to be addressed if oncology PROMs are to be used to successfully support labelling claims.

PCN143

ELECTRONIC PATIENT-REPORTED OUTCOME MONITORING IN TESTICULAR CANCER PATIENTS

Giesinger JM[1], Oberguggenberger A[2], Kemmler G[1], Gamper E[2], Steiner H[2], Sztankay M[2], Holzner B[1]
[1]*Innsbruck Medical University, Innsbruck, Tyrol, Austria,* [2]*Innsbruck Medical University, Innsbruck, Austria*

OBJECTIVES: Testicular cancer (TC) is the most common cancer in young men and its incidence is increasing. The low mortality rate makes quality of life (QOL) an important issue in this patient group. Thus, this study aimed at monitoring QOL, and patient-reported physical and psychosocial symptoms. **METHODS:** Patients with TC treated at the urological outpatient unit of Innsbruck Medical University were consecutively included in the study. QOL assessment was done with the generic EORTC QLQ-C30 questionnaire and recently also with the TC-specific EORTC QLQ-TC26 (scale range 0-100). For electronic data capture and result presentation to physicians we used a software tool called Computer-based Health Evaluation System (CHES). **RESULTS:** Since January 2008, we included 408 patients in the electronic patient-reported outcome monitoring with a total of 1087 symptom assessments. Mean patient age was 43.3 years (SD 11.9). To optimize patient recruitment and data quality a person was needed for approaching patients actively and to provide support in case of any questions arising. Collected symptom data enables longitudinal tracking of symptoms and screening for symptoms that patients do not volunteer within the patient-physician contact. Overall, most pronounced TC-specific symptoms were negative future perspective (mean 58.1), reduced sexual activity (mean 60.2), and impaired sexual enjoyment (mean 69.7). **CONCLUSIONS:** Patient-reported outcome monitoring was found to be feasible in the busy setting of an urologic outpatient unit. As TC patients are of younger age than most other cancer patient groups, electronic data collection is particularly feasible, given the high computer literacy in these patients. The software CHES used for electronic data capture was found to provide high user friendliness for patients as well as physicians. The data base created within this study allows comprehensive analyses for a range of research questions

.

PCN144

HEALTH-RELATED QUALITY OF LIFE IN PROSTATE CANCER – ONE YEAR FOLLOW-UP AND COMPARISON WITH GENERAL POPULATION NORMS

Roine R[1], Bergius S[2], Färkkilä N[3], Muhonen T[4], Räsänen P[1], Sintonen H[5], Taari K[6]
[1]*Helsinki and Uusimaa Hospital Group, Helsinki, Finland,* [2]*University of Helsinki and Amgen AB, Espoo, Finland,* [3]*University of Helsinki and GlaxoSmithKline Oy, Espoo, Finland,* [4]*Helsinki University Hospital and Amgen Ab, Espoo, Finland,* [5]*University of Helsinki, Helsinki, Finland,* [6]*Helsinki University Hospital, Helsinki, Finland*

OBJECTIVES: The incidence of prostate cancer has increased during the last two decades. Part of this increase has been attributed to prostate specific antigen (PSA) testing. As a consequence of testing many patients enter treatment at an early stage of the disease. This might be reflected in their health-related quality of life. **METHODS:** An ongoing observational follow-up study using the 15D generic health-related quality of life (HRQoL) instrument. Patients are asked to fill in the HRQoL questionnaire at baseline and 3, 6 and 12 months after entering treatment, and results are compared with those of an age-standardized general population sample. **RESULTS:** So far, 587 patients (mean age 66 years) have been assessed at baseline and 336 have completed the one-year follow-up. The mean HRQoL score (on a 0-1 scale) of the patients at baseline was statistically significantly better than that of the general population (0.904 vs. 0.874, $p < 0.001$). Furthermore, the patients were statistically significantly better off than the population on 9 of the 15 dimensions of the HRQoL instrument. Only the dimensions of elimination (i.e. urinating)($p < 0.001$) and sexual function ($p < 0.05$) showed statistically significantly worse levels in the patients than in the general population. In patients having completed the one-year follow-up, the total HRQoL score fell from 0.913 to 0.886 ($p < 0.001$). The greatest deterioration was seen in sexual activity ($p < 0.001$). By contrast, elimination did not change in a statistically significant manner during follow-up. **CONCLUSIONS:** The HRQoL of patients entering treatment is surprisingly good. Although HRQoL of the patients showed slight deterioration during follow-up, patients were on many of the dimensions of the 15D instrument one year after diagnosis still better off than the general population. The only clear exception was sexual activity which showed marked deterioration in the patients during follow-up.

PCN145

MEASUREMENT PROPERTIES OF THE ENGLISH AND CHINESE VERSIONS OF THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY – BREAST (FACT-B) IN ASIAN BREAST CANCER PATIENTS

Ng R[1], Lee CF[2], Wong NS[1], Luo N[3], Yap YS[1], Lo SK[1], Chia J[1], Yee A[4], Krishna L[4], Goh C[4], Cheung YB[2]
[1]*National Cancer Centre, Singapore,* [2]*Singapore Clinical Research Institute, Singapore,* [3]*Yong Loo Lin School of Medicine, National University of Singapore, Singapore,* [4]*National Cancer Center, Singapore*

OBJECTIVES: To examine the measurement properties of and comparability between the English and Chinese versions of the Functional Assessment of Cancer Therapy - Breast (FACT-B) in Singaporean breast cancer patients. **METHODS:** This is an observational study of 271 patients. Known-group validity of FACT-B total score and Trial Outcome Index (TOI) were assessed in relation to performance status, evidence of disease and treatment status cross-sectionally; responsiveness to change was assessed in relation to change in performance status longitudinally. Internal consistency and test-retest reliability were evaluated. Factor analyses were performed to examine the factor structure of the FACT-General which consisted of the first four subscales of FACT-B, and the breast cancer subscale (BCS). Multiple regression analyses were performed to compare the scores on the two language versions, adjusting for covariates. **RESULTS:** The FACT-B total score and TOI demonstrated known-group validity in differentiating patients with different clinical status. They showed high internal consistency (Cronbach's alpha = 0.87 to 0.91) and test-retest reliability (intraclass correlation coefficient = 0.82 to 0.89). The English version was responsive to the change in performance status. The Chinese version was responsive to decline but inconclusive to improvement in performance status due to too few such respondents. Four factors identified from FACT-General corresponded to the four subscales except two items. Three factors were identified from the BCS, namely psychological distress, feminine satisfaction, and physical complaints. Two items concerning sexuality had a high item non-response rate (50.2% and 14.4%). No practically significant difference was found between the two language versions despite minor differences in two items. **CONCLUSIONS:** The English and Chinese versions of the FACT-B are valid, responsive and reliable instruments in assessing health-related quality of life in Singaporean breast cancer patients. Data collected from the two language versions can be pooled and either version could be used for bilingual patients.

PCN146

GOOD PROGNOSIS, GOOD QUALITY OF LIFE? – LONGITUDINAL ASSESSMENT OF QUALITY OF LIFE IN THYROID CANCER PATIENTS

Gamper EM[1], Giesinger JM[1], Oberguggenberger A[2], Wintner L[1], Singer S[3], Buxbaum S[1], Waitz D[1], Putzer D[1], Nilica B[1], Virgolini I[1], Holzner B[1]
[1]*Innsbruck Medical University, Innsbruck, Tyrol, Austria,* [2]*Innsbruck Medical University, Innsbruck, Austria,* [3]*Bergische Universität Wuppertal, Wuppertal, Nordrhein-Westfa, Germany*

OBJECTIVES: Although the incidence of thyroid carcinoma is constantly rising, little is known about the issue of quality of life (QOL) in this patient group. A ten-year survival rate of 90% and therapeutic options with minor side-effects may blind physicians and researchers to the fact that patients not only have to face a cancer diagnosis and fear of recurrence, but are struggling with endocrine problems, severely affecting their QOL. Therefore, in the present study we aim at longitudinally assessing QOL in thyroid cancer patients from the beginning of radionuclide therapy onward. A further aim is to implement a computer-based QOL-monitoring. **METHODS:** Thyroid cancer patients admitted for inpatient stay (either for radionuclide therapy or aftercare) at the University Clinic for Nuclear Medicine were consecutively included in the study. Following an aftercare visit at 6 months after therapy, patients are monitored on an annual basis. QOL was assessed with the widely used EORTC Quality of Life Questionnaire (QLQ-C30) at each hospital visit. Data analysis was done using mixed linear models. **RESULTS:** Data from 55 patients (63.4% female, age 45.8+/−16.8) with a total of 236 measurements were analyzed. Patients showed significantly (α=0.05) more severe impairments at the time point of therapy compared to aftercare visits on several QOL dimensions (functioning: physical, social, role, emotional; symptoms: fatigue, pain, dyspnea). On the majority of these dimensions females reported significantly more symptoms than males. During early aftercare QOL scores returned to general population levels. Computer-based QOL-monitoring is being currently implemented. Results will be showed at the conference. **CONCLUSIONS:** The results show that the QOL of thyroid cancer patients is diminished during the time of therapy until early aftercare. To alleviate symptom burden the need for medical or psychosocial intervention needs to be identified timely. This can be done using computer-based QOL-monitoring, allowing immediate action.

PCN147

HEALTH-RELATED QUALITY OF LIFE IN HEAD AND NECK CANCER PATIENTS - COMPARISON WITH GENERAL POPULATION NORMS

Lahtiharju T[1], Mäkitie AA[2], Saarilahti K[2], Bäck L[2], Räsänen P[1], Sintonen H[3], Roine R[1]
[1]*Helsinki and Uusimaa Hospital Group, Helsinki, Finland,* [2]*Helsinki University Hospital, Helsinki, Finland,* [3]*University of Helsinki, Helsinki, Finland*

OBJECTIVES: Head and neck cancer can profoundly affect patients' quality of life (QoL) but disease-specific QoL instruments alone may not give an appropriate view of this multidimensional disease. **METHODS:** An observational follow-up study using the 15D standardized, self-administered generic health-related quality of life (HRQoL) instrument which the patients were asked to fill in at baseline and at 3, 6 and 12 months after entering treatment. Results of 91 patients having so far completed one-year follow-up were compared with those obtained from age-and gender-standardized representative sample of the general population. **RESULTS:** Mean HRQoL score (on a 0-1 scale) of the patients entering treatment (mean age 62 years, 60 % men) was only slightly worse than that of the general population (0.870 vs. 0.888, p=0.059). However, on the dimensions of depression, distress and sexual activity the patients were at baseline clearly worse off than the general population ($p<0.001$) Lesser impairment was seen on the dimensions of sleeping, eating and speech ($p<0.01$). During the one-year follow-up the total HRQoL score showed slight deterioration from 0.870 to 0.845 (p=0.019). The most marked worsening was seen on the dimensions of speech ($p<0.001$) and eating ($p<0.01$). By contrast, the dimensions of distress ($p<0.01$) and depression ($p < 0.05$) showed at the one-year follow-up some improvement compared to baseline. **CONCLUSIONS:** The HRQoL of patients entering treatment is fairly good in comparison to that of the general population. Nevertheless patients appear to suffer from significant depression, distress and impaired sexual activity which should be taken into account in the treatment of head and neck cancer patients. During the follow-up the overall HRQoL score showed, despite of intensive treatment, only slight deterioration. The dimensions of eating and speech were negatively affected by treatment but the dimensions reflecting psychological well-being (distress and depression) showed some improvement compared to baseline.

PCN148

ESTIMATING QUALITY OF LIFE IN ADVANCED MELANOMA; A COMPARISON OF STANDARD GAMBLE, SF-36 MAPPED, AND EORTC QLQ-C30 MAPPED UTILITIES

Batty AJ[1], Fisher D[1], Winn B[1], Wang Q[2], Tolley K[3], Rowen D[4]
[1]*BresMed Health Solutions, Sheffield, South Yorkshire, UK,* [2]*Bristol-Myers Squibb, Uxbridge, Middlesex, UK,* [3]*Tolley Health Economics, Buxton, UK,* [4]*University of Sheffield, Sheffield, South Yorkshire, UK*

OBJECTIVES: In order to construct a cost-utility model, evidence is required of the Health Related Quality of Life (HRQL) experienced by patients suffering from the disease. In advanced melanoma, data is available from a vignette-based standard gamble (SG) study in the general population. However, patient reported HRQL data was also captured in the ipilimumab pivotal trial, MDX010-20, using the EORTC QLQ-C30 and the SF-36 generic health surveys. **METHODS:** Patient level EORTC data from the MDX010-20 trial was mapped using the EORTC-8D algorithm to produce EQ-5D utilities, which were then stratified according to disease progression (progression-free or post-progression), and treatment arm. This process was repeated with the patient level SF-36 data based upon a nonparametric Bayesian method to generate SF-6D utility values. The results were then compared with results generated from the vignette-based study. **RESULTS:** In the progression free health state, the SG and EORTC data show a high degree of correlation in utility (0.77 vs 0.80), with the SF-36 value being significantly lower (0.64). In the post-progression state, comparing to the utility values in the progression free state, the SG data shows a significant fall of 0.18 (23.4%) in expected utility, however, this is not mirrored in patient data, where there is a fall of 0.04 (4.7%) in the EORTC data, and 0.02 (3.3%) in the SF-36 data, showing patients do not appear to have a significantly worsened HRQL with disease progression. **CONCLUSIONS:** Despite the limitations of the study in both patient numbers, and being limited to a single disease, investigators should be aware different measures administered to the same patients may yield differing results. Equally further research should be carried out on HRQL associated with disease progression from the viewpoint of both patients and

the general public, as it is possible there are differences in the valuation of states close to death.

PCN149

HEALTH STATE UTILITY VALUES IN BREAST CANCER: A REVIEW AND META-ANALYSIS

Peasgood T[1], Ward SE[2], Brazier J[1]
[1]University of Sheffield, Sheffield, UK, [2]Univerrsity of Sheffield, Sheffield, UK

OBJECTIVES: Health-related quality of life is an important issue in the treatment of breast cancer (BC) and health-state utility values (HSUVs) are essential for cost-utility analysis. The aim of the study was to identify published values for common health states for breast cancer and to determine pooled estimates of HSUVs for each identifiable health state. **METHODS:** A systematic review of HSUVs for conditions relating to BC was undertaken. Thirteen databases were searched in March 2009. HSUVs were allocated to six categories: screening related states, preventative states, adverse events in breast cancer and its treatment, non-specific breast cancer, early breast cancer (EBC) states and metastatic breast cancer (MBC) states. Where appropriate meta analysis was used to provide utilities based on combining all available evidence. Mean utility estimates were pooled using ordinary least squares with utilities clustered within study group and weighted by both number of respondents and inverse of the variance of each utility. Regressions included controls for disease state, utility assessment method and other features of study design. **RESULTS:** Forty-nine articles were identified, providing 476 unique utility values. From these, 117 values for MBC and 230 values for EBC were extracted and analysed by regression analysis. Utilities were found to vary significantly by valuation method (e.g. in EBC standard gamble had higher valuations than TTO and EQ-5D), and source of values. For MBC values significantly varied in expected direction by severity of condition, treatment and side-effects. **CONCLUSIONS:** Despite the numerous studies it was not feasible to generate a definitive list of HSUVs that could be used in future economic evaluations, due to the complexity of the health states involved and the variety of methods used to obtain values. Future research into quality of life in BC should make greater use of validated generic preference-based measures for which public preferences exist.

PCN150

WILLINGNESS TO PAY FOR A REDUCTION IN RISK OF TREATMENT SIDE EFFECTS IN PATIENTS WITH METASTATIC BREAST CANCER

Lalla D[1], Mclaughlin T[2], Brammer M[1], Bramley T[2], Bare A[2], Carlton R[2]
[1]Genentech Inc., S San Francisco, CA, USA, [2]Xcenda, LLC., Palm Harbor, FL, USA

OBJECTIVES: The objective of this analysis was to assess patients' willingness to pay (WTP) for a reduction in risk of breast cancer treatment side effects. **METHODS:** A survey was developed using continent valuation processes to assess the WTP for a reduction in side effects. The survey asked female MBC patients to provide the amount they were willing to pay for a 25%, 50% and 100% reduction in risk of the following side effects: diarrhea/dehydration, hair loss, fatigue, nausea, neutropenia/febrile neutropenia, pain and tingling in hands and feet. Patients were also asked to select the side effect they would pay the most to avoid. Demographic information such as age, race/ethnicity, region, employment status, insurance type, and treatment regimen was also collected. **RESULTS:** A total of 202 metastatic breast cancer patients completed the survey. The majority of respondents were white, married, over the age of 51, and well educated. Most respondents had private insurance (67%) or Medicare (24%). Of those who reported paying out of pocket for their last treatment (58%), the average payment was $459. For a 25%, 50%, and 100% reduction in the risk of side effects, respondents were willing to pay an extra $1886, $3837 and $7794, respectively. Hair loss (28%), pain (17%) and nausea (15%) were selected most often as the side effect respondents would pay the most to avoid. **CONCLUSIONS:** Patients with MBC highly value reduction in treatment side effects and are WTP 4.2 times more for a treatment devoid of side effects over a treatment with a 25% reduction in the risk of side effects. Additional research is warranted to quantify WTP for specific side effects.

Cancer – Health Care Use & Policy Studies

PCN151

VALUE OF OUTCOMES RESEARCH TO INFORM REIMBURSMENT DECISION-MAKING ILLUSTRATED BY AN OBSERVATIONAL STUDY IN CHRONIC LYMPHOCYTIC LEUKEMIA

Holtzer-goor K[1], Bouwmans C[1], Schaafsma MR[2], Uyl-de Groot CA[1]
[1]Erasmus University Rotterdam, Rotterdam, The Netherlands, [2]Medisch Spectrum Twente, Enschede, Overijssel, The Netherlands

OBJECTIVES: As outcomes research is being used to inform the decision-maker about continuation of reimbursement of expensive hospital drugs in the The Netherlands since 2006, this type of research is becoming more important. Our study started before 2006 and aimed to evaluate therapies in daily clinical practice and their costs and outcomes. This study gives an indication of the challenges that may arise from the design of outcomes research. **METHODS:** An observational follow-up study was performed including 160 patients with chronic lymphocytic leukemia (CLL). Data collection on treatment, costs and outcome was performed in 19 Dutch hospitals using medical records. **RESULTS:** Patients diagnosed between 1999 and 2003 were included and followed during 6.4 years on average. The mean age was 63 years (range: 30-86). 20% received one therapy-line, 12% two and 24% received three or more therapy-lines. Most patients received chlorambucil (87%) as first therapy and the second line was dominated by fludarabine (46%). However, therapies from the third line onwards varied extensively. Due to the development of new medicines like monoclonal antibodies, the treatment sequence changed in the more recently diagnosed patients. As a consequence of the relatively low incidence of CLL and the variety in therapy, the number of patients with comparable therapies was small. **CONCLUSIONS:** Management of CLL varied strongly especially after the second therapy-line. This may be caused by the introduction of monoclonal antibodies as first and second line treatment during the study period. Additionally, a comparison of alternative therapies was hampered due to relative small number of patients. Consequently, modeling studies or patient registrations might be necessary to obtain valid information about cost-effectiveness of new expensive inpatient medicines in (chronic) diseases with a low incidence rate and a highly variable or changing management strategy.

PCN152

CAN BREAST CANCER RISK PREDICTION REDUCE THE RISKS OF FALSE NEGATIVE AND FALSE POSITIVE SCREENING MAMMOGRAMS?

Armstrong K, Handorf E, Chen J, Bristol-Demeter M
Perelman School of Medicine at the University of Pennsylvania, Philadelphia , PA, USA

OBJECTIVES: Controversy continues about screening mammography, partially because of risks involved. Pre-test breast cancer risk prediction may improve positive and negative predictive value of screening mammography, particularly among women who have an abnormal screening mammogram. **METHODS:** We modeled one-year breast cancer risk in women with abnormal screening mammograms (BI-RADS3, BI-RADS4) by combining estimates of pre-test breast cancer risk based upon established risk factors, 12 validated SNPs and the average probability of cancer given BI-RADS category. We examined the degree to which the incorporation of pre-test breast cancer risk would reclassify women from current recommendations for short-term follow up of BI-RADS3 and biopsy of BI-RADS4 using biopsy thresholds of 1, 2 and 3% probability of breast cancer. **RESULTS:** Women with BI-RADS3 in the lowest 5% of pre-test breast cancer risk had a one-year average breast cancer risk of 0.24% compared to 2.7% for women in the highest 5% of pre-test risk. Women with BI-RADS4 in the lowest 5% of pre-test risk had a one-year average breast cancer risk of 4.9% compared to 39.8% for women in the highest 5% of pre-test risk. Incorporating BI-RADS 4 subclassifications increased the risk discrimination, women with BI-RADS 4A in the lowest 5% of pre-test probability had a one-year breast cancer risk of 1.4%. Using a biopsy risk threshold of 2%, 8% of women with a BI-RADS3 had a post-test risk above the threshold for biopsy and 7% of women with BI-RADS4A had a post-test risk below the threshold. **CONCLUSIONS:** Although incorporation of pre-test risk estimates changes decisions about management of abnormal mammograms for a relatively small proportion of women, the public health impact could be significant given the incidence of abnormal mammograms. Prospective studies are needed to determine effectiveness of breast cancer risk prediction in improving the positive and negative predictive value of mammography screening.

PCN153

COST OF HOSPITAL CARE IN POPULATION OF PATIENTS WITH NEOPLASMS IN POLAND

Macioch T[1], Paweska J[2], Niewada M[2], Hermanowski TR[1]
[1]Medical University of Warsaw, Warsaw, Poland, [2]HealthQuest Sp.z o.o., Warsaw, Poland

OBJECTIVES: Although cancer morbidity is lower than cardiovascular or metabolic diseases, it is still the second leading cause of mortality and also the major economic problem due to high cost of treatment. According to estimations by the Karolinska Institutet and Stockholm School of Economics, the direct costs of caring for cancer patients are approximately 6.5% of total healthcare costs. The aim of this study was to estimate cost of hospital care in population of patients with neoplasms in 2009. **METHODS:** We used National Health Fund (NHF) statistics on Diagnosis-Related Groups (DRGs) attrition in 2009 year. Precise, in respect to ICD-10 diagnosis, NHF statistics cover 85% of all data. We identified data only for malignant neoplasms (C00-C97), in situ neoplasms (D00-D09) and neoplasms of uncertain or unknown behavior (D37-D48). Values are presented in Euro (exchange rate: 1 EUR=4.00 PLN). **RESULTS:** Cost of hospital care in population of patients with neoplasms was estimated to amount of 246.3 million EUR (289.7 million EUR when correction for 85% statistics cover will be applied). The highest costs of hospital care were related to malignant neoplasm of bronchus and lung (34.3 million EUR) followed by malignant neoplasm of bladder (26.5 million EUR), and malignant neoplasm of colon (22.8 million EUR). Given the number of cancer patients in Poland which is estimated to be 270 thousands, cost of hospital care per cancer patient per year would be approximately 1073 EUR. However apart from DRGs, cost of hospital care in population of patients with neoplasms includes also separately contracted chemotherapy (374.3 million EUR) and some Therapeutics Programs with a new drugs such as trastuzumab in breast cancer (46.1 million EUR) . **CONCLUSIONS:** Cost of hospital care in population of cancer patients is substantial and account for over 11.5% of all costs of hospital care in Poland in 2009.

PCN154

DISCUSSING THE INTRODUCTION OF NATIONAL SCREENING PROGRAMS IN GREECE: A DELPHI STUDY

Skroumpelos A, Pavi E, Kyriopoulos J
National School of Public Health, Athens, Greece

OBJECTIVES: In the absence of national screening programs (NSP) for adults in Greece, the aim of this study was to examine experts' views and recommendations on a predefined set of NSPs **METHODS:** A systematic review was conducted to identify those screening programs that best meet the criteria of clinical effectiveness and cost efficiency. The programs identified were set for evaluation in a multiprofessional expert panel which completed a structured questionnaire in three rounds, using the Delphi method. Experts' agreement was investigated as well as

their recommendations for the implementation, the target-group, the rescreening interval and the primary screening methods of the programs proposed, and to recommend the social insurance reimbursement level. **RESULTS:** Of the 33 experts invited, 26 (78%) accepted to participate. The vast majority of them supported the implementation of an NSP for breast cancer, cervical cancer, colorectal cancer, vascular risk and abdominal aortic aneurysm. Both the rescreening interval and the primary screening method of each of the programs were considered adequately effective. The biggest debate was focused on the target-group of the colorectal cancer and the abdominal aortic aneurysm program. All of the experts argued that social insurance should fully reimburse the programs for the individuals that fulfill the eligibility criteria. Otherwise the cost should be borne by the individual, according to the 77% of the panelists. 68% of the experts argued that when the eligibility criteria are not fullfiled but the individual is referred by a general practitioner or a specialist for screening, social insurance should partly reimburse the cost. **CONCLUSIONS:** Despite any debates especially on the target-group of the programs, all of the programs were deemed necessary, stressing the need for organized screening in order to reduce mortality and morbidity from certain conditions and to optimize the allocation of resources invested in secondary prevention

PCN155

THE CHALLENGES OF ESTIMATING COSTS OF PALLIATIVE CARE: A SYSTEMATIC LITERATURE REVIEW

Hendry L[1], Tumur I[2], Farquharson R[3], Kroes MA[3]
[1]*Pfizer Ltd, Tadworth, Surrey, UK,* [2]*Pfizer Ltd, Tadworth, Surrey , UK,* [3]*Abacus International, Bicester, Oxfordshire, UK*

OBJECTIVES: To systematically review the literature for methods of estimating the costs of palliative care and to assess which costs are included in palliative care. **METHODS:** Preliminary scoping of health technology assessment appraisals identified high degree of heterogeneity in how palliative care is defined, in terms of the type of care, and the models and settings of delivery. To focus the review, patients with metastatic renal cell carcinoma (mRCC) were chosen as the reference population, in keeping with the PICO (population, indication, comparison, outcome) approach to formulating research questions. Relevant search terms were identified and searches conducted in EMBASE, MEDLINE, Cochrane library and Econlit. Results were filtered using pre-specified selection criteria and data extracted into a pre-defined template. **RESULTS:** Without a specified patient population, database searches identified almost 17,000 records; mRCC focussed searches identified 1,172 records. From mRCC searches 66 full text publications were assessed and only 17 met pre-defined inclusion criteria. Of these publications, nine assessed surgery costs; five were cost-effectiveness assessments; and three assessed burden of disease. Cost data collected was largely based on expert opinion and country-specific assumptions (with potential bias) making generalisation difficult. Notable levels of heterogeneity between the included publications (publication type, year, country and perspective) precluded consistent, qualitative synthesis of the data. **CONCLUSIONS:** Despite focussing on a specific disease population, high levels of heterogeneity in the reporting and study of palliative care, in terms of setting and delivery, prevented a robust interpretation of the data. A key driver of this heterogeneity may be the fact that palliative care is delivered in a variety of settings, using diverse models of care. Evidence-based assessments of costs of palliative care present methodological challenges. Therefore, we see a need for agreement on the definitions and parameters of palliative care, which would greatly assist future decision making.

PCN156

A SURVEY EXAMINING TREATMENT PATTERNS OF MELANOMA IN AUSTRALIA

Adams J[1], Cuyun Carter G[2], Strizek A[3], Rajan N[3]
[1]*Pretium, Sydney, NSW, Australia,* [2]*Eli Lilly and Company, Indianapolis, IN, USA,* [3]*Eli Lilly Australia, West Ryde, NSW, Australia*

OBJECTIVES: Australia has the highest incidence of melanoma in the world, however little published information exists regarding treatment patterns. A study was undertaken to define current treatment options offered to Australian patients. **METHODS:** A survey was developed from interviews with 7 scientific experts treating melanoma in Australia. Algorithms outlining referral and treatment patterns across all stages of melanoma were derived and validated by dermatologists and general surgeons for early stage and medical oncologists for later stage disease. **RESULTS:** A total of 115 oncologists were identified as treating melanoma in Australia and 26% of those responded. In addition, a sample of 40 dermatologists and surgeons were contacted and 43% of those participated. Results demonstrated that nearly all patients with local or locoregional melanomas undergo radical excision of their primary lesion; whereas 73.1% of patients with metastatic melanoma have their primary lesion excised. For metastatic disease, the majority of oncologists reported that current 1st line chemotherapy is dacarbazine (DTIC) (85%) or fotemustine (77%), although a large percentage also reported enrolling patients in clinical trials (73%). Nine oncologists (36%) surveyed indicated that they expect overall survival (OS) of 7-9 months after initiation of 1st line chemotherapy. Oncologists also reported that 48% of patients who relapse after 1st line therapy receive 2nd line therapy, of which enrollment into a clinical trial (69%) or treatment with fotemustine (62%) are the most common treatment options. Approximately half (48%) of oncologists surveyed expect OS in 2nd line to be 3-6 months. The most common sites for development of metastases were reported to be lung (48.0%), liver (47.6%) and brain (38.0%). **CONCLUSIONS:** To our knowledge, this is the first survey conducted to understand melanoma treatment patterns in Australia. This study provides information for evidence-based decision makers to understand how health resources are utilised in the treatment of melanoma in Australia.

PCN157

THE IMPACT OF A PATIENT SUPPORT PROGRAM ON ACCESS TO ORAL ONCOLOGY THERAPY IN THE UNITED STATES

Pashos CL[1], Cragin LS[2], Khan ZM[3]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*United BioSource Corporation, Bethesda, MD, USA,* [3]*Celgene Corporation, Summit, NJ, USA*

OBJECTIVES: Access to innovative medicines is sometimes challenging due to issues related to affordability, attributable at least in part to the heterogeneity and design of health insurance coverage. A support program (Program) to help patients requesting assistance in accessing oral oncology agents was evaluated to determine if it facilitated their access to medication. **METHODS:** Anonymized data from a random sample of patients enrolling in the Program in 2008-2009 and a random sample of control patients from Risk Evaluation and Mitigation Strategies (REMS) programs for lenalidomide and thalidomide were analyzed. Specifically, patient characteristics, type of assistance provided, and dispensing outcomes (proportion successfully dispensed medication, time from prescription authorization to first dispense, reason for non-dispense, and proportion of Program patients seeking further assistance following their initial request) were assessed. **RESULTS:** A random sample of 1000 Program and 1000 control patients was evaluated. Most patients had a primary diagnosis of multiple myeloma or of myelosdysplastic syndromes. Despite the expressed need for assistance in accessing medication among the Program patients, the percentage of Program patients receiving medication compared with patients in the control group was not statistically different (89% vs. 91%, respectively; $p = 0.270$), with a difference in median time to dispense of 3 days. Ninety-two percent of Program patients successfully obtained durable access to oral medication. **CONCLUSIONS:** The results suggest that a support program for patients needing assistance in a complex health insurance environment can effectively achieve a goal of helping them to obtain access to therapies prescribed by their physicians. Research should be conducted to better understand which elements of such programs are most valuable to patients, and therefore would be considered best practices for such programs.

PCN158

THE INFLUENCE OF HEALTH CARE POLICIES AND HEALTH CARE SYSTEM DISTRUST ON WILLINGNESS TO UNDERGO GENETIC TESTING

Armstrong K[1], Putt M[2], Hughes halbert C[1], Grande D[2], Shwartz JS[3], Liao K[2], Marcus N[1], Bristol-demeter M[1]
[1]*Perelman School of Medicine at the University of Pennsylvania, Philadelphia , PA, USA,* [2]*Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, USA,* [3]*Perleman School of Medicine at the University of Pennsylvania, Philadelphia , PA, USA*

OBJECTIVES: As the potential role of genetic testing in disease prevention and management grows, so does concern about differences in uptake of genetic testing across social and racial groups. Characteristics of how genetic tests are delivered may influence willingness to undergo testing and potentially alter disparities in testing. **METHODS:** Conjoint analysis study of the effect of three characteristics of genetic test delivery on willingness to undergo genetic testing for cancer risk. Data were collected using a random digit dialing survey of 337 individuals living in the US. Measures included conjoint scenarios, health care system distrust (values and competence subscales), health insurance coverage, and sociodemographic characteristics. Three attributes were studied: disclosure of test results to the health insurer, provision of the test by a specialist or primary care doctor, race specific or race neutral marketing. **RESULTS:** In adjusted analyses, disclosure of test results to insurers, having to get the test from a specialist, and race specific marketing were all inversely associated with willingness to undergo the genetic test, with the greatest effect for the disclosure attribute. Racial differences in willingness were not statistically significant ($p=0.07$) and the effect of the attributes on willingness to undergo testing did not vary by patient race. However, the decrease in willingness with insurance disclosure was greater among individuals with high values distrust ($p=0.03$) and the decrease in willingness to undergo testing from specialist access was smaller among individuals with high competence distrust ($p=0.03$). **CONCLUSIONS:** Several potentially modifiable characteristics of how genetic tests are delivered are associated with willingness to undergo testing. The effect of two of these vary according to the level of health care system distrust, suggesting that policy decisions about delivery of genetic testing may influence differences in uptake across patient subgroups defined by levels of distrust rather than by race.

PCN159

DIAGNOSTICS AND TREATMENT OF PATIENTS WITH NON-SMALL-CELL LUNG CANCER IN DAILY PRACTICE

Blommestein H[1], Groen H[2], Smit E[3], Thunnissen E[3], Uyl-de Groot C[1]
[1]*Erasmus University, Rotterdam, The Netherlands,* [2]*University Medical Center Groningen, Groningen, Groningen, The Netherlands,* [3]*VU University Medical Center, Amsterdam, Noord-Holland, The Netherlands*

OBJECTIVES: Lung cancer is the most common cause of cancer mortality in Europe. Gefitinib and erlotinib are two epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs) registered for patients with non–small-cell lung cancer (NSCLC). Patients with a positive EGFR-mutation benefit from first line treatment with EGFR-TKIs. However, since worse outcomes are observed among patients without the mutation, testing is crucial. Our study aims to investigate the use of diagnostics and treatment with EGFR-TKI of patients with NSCLC in daily practice. **METHODS:** We sent a semi-structured questionnaire to physicians and laboratories about EGFR-mutation tests and treatment strategies. Furthermore, sales numbers of gefitinib and erlotinib were obtained to calculate the number of patients treated with EGFR-TKI. **RESULTS:** Response covered more than two third of the Dutch lung cancer population. Approximately 70% of the patients, which should have been tested for EGFR-mutation, were tested. Sub-analyses revealed large re-

gional differences ranging from testing 44% to more than 100% of the eligible patients, implying overuse of diagnostic tests in the latter case. Moreover, there was a long waiting-time before results of EGFR-mutation tests were available (mean 11.9 days, SD 4.3 days). Considering treatment, on average about 45% of the eligible patients were treated with EGFR-TKI in the first line. Regional variation was observed ranging from 32% to 84%. Furthermore, extensive treatment variation was observed, which was not according to current clinical guidelines. **CONCLUSIONS:** The probability of testing patients for EGFR and treatments given varied considerably. This did not correspond with current clinical guidelines. Less than 50% of the eligible patients received EGFR-TKI in the first line. Reasons may be the long waiting-time for test results, physicians experience and individual patient characteristics. However, the large regional differences plead for optimal use of existing diagnostic and treatment strategies to improve outcomes for this patient group.

PCN160

PROSTATE CANCER SCREENING PRACTICES IN THE REPUBLIC OF IRELAND- THE DETERMINANTS OF UPTAKE

Burns R[1], Walsh B[2], Sharp L[3], O'Neill C[2]
[1]*National University of Ireland Galway, Galway City, Co. Galway, Ireland,* [2]*National University of Ireland Galway, Galway City, Co. Galway, Ireland,* [3]*National Cancer Registry Ireland, Cork, Cork, Ireland*

OBJECTIVES: To determine the extent of social inequality in uptake of prostate cancer screening in Ireland and compare inequalities across groups for whom the cost effectiveness of screening is thought to vary. **METHODS:** A series of decomposition analyses of inequalities in uptake of prostate cancer screening were undertaken using data collected as part of a large population based survey in the Republic of Ireland (SLAN 2007). Separate analyses were conducted for individuals differentiated by age on the basis of reported differences in the cost effectiveness of screening. A range of explanatory variables were used to explore the role of non-need factors in inequalities including education and possession of private medical insurance. **RESULTS:** Overall uptake of prostate screening in men aged 40 years and over in the preceding 12 months was 23.81%. Uptake was highest among those in the age group where the cost effectiveness of screening was deemed to be highest (based on the findings of the European Randomised Study of Prostate Cancer (ERSPC) trial). The lowest socioeconomic inequality was also observed among this age group. The decomposition of the concentration indices showed that possession of private insurance was the largest determinant of inequality among those 55-69 (36%) and remained a significant determinant among those aged 40-54 (26%) and aged 70 and over (17%). **CONCLUSIONS:** The decision to engage with screening is one likely to be taken in conjunction with a healthcare professional and reflect an assessment of the expected costs and benefits of screening to the individual. Where evidence as to the merits of screening is ambiguous and financial incentives to screen are evident patterns of uptake may emerge that does not represent an appropriate use of resources and warrant greater scrutiny. KEY WORDS: Prostate Cancer PSA Test Screening Incidence Diagnosis Concentration Indices Decomposition Analysis

PCN161

THE LOST ART OF NEEDS ASSESSMENT: THE CASE OF HEPATOCELLULAR CARCINOMA (HCC) CONTROL IN EUROPEAN COUNTRIES

Bridges JF[1], Gallego G[2], Joy SM[1], Blauvelt BM[3]
[1]*Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA,* [2]*Johns Hopkins University, Bloomberg School of Public Health, Baltimore, MD, USA,* [3]*University of Massachusetts, Hadley, MA, USA*

OBJECTIVES: The European Parliament called for a greater focus on viral hepatitis and hepatocellular carcinoma (HCC), yet there has been little action on this declaration. We conducted a needs assessment for HCC control and tested needs concordance in five European countries. **METHODS:** Clinical, policy and patient advocacy stakeholders were purposively sampled from France, Germany, Italy, Spain, and Turkey. Ten indicators were assessed subjectively: clinical education; early risk assessment; HBV strategy; HCV strategy; life-style risk factors; national statistics; funding for detection; funding for treatment; political awareness; and public awareness. Results were compared to a benchmark using a Z-score and concordance tested via the F-test. **RESULTS:** One hundred participants (response rate=37%) were drawn equally from the 5 countries. Respondents self-identified as having influence at the local (33%), national (39%), or international (28%) level. Greatest need is for improvement in life-style risk factors (Z=-9.51), political awareness (Z=-7.97), and public awareness (Z=-7.67), while the least need is for improved HBV strategies (Z=10.40). Overall, France performed best (Z=4.26), and Turkey worst (Z=-2.54). Significant discordances in needs ($P<0.05$) were found for half of the factors (funding for treatment and detection, public awareness, HBV strategy and national statistics), but concordance was accepted for the remaining factors. **CONCLUSIONS:** We demonstrated a statistical method for conducting a needs assessment for HCC control in Europe and found that the greatest needs are for improving life-style risk factors (especially related to obesity and diabetes) and political and public awareness. Despite being a cost-effective measure, HBV control strategies are needed the least (mainly due to prior adoption). With both concordant and discordant needs, there are roles for both national and European-wide efforts in HCC control. For example, the European parliament should lead efforts in driving political awareness and lifestyle risk factors, while member countries should focus on public awareness.

PCN163

FUNDING BY SHAS FOR RARER CANCERS IN ENGLAND: KEY SUCCESS FACTORS IN THE UPTAKE OF CANCER DRUGS FUND

Chaudhari SD[1], Kilby S[2]
[1]*PAREXEL International, Uxbridge, Middlesex, UK,* [2]*Surrey, West Sussex and Hampshire Cancer Network, Guildford, Surrey, UK*

OBJECTIVES: Overall 2506 patients gained access (from a total of 2880 applications) for oncology treatment from the Cancer Drugs Fund within the first 6 months of its launch. However, there are significant variations in the number of applications that different Strategic Health Authorities (SHAs) are able to process and approve. This study aims to assess the underlying reasons for the observed inter regional variability in the application rates, processing and outcomes within the Cancer Drugs Fund from October 2010 to March 2011. **METHODS:** The results on the application rates from an audit undertaken by Rarer Cancers Foundation using the Freedom of Information Act were analysed, especially, the change in application rate over time and the outcomes of these requests. The analysis led to the development of a framework to understand the key factors influencing the application rates and its outcomes, which was then validated through a telephone survey of key SHAs in 2011. **RESULTS:** Along with significant variations in the application rate, there appears to be a north-south divide, with SHAs in the south of England approving a lower proportion of applications. Some of the underlying reasons were identified to be linked with administration costs, levels of routine access to cancer treatments (which itself vary according to the area of the country) and 'timely' decision-making ability. **CONCLUSIONS:** Some of the notable practices identified towards expediting the processing of applications can form recommendations for robust process development in future for the upcoming clinical commissioning consortia to guide their commissioning activities. Future steps can include benchmarking of their application approval rates by clinical commissioning consortia (and SHAs until 2013) against that in other region and take action to identify the outliers and address the causes of this.

PCN164

DOES DIFFERENT AVAILABILITY OF ONCOLOGY CARE IS RESPONSIBLE FOR DIFFERENCES IN CANCER-RELATED MORTALITY RATES AMONG THE PROVINCES OF POLAND?

Macioch T[1], Paweska J[2], Niewada M[2], Hermanowski TR[1]
[1]*Medical University of Warsaw, Warsaw, Poland,* [2]*HealthQuest Sp.z o.o., Warsaw, Poland*

OBJECTIVES: Substantial differences in cancer-related mortality rates among the 16 provinces of Poland exist. Over the last 10 years the differences between the highest and the lowest observed standardized mortality rates varied at 33.9% to 54.2% in female population and at 24.1% to 40.9% in male population. The differences in mortality rates cannot be explained only by differences in cancer incidence rates among the provinces since weak correlation between both this values exist (Pearson's correlation r=0.33 and r=0.36 in male and female population, respectively). There are also substantial differences in availability of oncology care among the provinces since to some extent each of 16 regional departments of the National Health Fund (NHF) pursues its own health policy. The aim of this study was to estimate whether the differences in availability of oncology care are responsible for differences in cancer-related mortality among the provinces of Poland. **METHODS:** We used NHF data on contracts for oncology hospital and ambulatory care in 2008 and the National Cancer Registry (NCR) data on age-standardized mortality rates due to cancer in 2008. Data on hospital and ambulatory care and incidence data for each province were used to estimate availability of oncology care per cancer patient. Incidence data were used due to lack of cancer precise prevalence data. **RESULTS:** We have found no strict correlation between mortality rates and availability of hospital care with Pearson's correlation r=-0.01 and r=-0.05 in male and female population, respectively. Surprisingly weak positive correlations between mortality rates and availability of ambulatory care were found with Pearson's correlation r=0.36 and r=0.45 in male and female population, respectively. **CONCLUSIONS:** Further research, extended beyond simple relation between clinical outcomes and health care service financing is needed to explore inter-provinces variability. International Research Project on Financing Quality in Healthcare InterQuality, is aimed to address those discrepancies in health care.

PCN165

A FIRST ESTIMATE OF THE INCREMENTAL IMPACT OF MALES HPV VACCINATION ON HPV-RELATED DISEASES IN EUROPE

Bresse X[1], Largeron N[1], Marty R[2], Roze S[2]
[1]*Sanofi Pasteur MSD, Lyon, France,* [2]*HEVA, Lyon, France*

OBJECTIVES: Human Papilloma Virus (HPV) vaccination programs among women have been successfully implemented in Europe. Burden of HPV-related cancers is rising in Europe in men and represents around 30% of the overall HPV-related burden in both genders. Vaccinating girls have an indirect protective impact on males but doesn't avoid the whole HPV burden. Study objective was to have a first estimate of the incremental benefits of vaccinating males and females compared to females only, in Europe. **METHODS:** An Excel-based model was developed to estimate impact of vaccinating boys and girls with a quadrivalent-HPV6/11/16/18 vaccine on HPV-related diseases: anal, penile, head and neck, vaginal, vulvar and cervical cancers and genital warts. Epidemiological reductions due to vaccination were derived from a US dynamic transmission model. Epidemiological data and demographic inputs came from published literature. The analysis estimates the incremental clinical benefits of adding a cohort of 12-years old boys to a 12-years old girls vaccination program. Seventy percent vaccine coverage rates were assumed for both strategies. **RESULTS:** A validation of this model was achieved by being able to replicate US dynamic model results (number of cases avoided). In Europe, female-only vaccination would result in a 61% reduction in males HPV-related cancers (at steady state; 100 years). Adding a cohort of boys would increase this result to 86% and would avoid significant additional HPV-related diseases

(3,584 cancers, 88,514 genital warts annually). Head and neck cancers represent the majority of additional cancers avoided. Boys' vaccination would allow a further reduction in females' cases thanks to indirect protection. **CONCLUSIONS:** Model simulations were robust as they replicated US published results. This first analysis showed that vaccinating boys in addition of girls had the potential to prevent a significant number of additional cases. Country specific analysis will be useful to take into account different vaccination programs in place.

PCN166

PUBLIC ACCOUNTABILITY AND SOCIAL JUDGMENT IN THE REIMBURSEMENT DECISION FOR ONCOLOGY MEDICATIONS IN KOREA

Cho E, Kang M
Yonsei University, Seoul, South Korea

OBJECTIVES: Since the inception of economic evaluation for new drug reimbursement decisions in 2007, there have been modifications on this policy. While this reflects in itself the imperfect systematic adoption of economic evaluation from the beginning, it has been pointed out that the current scheme relying on the proof of cost-effectiveness value remains silent on crucial issues related to the opportunity cost from a system perspective and fair access to treatment. This study was aimed to discover how much social judgment was prudently considered in the reimbursement decision process especially for oncology medications in Korea. **METHODS:** Public review documents drawn by the Health Insurance Review and Assessment Agency on oncology medications were collected and analyzed to examine the concrete shape of public accountability. For external comparison, corresponding public documents presented by the Pharmaceutical Benefits Advisory Committee of Australia and the National Institute for Health and Clinical Excellence of UK were also pulled together and analyzed. Finally, not only clinical and economic evidence factors but also non-evidentiary factors such as equity and historical precedent revealed through the analytical works were discussed in depth by interviewing oncologists as representative stakeholders. **RESULTS:** Among 12 cancer drugs, five received positive decision from January, 2007 to June, 2009. Clinical study data and price of drugs seemed the mostly considered standard for reimbursement decision. The social judgment in this study implied the reconsideration on the following issues: 1) the composition of Drug Reimbursement Evaluation Committee; 2) the rationale of using cost-effectiveness data; 3) equity for rare cancer patients; 4) words clarity in public documents; 5) transparent decision process; and 6) budget impact results. **CONCLUSIONS:** Besides focusing on the improvement of technical evidence in HTA, a greater effort should be made for the reasonable decision process reflecting societal desirability, public agreement and judgments on social value.

PCN167

NATIONAL FORMULARY REVIEW OF THE DRUGS USED IN PANCREATIC NEUROENDOCRINE TUMORS IN KOREA

Lee YS[1], Park EJ[2]
[1]*Wonkwang University, Iksan, South Korea,* [2]*Sookmyung Women's University, Seoul, South Korea*

OBJECTIVES: Anti-cancer drug formulary has been managed by the government in Korea and needs to be updated for better clinical outcomes. This study was to evaluate current anti-cancer drug formulary focusing on pancreatic neuroendocrine tumors (PNET) and then propose the new formulary reimbursement criteria. **METHODS:** The drugs on the formulary and the drugs approved for the treatment of PNET were reviewed whether their use and reimbursement was appropriate in the view of the evidence-based approach. The oncology textbooks and clinical practice guidelines were reviewed also. PubMed search for the primary drug literature was performed with MeSH terms (pneuroendocrine tumors, pancreatic neoplasms, islet cell adenoma, islet cell carcinoma, and gastro-enteropancreatic neuroendocrine tumor) and the limits (clinical trial, and publication date to April 30, 2011). Published clinical research data were critically rated with the pre-determined literature evidence strength levels and the new formulary was proposed. **RESULTS:** Only one anti-cancer drug (sunitinib) was approved in Korea, although it was not proposed as a first-line in the clinical guidelines (NCCN, ESMO) and a textbook (Abeloff's). Although it was not on the national formulary list, a recently published randomized controlled phase 3 trial would support its use in a certain type of PNET as a primary chemotherapy. The already listed drugs revealed to be evidence-supported but with relatively weak strength levels. National formulary appeared to be reformulated with refined criteria (drug dosage and cancer types, etc). **CONCLUSIONS:** Sunitinib should be listed on the national anti-cancer drug formulary with a restricted reimbursement criteria of "treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumors with disease progression in adults" as described in the approved indication and pivotal clinical research data. Next step of the research of this area would be to examine clinical outcomes with this formulary change.

PCN168

COST-EFFECTIVENESS ANALYSIS OF DIFFERENT CERVICAL CANCER PREVENTION APPROACHES IN THE UNITED STATES

Qiao N, Noyes K, Dolan JG
University of Rochester School of Medicine and Dentistry, Rochester, NY, USA

OBJECTIVES: Cervical cancer is the third most common gynecologic cancer in the United States. Currently there are two proven approaches to cervical cancer prevention: conventional cytology screening and human papillomavirus (HPV) vaccination. Prevention guidelines recommend screening every one to three years after onset of sexual activity. In addition, many states have passed legislation to require mandatory HPV vaccination for school children. The study aims to compare the cost-effectiveness of HPV vaccination combined with conventional cytology screening versus HPV vaccination alone on cervical cancer prevention in the US. **METHODS:** A decision tree was used to estimate the lifetime costs (in 2004 US$) and outcomes for U.S. women receiving HPV vaccination or mandatory HPV vaccination combined with conventional cytology screening from the societal perspective. The costs and epidemiological data were derived from published literature and health institution websites. Outcomes included life expectancy and quality-adjusted life years (QALYs) gained. **RESULTS:** The incremental cost-effectiveness ratio (ICER) for HPV vaccination combined with the triennial screening compared to vaccination alone was $251,965 per QALY gained. The result was most sensitive to the total costs of conventional cytology screening. When the total costs of conventional cytology screening varied from $30 to $319, the ICER increased from $98,669 to $1,006,860 per QALY gained. When increasing the frequency of screening to biennial and annual, the ICER of HPV vaccination combined with screening compared to vaccination alone changed to $335,533 and $592,991 per QALY gained respectively. **CONCLUSIONS:** These results indicate that conventional cytology screening provides little benefit beyond that provided by HPV vaccination. They suggest that routine cytology screening should no longer be recommended for women who have been successfully vaccinated.

PCN169

DIFFERENCES IN THE USE OF INNOVATIVE ANTI-CANCER DRUGS AMONG FRENCH HOSPITALS

Bonastre J[1], Chevalier J[2], Van der Laan C[3], Delibes M[4], De pouvourville G[5]
[1]*Institut Gustave Roussy, Villejuif Cedex, France,* [2]*ESSEC Business School, Cergy Pontoise, France,* [3]*GERS SAS, BOULOGNE BILLANCOURT, France,* [4]*HosMedis, Issy Les Moulineaux Cedex, France,* [5]*ESSEC Chair of Health Economics, Cergy-Pontoise, France*

OBJECTIVES: Expensive hospital anti-cancer drugs are funded separately from the activity-based payments. Reimbursement tariffs are set for a list of drugs including a large proportion of anti-cancer drugs. This funding aims to ensure equity of access to innovation throughout the French territory. Our objective was to describe the use of the expensive anti-cancer drugs in French hospitals and to investigate whether differences existed between the public and private sector and between regions. **METHODS:** We used a sample of 448 hospitals authorized to deliver chemotherapies. The Groupement pour l'Elaboration et la Réalisation de Statistique provided the sales per drug and per hospital in the year 2008. Hospital characteristics were extracted from two national surveys (Programme de Médicalisation des Systèmes d'Information and Statistique Annuelle des Etablissements de santé). We conducted a multilevel analysis. The dependent variable was the mean expenditure per chemotherapy session and per hospital. Independent variables were hospital capacity, the volume of activity, case-mix for chemotherapies and the percentage use of biological drugs. At the regional level, we used the mean annual wage, inequality of wage distribution, the density of general practitioners, cancer incidence and mortality. **RESULTS:** The sales of anti-cancer drugs were estimated at 1713 million Euros. The mean expenditure per chemotherapy session was € 923 [CI: 890-954]. It was significantly higher in the private sector: €970 versus €891, p=0.02. At the hospital level, a case-mix of specialized chemotherapies for breast cancers and the percentage use of biological drugs were associated with a higher expenditure of anti-cancer drugs per session. There were no differences between the mean expenditures per region. **CONCLUSIONS:** The absence of disparities in the use of anti-cancer drugs between regions suggests that the reimbursement tariffs have promoted equal access to innovative treatments throughout the territory.

PCN170

DIRECT COSTS OF HEAD AND NECK CANCER IN THE US: AN ANALYSIS USING 2008 MEDICAL EXPENDITURE PANEL SURVEY (MEPS) DATA

Rascati ME[1], Park H[2], Rascati KL[2]
[1]*Texas Hospital Association, Austin, TX, USA,* [2]*University of Texas at Austin, Austin, TX, USA*

OBJECTIVES: To estimate direct annual healthcare utilization and costs of for patients with head and neck cancer. **METHODS:** The 2008 Medical Expenditure Panel Survey (MEPS) database, a nationally representative annual survey of the civilian non-institutionalized population of the U.S was used. Patients' data were extracted if they had a Clinical Classification Code (CCC) for head and neck cancer (code 11) and International Classification of Disease 9 (ICD-9) code of 140.xx-149.xx or 160.xx-161.xx. The SURVEYREG procedure in SAS for weighted populations was used. **RESULTS:** Only 17 patients (representing 223,263 persons) met inclusion criteria, therefore weighting may not be robust. Direct unweighted medical costs attributable to cancer were estimated at $6,171 + 11,288 (mean ± standard deviation) per patient. Approximately half ($ 2860 + 6399) of this estimate was generated by outpatient costs. Physician office visits ($1,609 +4,291) and inpatient hospital visits ($1225+ 5054) contributed to most of the remaining costs. If MEPS weightings were used, the total costs were estimated at $ 8629 - again with about half generated by outpatient costs, and the majority of remaining costs split between office visits and hospitalizations. Since MEPS only provides 3 digits of the 5-digit ICD-9, some patients may have been missed as we did not include some ICD9s listed by CCC 11; such as 195.xx "Malignant neoplasm of other and ill-defined sites" nor 230.xx "Carcinoma in situ of digestive organs" which included some cancers related to the head and neck (e.g. 230.0 - Carcinoma in situ of lip oral cavity and pharynx) as well as others not related to these areas (e.g. 230.3 - Carcinoma in situ of colon). **CONCLUSIONS:** The sample size was small in this database. Future studies should be conducted using databases with more patients and/or a more precise level of diagnosis coding.

PCN171

UNDERLYING CAUSES FOR SUB-OPTIMAL UTILISATION OF CANCER DRUGS FUNDS IN ENGLAND

Viejo Viejo I[1], Kilby S[2]
[1]PAREXEL INTERNATIONAL, Uxbridge, UK , [2]Surrey, West Sussex and Hampshire Cancer Network, Guildford, Surrey, UK

OBJECTIVES: According to a report from the Rarer Cancers Foundation of England, within the first six months of the launch of the Cancer Drugs Fund in England, only £ 27,437,466 were used while the total amount allocated for the same period was £50,000,000. This means that only a 56% of allocated funds for that period were used. In a health system that restricts access to those oncological treatments that have not shown to be cost-effective or have not been assessed by NICE a more optimal use of the available funds would have been expected. In this study the authors try to explore and determine the possible underlying reasons for the observed underspent of allocated budget within the Cancer Drugs Fund in England from October 2010 to March 2011. **METHODS:** Interviews were conducted across different SHAs (Strategic Health Authorities) in England (n=5) in 2011. A specific questionnaire was designed to conduct this research **RESULTS:** Majority of respondents mentioned delays in application for drug funding, miscalculation of expected number of application by clinicians, among other reasons for underspent of Cancer Drugs Fund **CONCLUSIONS:** SHAs should make sure that funds are properly allocated and used in the benefit of patients and no application should be rejected in the basis of an economic reason but just on pure clinical reasons

PCN173

CANCER INCIDENCE EVALUATION AND PATHWAY IDENTIFICATION FOR TREATMENT COURSE DETECTION USING BILLING DATA FOR AUSTRIA

Zauner G[1], Einzinger P[2], Endel G[3], Breitenecker F[4]
[1]Dwh Simulation Services, Vienna, Austria, [2]Dwh Simulation Services, Vienna, Vienna, Austria, [3]Main Association of Austrian Social Security Institutions, Wien, Wien, Austria, [4]Vienna University of Technology, Vienna, Austria

OBJECTIVES: Analyzing the cancer incidence and TNM – classification is done by national statistic in high spatial resolution, but no detailed data regarding pre-existing illnesses and treatment pathways are gathered. That is why these problems are focused on using billing data from extramural and intramural anonymised patients datasets extended by drug prescription information. **METHODS:** Starting with anonymized single person spatio-temporal hospital data including diagnoses coded by ICD10, medical attendance data and patient identity key a pre-selection is realized. In the next step the intramural patient history is focused on, detecting the first indicated hospitalization. Afterwards criteria for the number of reuptakes as well as for exclusion of cases (filtering not new diseases) are defined based on the intramural patient history. Analyzing cancer indicated drug administration and drug prescription the year before the first hospitalization, knowledge about risk groups is collected and evaluated. Additionally the probability of surviving regarding different treatment courses is measurable. These calculations are done exemplary. **RESULTS:** Comparing the incidences calculated out of casemix datasets for liver cancer, lung cancer and mamma carcinoma high accordance comparing to cancer registry of Austria is observed. In case of liver cancer the overall deviation is 14 cases per year; equal to a difference of 1.5 percent. In case of mamma carcinoma 4882 detected new infections in control year 2007 are faced with 4833 new cancer diseases registered by national statistics. **CONCLUSIONS:** Using detailed single person spatio-longitudinal billing datasets in combination with extended search strategies using exclusion criteria based on expert knowledge as well as data structure information and modeling skills, highly reliable datasets are edited. The analyzed background knowledge can be used in modern dynamical simulation models producing reliable results.

PCN174

VARIATIONS IN DRUG ADMINISTRATION COSTS FOR STAGE III/IV NSCLC IN EUROPE

Rosery H[1], Zerwes U[2], Walzer S[3]
[1]AiM GmbH - Assessment in Medicine, Research and Consulting, Loerrach, Germany, [2]AiM GmbH, Assessment-in-Medicine - Research and Consulting, Loerrach, Germany, [3]F. Hoffmann-La Roche Pharmaceuticals AG, Basel, Switzerland

OBJECTIVES: European payer authorities reimburse the administration of anticancer agents for mNSCLC patients according to diverging tariffs and varying codes. This poses the question of whether there is the need for a sensitivity analysis of administration costs in health economic models when applied in France, Germany, Italy, Spain, and the UK. **METHODS:** Two systematic literature reviews of the bibliographic database Medline were performed in order to identify relevant publications (of year 2000+) on administration costs of chemotherapy for the treatment of NSCLC. The review was supplemented by a search in the databases of the Cochrane Library, EMA-EPAR, and ClinicalTrial.GOV. In addition, treatment guidelines, reimbursement databases, and national reimbursement tariffs were hand-searched. Semi-structured interviews with expert oncologists were completed. Data extraction and evidence synthesis from these sources formed the basis of this evaluation. **RESULTS:** Twenty-three manuscripts, 108 phase III study protocols, 6 EMA-labels, and 12 European treatment guidelines were included in the analysis. The ten NSCLC antineoplastic drugs mentioned in the ESMO and NCCN guidelines cover a wide set of administration patterns with respect to 1st or 2nd line monotherapy, combination therapy, and mono-or combination-maintenance therapy. The treatment schedules vary in dose per application, composition per cycle, and number of cycles. The main tariff for France is GHS 9606/GHM 28Z07Z (€386), for Germany daycase DRG 71B (€720) and several separate agreements ("Onkologievereinbarung") and for the UK daycase HRG SB97Z+SB13Z (£399). For Italy and Spain the actual DRG values vary tremendously, for instance in Italy for DRG410 (€310 for Emilia Romagna vs. €40 for Basilicata), and in Spain C.6 for Galicia (€170) or 1.7.2.2 for Asturia (€149). **CONCLUSIONS:** The difference in treatment schedules in combination with the variation in national administration tariffs shows the importance of a sensitivity analysis when conducting a health economic analysis of NSCLC administration costs in Europe.

PCN175

REIMBURSEMENT OF ANTICANCER DRUGS IN CANADA: WHAT CAN WE LEARN FROM THE NICE NEW APPRAISAL PROCESS FOR LIFE-EXTENDING END-OF-LIFE TREATMENTS?

Cooper D[1], Tarride JE[2], Goeree R[2]
[1]Institut National d'Excellence en Sante et en Services Sociaux (INESSS), Quebec, QC, Canada, [2]McMaster University, Hamilton, ON, Canada

OBJECTIVES: In January 2009, the National Institute for Health and Clinical Excellence (NICE) adopted an evaluation process for life-extending end-of-life treatments. For eligible drugs, QALYs are weighted to favour the incremental cost-utility ratios (ICUR). Also, patient access scheme (PAS, pricing agreements) are sometimes established between the NHS and drug manufacturers to lower the economic impact of costly drugs. The purpose of this study was to document the effects of the end-of-life evaluation process (EOL) on anticancer drugs listing recommendations. **METHODS:** NICE website was searched to identify published technology appraisal guidances of anticancer drugs issued between January 2009 and May 2011. We documented EOL and PAS status, the listing recommendation and the supporting ICURs. Positive and negative recommendations were stratified by EOL and PAS status. **RESULTS:** We retrieved 32 recommendations among which 50% were approvals. The proportion of accepted drugs tends to be higher among those evaluated with the EOL (9/16; 56%, p=0,8). The ICURs of positive recommendations associated with drugs not eligible or not considered for the EOL were mostly comprised between 20,000£/QALY and 30,000£/QALY gained. On the other hand, ratios of positive recommendations for drugs eligible to the EOL were higher and varied from 30,350£/QALY to 54,366£/QALY gained. Among drugs evaluated with the EOL, the proportion of accepted drugs analysed with PAS (6/9; 67%, p=0,51) tends to be higher than for drugs accepted without PAS. **CONCLUSIONS:** Despite the small number of evaluations since its implementation, we observed with the EOL a higher ICUR threshold that may have led NICE to recommend to list more anticancer drugs that it would have been without the EOL. When the EOL was considered, PAS also seems to have contributed to a higher rate of positive listing. These findings have raised questions about the economic evaluation of anticancer drugs in Canada.

PCN176

CANCER DRUG PRICES IN THE UNITED STATES AND THE UNITED KINGDOM: IMPLICATIONS FOR PRICING STRATEGY AND DRUG ACCESS

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: To understand relative price differential for cancer drugs in the US and the UK. Develop implications for pricing strategy and patient access for cancer drugs. **METHODS:** Ten branded cancer drugs were selected and their prices for similar dose and packaging were compared in the US and the UK. Prices were analyzed for the end of 2010 and early 2011. Historical exchange rates were used to convert British pounds to US dollars. Relative price discount was calculated for all selected cancer drugs. KOLs and payers were interviewed to understand current and future implications of this price differential. **RESULTS:** The median price discount for selected ten branded cancer drugs in the UK versus the US was ~50%. The range of discount for 10 branded cancer drugs was 27%-61%. The price discount for oral small molecule drugs was higher than for biologics (55% versus 45%). Since UK is one of the few remaining free pricing markets in Europe, other European markets are likely to have even higher discounts relative to the prices in the United States. Due to rising coinsurance of speciality products, US cancer patients bear significantly higher cost than patients in the UK. KOL and payer interviews suggest US pricing trends for cancer drugs are unlikely to be sustained at this level in the future. **CONCLUSIONS:** US cancer drug prices are significantly higher than the prices in the UK. This price differential is unlikely to be sustained in the future.

PCN177

ASSESSMENT OF REIMBURSEMENT PROCESSES AND OUTCOMES FOR CANCER DRUGS IN CROATIA – COMPARISON TO NICE AND NCCN GUIDELINES

Vitezic D[1], Vrdoljak E[2], Bolanca S[3]
[1]University of Rijeka Medical School and University Hospital Centre Rijeka, Rijeka, Croatia, [2]University Hospital Center Split, Split, Croatia, [3]CARPC (Croatian Association of Research Based Pharmaceutical Companies), Zagreb, Croatia

OBJECTIVES: Objective of this study was to assess reimbursement outcomes and patient access to oncology drugs in Croatia. National Institute of Clinical Excellence (NICE) cancer guidelines and National Comprehensive Cancer Network (NCCN) guidelines were used as benchmark. NICE is known for being committed to complying with legal obligations on equity and human rights, conducting their work based on identified cost effectiveness thresholds and known to be restrictive in their recommendations. On the other hand, NCCN professional guidelines are key international guidelines for oncology professionals which have been accepted and followed worldwide. **METHODS:** Reimbursement processes, specific indications and restrictions for 23 studied cancer drugs, ATC L01 class (antineoplastic agents) have been analyzed and compared to UK NHS funding and reimbursement recommendations given through NICE cancer guidelines as well as recommendations given through NCCN guidelines. **RESULTS:** Studied cancer drugs were used for the treatment of 14 different tumor locations: breast, colon, lung, leukemia, renal, GIST, ovary, lymphoma, glioblastoma, prostate, liver, gastric, myeloma. Among 57 registered indications, Croatian Health Insurance Fund has in total reimbursed 43 (75%) while NICE has issued positive recommendations for only 35 (60%). On the other hand, all investigated drugs and relevant indications except of one partially

have been recommended by NCCN guidelines. At the same time, we identified many instances where the recommendations given by the NCCN guidelines have not been endorsed by HZZO. **CONCLUSIONS:** Considering process related inconsistencies and consequential differences in reimbursement outcomes and patient access to cancer drugs in Croatia compared, there is a strong need for the expedited implementation of transparent HTA processes for cancer drugs. Multiple technology assessments of the main indication groups and the highest cost drivers are highly needed to ensure the full transparency of the reimbursement system and the equity of patients' access to the treatment options irrespectively of the disease.

PCN178

REIMBURSEMENT OF CANCER DRUGS IN THE UK: NEW APPROACH TO END-OF-LLIFE TREATMENTS AND THE TECHNOLOGY APPRAISAL PROGRAMME OF NICE

Corbacho B[1], Pinto JL[2], Navarro JA[1]
[1]*Andalusian Agency for Health Technology Assessment, Seville, Seville, Spain,* [2]*University Pablo de Olavide, Seville, Seville, Spain*

OBJECTIVES: Determine the impact of new end of life criteria on reimbursement decisions of cancer drugs appraised by NICE. **METHODS:** Review of Single and Multiple Technology Assessments on cancer treatments appraised by NICE from January 2009 to April 2011. **RESULTS:** NICE appraised 30 cancer treatments. 16 were recommended with restrictions and 13 were not recommended. The reason for not recommending was poor cost effectiveness (7) and lack of evidence (6). The Committee considered the impact of giving a greater weight to QALYs achieved in the later stages of terminal diseases in nine of the positive recommended drugs. End of life criteria were considered when the most plausible ICERs fall above the threshold normally considered as cost-effective. End of life criteria were not taken into account when the appraised drugs had ICERS below £30,000 per QALY gained (6 cases) or when it resulted in cost saving for the NHS. When ICERs estimates exceeded what NICE considers a reasonable use of NHS resources for the whole population covered by the marketing authorisation the Committee discussed whether the magnitude of weight required for the ICER to be in a cost effective range was acceptable in special subgroups of population. **CONCLUSIONS:** The discussion of end of life criteria was straight forward when the new drug provided a marked change in the treatment of the disease or its high price was compensated by a patient access scheme agreement. On contrary, it was more difficult to decide whether survival benefits offered the extension of life required in order the supplementary advice to be considered. The supplementary advice facilitated the appraisal process of cancer drugs however the Committee had to make judgments to interpret the incomplete evidence in order to decide what is good for patients and who can benefit from new cancer treatments.

PCN179

CLINICAL TRIALS IN ONCOLOGY IN GREECE

Mylona K, Kyriopoulos J
National School of Public Health, Athens, Greece

OBJECTIVES: Reducing the burden of cancer through interventions based on clinical trials remains an important strategy of oncology research. Public access to information on clinical trials increases transparency of medical research and helps patients to find information. The aim of this study was to investigate the number of clinical trials in oncology carried out in Greece. **METHODS:** We searched the EU Clinical Trials Register website. We analyzed the trends regarding the number of approved by the National Organization for Medicines trials in a 7-year basis. We also examined the number of trials by the type of cancer, the Phase and the status of the trial and the trends in funding. In our survey we included only Phase II and Phase III interventional trials, recruiting by adults and elderly, both men and women, between 2004-2010. **RESULTS:** Greece ranks 14th among EU countries for the clinical trials conducted in oncology, as 24,29% of all clinical trials carried out in Greece concern cancer. Since 2004, 44 Phase II and 95 Phase III trials were approved, the majority of which were related to target therapies of breast cancer (21.73%) and non-small cell lung cancer (21.01%). 81.88% are still ongoing trials, 6.52% have been completed while there is no feedback about the results. Finally, in Greece the main sponsor in clinical research is industry (88.4%) while only 11.59% is funded by research institutes. **CONCLUSIONS:** Although in Greece there is significant clinical investigation in oncology, the need for the development of a new framework as well as a well organized network that will inform key stakeholders, reduce bureaucracy and increase the number of clinical trials remains and calls for international cooperation.

PCN180

THRESHOLD VALUES FOR COST-EFFECTIVENESS IN AHTAPOL AND NICE FOR CANCER DRUG TECHNOLOGIES

Kiljan A, Kolasa K, Hermanowski T
Department of Pharmacoeconomics, Medical University of Warsaw, Warsaw, Poland

OBJECTIVES: To identify empirical threshold values for cost-effectiveness on the basis of past decisions in Agency for Health Technology Assessment (AHTAPol) in Poland and National Institute for Health and Clinical Excellence (NICE) in the UK for cancer drug technologies. **METHODS:** Review of recommendations issued by AHTAPol and NICE for cancer drug technologies was performed. Period under investigation was August 2007 to March 2011 for AHTAPol and March 2000 – March 2011 for NICE. To identify empirical threshold values in both agencies, a comparison of ICER cost/QALY and past decisions was made. **RESULTS:** In the studied period AHTAPol and NICE issued, respectively, 44 and 54 recommendations for cancer drug technologies. Negative recommendations prevailed in Poland (43%). Most common recommendations in NICE were positive recommendations with major restriction (39%).The most commonly used measure of cost-effectiveness in NICE was ICER cost/QALY (41 recommendations) while in Poland it was identified only in 16 recommendations. As a result of a comparison of ICER cost/QALY and past decisions empirical threshold values in both agencies were not identified. In Poland four positive recommendations with restrictions and 9 negative ones were placed above official AHTAPol's threshold. In the same time, only 3 positive recommendations with or without restriction were below the threshold. In NICE, 17 positive recommendations with or without restrictions and 11 negative ones were above the official threshold value of £30,000/QALY. Below this threshold, there were 13 positive recommendations with or without restrictions. **CONCLUSIONS:** AHTAPol, as well as NICE, don't have definite empirical cost-effectiveness threshold values for cancer drug technologies. The official threshold values set in both agencies are not respected in the case of cancer drugs. Implementation of additional guidelines for "end-of-life" treatment in NICE may have potential impact on decisions concerning cost-effectiveness of cancer drug technologies.

PCN181

THE HEALTH RELATED QUALITY OF LIFE DATA (HRQOL) FOR HEALTH TECHNOLOGY ASSESSMENT (HTA) PROCESS IN EUROPE: THEIR UTILIZATION AND IMPACT ON OPINIONS ACROSS HTA AGENCIES

Stamenkovic S
Haute Autorité de Santé, Saint Denis La Plaine Cedex, France

OBJECTIVES: After marketing authorization, European HTA agencies may take HRQoL data into account to support reimbursement. We want to explore here how HRQoL have been included into HTA process and what their impact was on reimbursement decisions. **METHODS:** Initially, we've analyzed French HRQoL data on oncology drugs to assess quality, type and impact of these data on the reimbursement opinions made by the French National Autority (HAS). In the second stage, we have performed a qualitative analysis to explore the main similarities and differences across HTA bodies in assessment of HRQoL to support reimbursement. **RESULTS:** First stage: since 2008, 23 files were assessed by HAS. HRQoL data were available for 11 oncology drugs; for 3 drugs HRQoL data were not taken into account (open trial or missing data). For 5 drugs, no difference in HRQoL (on EORTC QLQ-C30) was observed and in 3 cases, change in HRQoL might have had an impact on final decisions.Second stage: more and more often HRQoL data are included into files submitted for HTA and their quality is gradually improving over time. However, confusion still remains between functional measures and HRQoL. Some countries only consider HRQoL data from randomised clinical trials. For other countries, data from observational studies may also be of interest to provide additional information in real conditions of use. In addition, many countries consider utility measures as one of HRQoL. In all cases, HRQoL remains a secondary endpoint in relative effectiveness assessment (REA) process. **CONCLUSIONS:** In Europe, the impact of HRQoL on reimbursement decisions could be enhanced if the quality of data increases. Our analysis confirms the interest of the ongoing work on the EUnetHTA guideline that should help assessors of European HTA agencies deal with HRQoL and contribute to the harmonization of HRQoL definitions and use across agencies.

PCN182

WHAT KIND OF CHANGES DID THE PUBLICATION OF TWO LARGE-SCALE RCTS LEAD TO IN PROSTATE CANCER SCREENING GUIDELINES?

Hamashima C
National Cancer Center of Japan, Tokyo, Japan

OBJECTIVES: Although prostate-specific antigen (PSA) screening is conducted worldwide, its effectiveness in reducing mortality from prostate cancer has remained controversial. In March 2009, intermediate results from the European Randomized Study of Screening for Prostate Cancer (ERSPC) and the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial were released. However, the results of the two studies were inconsistent: the PLCO trial demonstrated no benefits to screening, whereas the ERSPC study reported a 20% reduction in prostate cancer mortality. We found and compared the assessment of the two RCTs in guidelines, evidence reports and statements. **METHODS:** A search was performed from March 2009 to May 2011 using MEDLINE, the Guideline International Network library and the National Guidelines Clearinghouse to identify guidelines, evidence reports and statements which have evaluated the two RCTs. Additional reports recommended by experts were also included as needed. The changes in the revised guidelines, evidence reports and statements were compared. **RESULTS:** Four guidelines, two evidence reports and one statement matching our criteria were found, but none contained any change in basic recommendation for PSA screening. In addition, the American Society of Clinical Oncology evaluated the results of the two studies in their review for major research in 2009. Although the American Urological Association recommended PSA screening for men 40 years of age and over, in other guidelines, PSA screening was not recommended for asymptomatic persons. Most of the US reports were for opportunistic screening and pointed out the necessity of shared decision-making for PSA screening. The European Urological Association and the UK-NHS Cancer Screening Committee did not recommend PSA for population-based screening. In contrast, the Japanese Urological Association strongly recommended PSA screening in communities. **CONCLUSIONS:** Even after the releases of two RCTs results, most reports have not revised their assessment of PSA screening.

PCN183

A POPULATION-BASED REGISTRY FOR THE EVALUATION OF NEW TREATMENT OPTIONS FOR PATIENTS WITH METASTATIC RENAL CELL CARCINOMA

De groot S[1], Redekop W[1], Kiemeney L[2], Uyl-de Groot C[1]
[1]*Erasmus University Rotterdam, Rotterdam, The Netherlands,* [2]*Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands*

OBJECTIVES: Through advances in molecular biology, new treatment options for patients with metastatic renal cell carcinoma (RCC) have become available. Although the efficacy of these new treatments has been demonstrated in large randomised controlled trials, their effectiveness in daily practice is currently unknown. The aim of this study was to evaluate the use of new treatment options for patients with metastatic RCC in Dutch daily practice. **METHODS:** A population-based registry has been created to collect data about patients diagnosed with metastatic RCC in 2008, 2009 and 2010. This registry contains data on patient and tumour characteristics, treatment details (e.g., dosing) and response to treatment. All patients living within the regions of four Dutch Cancer Registries are being included in this study. Together these registries cover 55% of The Netherlands. **RESULTS:** Forty-three patients, all diagnosed with metastatic RCC in 2008, are currently included in our registry. Of these, 47% received systemic therapy (mostly sunitinib), while all others received surgery or palliative care. Patients treated with sunitinib in Dutch daily practice were five years older and had a worse ECOG performance status than patients treated with sunitinib in the pivotal phase 3 trial. While the mean daily dose seen in Dutch daily practice in the first cycle was comparable to the recommended dose (50 mg), the mean daily dose in the second cycle was lower, i.e. 44 mg. **CONCLUSIONS:** The number of Dutch patients with metastatic RCC treated with systemic therapy will increase because of new treatments available since 2008. This study suggests that patients treated with systemic therapy in daily practice have a different profile and receive different dose schedules than patients treated in the pivotal trial. Consequently, the effectiveness of the new treatment options in Dutch daily practice may also differ from what was seen in the trial.

PCN184

TRENDS IN CHEMOTHERAPY AND BIOLOGIC TREATMENT OF US COLORECTAL CANCER PATIENTS

Meyer N, Weldon D, Huse DM
Thomson Reuters, Cambridge, MA, USA

OBJECTIVES: To examine trends in chemotherapy and biologic regimens used in 1st, 2nd and 3rd line treatment of patients with colorectal cancer (CRC) in the US. **METHODS:** Adult patients newly diagnosed with CRC from January 1, 2005- December 31, 2009 were selected from the Thomson Reuters MarketScan® Commercial and Medicare Supplemental insurance claims databases. Patients were required to have at least one cycle of chemotherapy and were followed from the administration of the first dose until the end of continuous insurance coverage or December 31, 2009, whichever came first. Evolution of first-, second-, and third-line treatments from 2005 to 2009 is described. **RESULTS:** A total of 13,670 patients met the study criteria. All had data on first-line treatment, 4,442 on second line, and 1,610 on third line. The most common first-line regimens were 5-fluorouracil (5-FU), 5-FU and leucovorin (5-FU/LV), 5-FU/LV plus oxaliplatin (FOLFOX), and capecitabine. Between 2005-2009, first-line use of FOLFOX increased from 25% to 35%, while use of 5-FU/LV decreased from 18% to 7%. Second-line regimens were more diverse with the most prevalent regimens being FOLFOX alone, FOLFOX plus bevacizumab, 5-FU/LV, and 5-FU/LV plus irinotecan (FOLFIRI) plus bevacizumab. Use of 5-FU/LV as second-line treatment decreased from 12% in 2005 to 4% in 2009 as patients received more diverse treatments. Between 2005-2009, third-line standard of care moved toward biologic-containing regimens including FOLFIRI plus bevacizumab and irinotecan plus cetuximab. Use of biologic regimens increased with each therapy line and over time with 73% of third-line regimens in 2009 containing at least one biologic compared with 57% in 2005. **CONCLUSIONS:** Over time the standard of care chemotherapy for first-line CRC therapy has shifted away from 5-FU/LV to FOLFOX, second line from 5FU/LV to more diverse treatments, and third line therapy toward biologic containing regimens. Use of biologic regimens increased with subsequent therapy line and over time.

PCN185

A MULTI-COUNTRY RETROSPECTIVE STUDY OF PATIENT CHARACTERISTICS AND TREATMENT PATTERNS IN CHRONIC MYELOID LEUKEMIA

Mitra D[1], Trask PC[2], Iyer S[3], Candrilli SD[1], Kaye JA[4]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*Pfizer Inc., Groton, CT, USA,* [3]*Pfizer Inc, New York, NY, USA,* [4]*RTI Health Solutions, Waltham, MA, USA*

OBJECTIVES: To examine patient and disease characteristics and treatment patterns among patients with chronic myeloid leukemia (CML) in multiple countries. **METHODS:** Oncologists and hematologists in the United States (US), UK (UK), Germany, and Japan abstracted medical charts of adult patients with CML between January 1, 2005 and December 31, 2009. Patients were in chronic phase at diagnosis, either Ph or BCR-ABL positive, had received first line treatment with imatinib, and had not participated in a randomized clinical trial for CML. A subset of patients received 2nd-line therapy with nilotinib or dasatinib. **RESULTS:** A total of 214 physicians provided data on 1,063 patients (range 220 – 300 per country). Patients were 55 years of age on average and 60% were male. Nearly 67% of patients did not have any comorbidity, although when present, diabetes was most common in all countries (5% in Japan to 18% in Germany). Patients initiated imatinib within 3 months after diagnosis, and received therapy for 22 months on average (19 months [US] to 25 months [Japan]), at a median daily dose of 400mg in all countries. Approximately 13% of patients (8% in Japan to 16% in UK) had a dose escalation to a median dose of 800mg. 29% of patients discontinued imatinib, primarily due to resistance to therapy or disease progression. 2nd-line treatment patterns were studied among 261 patients (148 dasatinib, 113 nilotinib). Patients in the US and Germany had more nilotinib use (54%) while only 17% of UK patients used nilotinib. Patients initiated 2nd-line therapy 25 months after initial diagnosis, and received treatment for 11 months (dasatinib) or 7 months (nilotinib). More patients initiating dasatinib had advanced disease (25% accelerated, 4% blast phase) compared to nilotinib (25% accelerated, <1% blast phase). **CONCLUSIONS:** Patient characteristics and treatment patterns in CML vary by country.

PCN186

AN EPIDEMIOLOGICAL EVALUATION OF CHEMOTHERAPY USED IN THE TREATMENT OF METASTATIC PROSTATE CANCER

Chevalier P[1], Moeremans K[2]
[1]*IMS consulting group, Vilvoorde, Belgium,* [2]*IMS Health, Brussels, Belgium*

OBJECTIVES: This retrospective study aimed at collecting real-life data regarding chemotherapeutical treatments administered for metastatic prostate cancer in Belgium. **METHODS:** From the Hospital Disease Database (year 2008), which includes data on full hospitalizations and day clinic for 34.3% of Belgian hospital beds, stays of patients with metastatic prostate cancer were selected based on the combination of ICD-9-CM codes for prostate cancer (185) and metastasis (196-197-198-199). Chemotherapy sessions were identified using the ICD-9-CM code V58.1. Identification of chemotherapeutical regimens was based on drug names. In addition, grade III/IV haematologic toxicities were identified using ICD-9-CM codes. **RESULTS:** Among the 1171 patients identified with metastatic prostate cancer in 2008, 387 (≈ 33%) were administered chemotherapy. The total number of chemotherapies administered was 521; 272 patients (70.3%) received only one regimen, 97 (25.1%) received two different regimens, 17 (4.4%) and 1 (0.3%) patient received respectively three and 4 regimens during the year. For 38.7% of chemotherapies, the regimen could not be identified. These may represent chemotherapies administered in clinical trial or compassionate use setting. 201 (51.9%) of chemotherapy patients received at least one docetaxel-containing regimen. 194 (50.1%) received docetaxel monotherapy and 10 (2.6%) received docetaxel in combination with another chemotherapeutical agent. The second most commonly identified regimen was mitoxantrone monotherapy, administered to 39 patients (10.1%): 22 of them had received prior docetaxel within the same calendar year. The average number of cycles was 5.83 for docetaxel and 3.27 for mitoxantrone. Other chemotherapy regimens included carboplatin-, fluorouracil- and cisplatin-containing regimens (respectively 4.9%, 3.9% and 2.6% of patients). Among the patients treated with chemotherapy, 21 (5.4%) developed (febrile) neutropenia, 90 (23.3%) had anemia and 37 (9.6%) had thrombocytopenia. **CONCLUSIONS:** This study shows that real-life practice is in line with the European guidelines, recommending docetaxel as first option for chemotherapy in metastatic prostate cancer.

PCN187

TREATMENT PATTERNS IN PATIENTS WITH METASTATIC MELANOMA

Zhao Z, Wang S, Barber B, Gao SK, Wagner V
Amgen, Inc., Thousand Oaks, CA, USA

OBJECTIVES: To describe treatment patterns in patients with metastatic melanoma (MM) in the US. **METHODS:** Using a large US medical claims database, patients were identified between 2005 and 2010 using ≥2melanoma diagnoses (ICD-9-CM: 172.xx, V10.82) and ≥2 diagnoses for metastasis (ICD-9-CM: 197.xx, 198.xx). The index date was the first date of metastasis diagnosis. Patients who had other primary malignant tumors prior to the melanoma diagnosis, were younger than 18 years old at the index, or had a pre-index period of less than 6 months, were excluded from the analysis. Patients were followed from the index date to death, disenrollment, or end of the study period (June 30, 2010), whichever occurred first. Drug, surgery, and radiation therapy were examined descriptively. The trend of treatment patterns over the years was also examined. **RESULTS:** A total of 2546 MM patients who met the study inclusion and exclusion criteria were included in the analyses. Mean (± standard deviation) age was 60.6 (± 14.0) years old and 36.5% were female. Mean length of follow-up observation period was 322 days. The most common site of metastasis at the index date was lung (21.2%), brain and spinal cord (18.7%), distant area of the skin (11.4%), bone (11.2%), and liver (10.0%). Overall, 56.8% of patients received cancer-related surgery, 38.7% received drug treatment, and 44.7% received radiation therapy after MM diagnosis. Among patients who received drug treatment, 48.7% received temozolomide, 22.3% paclitaxel, 19.4% carboplatin, 17.6% interleukin-2 (IL-2), 17.2% dacarbazine (DTIC), 14.4% interferon alfa-2b (IFN), 9.9% cisplatin, 6.3% vinblastine, 4.7% granulocyte-macrophage colony-stimulating factor (GM-CSF), 4.5% docetaxel, 2.0% carmustine, and 0.2% bacillus calmette-guerin (BCG). **CONCLUSIONS:** Approximately 39% of MM patients were treated with chemotherapy or immunotherapy and this pattern remained similar during the last decade, which suggests an unmet need for patients with advanced melanoma.

PCN188

DID DECISION-MAKING MODELS FROM NATIONAL GUIDELINES CHANGE 1ST LINE TREATMENT STRATEGY FOR PATIENTS WITH METASTATIC COLORECTAL CANCER (MCRC)? THE RESULTS OF LARGE POPULATION BASED SURVEY IN GERMANY 2009

Kellermann I[1], Hofheinz RD[2], Arnold D[3]
[1]*OncologyInformationService, Freiburg, Germany,* [2]*University Mannheim, Mannheim, Germany,* [3]*University Hamburg, Hamburg, Germany*

OBJECTIVES: The survey was initiated to gain insights into the implementation of decision-making tools in national guidelines in treatment patterns of mCRC in daily practice. The tools define treatment intensity for subgroups of patients by clinical characteristics and anticipated treatment aims. **METHODS:** Physicians in representative sample of centres (69) reported all pts. with treatment decision in October-December 2009. The database contains 1019 pts. with retrospective record of treatment history. Treatment decisions were analysed in 3 predefined subgroups according to a model based on the German guidelines. Statistics were performed in

SPSS by bivariate analyses with two-sided Chi-square test. In the next step the subgroups of patients with comparable treatment in clinical practice were defined and analysed in a multivariate analysis. **RESULTS:** By contrast to the recommendation of national guidelines, intensified therapy was administered less frequently in patients with the aim of "resection of metastases" (43%), whereas the highest use (64%) was reported in "patients with tumor related symptoms or at risk for rapid progression or deterioration". This group represents only 12% of the 1st line. Factors with an influence on the use of intensified therapy in daily practice were analyzed in a multivariate analysis. Three treatment clusters (comprising 89% of patient sample) were determined. (all $p<0,05$) The cluster with significantly higher use of intensified therapy (+18% above mean value of 54%) is distinguished by: Age <70 y., better PS (>=80% KI), no symptoms and/or without concomitant diseases, treatment in office based setting. Patients in this cluster show less tumor dynamics. **CONCLUSIONS:** In daily practice, the application of the decision model based on treatment aims for clinical subgroups is not generally used. Intensified treatment is more likely associated with individual patient characteristics and institutional framework. This, however, underlines the need for a critical discussion of the currently suggested decision-making models.

Cancer – Research On Methods

PCN189

THE USE OF PARAMETRIC SURVIVAL ANALYSIS TO PREDICT PROGRESSION FREE AND OVERALL SURVIVAL OF NEWLY DIAGNOSED CHRONIC MYELOID LEUKEMIA (CML) PATIENTS

Mealing S[1], Scott D[1], Taylor M[2], Clark J[3], Wang Q[4], Davis C[5], Gilloteau I[6]
[1]*Oxford Outcomes Ltd, Oxford, UK,* [2]*York Health Economics Consortium, York, North Yorkshire, UK,* [3]*Oxford Outcomes Ltd., Oxford, UK,* [4]*Bristol-Myers Squibb, Uxbridge, Middlesex, UK,* [5]*Bristol-Myers Squibb Ltd., Princetown, NJ, USA,* [6]*Bristol-Myers Squibb, Rueil Malmaison, France*

OBJECTIVES: Reimbursement agencies require estimates of the long-term (i.e. lifetime) costs and benefits associated with each treatment option as part of the decision making process. As such, extrapolation of reported survival estimates is inevitable. Conventionally, information on all-cause mortality or disease progression is used. However, data for newly diagnosed CML may not be suited to such an extrapolation due to the paucity of observed events. One of solutions is to use a 'surrogate approach'. **METHODS:** A 40 year Excel® based model was created to estimate overall (OS) and progression-free (PFS) survival in newly diagnosed CML patients receiving 1st or 2nd generation tyrosine kinase inhibitor (TKI) therapy through the use of a surrogate clinical endpoint (cytogenic response - CyR). Three response categories (complete, partial or no CyR at one year) were used. Long term response category specific OS and PFS data from IRIS clinical trial was used to inform the fitting of Weibull functions with goodness of fit assessed via the R2 statistic. CyR response rates were taken from a recently published network meta-analysis of first-line interventions. **RESULTS:** Using the conventional approach, CML patients were predicted to have an equivalent survival profile to the non-CML general population (31.6 versus 32.6 years), and the survival difference between 1st and 2nd generation drugs are 9 years (31.6 versus 22.8 years) (Botteman et al 2010). However, predicted OS estimates for 1st and 2nd generation TKI's using the surrogate approach are 18.6 and 20.1 years respectively (R2 values 0.97, 0.94). Compared to 1st generation drugs the use of 2nd generation TKI's results in approximately 1.5 additional years of survival. **CONCLUSIONS:** Extrapolating short term overall OS data in newly diagnosed CML results in inflated survival estimates. When a valid clinical surrogate is used there is a much smaller, and believable, difference in the predicted survival values.

PCN190

USE OF SURROGATE MEASURES OF SURVIVAL IN ECONOMIC EVALUATIONS OF METASTATIC BREAST CANCER TREATMENTS

Beauchemin C[1], Cooper D[2], Lachaine J[1]
[1]*University of Montreal, Montreal, QC, Canada,* [2]*Governement du Quebec, Conseil du Medicament, Quebec, QC, Canada*

OBJECTIVES: Progression-free survival (PFS) is frequently used to establish the clinical efficacy of anti-cancer drugs. However, this surrogate measure of survival is of limited interest for the economic evaluation of these treatments. Therefore, the aim of this study is to develop a predictive model for OS based on PFS data in the context of metastatic breast cancer (mBC), which would be suitable for cost-effectiveness (cost per life-year saved) and cost-utility analyses. **METHODS:** A systematic review of the literature was conducted according to the PICO method: Population consisted of women with mBC; Interventions and Comparators were standard treatments for mBC or best supportive care; Outcomes of interest were median PFS and median OS. All selected studies were randomized trials published from 1990 to 2010. Two independent reviewers screened titles, abstracts, and full papers for eligibility. Then, reviewers independently extracted data from selected studies (median PFS, median OS, and potentially predictive covariates). The relationship between PFS and OS was assessed by calculating Pearson's correlation coefficient. Finally, statistical analyses (ANOVA and Pearson's correlation) were performed to identify covariates having a significant impact on OS. **RESULTS:** A total of 5041 studies were identified and 151 fulfilled the eligibility criteria. According to the data extracted from selected studies, there is a significant relationship between median PFS and median OS ($r=0.373$;$p<0.01$). Moreover, many covariates have a statistically significant impact on OS including age ($p<0.01$), type of treatment ($p<0.01$), line of treatment ($p<0.01$), ECOG status ($p<0.01$), and number and sites of metastasis ($p<0.01$). **CONCLUSIONS:** Results of this systematic review point toward a significant relationship between PFS and OS in the context of mBC. These findings will enable the development of a predictive model for OS based on PFS and significant covariates, which will eventually bring answers to an important challenge in the economic evaluation of anti-cancer drugs.

PCN191

ECONOMIC EVALUATION OF XELOX VS FOLFOX4 AS ADJUVANT TREATMENT FOR PATIENTS WITH STAGE III COLON CANCER IN SOUTH KOREA

Kim CM[1], Ju SY[2], Kim SH[2], Kang M[3], Park J[3], Choi WS[2]
[1]*Catholic University College of Medicine, Seoul, South Korea,* [2]*Catholic University, Seoul, South Korea,* [3]*Roche Korea Co., Ltd., Seoul, South Korea*

OBJECTIVES: To compare the costs of XELOX (Xeloda + Oxaliplatin) and FOLFOX4 (5-FU + Oxaliplatin + Leucovorin) for adjuvant treatment of stage III colon cancer in a South Korean setting. **METHODS:** Based on the equivalence in efficacy of XELOX from NO16968 trial and FOLFOX4 from MOSAIC trial (the 5 yrs disease free survival rates were very similar 66.1% for XELOX and 66.4% for FOLFOX4), a cost-minimization approach was chosen. The model adopts a payers perspective. Efficacy/Safety data and protocol information were acquired from NO16968 for XELOX, and from the MOSAIC trial for FOLFOX4. As no direct comparison of XELOX and FOLFOX4 for this indication is available, we collected several medical resource use data for these two regimens, which were chemotherapy drug doses, adverse events, hospitalization-ambulatory visits, and drug administration methods. The medical costs for FOLFOX4 were acquired from real world claims data (electronic data interchange, EDI); Catholic medical center in Korea. The direct medical costs for XELOX were also estimated by EDI from Catholic medical center with NO16968 trial. Also, health care utilizations were measured. All data analyses were performed using STATA software. **RESULTS:** The total direct medical costs for XELOX were estimated to be 13,884,894 KRW and for FOLFOX4 14,509,341 KRW per patient for 24weeks of chemotherapy treatment at same body surface area. The drug costs of XELOX were 12,468,748 KRW and of FOLFOX4 10,831,699 KRW. The line costs and drug administration costs were 82,960 KRW for XELOX and, 943,176 KRW for FOLFOX4, respectively. XELOX is more expensive in terms of drug acquisition costs. However, this is more than compensated by cost savings for drug administration, ambulatory encounters, AE medications, costs for central venous lines, and hospitalization. Additional incidence of hospitalization for FOLFOX4 was 2.3 times greater than for XELOX related hospitalization. **CONCLUSIONS:** XELOX offers cost savings of 644,447 KRW (about 585 US $) per patient compared to FOLFOX4 from the payers perspective in South Korean Universal Health Insurance System.

PCN192

BIA RESULTS COULD STOP INTRODUCTION OF COST-EFFECTIVENESS THERAPY INTO STANDARD TREATMENT : EXAMPLE FROM CROATIA

Culig J[1], Leppée M[1], Vrca V[2]
[1]*Public Health Institute, Zagreb, Croatia,* [2]*Clinical Hospital Dubrava, Zagreb, Croatia*

OBJECTIVES: In order for a new therapy to be included and reimbursed on the basic list of treatments covered by Croatian Institute for Health Insurance (HZZO), it must prove to have a positive effect on the budget impact analysis (BIA). The standard therapy for patients suffering from advanced head and neck cancer is chemoradiotherapy (mainly platinum and radiotherapy). However, if chemotherapy proves to be contraindicative, only radiotherapy is applied. Cetuximab inhibits EGFR, which induces the apoptosis of cancer cells. It has been proven that the implementation of immunoradiotherapy contributes to the overall survival of patients. **METHODS:** Known costs of the standard therapy for advanced head and neck cancer were compared with the costs of the proposed new therapy (cetuximab + radiotherapy). The costs are shown in the croatian currency (HRK) (1 Euro = 7,4 HRK). The increased costs of immunotherapy are compared to the data on efficiency from published literature. **RESULTS:** Approximately 212 patients with advanced head and neck cancer receive treatment in Croatia every year. If chemotherapy is contraindicative, a standard radiotherapy is applied (42 patients). The HZZO spends yearly 840.000,00 HRK on the treatment of those patients. The inclusion of cetuximab into the standard therapy would increase the total yearly costs by 3,082.650,90 HRK. When compared to radiatiotherapy, immunoradiotherapy prolongs the control of the illness (14,9 vs. 24,4 months), and the overall survival of patients (29,3 vs. 49,0 months). The cost for one added life-year per patient, would be approximately 89.738,00 HRK. **CONCLUSIONS:** The inclusion of immunotherapy into the standard treatment of patients with advanced head and neck cancer would have a negative impact on the budget of the HZZO. The average costs for one added life-year are lower than the average costs of chronic kidney insufficiency patients.

PCN193

USING WHOLE DISEASE MODELLING TO INFORM ECONOMIC RECOMMENDATIONS FOR THE DETECTION, DIAGNOSIS, TREATMENT AND FOLLOW-UP OF COLORECTAL CANCER

Tappenden P, Brennan A, Chilcott J, Squires H
University of Sheffield, Sheffield, South Yorkshire, UK

OBJECTIVES: Conventional economic evaluation typically involves piecewise comparisons of competing technologies at a single isolated point in a broader care pathway. This study assesses the value of simulating whole disease and treatment pathways to provide a common economic basis for informing resource allocation decisions across an entire disease service. This "Whole Disease Modelling" approach was applied to the evaluation of technologies for the detection, diagnosis, treatment and follow-up of colorectal cancer. **METHODS:** A patient-level simulation model was developed with the intention of informing NICE's colorectal cancer clinical guideline. The model simulates disease and treatment pathways from pre-clinical disease through to detection, diagnosis, adjuvant treatment, follow-up, treatments for metastases and supportive care. The model was populated using randomised trials, observational studies, health utility studies, costing sources and expert opinion. Unobservable natural history parameters were calibrated against

external data using Bayesian MCMC methods. Economic analysis was undertaken using 1) standard cost-utility decision rules within each topic, and 2) constrained optimisation across all modelled topics. **RESULTS:** The guideline included fifteen individual economic evaluation topics. Under usual processes, piecewise economic modelling would have been used to evaluate between one and three guideline topics. The Whole Disease Model provided a consistent platform for the economic evaluation of eleven of the fifteen guideline topics, ranging from alternative diagnostic technologies through to cytotoxic treatments for metastatic disease. The constrained optimisation analysis identified a configuration of colorectal services which was expected to maximise QALY gains without exceeding current expenditure levels. **CONCLUSIONS:** This study demonstrates that Whole Disease Modelling is feasible and can allow for the economic analysis of virtually any intervention across a disease service within a consistent conceptual and mathematical infrastructure. The approach may be especially valuable in instances whereby a substantial proportion of a disease service has not previously been subjected to economic evaluation.

PCN194

THE USE OF LARGE GPS LONGITUDINAL DATABASE IN THE REASEARCH OF CAUSAL ASSOCIATIONS AMONG PATHOLOGIES: THE CASE OF DIABETES AND CANCER INCIDENCE

Katz P[1], Ripellino C[1], Heiman F[1], Chatenoud L[2]
[1]CSD Medical Research S.r.l., Milan, Italy, [2]Istituto di Ricerche Farmacologiche , Milan, Italy

OBJECTIVES: To study the association between Diabetes Mellitus (DM) and the incidence of Cancer, focusing on type-specific and sex-specific cancers. **METHODS:** Study's data were obtained from CSD LPD, an Italian General Practitioner's longitudinal database. We have evaluated the risk of Cancer incidence among people with DM compared with those without this pathology, in patients who had no reported history of Cancer at the start of the follow-up on January 2006. For the DM group, patients with at least one diagnosis of DM and a GP contact from January - December 2005 have been selected, while for the DM free group, patients without a diagnosis of DM and a contact with the GPs in the same period have been selected. Both groups have been followed-up for 5 years. In order to evaluate an association between the presence of DM and the incidence of Cancer multivariate logistic models adjusted by age and sex have been implemented. **RESULTS:** A total of 73.144 (6 %) patients with a diagnosis of DM and 1.119.652 (94%) patients without DM diagnosis were selected. During follow-up 8.824 and 82.477 incident cases of Cancer were documented from the DM and DM free groups respectively. Statistical analysis showed an Adjusted (age and sex) Odds Ratio of 1,06 (95% Cl 1,06-1,20) suggesting that patients with DM have a 6% increased risk of cancer incidence (all types). Regarding type-specific cancer analysis the OR for Liver cancer (2,44 [95% Cl 2,11-2,82]) and Pancreas cancer (2,27 [95% Cl 1,95-2,66]) were higher for DM patients. Regarding sex-specific cancers, the risk of Uterine body cancer was higher for diabetic women (1,52 [95% Cl 1,17-1,99]), while in men DM seems to have a protective effect, for example in Prostate cancer (0,86 [95% Cl 0,79-0,95]). **CONCLUSIONS:** Patients with DM may be at increased risk of total, site-specific and sex-specific cancer.

PCN195

BAYESIAN CALIBRATION OF A CERVICAL CANCER MODEL USING MARKOV CHAIN MONTE CARLO

Walsh C[1], Ortendahl J[2], Sy S[2], Kim J[3]
[1]Trinity College Dublin, Dublin, Ireland, [2]Harvard University, Boston, MA, USA, [3]Harvard School of Public Health, Boston, MA, USA

OBJECTIVES: Simulation models are an essential tool in estimating the impact of vaccination, screening and treatment on cancer rates. Model calibration is the process of identifying reasonable values for model parameters, such that the outputs of the model are close to values observed in a real population. The purpose of this work was to calibrate an existing model for cervical cancer using Irish data and Markov Chain Monte Carlo (MCMC) in a Bayesian framework. This is compared and contrasted with a previous random search calibration. **METHODS:** An existing microsimulation model for cervical disease which was coded in C was embedded in a loop running in R. MCMC, which is an iterative algorithm was implemented in parallel on multiple desktop machines and the results were collated for analysis. The calibration method used differs from pure optimisation strategies and identifies a probability distribution on the parameter space, which is of benefit for models requiring probabilistic sensitivity analysis. **RESULTS:** Estimates of the model parameters were obtained from both MCMC and from the fitting of existing reference parameter sets resulting from a random search of the parameter space. These are compared on the basis of goodness of fit statistics (the sum of squared errors between targets and fitted values). Of 20 MCMC chains that were run, 5 of them gave better fits than the best fit sets for the random search method. However, 8 of the 20 chains had not reached parameter sets that gave good fits when compared with the best 135 fitted sets from the random search method. **CONCLUSIONS:** MCMC is a useful technique which provides probabilistic estimates of the parameters of interest in a calibration exercise. Care is needed with starting values and proposal distributions to ensure that the chains have converged and that the parameter space is properly explored.

PCN196

REVIEW OF COST EFFECTIVENESS OF TRASTUZUMAB IN EARLY BREAST CANCER

Van rooijen EM[1], Krol M[2]
[1]institute for Medical Technology Assessment (iMTA), Rotterdam, The Netherlands, [2]Erasmus University, Rotterdam, The Netherlands

OBJECTIVES: The treatment of breast cancer is associated with high costs, influenced by the introduction of more effective but expensive drugs, such as trastuzumab. This study aims to review cost-effectiveness studies of trastuzumab in the adjuvant setting of early breast cancer and to explore the relation between (methodological) differences in study design and cost-effectiveness outcomes. **METHODS:** A systematic review was performed to identify cost-effectiveness studies of trastuzumab published between January 1998 and March 2011. All costs were converted to 2009 Euros. Sources of variation in study design were identified and divided into three categories: 1) methodological factors prescribed by national guidelines; and 2) intrinsic factors, such as methodological or practical choices made by the principal researchers; 3) extrinsic factors, such as the price of trastuzumab. **RESULTS:** Fourteen cost-effectiveness studies were identified of which one was a meta-analysis integrating data of multiple clinical trials. All were modelling studies. ICERs of chemotherapy + trastuzumab vs. chemotherapy alone ranged from being the dominant strategy to € 87.889/QALY gained. The level of detail presented regarding study design and outcomes differed strongly, hampering the identification of factors influencing this wide range of outcomes. However, of the mutually presented aspects, especially the treatment regimen of the underlying clinical trial seemed to influence outcomes. Variation among studies using the same clinical trial appeared related to methodological factors prescribed by national guidelines, such as perspective and time horizon, intrinsic factors, such as assumed duration of benefit and extrinsic factors, e.g. country specific practice variation. **CONCLUSIONS:** Cost-effectiveness levels of trastuzumab differed strongly, even between modelling studies based on the same clinical trial. Outcomes were influenced by methodological aspects such as time horizon chosen and assumed duration of benefit. A higher level of detail presented in the articles is needed to increase insight in causes of variation in cost-effectiveness outcomes.

PCN197

HEALTH RELATED QUALITY OF LIFE IN LONG TERM SURVIVORS OF LYMPHOMA: A POPULATION BASED STUDY

Blommestein H[1], Versteegh M[1], Oerlemans S[2], Van de Poll-Franse L[2], Uyl-de Groot C[1]
[1]Erasmus University, Rotterdam, The Netherlands, [2]Comprehensive Cancer Centre South, Eindhoven, The Netherlands

OBJECTIVES: To assess the health related quality of life (HRQoL) in the growing group of long term lymphoma survivors with preference based instruments. **METHODS:** Population based cross-sectional data was collected in patients diagnosed with Hodgkin lymphoma (HL) or non-Hodgkin lymphoma (NHL) (N=778). HRQoL was measured using both a generic and a disease specific preference-based instrument, the EQ-5D 5-level and a time-trade-off valued version of the EORTC QLQ-C30. **RESULTS:** On average patients with HL or NHL were diagnosed 4.35[±SD 2.56] years prior to the study. Mean QoL was 0.83 using EQ-5D [±SD .16, Range -.11 - 1.0] and 0.88 using QLQ-C30 [±SD .10 Range .38 - 1.0]. Mean EQ-5D score for lymphoma survivors is significantly lower than the average HRQoL found in the Dutch population ($p<0.001$). However, mean QLQ-C30 score for lymphoma survivors did not differ from the Dutch population. Regression analysis identified a significant lower HRQoL with having active disease (measured by treatment activity) and comorbidities depression, high blood pressure, respiratory diseases, osteoarthritis, and back-pain. Age, type of lymphoma, and time passed since diagnosis did not affect HRQoL. The discrepancy between EQ-5D and QLQ-C30 in deviation from the Dutch population is likely to be caused by better discrimination of worse health states in the EQ-5D. **CONCLUSIONS:** The average HRQoL in long-term lymphoma survivors seems relatively high, especially when measured by the QLQ-C30. However, subgroup analyses revealed HRQoL was affected by active disease and comorbidities, other than, but perhaps related to, cancer. This has two important implications. Firstly, population-based studies need to incorporate comorbidities to adequately assess and forecast HRQoL in lymphoma survivors. Secondly, in economic evaluations the modelling of cancer free survival needs to be reconsidered since HRQoL in life years gained is affected by comorbidities. Future economic evaluations should incorporate these two implications to obtain more accurate HRQoL estimates.

PCN198

REVIEW OF ECONOMIC ASSESSMENTS OF EMERGING GENOMIC TECHNOLOGIES IN ONCOLOGY

Quecedo L[1], Del Llano J[2]
[1]Fundacion Gaspar Casal, madrid, Spain, [2]Gaspar Casal Foundation, Madrid, Spain

OBJECTIVES: A systematic review of the economical assessment studies on genomics and proteomics in the field of oncology. Our aim is to analyze those emerging diagnostic and therapeutic technologies whose cost effectiveness ratio make them suitable for its adoption in the different health systems from a social point of view. **METHODS:** We locate the most relevant studies in the last 10 years in Medline, Embase, Cancerlit, Cochrane Library databases and we analyze the results. The following keywords were used: genetic screening, gene, pharmacogenomics, proteonomics, microarrays, biochips, cost analysis, cost effectiveness, cost benefit, cost minimization, neoplasm, tumour and cancer. **RESULTS:** We analyze 13 studies from which 5 assess aspects about breast cancer, 7 about colorectal neoplasm, and 1 about urologic pathology. From these analyzed studies, 4 were cost utility studies, 8 were cost effectiveness studies, and one was a cost minimization study. **CONCLUSIONS:** We highlight the increase of economical assessment studies on genomics and proteomics, constituting an invaluable help for the sanitary and medical decision makers over the suitability and relevance of incorporating the contributions of genomics and proteomics in the field of oncology, introducing the specific ethical and social aspects of this specialty.

PCN199

AN EVALUATION OF STATISTICAL METHODS USED TO ANALYSE PATIENT-REPORTED OUTCOMES (PRO) DATA IN PUBLISHED METASTATIC CANCER STUDIES

Gilet H[1], Brédart A[1], Regnault A[1], Bhandary D[2], Parasuraman B[3]
[1]*Mapi Values, Lyon, France,* [2]*AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA,* [3]*AstraZeneca, Glen Mills, PA, USA*

OBJECTIVES: As metastatic cancers are generally incurable, treatment goal is to control the cancer and relieve symptoms with minimal side effects, making patient-reported outcomes (PRO) of particular interest in addition to traditional clinical outcomes. The objective of this literature review was to explore and evaluate the PRO data analyses reported in published metastatic cancer studies. **METHODS:** The literature search was conducted on Medline and Embase databases (1999-2009). The search focused on two types of PRO analyses: the association between PRO scores and clinical outcomes, and the assessment of treatment benefit in terms of PROs. General keywords related to the tumour site and PROs, and keywords specific to each type of analysis were defined. A total of 931 different abstracts were reviewed by one statistician, among which 47 were finally selected for in-depth review based on their relevance to review objectives. **RESULTS:** The relationship between PRO scores and clinical outcomes was mainly analysed with Cox models, since clinical endpoint was generally survival. When analyses did not involve survival, the association between PRO and clinical outcomes and the use of PRO scores as endpoints were appropriately analysed with various descriptive, non-parametric and parametric statistical methods, depending on parameters like study objectives, design, PRO endpoints used and sample size. Only a few studies discussed the clinical meaningfulness of results alongside statistical significance. **CONCLUSIONS:** While a clear consistency was found in the statistical method for the analysis of the link between PRO scores and survival measures, a large heterogeneity of statistical methodologies was observed for other types of PRO analysis. In most studies, the method was appropriate from a statistical perspective but not adapted to the specific nature of PRO data, including under-use of clinically meaningful interpretation of statistical results and absence of specific PRO approaches such as cumulative distribution curves.

PCN200

USING A WEIBULL PARAMETRIC MODEL FOR FAILURE-TIME DATA TO ASSESS PROGRESSION-FREE SURVIVAL AS A SURROGATE ENDPOINT FOR OVERALL SURVIVAL IN A TRIAL OF PATIENTS WITH METASTATIC RENAL CELL CARCINOMA

Negrier S[1], Bushmakin AG[2], Cappelleri JC[2], Charbonneau C[3], Sandin R[4], Michaelson MD[5], Figlin RA[6], Motzer RJ[7]
[1]*Centre Leon Berard, Lyon, France,* [2]*Pfizer, Inc., Groton, CT, USA,* [3]*Global Outcomes Research, Pfizer Oncology, New York, NY, USA,* [4]*Global Health Economics and Outcomes Research, Pfizer Oncology, Sollentuna, Stockholm, Sweden,* [5]*Massachusetts General Hospital Cancer Center, Boston, MA, USA,* [6]*Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA, USA,* [7]*Memorial Sloan-Kettering Cancer Center, New York, NY, USA*

OBJECTIVES: Among surrogate endpoints for overall survival (OS) in oncology trials, progression-free survival (PFS) is increasingly taking the lead. Although there have been some empirical investigations on inter-dependence of OS and PFS in different tumor types, new ways to model and interpret this inter-dependence are scarce, and only limited evidence is available for metastatic renal cell carcinoma (mRCC). **METHODS:** We assessed the relationship between PFS (primary endpoint) and OS in 750 patients with treatment-naïve mRCC randomized 1:1 to receive sunitinib (SU) or interferon-alfa (IFN) in a pivotal phase III study, pooling data for all available patients across treatment arms. A Weibull parametric model for failure-time data was applied to the dataset. The difference between OS and PFS was used as the outcome to remove inherent dependencies between PFS and OS. By excluding PFS time from OS time we obtain a distinct measure of survival beyond PFS: post-progression survival (PPS). **RESULTS:** The model demonstrated that longer PFS was significantly predictive of longer PPS ($P<0.001$). Estimated median PPS time was linked to a particular PFS time. For example, for PFS of 20 weeks, the median PPS was 43.9 weeks (95% confidence interval [CI]: 40.1, 48.1); for PFS of 60 weeks, the median PPS was 57.9 weeks (95% CI: 50.3, 66.7). A non-parametric Kaplan-Meier approach supported these results. **CONCLUSIONS:** For patients with mRCC randomized to either sunitinib or IFN, a distinct and quantifiable relationship was found between PFS and PPS. This suggests that PFS can be used as a surrogate measure for OS in mRCC, although more research is needed to generalize this finding beyond this particular study. This novel statistical approach using the Weibull parametric model can enrich the interpretation and understanding of that relationship, with potential implications for clinical trial design.

PCN201

COST-EFFECTIVENESS LITERATURE ON CANCER THERAPIES, TRENDS AND THE INFLUENCE OF INDUSTRY INVOLVEMENT ON OUTCOMES

Al-Badriyeh D, Al-Okka R, Al-Ameri M
Qatar University, West Bay, Doha, Qatar

OBJECTIVES: Within the context of cost-effectiveness evaluations of cancer drug-based therapies, the current project aims to describe trends over time in cost-effectiveness literature, and investigate any potential 'relationship' between the pharmaceutical industry involvement in literature and study outcomes. **METHODS:** This study involves reviewing all eligible cancer cost-effectiveness studies that were published during the five subsequent time blocks 1991-1994, 1995-1998, 1999-2002, 2003-2006, and 2007-2010. Descriptive and association statistical analyses were conducted as appropriate. **RESULTS:** Of 307 articles for inclusion in the study, 260 (85%) articles have been analyzed to date. While there is a general increase in the publishing journals, the discipline of these has significantly shifted from being mainly "medicine" and/or "hematology/oncology" to being "healthcare science and services", especially during the last time block. Also, retrospective data is increasingly the major type of data utilized in the studied literature, with lack of meta-analysis data. There has been a significant increase in the external funding of studies as well, both industry and nonprofit. Similar trend was observed with the involvement of paid industry consultation. Surprisingly however, this is associated with an increase in paid consultations with no sponsorships declared. This was also associated with general increasing absence of conflict of interest declaration. Importantly, there has been a significant association between industry funding and reported outcomes of sponsored-drug studies. This did not exist when other type of funding was also involved in the sponsorship. **CONCLUSIONS:** This is the first analysis of cost-effectiveness literature, whereby, it demonstrated a clear evolvement over the past 20 years in terms of size, study design and characteristics as well as funding. It seems that the absence of a declaration of potential conflict of interest is inappropriately not decreasing in journals, in addition to that financial sponsorship by pharmaceutical industries is associated with favorable result to the sponsor.

Diabetes/Endocrine Disorders – Clinical Outcomes Studies

PDB1

ASSOCIATION BETWEEN HYPOGLYCEMIA AND MEDICATION POSSESSION RATIO AMONG VETERANS WITH TYPE 2 DIABETES MELLITUS (T2DM)

Zhao Y[1], Shi L[1], Fonseca V[1], Campbell C[1], Wu EQ[2]
[1]*Tulane University, New Orleans, LA, USA,* [2]*Analysis Group, Inc., Boston, MA, USA*

OBJECTIVES: This retrospective cohort study aimed to examine the association between hypoglycemia and medication adherence among veterans with type 2 diabetes mellitus (T2DM) in the United States. **METHODS:** Electronic medical and pharmacy records were obtained for patients with at least 2 records of T2DM diagnosis (ICD-9-CM codes: 250.xx except for 250.x1 and 250.x3) from the Veterans Integrated Service Network (VISN) 16 data warehouse from January 1, 2004 to September 1, 2010. The VISN 16 serves veterans in Arkansas, Louisiana, Mississippi, Oklahoma, and parts of Alabama, Florida, Missouri, and Texas. The first dispense date of a new antihyperglycemic agent (index drug) was defined as the index date. The hypoglycemia and control cohorts were identified by the occurrence of hypoglycemia (ICD-9-CM codes: 250.8, 251.0, 251.1 and 251.2) during the index-treatment period and no hypoglycemia during one-year post-index period, respectively. Selected patients had no records of hypoglycemia, cardio-vascular disease, or micro-vascular complications during the one-year pre-index period. Selection bias across cohorts was reduced using propensity score matching. The medication possession ratio (MPR) and proportion of MPR>=80% of the index drug and overall anti-hyperglycemic medications were used as indicators for medication adherence. Generalized linear model and logistic regression model were used to compare MPR and proportion of MPR>=80% between the two groups, respectively. **RESULTS:** The 761 patients in the hypoglycemia group were matched with 761 patients from the control group of 43,500 patients. As to the index drug, MPR was slightly higher in the hypoglycemia group (0.66 vs. 0.63; $p=0.009$), but proportion of MPR>=80% did not significantly differ between the groups (hypoglycemia: 38.44% versus control: 36.06%; $p=0.3387$), controlling for the covariates. Also no differences in MPR and proportion of MPR>=80% to overall antihyperglycemics were found between the groups. **CONCLUSIONS:** It appears that there is little impact of hypoglycemic event during treatment on the MPR statistics in this population.

PDB2

CONSIDERABLY INCREASING INCIDENCE OF SEVERE HYPOGLYCEMIA 2007-2010 VERSUS 1997-2000 – A GERMAN LONGITUDINAL POPULATION-BASED STUDY

Holstein A[1], Patzer OM[1], Machalke K[1], Holstein JD[2], Dippel FW[3], Kovacs P[2]
[1]*Klinikum Lippe-Detmold, Detmold, Germany,* [2]*University of Leipzig, Leipzig, Germany,* [3]*Sanofi-Aventis Germany, Berlin, Germany*

OBJECTIVES: In a prospective population-based study covering a German region with 200.000 inhabitants, the incidence of severe hypoglycaemia (SH) and clinical characteristics of the corresponding patients were longitudinally compared over two four-year periods between 1997-2000 versus 2007-2010. **METHODS:** Blood glucose testing was systematically performed in every emergency patient irrespective of the presenting condition, either already prehospitally at the scene of the emergency or immediately after the arrival at the emergency department, respectively. SH was defined as a symptomatic event requiring treatment with intravenous glucose and was confirmed by a blood glucose measurement of <50 mg/dl. **RESULTS:** Warranting identical methodological conditions, our study revealed a drastic increase of 87.5% in the frequency of SH (495 events in 2007-2010 versus 264 events in 1997-2000). There was no change in the distribution of SH within the different types of diabetes. The incidence of SH between 1997-2000 versus 2007-2010 increased considerably from 11.5 to 22.7 in patients withT1DM and from 18.5 to 32.5 in those with T2DM. We observed a clear shift towards intensification of antihyperglycemic therapy as indicated by lower HbA1c values in increasingly multimorbid subjects. Especially hypoglycemic subjects with T2DM were characterized by a geriatric and multimorbid state (mean age >75 years) receiving additional comedication of 3.3 (1997–2000) versus 7.7 drugs (2007–2010) and suffering from 3.6 versus 4.4 concomitant diseases with an increase in renal insufficiency from 54% to 76% (respective p-values <0.001). **CONCLUSIONS:** The nationwide growing incidence of diabetes might have substantially contributed to the considerable increase of SH between 2007-2010. Furthermore, the increase of SH correlated with the shift towards more stringent goals for metabolic control by official German guidelines (currently HbA1c<6.5%) and the implementation of Disease

Management Programs for Diabetes in 2003 leading to intensification of antihyperglycemic therapy and thus increasing the risk for SH.

PDB3

HYPOGLYCAEMIA-RELATED EMERGENCY DEPARTMENT VISITS AND HYPOGLYCAEMIA-RELATED HOSPITALIZATIONS AMONG NEWS USERS OF ANTIDIABETES TREATMENTS

Moisan J[1], Breton MC[2], Gregoire JP[1]
[1]*Université Laval, Québec, QC, Canada,* [2]*Chaire sur l'adhésion aux traitements, Québec, QC, Canada*

OBJECTIVES: Hypoglycaemia is a major side effect of antidiabetes drugs. Mild episodes of hypoglycaemia are frequent and are generally self-treated. On the other hand, severe hypoglycaemia can have deleterious effects on mortality, morbidity and quality of life. The objective was to describe the burden of severe hypoglycaemia among new users of insulin and oral antidiabetes drugs (OAD) in terms of two hypoglycaemia-related outcomes: emergency department (ED) visit and hospitalization. More specifically: 1) to describe the frequency of hypoglycaemia-related ED visits and hospitalizations, and 2) to calculate the incidence rate of these two outcomes. **METHODS:** We conducted an inception cohort study using the databases of the Quebec health insurance board and the Quebec registry of hospitalizations. The source population was made of individuals aged 18 years or over; newly dispensed an antidiabetes treatment made of either insulin or OAD between January 1, 2000 and December 31, 2008. Individuals were followed from initiation of antidiabetes treatment to December 31, 2008, occurrence of hypoglycaemia-related outcome, loss of eligibility to the drug plan or death, whichever came first. Individuals' characteristics at antidiabetes treatment initiation were described using frequency distributions. The incidence rate for the occurrence of hypoglycaemia-related ED visit and hypoglycaemia-related hospitalization were calculated using the Kaplan–Meier method. **RESULTS:** A total of 188,659 new users of antidiabetes treatment were included in the cohort. A total of 3575 (1.9%) individuals had at least one hypoglycaemia-related ED visit while 194 (0.1%) had at least one hypoglycaemia-related hospitalization. Incidence rates for the occurrence of hypoglycaemia-related ED visits and hypoglycaemia-related hospitalizations were 5.2, and 0.3 cases per 1000 patient-years, respectively. **CONCLUSIONS:** Although the incidence of ED visit or hospitalization due to hypoglycaemia seems low, severe hypoglycaemia episodes could be associated with a high economic burden.

PDB4

CHARACTERIZATION OF THE RISK FOR URINARY TRACT INFECTIONS IN US PATIENTS WITH TYPE 2 DIABETES MELLITUS

Lento K[1], Qiu Y[1], Fu AZ[2], Engel SS[1], Shankar R[1], Davies MJ[1], Brodovicz K[1]
[1]*Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA,* [2]*Cleveland Clinic, Cleveland, OH, USA*

OBJECTIVES: To assess whether the presence of type 2 diabetes mellitus (T2DM) increases the risk of urinary tract infections (UTI) in men and women. **METHODS:** In a retrospective cohort study, patients ≥18 years with a diagnosis of T2DM or prescriptions for antihyperglycaemic therapy were identified within MarketScan, a US-based insurance claims database. Date of first T2DM diagnosis or prescription in 2008 was the index date. Patients without T2DM were age and gender matched to those with T2DM. Eligible patients had medical records for 1 year prior to (baseline) and 1 year after (follow up) the index date. UTI diagnosis during follow up was assessed with ICD-9 codes. Logistic regression adjusted for patient characteristics and comorbid conditions was used to assess the likelihood of experiencing UTI. **RESULTS:** A total of 106,623 matched pairs were selected. The mean age at index date was 56 years and 50% were male. Patients with T2DM had more pre-existing comorbid conditions compared to patients without T2DM. In the 1-year follow up, more patients with T2DM were diagnosed with UTI (12.9% vs. 7.7%; $p<0.0001$) compared to non-T2DM patients. The proportion of women with T2DM experiencing UTI was greater (18.3% vs. 11.8%; $p<0.0001$) than for women without T2DM. A lower proportion of men had UTI, but the difference between T2DM and no T2DM remained and was significant (7.6% vs. 3.6%; $p<0.0001$). In a logistic regression, patients with T2DM had a greater likelihood of experiencing UTI during follow up (adjusted odds ratio = 1.71 [95% CI 1.66, 1.77]). For each gender alone, the odds were still significantly greater for patients with T2DM. Measurements of glycemic control were not available and thus their influence on UTI risk could not be assessed. **CONCLUSIONS:** Patients with T2DM were more likely to experience a UTI compared to patients without T2DM.

PDB5

MICRO- AND MACROVASCULAR OUTCOMES IN PRIMARY CARE PATIENTS WITH TYPE 2 DIABETES TREATED WITH INSULIN GLULISINE OR HUMAN REGULAR INSULIN: A RETROSPECTIVE GERMAN DATABASE ANALYSIS

Kress S[1], Dippel FW[2], Kostev K[3], Giani G[4], Rathmann W[5]
[1]*Vinzentius-Krankenhaus, Landau/Pfalz, Germany,* [2]*Sanofi-Aventis Germany, Berlin, Germany,* [3]*IMS HEALTH GmbH & Co. OHG, Frankfurt am Main, Germany,* [4]*Diabetes Forschungsinstitut an der Heinrich-Heine Universität, Duesseldorf, Germany,* [5]*German Diabetes Center at Heinrich Heine University, Duesseldorf, Germany*

OBJECTIVES: Analog insulin glulisine has a higher efficacy in reducing postprandial glucose excursions and in restoring normal postprandial microcirculation than regular human insulins. Besides glycemic control, insulin glulisine has also favorable effects in maintaining normal endothelial function. Therefore, the aim was to compare the incidence of macro- and microvascular outcomes in type 2 diabetic patients treated with insulin glulisine or regular human insulin. **METHODS:** Computerized data from 952 glulisine (age: 61 ± 11 yrs) and 11,157 regular insulin (65 ± 11 yrs) users in general practices throughout Germany (Disease Analyzer, 11/2004 to 3/2010) were analysed. Hazard ratios (HR; Cox regression) for 3.5-year risk of macro- or microvascular outcomes were adjusted for age, sex, diabetes duration, health insurance, residency, diabetologist care, hypertension, hyperlipidemia, depression, and co-medication (basal insulin, oral antidiabetics). Furthermore, adjustment was carried out for baseline microvascular complications when analyzing macrovascular outcomes and vice versa. **RESULTS:** Overall, risk for both macro- and microvascular outcomes was 20% lower for patients using insulin glulisine ($p<0.05$). There was a decreased risk for coronary heart disease (HR; 95% CI: 0.78; 0.62–0.99), and a trend for lower events of myocardial infarction (0.66; 0.43–1.02). Also for microvascular complications, the adjusted hazard ratios for retinopathy, nephropathy and neuropathy were below 1.0, indicating a lower risk for the insulin glulisine group, however, which was statistically significant for neuropathy only (0.74; 0.58–0.93). **CONCLUSIONS:** The prescription of the rapid-acting insulin analog glulisine was associated with a reduced incidence of macro- and microvascular outcomes in type 2 diabetes under real-life conditions in a retrospective database analysis. It is important to confirm this finding in a randomized controlled trial.

PDB6

DESCRIPTION OF COMORBIDITIES AND BODY MASS INDEX IN US ADULTS WITH AND WITHOUT DIABETES FROM THE MEDICAL EXPENDITURE PANEL SURVEY, 2008

Mitchell B
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: The World Health Organization has recognized diabetes and other selected chronic health conditions are at an epidemic level all of which can be impacted by weight. The purpose of this project was to classify US adults by Body Mass Index (BMI) categories and compare adults with diabetes to those adults without diabetes by BMI categories and other selected priority health conditions to see if there was a difference between groups. **METHODS:** The Medical Expenditure Panel Survey (MEPS) is publically available database providing nationally representative estimates of health care use, expenditures, sources of payment, and health insurance coverage for the US population. Analysis of the survey data utilized design-based methods that utilized the complex survey stratification and weighting provided within the MEPS datasets, in addition to use of the Rao-Scott Chi-square test, to compare people with and without diabetes. The level of significance was two-tailed $\alpha=0.05$. **RESULTS:** In 2008, approximately 64 percent of the U.S. adult population was overweight (BMI of 25.0 to 29.9), obese (BMI of 30.0 to 39.9), or extremely obese (BMI greater than or equal to 40). Adults with diabetes had significantly higher percentages of being overweight, obese, and extremely obese, where more likely to have asthma and more than twice as likely to have hypertension, and were nearly three times as likely to have heart disease and more than three times more likely to have a stroke than adults without diabetes (p-value=0.001). **CONCLUSIONS:** Patients with diabetes were more likely to be overweight, obese, and extremely obese compared to those without diabetes. Patients with diabetes were also more likely to have chronic health conditions such as hypertension, heart disease, and stroke.

PDB7

PREVALENCE, DEMOGRAPHICS AND TREATMENT CHARACTERISTICS OF DIABETES WITH LANTUS, NPH AND PREMIX INSULIN IN A REPRESENTATIVE CANADIAN COHORT

Petrella RJ[1], Sauriol L[2], Villeneuve J[3]
[1]*Lawson Health Research Institute, London, ON, Canada,* [2]*Sanofi-Aventis Canada, Laval, QC, Canada,* [3]*Sanofi-Aventis, Laval, QC, Canada*

OBJECTIVES: To determine the prevalence and incidence of Lantus vs NPH and premix insulin use in diabetes including the treatment characteristics, comorbidity and resource use in a representative population in Canada. **METHODS:** Records from a longitudinal population-based database of more than 225,000 primary care patients in southwestern Ontario, Canada were analyzed between January 1 2008 to September 30 2010. Patients were considered to have diabetes if at least one of the following conditions was met: 1) physician diagnosed type 1 or 2 diabetes; 2) > 1 measurement of HbA_1 greater than the recommended target; or 3) at least one prescription for a diabetes medication. **RESULTS:** A total of 76,077 adult patients with representative data were included between 2008-2010. Prevalence of T2DM was 7.9% and Type 1 diabetes was 2.9%. Patients on Lantus had less hypertension, nephropathy or Stage 5 kidney disease than NPH or Premix insulin patients ($p<0.05$). Patients receiving Premix insulin tended to have more primary care visits, ER visits, hospitalizations and total referrals than Lantus. More patients received new scripts for NPH than Lantus or Premix insulin during the study period. The average dose of Lantus was 10.5-10.7 units, with a high rate of annual renewal (89.8-96.6%) for the same dose or any dose (93.8-98.7%). There were very few dose switches or discontinuations for Lantus while NPH and Premix insulin were renewed less, underwent more dose switches and less discontinuations. **CONCLUSIONS:** In a real-world setting the prevalence of diabetes was similar to nationally reported data. Patients receiving Lantus tended to have less hypertension, nephropathy or Stage 5 kidney disease, while those who took Premix insulin utilized more health services than Lantus or NPH. Lantus scripts were renewed more often, had less dose changes or switches and less discontinuations than NPH or Premix insulin.

PDB8

A NETWORK META ANALYSIS TO COMPARE GLYCAEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES TREATED WITH EXENATIDE ONCE WEEKLY OR LIRAGLUTIDE

Scott D[1], Boye KS[2], Timlin L[3], Best JH[4], Clark J[5]
[1]*Oxford Outcomes Ltd, Oxford, UK,* [2]*Eli Lilly and Company, Indianapolis, IN, USA,* [3]*Lilly, Windlesham, Surrey, UK,* [4]*Amylin Pharmaceuticals, Inc., San Diego, CA, USA,* [5]*Oxford Outcomes Ltd., Oxford, UK*

OBJECTIVES: A once-weekly formulation of exenatide (EQW) received positive opinion from the EMA in April 2011 for the treatment of type 2 diabetes. No head-to-head study of EQW and liraglutide 1.2mg once-daily (the dose recommended by NICE) has been conducted therefore a network meta-analysis to compare EQW to liraglutide 1.2mg in terms of effect on HbA1c was performed. **METHODS:** A systematic review was conducted to identify randomized controlled trials of EQW and liraglutide (1.2mg and 1.8mg) of 24 weeks or more, and the common comparators insulin glargine and exenatide bid to allow a network meta-analysis. Additionally, the manufacturing companies were asked to provide any unpublished data from studies meeting the criteria. 22 studies including 10,816 patients met our inclusion criteria. Treatments were compared in terms of mean difference in HbA1c relative to placebo. Additionally, EQW was compared to both doses of liraglutide, and liraglutide 1.2mg was compared to liraglutide 1.8mg. **RESULTS:** Results from random effects models controlling for baseline HbA1c are presented. Analysis of change in HbA1c produced estimated mean differences relative to placebo of -1.15% (95% CI -1.31, -1.00) for EQW, -1.01% (95% CI -1.18, -0.85) for liraglutide 1.2mg, and -1.18% (95% CI -1.32%, -1.04%) for liraglutide 1.8mg. The comparison of EQW to liraglutide 1.2mg and liraglutide 1.8mg showed a mean difference (95% CI) of -0.14% (-0.34, 0.06) and 0.03% (-0.14, 0.18) respectively. Liraglutide 1.2mg compared to liraglutide 1.8mg showed a mean difference in HbA1c of 0.17% (0.02, 0.30). Results were consistent when controlling for use of background antihyperglyemic medications. **CONCLUSIONS:** Our analysis suggests EQW and both doses of liraglutide have robust and similar efficacy with respect to lowering of HbA1c. Further analysis is warranted to investigate the inconsistency between the direct and indirect evidence with respect to the comparison of EQW to liraglutide 1.8mg.

PDB9

WEIGHT LOSS, INDEPENDENT OF DRUG CLASS, PREDICTS HBA1C GOAL ATTAINMENT IN PATIENTS 65 YEARS AND OLDER IN A REAL-WORLD SETTING

McAdam-Marx C[1], Brixner D[1], Ye X[1], Unni S[1], Mukherjee J[2]
[1]*University of Utah, Salt Lake City, UT, USA,* [2]*Bristol-Myers Squibb, Wallingford, CT, USA*

OBJECTIVES: To evaluate weight change and glycemic control in patients age 65+ with type 2 diabetes (T2DM) in a usual-care setting. **METHODS:** Treatment naïve patients age 65+ years with T2DM and a prescription (index date) for a sulfonylurea (SU), metformin (MET), thiazolidinedione (TZD), GLP-1 agonist (GLP-1), or DPP-4 inhibitor (DPP-4) were identified in an electronic medical record database from 1/1/2000 to 6/30/2010. HbA1c <7% or ≥7% and weight gain or loss of ≥3% were assessed 1 year post-index. Logistic regression identified the likelihood of weight loss and attaining HbA1c goal by antidiabetic drug class, controlling for baseline HbA1c and weight, and for weight change for HbA1c goal attainment. **RESULTS:** Of 12,473 patients, 46.4% were male and the mean age was 71.7 (±3.9) years. At baseline 26.7% had HbA1c <7.0%; mean weight 86.8 (±18.7) kg. Breakdown by drug class was: SU - 31.0%, MET - 55.0%, TZD - 11.6%, DPP-4 - 1.9%, and GLP-1 - 0.6%. At 1 year, 34.8% lost ≥3% of body weight and 46.5% had an HbA1c <7.0%. In logistic regression analyses, MET and DPP-4 (OR 1.4 and 1.36; p<.05) were associated weight loss relative to SU, TZDs were negatively associated with weight loss (OR 0.86; p<.05), and GLP-1 did not differ (OR 1.55; p=0.08). Patients who lost weight were 2.26 times as likely as those who did not to attain HbA1c goal (p<.05). Drug class was not associated with HbA1c goal attainment (p>0.05). **CONCLUSIONS:** In patients with T2DM age 65+, those who lost weight were more likely to attain HbA1C goal than those who did not. MET and DPP-4 were associated with weight loss vs. SU, but drug class was not associated with HbA1C goal attainment. These findings support guideline recommendations to consider weight-effect properties of antidiabetics in treating T2DM with data specific to patients age 65+.

PDB10

ACHIEVING TARGET GOALS IN PATIENTS WITH T2DM TREATED WITH EXENATIDE ONCE WEEKLY OR INSULIN GLARGINE: A RETROSPECTIVE ANALYSIS OF THE NUMBER-NEEDED-TO-TREAT

Bruhn D[1], Han J[2], Meloni A[2], DeYoung MB[2], Anderson PW[1]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*Amylin Pharmaceuticals, Inc., San Diego, CA, USA*

OBJECTIVES: This post hoc analysis analyzed the number of patients needed to be treated (NNT) with the GLP-1 receptor agonist exenatide once weekly (ExQW) vs titrated insulin glargine (IG) over 26 weeks to allow one additional patient to achieve single or combined recommended treatment goals. **METHODS:** Data from the DURATION-3 trial was analyzed retrospectively. Treatment targets included: 1) glycaemia (HbA1c ≤6.5% or fasting plasma glucose (FPG) <7 mmol/L); 2) systolic blood pressure (SBP <130 mmHg); 3) low-density lipoprotein cholesterol (LDL <2.59 mmol/L); and 4) weight loss or maintenance. Hypoglycemic events were also assessed. NNT was calculated for the entire intent-to-treat (ITT) population (ExQW n=233, IG n=223) and for subpopulations of patients on different background therapies (metformin ± sulfonylurea). NNT was calculated using 1/Absolute Risk Reduction (percent of patients reaching goal in the ExQW treatment arm - percent of patients reaching goal in the IG treatment arm). **RESULTS:** Baseline mean characteristics were similar for both treatment groups: 45-48% women, age 58 years, HbA1c 8.3%, and body mass index 32 kg/m^2. Regardless of background therapy, 8 patients would need to be treated with ExQW in place of IG for 26 weeks to allow one additional patient to attain the HbA1C goal. Five patients (ITT) would need to be treated with ExQW vs IG to allow one additional patient to attain the HbA1c goal with weight control and the absence of hypoglycaemia. Furthermore, 14 patients (ITT) would need to be treated with ExQW versus IG to allow one additional patient to reach combined HbA1c, SBP, and LDL goals. Only the FPG goal favored insulin use with an NNT of -8 (ITT). Minor differences in the NNT values were observed between subpopulations for most goals. **CONCLUSIONS:** Both ExQW and IG treated patients achieved therapeutic target goals. In this post hoc analysis the NNT results favored ExQW for most goals.

PDB11

GLYCEMIC OUTCOMES AMONG PATIENTS RECEIVING EXENATIDE BID OR LIRAGLUTIDE FOR TYPE 2 DIABETES IN CLINICAL PRACTICE: A RETROSPECTIVE ANALYSIS OF THE GE CENTRICITY EMR DATA

Best JH[1], Wintle M[1], Saunders WB[2], DeYoung MB[1], Blickensderfer A[1], Maggs D[1]
[1]*Amylin Pharmaceuticals, Inc., San Diego, CA, USA,* [2]*GE Healthcare, Charlotte, NC, USA*

OBJECTIVES: Exenatide twice daily (exenatide) and liraglutide once daily, GLP-1 receptor agonists, have demonstrated improvements in glycemic outcomes for patients with type 2 diabetes (T2D) in randomized clinical trials. We evaluated A1c outcomes for patients initiating exenatide or liraglutide in a real-world setting. **METHODS:** This retrospective cohort study used data from the Medical Quality Improvement Consortium of ambulatory medical practices that use Centricity Office from GE Healthcare IT as their electronic medical record. Patients with T2D receiving a prescription between Jun 2005 and May 2011 were identified (exenatide=61,485; liraglutide=9,316). Baseline A1c measures were documented from 45 days prior to 15 days after initiating exenatide or liraglutide with follow-up measures documented at 6 months+45 days. An ANCOVA model including baseline A1c, age, gender, concomitant glucose-lowering medications, and modified Charlson Comorbidity Index (CCI) was used to estimate least squares mean A1c. **RESULTS:** Mean(SD) age was 55(12) and 55(12), CCI 2.0(1.3) and 2.1(1.3), % male 41% and 42% for exenatide and liraglutide patients, respectively. Baseline BMI was 38.4(7.8) and 37.9(7.7) for exenatide and liraglutude patients, respectively, who had baseline and 6 month BMI data. Of patients not at A1c goal of <7.0% at baseline, the mean(SD) baseline A1c was 8.7(1.4) for exenatide and 8.6%(1.3) for liraglutide, and at 6 months was 8.0%(1.6) for exenatide and 7.9%(1.6) for liraglutide; 29.8% of patients receiving exenatide and 30.8% of patients receiving liraglutide achieved <7% A1c goal at 6 months. At baseline, 47% of exenatide patients were prescribed 10 mcg BID daily; 7.7% and 83.9% of liraglutide patients were prescribed 1.2 and 1.8 mg daily, respectively. At 6 months, 66% of exenatide patients were prescribed 10 mcg BID daily; 11.2% and 75.4% were prescribed liraglutide 1.2 and 1.8 mg daily, respectively. **CONCLUSIONS:** In this retrospective cohort study, glycemic outcomes similarly improved for patients initiating exenatide or liraglutide.

PDB12

GLARGINE UTILISATION IN RUSSIA: A PROSPECTIVE STUDY TO EVALUATE PATIENTS SWITCHED FROM NPH INSULIN TO INSULIN GLARGINE COMPARED WITH THOSE MAINTAINED ON NPH

Skudaev S, Verbovaya N
Samara State Medical University, Samara, Russia

OBJECTIVES: The LAntus Utilisation in RUSsia Study 2 (LAURUS 2) was an observational study undertaken at 245 sites as a follow-up to the LAURUS study. It evaluated the efficacy of switching patients with type 2 diabetes mellitus (T2DM) from NPH insulin to insulin glargine in real-life clinical practice. **METHODS:** Eligible adult patients had taken NPH and 2 oral antidiabetes drugs (OADs) for ≥ 12 months. During the 12-week study period all patients continued OADs. The active arm included patients whose physicians switched their basal insulin from NPH to glargine. Patients in the control group continued on NPH. Primary end point was change in HbA_{1C}. Secondary end points included changes in fasting blood glucose (FBG) and insulin dose and hypoglycaemic episodes (HEs). **RESULTS:** Data were available for 2395 of the 3000 enrolled patients. Patients had a mean duration of diabetes of 9.3 ± 5.1 y and mean duration of insulin therapy of 2.6 ± 2.6 y. Mean baseline HbA_{1c} was 9.0 ± 1.5 % and 9.2 ± 1.4 % in the NPH and glargine groups, respectively. After 12 weeks, mean HbA_{1c} decreased by 0.6 % and 1.7 % in the NPH and glargine groups, respectively (P <0.001). HbA_{1c} < 7% was attained by 8.4% and 25.8% of patients, respectively. Mean FBG decreased 1.4 ± 1.7 mmol/L and 3.3 ± 2.1 mmol/L, respectively (P <0.001). Mean insulin dose increased in both groups. At baseline, ≥ 1 severe hypoglycaemic episode was reported by 0.4% and 0.7% of NPH and glargine patients, respectively. At 12 weeks, no glargine patients reported severe hypoglycaemia, but 2 (0.8%) NPH patients had at least 1 episode. **CONCLUSIONS:** In this observational study, switching patients with T2DM who were inadequately controlled on NPH to glargine improved glycaemic control with minimal incidence of severe hypoglycaemia.

PDB13

A PROSPECTIVE REGISTRY TO IDENTIFY PATIENTS' CHARACTERISTICS ASSOCIATED WITH ACHIEVING TARGET METABOLIC CONTROL AFTER THREE MONTHS TREATMENT WITH INSULIN GLULISINE IN TYPE 1 AND 2 DIABETES MELLITUS PATIENTS PREVIOUSLY UNCONTROLLED ON BASAL INSULIN AND/OR OTHER ANTI-DIABETIC TREATMENT (API REGISTRY)

Gottesman I[1], Girard M[2], Shorey S[3]
[1]*University of Toronto, Mississauga, ON, Canada,* [2]*Sanofi-Aventis, Laval, QC, Canada,* [3]*Brampton Civic Hospital, Brampton, ON, Canada*

OBJECTIVES: Results from Canadian population-based studies show that glycaemic control (HbA_{1c} ≤7.0%) is often not achieved in patients with either type 1 (T1DM) or type 2 (T2DM) diabetes mellitus. The aim of this prospective registry was to identify patient characteristics associated with achieving HbA1c ≤7.0% in a real-life setting 3 months after adding insulin glulisine to previous anti-hyperglycaemic therapies. **METHODS:** The API registry included adult patients with T1DM or T2DM who were receiving basal insulin (± anti-diabetic agents) and still had HbA_{1C} >7%. Patients for whom the treating physician had initiated the addition of insulin glulisine within the month prior to study entry were assessed at baseline and 3 months. Logistic regression using the backward elimination technique was performed to identify the patient characteristics. **RESULTS:** HbA_{1C} was available at

baseline and 3 months in 344/383 patients who took ≥1 dose of study drug. Patients were obese (mean [± SD] BMI = 32.3 [± 7.7] kg/m^2) and >80% had T2DM. Mean HbA_{1c} was 9.1% (± 1.5) at baseline and 8.3% (± 1.2) after 3 months; 11.6% reached HbA_{1c} ≤7%. The mealtime insulin dose at 3 months was 38.6 IU (± 28.0). A cluster of 4 factors that favourably affected glycaemic control was identified: T2DM, lower baseline HbA_{1c} >1 hypoglycaemic event, and being Caucasian. Patients with T1DM and those taking at least one cardiovascular medication were less likely to reach target. Comparing the overall p-values for the crude and adjusted odds ratios suggested that HbA_{1c} at baseline, type of diabetes and higher number of hypoglycaemic events were interrelated, while racial group was independent of the other factors. **CONCLUSIONS:** Patients who achieved HbA_{1c} ≤7.0% 3 months after the addition of insulin glulisine were likely to have T2DM, a lower baseline HbA_{1c}, more hypoglycaemic episodes and be Caucasian.

PDB14

ASSESSMENT OF THE CLINICAL AND ECONOMIC BENEFITS OF ADEQUATE INSULIN INITIATION AND INTENSIFICATION IN PEOPLE WITH TYPE 2 DIABETES MELLITUS

Asche CV[1], Bode B[2], Busk AK[3], Nair SR[4]
[1]*Center for Health Outcomes Research, University of Illinois College of Medicine and University of Utah College of Pharmacy, Salt Lake City, UT, USA,* [2]*Atlanta Diabetes Associate, Atlanta, GA, USA,* [3]*Novo Nordisk A/S, Søborg, Denmark,* [4]*Cardiff Research Consortium, Capita India Pvt. Ltd, Mumbai, Maharashtra, India*

OBJECTIVES: To assess the clinical and economic benefits associated with adequate and early insulin initiation and intensification in people with T2DM. **METHODS:** A systematic review was performed using published papers from January 2000 to August 2010 that assessed intervention, disease, study design and outcomes. Studies were classified as initiation and intensification based on predefined criteria. Individual studies from systematic reviews and meta-analysis identified in our review were searched and included if relevant. **RESULTS:** We screened 2690 articles, of which 76 (40 initiation and 36 intensification) studies were included. Baseline HbA1c values were in all initiation studies >8.5%. Endpoint HbA1c values were reduced with insulin in all studies, with endpoint values ranging from 6.6% to 9.8%. Similar baseline and endpoint HbA1c were seen with the intensification studies (endpoint HbA1c ranging from 6.4% to 9.6%). Addition of insulin to oral anti-diabetic agents (OADs) resulted in better glycaemic control in most studies. Blood glucose levels reduced substantially with OADs+insulin compared to OADs alone. Quality of life outcomes and treatment satisfaction were reported in six studies and not significantly different for insulin versus OADs. Hypoglycaemic events were lower with insulin initiation versus OADs (1.39+1.16 vs. 2.30+1.87; 9/27 vs. 17/28). However, all insulin types were associated with weight gain though the comparison with OADs elicited varying results. Economic outcomes were reported in four studies with insulin initiation. Some studies reported a reduced incidence in diabetes-related complications with insulin, resulting in lower diabetes-related medical and total healthcare costs in these patients. Two studies showed that initiating insulin in those failing OADs resulted in increase in life expectancy and quality-adjusted life expectancy. **CONCLUSIONS:** Proactive management of uncontrolled glycaemia in people with T2DM should be considered with early insulin initiation and intensification. Further studies are required to explore the economic benefits with early insulin initiation and intensification.

PDB15

USE OF HYPOGLICEMIC DRUGS IN SERBIA: PHARMACOTHERAPEUTIC VERSUS PHARMACOECONOMIC ASPECTS

Sabo A, Tomic Z
Medical faculty Novi Sad Serbia, Novi Sad, Serbia and Montenegro

OBJECTIVES: To analyse the use of hypoglycemic drugs in Serbia from pharmacotherapeutic and pharmacoeconomic point. To see the influence of pharmacotherapeutic guidelines and cost on use of hipoglicemic drugs when compared with the countries with developed pharmacotherapy. **METHODS:** Use of hypoglicemic drugs in Serbia was obtained from National Agency for drugs in Serbia (ALIMS). The costs of hypoglycemic drugs was obtained from Serbian reimbursment company. The use of drugs was expressed in DDD/1000 inh/day, and compared to the price of drugs in the cathegory. **RESULTS:** The total use of hypoglycemic drugs in Serbia (56 DDD/1000inh/day) was similar to the use of drugs in this cathegory in another countries. Use of insulins was lower in Serbia, probably because slightly different pharmacotherapeutic approach to DM Typ II in Serbia. The structure of oral hypoglycemics was similar in Serbia and in comparator countries (Norway, Finland). While metformin was the most often used hypoglicemic drug in countries with developed pharmacotherapy, in Serbia the most often used drugs were sulfonylurea drugs, with glibenclamide and gliclaside being in the first place. Gliclaside, being on the second place in Serbia, is the most expensive hypoglicemic drug (price per DDD 12.15 Serbian dinars). If gliclaside would be changed with another, less expensive drug, the national reimbursment company would spare significant amount of money. Glimepiride, the most often used and the cheaper sulfonylurea derivative in countries with developed phrmacotherapy, was on the third place in Serbia. **CONCLUSIONS:** The total use of hypoglycemics in Serbia is comparable to countries with developed pharmacotherapy, indicating the satisfiing level of the treatment of diabetes mellitus. However, the structure og hypoglycemics used is suboptimal from pharmacotherapeutic and from pharmacoeconomic point of wiev. Significant improvement are needed, which would improve pharmacotherapy and pharmacoeconomic aspect of use of this drugs.

PDB16

FIRST RESULTS OF THE POST-MARKETING SURVEY OF VILDAGLIPTIN IN FRANCE

Attali C[1], Bringer J[2], Simon D[3], Eschwège E[4], Deschaseaux C[5], Dejager S[5], Quere S[5], Bouee S[6], Detournay B[6]
[1]*Cabinet Médical de Groupe, Epinay sous sénart, France,* [2]*CHRU Montpellier, Montpellier, France,* [3]*Hôpital de la Pitié, Paris, France,* [4]*INSERM, Villejuif, France,* [5]*Novartis Pharma, Rueil Malmaison, France,* [6]*Cemka, Bourg la Reine, France*

OBJECTIVES: To assess the characteristics of type 2 diabetes patients treated with vildagliptin (a new DPP-4 inhibitor) and to evaluate potential misuse, treatment adherence, effectiveness and tolerability of vildagliptin under real-life conditions of care in France. **METHODS:** Following a request by the French Health Technology Agency (Haute Autorité de Santé) an observational cohort study was started in 2010. The study population included a representative sample of patients with type 2 diabetes initiating a treatment with vildagliptin. Patients were enrolled through a national sample of vildagliptin prescribers Data collected included sociodemographic characteristics, clinical history, comorbidities, detailed treatment and laboratory data, physical exam and adherence. **RESULTS:** Overall, 482 GPs and 84 endocrinologists enrolled 1702 patients. Sixty percent were males, mean age was 63 (±11) years, mean disease duration was 7 (±6.5) years and mean HbA1C 7.8% (±1.2). Forty-five percent were obese and 39% overweight, 70% were treated for hypertension and 66% for dyslipidaemia, and 1256 patients (74%) were treated with vildagliptin/metformin fixed combination (Eucreas, FC) and 442 (26%) with vildagliptin (Galvus). Main reasons for initiating vildagliptin were: previous treatment failure (82%), weight gain (17%), reducing the numbers of pills (16%) and intolerance to a previous treatment (12%). In accordance to the precautions of use, 1366 patients (80%) underwent liver function tests, and 1552 patients (91%) blood creatinine measurement prior to treatment initiation. In few cases, vildagliptin was prescribed to patients for whom the product was not recommended: at baseline, 2.1% of treated patients presented elevations in alanine/aspartate aminotransferase > 3 times the upper limit of normal, 0.3% a NYHA class III congestive heart failure (no class IV) and 9.3% did not respect the precautions of use for renal function. **CONCLUSIONS:** Most prescriptions of vildagliptin were in accordance with the summary of product characteristics in this large, randomly selected French population.

PDB17

OFF-LABEL AND NON-LICENSED ENDOCRINOLOGY MEDICINE USE IN TURKEY: A RETROSPECTIVE ANALYSIS OF COMPUTER RECORDS IN THE TURKISH MINISTRY OF HEALTH

Kockaya G, Tanyeri P, Vural &M, Akbulat A, Akar H, Tokaç M, Kerman S
General Directorate of Pharmaceuticals and Pharmacy, Ankara, Turkey

OBJECTIVES: Off-label is defined by the Turkish Ministry of Health (MoHT) as the use of licensed pharmaceutical products in doses outside of or exceeding the scope of the registered indication, and the use of non-licensed but imported medicinal products for the purpose of individual treatment. The use of off-label or non-licensed endocrinology medicines were evaluated in order to provide an understanding of Turkey's perspective within this area of healthcare provisions. **METHODS:** A computer search was performed of IEGM's database. A patient base using off-label endocrinology medicine applications from 19 June 2009 to 19 June 2010 were searched. **RESULTS:** The computer search for the showed that 357 applications were submitted for off-label endocrinology medicine use. It was concluded that the highest application percentage was established by "osteoporosis" in all of the applications (43%, 155/357). The highest application was established by Ankara province (28%, 44/155). University hospitals had the highest off-label osteoporosis medicine use applications within the given timeline (65%, 102/155). Specialized physicians in the fields of endocrinology and metabolism (adult and paediatric) had the highest number of off-label osteoporosis applications (71%, 111/155). It was concluded that the highest application percentage was established by "teriparatide use in osteoporosis" (87%, 136/155) in all of the osteoporosis applications. 92 of 136 applications were approved. There was a significiant difference between the T score (L1-4) of rejected and approved applications for patients (3.07±1,85 and 3.23±1.63, respectively) ($p<0.001$). Yet there was not a significiant difference between ages of patients for whom applications were rejected or approved. **CONCLUSIONS:** It could be said that off-label use can lead to reimbursement restrictions in endocrinology, especially for teriparatide-like oncology medicines. In Turkey, physicians who want to prescribe an off-label or non-licensed pharmaceutical or a medicine which has a different use from reimbursement indications, need to apply through the off-label medicine use process.

PDB18

AUSTRALIA: MANAGEMENT OF THE DIABETIC FOOT WITH PEDIMED® UNDER REAL USE CONDITIONS

Taieb C, Auges M
PFSA, Boulogne Billancourt, France

OBJECTIVES: Xerosis is a common disorder among diabetic patients; 82.1% of diabetic patients suffer from xerosis, which may or may not be combined with fissures or cracking. It causes disorders which play a major role in the onset of ulceration. Xerosis exacerbates the development and the recurrence, in particular, of hyperkeratosis. To evaluate, under real use conditions, the effect of Pedimed (Glycerine, petroleum jelly, piroctone olamine, tocopheryl nicotinate, hydroalcoholic ruscus extr) on diabetic foot. **METHODS:** Observation study of diabetic patients with high risk factor for foot ulceration in Australian centres, with data collected via questionnaires from patients receiving PediMed® to measure acceptability and xerosis assessment from physicians and healthcare professionals. **RESULTS:** Mean age of subjects is 57 years (± 13.3), 64% presenting with type 2 diabetes. The XAS score measured by the doctor at inclusion is 6.4 (± 2.4) and 6.3 (± 2.6), respectively for the right and left foot. At 4 weeks, measured by the same doctor, the XAS score is 2.7 (± 2.3) and 3.0 (± 2.3) respectively for the right and left foot. Improvements are statis-

tically significant for both feet ($p<0.001$). Hyperkeratosis of both feet, evaluated by the doctor, significantly improves after 4 weeks of treatment. The efficacy score measured by the patient is 16.4 (± 4.8) on inclusion. Measured under the same conditions, it is 7.7 (± 3.2) at 4 weeks. The difference is statistically significant ($p<0.001$). Treatment compliance is good since 89% confirm that they respected the dosage, a trend confirmed by the fact that 94% of subjects say that they are satisfied with the product. **CONCLUSIONS:** By means of a validated score (XAS) and a patient evaluation scale, the efficacy of Pedimed in treating the diabetic foot is confirmed.

PDB19

PREVALENCE OF DIABETES MELLITUS AMONG PATIENTS WITH VASCULAR COMPLICATIONS IN POLAND

Fedyna M[1], Mucha A[1], Kapusniak A[1], Bebrysz M[1], Rutkowski J[1], Schubert A[2], Skrzekowska-Baran I[2], Rys P[1]
[1]*HTA Consulting, Krakow, Poland,* [2]*Novo Nordisk Pharma Sp z.o.o., Warsaw, Poland*

OBJECTIVES: The objective of this study was to estimate a prevalence of diabetes mellitus (DM) among patients with micro- and macrovascular complications in Poland, like angina pectoris, myocardial infarction (MI), stroke, lower limb ischemia, end-stage renal disease (ESRD), and their consequences like heart failure, visual disorders or amputations. **METHODS:** The estimation was based on observational studies, which were identified by searching medical databases and Polish registries. Publications were selected in a specific order, to ensure that included data are the most representative for Polish population. Firstly, studies conducted in Polish settings were included and, if no reliable publications were found, European, non-European Caucasian and other (not specified) population were analyzed. Population based registries were considered as the most appropriate type of data. When no registry was available systematic reviews of observational studies were included. If systematic review was not available – data from clinical studies were taken into account. **RESULTS:** According to polish registries, DM was present in 28% of patients with non-ST-elevation MI, 20% of patients with ST-elevation MI, 22% of patients with unstable angina and 22% patients with ESRD. The results of two studies regarding Polish population indicate that 15.3% of patients with stable angina pectoris suffer from DM. The results of studies coming from European countries identified by literature search showed that DM was diagnosed in 26.2% of patients with heart failure, 21.5% of patients with stoke, 40% of patients hospitalized for peripheral artery disease, 52.8% of patients with lower-extremity amputation and 67.1% of patients with non-traumatic amputations. Diabetes was present in 34.9%, 9.4% and 7.1% of patients with retinopathy, vision disorders and blindness respectively. **CONCLUSIONS:** DM often co-exists with vascular disorders in Poland. It affects 15% of patients with macrovascular complications and more than 20% of patients with microvascular complications.

PDB20

A1C VARIABILITY AND THE RISK OF DEVELOPING NEW DIABETES FOR THE HEALTHY ADULTS IN JAPAN

Takahashi O
St.Luke's International Hospital, Tokyo, Japan

OBJECTIVES: To evaluate the effect of A1C variability on the risk of developing new diabetes in healthy adults in Japan. **METHODS:** Population-based, retrospective cohort from 2005 to 2008 in Tokyo, Japan. In healthy adults not taking diabetes medication and with lower than 6.5 of HbA1c at baseline, we measured annually the serum HbA1c and calculated the annual visit-to-visit variability. **RESULTS:** At baseline, 14,764 people (49% female) with a mean age of 50 years old (SD: 12 years, range: 23 to 92), a mean fasting plasma glucose (FPG) level of 98.4 mg/dl (SD: 9.3 mg/dl) and a mean HbA1c level of 5.3 % (SD: 0.4 %) had annual check-ups over 4 years. Using the multivariate logistic regression, the A1C variability (odds ratio (OR): 7.8 for highest quantile interval (>= 0.16%)) versus the lowers quantile (<0.08 %), 95%CI: 4.8 – 12.8) and the baseline A1C (OR: 43.3 for group with 6.0 – 6.4 % of A1C versus with <5.0 %, 95% CI: 10.4 – 181.4) were independently predictive of new diabetes after adjusting for the other potential risk factors. FPG (OR: 1.1, 95%CI: 1.1 – 1.2) and Smoker (OR: 1.6, 95%CO: 1.2 – 2.3) also significantly related to develop the new diabetes. **CONCLUSIONS:** Visit-to-visit variability in A1C independently added to the baseline A1C in predicting the risk of developing new diabetes for the healthy adults.

PDB21

NATURAL HISTORY OF BETA CELL RATE OF DECLINE AND ITS EFFECT ON DEVELOPMENT OF SECONDARY COMPLICATIONS IN TYPE 1 DIABETES

Rodriguez RD, Sarsour K, Mitchell B, Bowman L
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: Beta cells in the pancreas are responsible for secreting insulin in response to increases in blood glucose. Proinsulin C-peptide (C-peptide), co-secreted with insulin, is a marker for beta cell function. C-peptide levels at type 1 diabetes (T1D) diagnosis and rate of decline (ROD) post diagnosis are important when evaluating the potential beta cell-preserving therapies to maintain better glycemic control and reduce complications. Because little is known about factors that affect C-peptide levels at diagnosis and ROD, we aimed to summarize known factors. **METHODS:** We conducted a systematic review of literature in PubMed (English only) from 1987 using the following key words alone and in combination: type 1 diabetes, c-peptide, rate of decline, concentration, epidemiology, residual beta cell function, diagnosis. Additionally articles were identified from the reference lists of selected journal articles. **RESULTS:** The review indicated that: 1) Decline of beta-cell function begins years before T1D diagnosis; 2) At diagnosis stimulated C-peptide concentrations range from 0.32±0.26 pmol/mL (mean±SD) to 1.4±0.8 pmol/mL (mean±SD); 3) Stimulated C-peptide ROD can range from -0.00 to -0.01 pmol/mL/month; 4) Lower C-peptide concentrations at diagnosis are partly explained by younger onset age, time since diagnosis, genetic factors and a high-titer presence of islet cell autoantibodies; and 5) Intensive therapy to treat T1D of ≥3 insulin injections daily reduces the C-peptide level after 1 year by 0.21±0.03 pmol/mL versus 0.15±0.02 pmol/mL for less intensive treatment of 1-2 injections. **CONCLUSIONS:** Understanding the factors that influence C-peptide ROD may help researchers develop strategies which address heterogeneity of response to therapy, resulting in improved glycemic control and reduction in complications such as ketoacidosis, neuropathy or nephropathy. Including parameters for C-peptide and its ROD in pharmacoeconomic models may help estimate the burden of these complications in T1D, and help quantify the benefits of preserving beta cells.

PDB22

'REAL-WORLD' CLINICAL OUTCOMES OF EXENATIDE BID COMPARED TO INSULIN GLARGINE IN PATIENTS WITH TYPE 2 DIABETES

Pawaskar M[1], Li Q[2], Hoogwerf B[1], Reynolds MW[2], Faries DE[1], Bruhn D[1], Bergenstal R[3]
[1]*Eli Lilly and Company, Indianapolis, IN, USA,* [2]*United BioSource Corporation, Lexington, MA, USA,* [3]*International Diabetes Center at Park Nicollet, Minneapolis, MN, USA*

OBJECTIVES: The safety and efficacy of exenatide BID (exenatide) compared to insulin glargine (glargine) has been studied in clinical trials and use of exenatide has been associated with reductions in A1C and weight. This study examined the clinical outcomes of exenatide versus glargine in patients with type 2 diabetes in a 'real-world' ambulatory care setting. **METHODS:** A retrospective analysis was conducted using the General Electric electronic medical record database to select exenatide (n=4,494) and glargine (n=5,424) cohorts. These cohorts were propensity-score matched to control for baseline demographic, clinical, and resource use variables (2,683 matched pairs). Matched cohorts were compared using paired t-tests and nonparametric tests as appropriate. The effectiveness endpoints were changes in A1C (primary endpoint), weight, body mass index (BMI), blood pressure (BP), lipid levels, and hypoglycemia rates. **RESULTS:** The matched exenatide and glargine cohorts had comparable age (58 vs. 58 years), females (55% vs. 53%), and baseline clinical characteristics. In a 12-month follow-up period, the exenatide cohort achieved greater mean (±SD) reduction in A1C (-0.66% [±1.5] versus -0.41% [±1.7], $P<0.01$), weight (-2.6 [±6.8] vs. -0.2 [±9.2] kg, $P<0.01$), BMI (-0.9 [±2.6] versus -0.1 [±2.7] kg/m^2, $P<0.01$), and systolic BP (-1.8 [±17] vs. -0.3 [±18] mmHg, $P<0.01$). More exenatide-treated patients reached the A1C goal of <7% (46% vs. 36%, $P<0.01$). There were no clinically significant differences in diastolic BP, lipid levels, and hypoglycemia rates between cohorts. **CONCLUSIONS:** Exenatide-treated patients experienced significantly greater reductions in A1C, weight, BMI, and systolic BP than the glargine cohort. These results demonstrated the clinical effectiveness of exenatide compared to glargine in a large, diverse, 'real-world' patient population treated in the ambulatory care setting.

Diabetes/Endocrine Disorders – Cost Studies

PDB23

BUDGET IMPACT ANALYSIS OF THE REIMBURSEMENT OF LONG-ACTING INSULIN ANALOGUES IN POLAND

Orlewska E[1], Gulacsi L[2]
[1]*Centre for Pharmacoeconomics, Warsaw, Poland,* [2]*Corvinus University Budapest, Budapest, Hungary*

OBJECTIVES: According to HTA reports regarding long-acting insulin analogues (LAIA) these drugs should be reserved for use in selected diabetic patients only. In line with recent knowledge LAIA in Poland are planned to be reimbursed in framework of therapeutic programme (LAIA-TP). This study assess the impact of this decision on public health-payers budget. **METHODS:** The analysis was perfomed using modelling technique, based on systematic review of LAIA, Polish epidemiologic and costing data. Two scenarios were compared: (A) LAIA not reimbursed, (B) LAIA reimbursed for patients with episodes of severe hypoglicaemia (after 6 months reimbursement continued only in patients successfully treated). In each scenario annual costs of insulinotherapy, monitoring and tretament of hypoglicaemia were estimated in 3-years time horizon. Model was run by having the current patient cohort progress through the model accompanied by the addition each year of a new cohort of eligible patients. Extreme scenario sensitivity analyses were performed. **RESULTS:** The expected number of diabetic patients eligible for LAIA would be 12,611 in the 1st year, and each year 661 "new" patients will meet inclusion criteria. Only 25% patients with type 1 and 30% patients with type 2 diabetes will be successfully treated with LAIA. The introduction of LAIA-TP is expected to increase public-payers expenditure in years 1st -3th by 12,168,582, 7,972,737 and 8,321,552 PLN, respectively (1 PLN=0.25 EURO, 2011). Such an increase in cost would be associated with acquisition cost of LAIA and would be only partially compensated by lower costs of monitoring and treatment of hypoglicaemia. Depending on assumptions about population and effectiveness of LAIA the additional expenditures of public payer varies between 11,295,941- 8,962,648 PLN, 7,219,765-9,627,449 PLN and 7,556,552-10,505,485 PLN in 1st, 2nd and 3rd year, respectively. **CONCLUSIONS:** Budget impact analysis indicates that reimbursement of LAIA-TP seems to be affordable to the budget holder.

PDB24

BUDGET IMPACT ANALYSIS OF THE USE OF ASPART INSULIN DURING HOSPITALIZATION OF PATIENTS WITH HYPERGLYCAEMIA IN ITALY

Iannazzo S[1], Pradelli L[1], Montagnoli R[2], Militano L[2]
[1]*AdRes HE&OR, Turin, Italy,* [2]*Novo Nordisk Farmaceutici Spa, Rome, Italy*

OBJECTIVES: Hyperglycaemia is a frequent condition in hospitalizations for acute conditions, not always correlated with a previous presence of diabetes. Patients with hyperglycaemia experiment a worse prognosis, with increased mortality, complications and a longer hospital stay than normal ones. Several evidences in

literature demonstrate that the outcome can also be influenced by the insulin regimen used by the hospital. Objective of this study is the Budget Impact Analysis (BIA) of the hospital use of aspart insulin with respect to other rapid insulin alternatives available on the market. **METHODS:** All the hospitalizations with evidence of hyperglycaemia in one year in Italy were considered. Four alternatives were evaluated: 1) aspart insulin; 2) lispro insulin; 3) glulisine insulin; 4) human insulin. Administration of insulin regimen (basal + rapid), length of hospital stay and incidence of hypoglycaemic events were simulated. The rates of hypoglycaemic events with rapid insulin alternatives, and the prolongation of hospital stay caused by such an event were derived from international literature. Only differential costs among alternatives were accounted for, i.e. purchase and administration of rapid insulin and management of hypoglycaemic events. Epidemiologic and healthcare resource consumption data derived from Italian published sources. Current prices and tariffs were applied in the perspective of the hospital. **RESULTS:** A total of 7.7 million hospitalizations of adult patients in one year were considered, of which 23.6% (1.8 million) with evidence of hyperglycaemia. Total costs with the aspart insulin resulted: €7.8 million for insulin, €7.4 million for administration and €507.0 million for hypoglycaemic events management (total: €522.2 million). Total costs with the other rapid insulin alternatives were higher (range: +4% to +37.2%). **CONCLUSIONS:** Aspart insulin has a listed purchasing cost in Italy equal or higher than alternatives, but the BIA indicates that its adoption can yield savings for the hospital, being the hypoglycaemic events management the main cost driver.

PDB25

REAL-WORLD OUTCOMES OF INITIATING TWO DIFFERENT BASAL INSULIN THERAPIES VIA DISPOSABLE PENS AMONG PATIENTS WITH TYPE 2 DIABETES IN US EMPLOYER-SPONSORED HEALTH PLANS

Du J[1], Wei W[2], Xie L[1], Pan C[3], Baser O[1]
[1]*STATinMED Research, Ann Arbor, MI, USA,* [2]*sanofi-aventis U.S., Inc, Bridgewater, NJ, USA,* [3]*Pro Unlimited, Boca Raton, FL, USA*

OBJECTIVES: Among patients with type-2 diabetes mellitus (T2DM) previously treated with only OADs, to evaluate real-world differences in clinical and economic outcomes following initiating basal analog insulin therapy via disposable pen with either glargine (GLA-P) or detemir (DET-P). **METHODS:** The MarketScan databases (2006–2010) were used to identify patients with T2DM aged 18–79 years and receiving ≥1 OAD, but no insulin before initiation of GLA-P or DET-P. Patients had continuous health plan enrollment for 6 months prior to (baseline) and 1 year after GLA-P or DET-P initiation (follow-up). Propensity score matching 1:1 was applied to match the two patient cohorts using baseline demographic and clinical factors. Study outcomes included treatment persistence and adherence, hypoglycemia-related medical events, and healthcare utilization and costs during the follow-up. **RESULTS:** The 2 matched cohorts (n=5771 each, mean age 54, female 49%) were well balanced for baseline characteristics (all $P>0.1$). During follow-up, patients initiating GLA-P were more likely to be persistent (42.9 vs. 38.4%, $P<0.001$) and adherent (adjusted medication possession ratio 0.70 vs. 0.67, $P<0.001$) with treatment versus those initiating DET-P. The average daily study drug consumption dose was 33U in both cohorts. Fewer GLA-P than DET-P users returned to OAD-only (18.6 vs. 20.5%, $P=0.011$). Hypoglycemia-related medical events were similar (0.7 vs. 1.0%, $P=0.093$), while the mean number of hypoglycemia-related emergency room (ER) or hospital events per patient was lower for GLA-P (0.006 vs. 0.012, $P=0.010$). The diabetes-related pharmacy costs were similar for GLA-P and DET-P ($2,465 vs. $2513, $P=0.155$), as were the total health care costs ($16,058 vs. $16,209, $P=0.69$). **CONCLUSIONS:** Real-world T2DM patients initiating insulin therapy via disposable pen with GLA-P were more likely to persist and adhere with treatment compared with patients initiating with DET-P. GLA-P users had fewer ER-/hospital-related hypoglycemia events, while costs were similar for both.

PDB26

PROJECTED LONG-TERM CLINICAL AND ECONOMIC OUTCOMES OF EXENATIDE ONCE WEEKLY VERSUS SITAGLIPTIN FOR THE TREATMENT OF TYPE 2 DIABETES IN THE UK

Beaudet A[1], Wilson B[2], Caputo J[3], Timlin L[4]
[1]*IMS Consulting Group, Basel, Switzerland,* [2]*Lilly, Basingstoke, Hampshire, UK,* [3]*IMS Consulting Group, London, UK,* [4]*Eli Lilly and Company, London, Surrey, UK*

OBJECTIVES: The aim of this analysis was to estimate the long-term incremental clinical and cost outcomes associated with exenatide once weekly (EQW) versus sitagliptin therapy in type 2 diabetes patients in the UK. Data from DURATION-2; a phase 3, multinational, randomised, double-blind clinical trial in 491 patients with type 2 diabetes previously treated with metformin were used. After 26 weeks, patients receiving EQW (n=160) had a significantly greater LS mean HbA1c reduction (-1.6% versus -0.9%, respectively) and weight reduction (-2.3 kg versus -0.8 kg, respectively) than patients who received sitagliptin (n=166). **METHODS:** A previously published and validated diabetes model (IMS CORE Diabetes Model) was used to make 50 year projections of clinical and cost outcomes based on DURATION-2 baseline patient characteristics and study results. Costs were derived from published sources and expressed in 2010 UK Pounds. A discount rate of 3.5 % was applied to both costs and outcomes. Various sensitivity analyses were performed. **RESULTS:** EQW treatment was projected to improve quality-adjusted life expectancy by 0.22 quality-adjusted life years (QALYs) (95% confidence interval 0.12 to 0.32) versus sitagliptin. Total direct medical costs associated with EQW were projected to be higher over patient lifetimes than with sitagliptin (difference of £1405, 95% confidence interval £444 to £1982), due to higher drug acquisition costs, which were partially offset by the lower incidence of diabetes-related complications during treatment with EQW, and hence cost of treating. The projected incremental cost effectiveness ratio (ICER) was £6418 per QALY gained. Results of the sensitivity analysis showed that the ICER was influenced by a reduction in time horizon, decrease in EQW benefits on HbA1c and increased time on EQW. **CONCLUSIONS:** Projected from the DURATION-2 trial, EQW can be considered cost-effective versus sitagliptin in the UK setting from the NHS perspective. The results were robust to sensitivity analyses.

PDB27

PROJECTED COST-EFFECTIVENESS OF EXENATIDE ONCE WEEKLY VERSUS EXENATIDE BID FOR THE TREATMENT OF TYPE 2 DIABETES IN THE UK

Wilson BP[1], Beaudet A[2], Caputo J[3], Timlin L[4]
[1]*Eli Lilly and Company, London, Hampshire, UK,* [2]*IMS Consulting Group, Basel, Switzerland,* [3]*IMS Consulting Group, London, UK,* [4]*Eli Lilly and Company, London, Surrey, UK*

OBJECTIVES: The aim of this analysis was to estimate the cost-effectiveness of exenatide once weekly (EQW) versus exenatide BID therapy, two formulations of the same glucagon-like peptide-1 receptor agonist molecule, in type 2 diabetes patients in the UK. Pooled data from DURATION-1 and DURATION-5, phase 3, randomised, open label clinical trials in 295 and 252 patients respectively, were used. EQW was associated with greater LS mean HbA1c reduction (-1.7% versus -1.2%, respectively, p<0.001) and weight reduction (-2.9 kg versus -2.4 kg, respectively, p=0.126). **METHODS:** A previously published and validated diabetes model (IMS CORE Diabetes Model) was used to make 50 year projections of clinical and cost outcomes based on pooled DURATION-1 and 5 baseline patient characteristics (age 55.3 years, duration of diabetes 7 years, HbA1c 8.36%) and study results. Costs were derived from published sources and expressed in 2010 UK Pounds. A discount rate of 3.5 % was applied to both costs and outcomes. Various sensitivity analyses were performed. **RESULTS:** EQW treatment was projected to improve quality-adjusted life expectancy by 0.18 quality-adjusted life years (QALYs) (95% confidence interval 0.10 to 0.25) and life expectancy by 0.16 years (95% confidence interval 0.07 to 0.26) versus exenatide BID. EQW was associated with delayed onset of any diabetes-related complication versus exenatide BID by almost 6 months on average. Due to the lower incidence of diabetes-related complications during treatment with EQW, and hence reduction in their treatment costs, EQW was associated with direct medical cost savings (difference of -£305, 95% confidence interval -£715 to £35). EQW was therefore projected to be dominant versus exenatide. This result was robust to all sensitivity analysis. **CONCLUSIONS:** Based on DURATION-1 and 5, EQW was projected to be less costly and more effective than exenatide BID over a patients' lifetime in the UK setting.

PDB28

THE ROLEOF DIABETES AND BODY MASS INDEX ON MEDICAL EXPENSES, AN ANALYSIS OF THE MEDICAL EXPENDITURE PANEL SURVEY, 2008

Mitchell B
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: The World Health Organization has recognized diabetes and other selected chronic health conditions are at an epidemic level all of which can be impacted by weight. The purpose of this project was to evaluate the role of diabetes and Body Mass Index (BMI) on total medical expenses. **METHODS:** The Medical Expenditure Panel Survey (MEPS) is publically available database providing nationally representative estimates of health care use, expenditures, sources of payment, and health insurance coverage for the US population. Analysis of the survey data utilized design-based methods that utilized the complex survey stratification and weighting. Regression was utilized to determine the effect of diabetes and BMI class on total medical expenses in 2008, with inclusion of age, gender, race/ethnicity, and insurance status as additional covariates. Models with and without two-way interactions were performed. Summary statistics are presented as mean ± standard error. **RESULTS:** All adults (≥18 years; n=22,128) were included, and average 2008 medical expenses were estimated at $4493 ± 105. All variables in the model were significant (p<0.001), and adjusting for these factors, patients with diabetes had an average medical expense of $4,512 ± 410 higher than those without diabetes. Across both cohorts, the morbid obese (BMI ≥ 40) had significantly higher covariate adjusted medical expenses than normal (18.5≤ BMI<25; +$1340 ± 414; p=0.001) and overweight (25≤ BMI<30; +$1517 ± 420; p<0.001) individuals, whereas differences with obese (30≤ BMI<40; +$784 ± 439; p=0.08) and underweight (BMI<18.5; -$88 ± 754; p=0.91) were not significant. **CONCLUSIONS:** Both diabetes and high BMI are independently associated with significantly higher medical expenses, and appear to be generally an additive effect. Increase in BMI was associated with significantly higher medical costs even without diabetes. Morbidly obese patients with diabetes had annual expenses averaging $12,004.

PDB29

MODELING THE IMPACT OF ENHANCED TREATMENT OF TYPE 2 DIABETES MELLITUS IN BULGARIA

Boyanov M[1], Petrova G[2], Henriksen O[3], Valov V[4]
[1]*University Alexandrovska Hospital, Sofia, Bulgaria,* [2]*Medical University, Faculty of Pharmacy, Sofia, Bulgaria,* [3]*Novo Nordisk, Inc., Bagsvaerd, Denmark,* [4]*Novo Nordisk Pharma EAD, Sofia, Bulgaria*

OBJECTIVES: To model and evaluate consequences of enhanced treatment of type 2 diabetes mellitus on cost, life expectancy and development of complications in the Bulgarian health care system. **METHODS:** The extensively published and validated CORE Diabetes Model was used to perform lifetime simulations for the representative diabetic patient in Bulgaria diagnosed at 55 years. The analysis compared two alternative treatment scenarios with current standards of care. In the first alternative scenario the model examined the human and economic costs of 10% reduction in the risk factors for developing diabetes related complications. In the second scenario consequences of treating to targets set in American Diabetes

Association (ADA) guidelines were simulated. Cost of treatment and complications were based on officially published sources for medicines prices (www.mh.government.bg), for hospital charges (www.nhif.bg) and verified by expert opinion survey (1 BGN = 0.51 EUR). Future costs were discounted with 5%. **RESULTS:** Treatment to targets postpones minor complications by up to 4 years, delays major complications by 3 to 4 years and extends life expectancy from diagnosis by 3 years compared with the baseline scenario. Total discounted cost savings over remaining life expectancy from the diagnosis were from 2483 BGN to 2908 BGN per person. **CONCLUSIONS:** Enhanced treatment leads to avoidance or delay of the complications of diabetes. This significantly reduces the impact diabetes can have on patients' quality of life, life expectancy and cost of diabetes treatment in Bulgarian health care system settings.

PDB30

ASSESSMENT OF THE IMPACT OF THE NEW ANTIDIABETIC TREATMENT WITH VILDAGLIPTIN TO CHANGE THE TOTAL COSTS ON DIABETES TYPE 2

Yanovskaya MY

Endocrinology center of Yaroslavl region, Moscow, Russia

BACKGROUND: Under the data of Russian Federal State Registry 2010 there are around 3 million patients in diabetes. Also data of epidemiology assessment in the frame of national project "Health" demonstrates that estimated number of patients consists of 5-7% from total population that is 4 times higher. Death rate of cardiovascular complications is 1.5 thousand people per year. Every second patient gets invalidity. So total expenditures for complications treatment tens times more than costs on medical products and control devices. **OBJECTIVES:** 1) Provide local costs of the disease, and 2) Assess benefits of new technology treatment versus traditional therapy. **METHODS:** Retrospective analysis of case studies of patients in D2T from 4 regions of Russia. Average age - 61 years, duration of D2T - 7.5 years, body mass index - more than 32 kg/m^3, Hb1Ac - 8.1%. Isolation of two groups of patients: 1 - treated with adding of vildagliptin (n=264); 2 - treated by traditional OAD with sulfonylurea (n=600). Comparative analysis "Cost of Illness" of two groups, and correlation between antidiabetic medical products and risk of fatal complications. **RESULTS:** Average cost of antidiabetic medical treatment of group 1 versus 2 is more than 2 times expensive, 16,600 rub versus 7,000 rub per patient rep year. Exchange rate is $1 = 30 rub. But total costs for the treatment of patients group 2 versus 1 is 30% higher (26,000 rub and 18,000 rub per patient per year accordingly). The main reason - more number of vital important cardiovascular events and exacerbations of hypertension and heart disease in group 2. Part of direct medical costs for the treatment without antidiabetic products is 7% and 73% from total costs for groups 1 and 2 accordingly. **CONCLUSIONS:** Usage of new antidiabetic products - vildagliptin is a way to control of diabetes, development of cardiovascular complications and total budget for the disease.

PDB31

COST OF DIABETES IN CROATIA IMPACT OF COMPLICATIONS ON THE COSTS OF TYPE II DIABETES

Saric T[1], Benkovic V[2], Poljicanin T[3], Stevanovic R[4]

[1]*Promeritus savjetovanje, Zagreb, Croatia,* [2]*Croatian society for pharmacoeconomics, Zagreb, Croatia,* [3]*Vuk Vrhovac University Clinic Zagreb, Croatia, Zagreb, Croatia,* [4]*Croatian Society for Pharmacoeconomics and Health Economics, Zagreb, Zagreb, Croatia*

OBJECTIVES: The prevalence of diabetes continues to grow, and it is estimated that in Croatia we have 315.900 adults with diabetes (9.2% adult population), although in many patients the disease has not yet been diagnosed. Majority of patients - 92,8% suffers from diabetes mellitus type 2. The objectives of this study are to quantify the economic burden of illness caused by increased health resource use and to provide detailed breakdown of the costs attributed to diabetes. **METHODS:** Prevalence-based cost-of-illness methodology was used to estimate the direct costs (hospital care, drugs, physician care, institutional care, additional costs) and indirect costs (sickness leave) associated with micro and macro vascular complications, diabetes monitoring and drugs analyzed by types of diabetes complication and health resource categories. **RESULTS:** Total cost of diabetes mellitus type 2 in Croatia sums to 11,49% of national insurer's budget, i.e. 351,7 mil EUR in 2009. Direct medical costs include 50,2 mil EUR to directly treat and monitor diabetes, and 301,5 mil EUR to treat diabetes-related chronic complications. Diabetes medications make 8,75% of total illness cost. The largest components of medical expenditures are hospital inpatient care (36,75%) and prescriptions for treating complications (28,49%). Hypertension and cardiopathy incur largest amount of expenditures related to diabetes complications (76,2 mil EUR), followed by acute myocardial infarction (68,6 mil EUR) and peripheral vascular disease (52 mil EUR). Indirect costs equal 4,6 mil EUR. **CONCLUSIONS:** An average expenditure per person with diagnosed diabetes type 2 in Croatia is 1.956 EUR yearly. These cost data provide additional rationale for better disease monitoring and complication prevention.

PDB32

COST OF DIABETES AND ITS COMPLICATIONS IN POLAND: PRELIMINARY RESULTS

Lesniowska J[1], ul;2?>Schubert [2], Skrzekowska-Baran I[2]

[1]*Kozminski University, Warsaw, Poland,* [2]*Novo Nordisk Pharma Sp z.o.o., Warsaw, Poland*

OBJECTIVES: Diabetes mellitus (DM) is a major health problem with severe complications and a significant impact on quality of life. It constitutes an enormous burden of disease due to high prevalence, severe co-morbidities and high costs for society. This study is the first comprehensive study on direct and indirect cost of DM (type 1 and type 2) and its complications in Poland. **METHODS:** In order to estimate the direct medical costs of DM and its complications, including the costs of medical consultation, hospitalization, rehabilitation, drugs and medical equipment data for the years 2004-2009 of the National Health Fund were used. Indirect costs like costs of pensions for incapacity for work, the costs of rehabilitation and loss of productivity due to diabetes and its complications were obtained from the Department of Social Security for the years 2004-2009. **RESULTS:** Direct medical costs of DM in Poland increased in the analysed period. The significant share of these costs constitutes the costs of drugs (25.7% increase 2005 vs. 2007). Direct costs of DM treatment, without costs of drugs, increased in the analysed period at similar rate (type 1 – 22,7%, type 2 – 22,1%). The highest costs are associated with treatment of diabetes complications. The total cost of treatment of DM showed in the analysed period an upward trend. The indirect costs are mainly determined by loss of productivity, cost of pensions for incapacity for work and cost of rehabilitation. The number of diabetic patients receiving pensions for incapacity for work is declining, but this trend is being seen in the whole disability pensions system in Poland. **CONCLUSIONS:** From year to year DM causes a growing economic burden on the health care and to the Polish society in terms of health care and productivity loses.

PDB33

COST OF DIABETES MANAGEMENT TO COCOA CLINICS IN GHANA

Quaye EA[1], Akweongo P[2], Aikins MK[2]

[1]*Medical Department, Ghana Cocoa Board, Accra, Gt. Accra, Ghana,* [2]*University of Ghana, Legon, Accra, Ghana*

OBJECTIVES: To determine the financial cost of diabetes management to Cocoa clinics for 2009. **METHODS:** A descriptive cross-sectional study of diabetes management at the four Cocoa clinics in Ghana from May to July 2010 was conducted. The prevalence-based 'Cost-of-illness' approach from the institutional perspective was employed. A pre-tested data extraction form was used to review the medical records of 304 diabetes patients randomly selected. **RESULTS:** The mean age was 55.4 years. The annual financial cost of managing one diabetes patient was estimated to be GH¢ 541.35 (US$ 373.34). Service cost constituted 22% whiles direct medical cost was 78%. Drug cost was 71% of the financial cost. The cost of hospitalization per patient-day at Cocoa clinic was estimated at GHø 32.78 (US$ 22.61). The total financial cost of Diabetes management was estimated at GH¢ 420,087.67 (US$ 289,715.63). This accounted for 8% of the total expenditure for the Clinics in year 2009. The study showed that facility type, type of diabetes and presence of complications is associated with the cost of Diabetes management to Cocoa clinics. **CONCLUSIONS:** The cost of managing Diabetes Mellitus and accompanying complications can be used to forecast the economic burden of the disease to the clinics. The mean age indicates delay in diagnosing diabetes and accompanying complication which has cost implications. This calls for policies that will help in the early detection in clinical practice and effective management protocols by Cocoa clinics.

Keywords: Diabetes, financial cost, Cocoa clinics, complication, Cost-of-illness, Ghana.

PDB34

MEDICAL TREATMENT COSTS ATTRIBUTABLE TO OBESITY IN DIABETIC PATIENTS IN THE UNITED STATES

Suh DC[1], La HO[2], Yi SY[3], Choi IS[3], Sohn HS[4], Jang SM[5]

[1]*College of Pharmacy, Chung-Ang University, Seoul, NJ, South Korea,* [2]*Catholic University College of Medicine, Seoul, South Korea,* [3]*Rutgers University, Piscataway, NJ, USA,* [4]*Sookmyung Women's University, Seoul, South Korea,* [5]*Health Insurance Review Agency, Seocho-gu, South Korea*

OBJECTIVES: To estimate annual treatment costs attributable to obesity (TC-ATO) in diabetes patients in the US. **METHODS:** The study used Medical Expenditure Panel Survey data from 2001-2008, a nationally representative sample of US non-institutionalized population. Diabetic patients(≥18 years old) were identified using ICD-9-CM code 250, clinical classification codes 049 and 050, or physician reported diagnosis. Patients were classified as normal (body mass index(BMI)18.5-<25 kg/m^2), overweight (BMI 25-<30 kg/m^2), or obese (BMI≥30 kg/m^2). Patients with pregnancy, malignancy, kidney dialysis, immunodeficiency, or low BMI<18.5 kg/m^2 were excluded. Treatment costs included all costs for treating diabetic patients, excluding dental health and injury costs. Adjusted costs were calculated using generalized linear model(GLM) with log link function and gamma distribution. TC-ATOs were estimated using recycled prediction and quantile regression method. The recycled prediction method predicted costs for obese patients by calculating costs using estimated coefficients from normal patients using GLM after adjusting for the study variables. TC-ATO was the differences between actual costs and predicted costs in the obese patients. In quantile regression, TC-ATO for each quantile was estimated as the coefficient of the obese patients. All costs were converted to 2010 US dollars using price indices. **RESULTS:** The average treatment costs were $9,196 (95%CI:$8,213-$10,178) and $9,614 (95%CI:$9,124-$10,104) for normal and obese patients, respectively. The treatment costs in obese patients were 12% higher than those in normal patients after adjusting for other study variables(p=0.029). Overall, the average TC-ATO in diabetic patients was predicted to be $527(95%CI:$49-$1,005). TC-ATO calculated by quantile regression were $154(95%CI:$68-240), $253(95%CI:$165-$342), $395(95%CI:$246-$545), $705(95%CI:$395-$1,015) and $920($443-$1,397) for 10th, 25th, 50th, 75th, and 90th percentile, respectively. **CONCLUSIONS:** Obese patients with diabetes have significantly higher treatment costs compared to normal diabetic patients. The increased economic burden attributable to obesity represents potentially avoidable costs, which justifies allocating additional resources to therapeutic interventions aimed at reducing weight.

PDB35

ESTIMATING THE REAL LIFE DAILY USAGE AND DAILY COST OF GLP-1 RECEPTOR AGONISTS IN THE UK SETTING

McDonell A[1], Zammit DC[2], Haslam T[1], Gregor Z[3], Wilson BP[4]

[1]IMS Health, London, UK, [2]IMS Health, Basel, Switzerland, [3]Eli Lilly & Company, Prague, Czech Republic, [4]LILLY UK, Hampshire, UK

OBJECTIVES: Glucagon-like peptide-1 (GLP-1) receptor agonists are indicated to improve glycemic control in adults with Type 2 diabetes mellitus. The maximum daily licensed dosages in the UK are 20μg and 1.8mg for exenatide and liraglutide respectively. In addition to factors such as glycaemic control, cost is an important consideration when selecting treatments. The aim of this analysis was to describe the real-world daily usage and cost of exenatide BID and liraglutide in the UK setting. **METHODS:** Data and study period: UK records between October 2008 and March 2011 from the IMS Dynamic Prescription database. This database captures data from pharmacy records (45% national coverage) of actual prescriptions dispensed, linked to individual patients (anonymised). Inclusion criteria: patients have filled a prescription for a GLP-1 receptor agonist at least twice during the study period; all key prescription fields are complete. The weighted average daily usage was calculated for each agent using the total volume of product dispensed and the number of patients filling prescriptions per month. Drug costs (British National Formulary 61, 2011) were applied to estimate average daily cost (ADC). Key assumptions: patients are not stockpiling or disposing of drug; each prescription equals one pack; patients are filling their prescriptions at the same pharmacy. **RESULTS:** Data was available for a total number of unique patients of 19,200 and 12,690 for exenatide BID and liraglutide (data available from July 2009) respectively. The average daily usage during the investigated time period was estimated to be 20.49μg for exenatide and 1.51mg for liraglutide, with an estimated ADC of £2.53 and £3.29 respectively. **CONCLUSIONS:** Based on the data described, GLP-1 receptor agonists are being dispensed in amounts within an acceptable range of the maximum daily licensed dosage. The ADC appears to be 30% higher for liraglutide with an estimated additional daily spend of £0.76.

PDB36

ESTIMATING THE AVERAGE ANNUAL COST OF TREATMENT WITH INSULIN FOR PATIENTS WITH TYPE 2 DIABETES MELLITUS

Burslem K[1], Das Gupta R[1], Hussein A[2]
[1]Boehringer Ingelheim Ltd, Berkshire, Berkshire, Brack, UK, [2]Boehringer Ingelheim Ltd, Berkshire, Bracknell, UK

OBJECTIVES: To estimate the average annual cost of treating patients with type 2 diabetes mellitus with insulin including: the cost of insulin, test strips for self-monitoring of blood glucose levels, and additional healthcare professional (HCP) time spent with patients following insulin initiation. The secondary objective was to describe insulin prescribing patterns in the UK. **METHODS:** For insulin and test strip costs a retrospective analysis of 2009/10 UK patient-level data was undertaken using Cegedim Strategic Data. Costs were applied using the BNF and MIMS. To estimate HCP resource use, 100 HCPs were surveyed on the number of contacts with insulin patients in the 3 years prior to and the 3 years post insulin initiation. Costs were applied using PSSRU 2010. **RESULTS:** A projected 24.5 million insulin items were prescribed to 400,000 patients, generating an estimated average annual insulin cost of £393 per patient. Long-acting and biphasic insulins together accounted for more than 75% of the total volume and costs of insulin prescribed; intermediate acting insulins accounted for 6% and 4% of the volume and costs respectively. A projected 4.5 million packs of test strips were prescribed to 360,000 patients, generating an estimated average annual cost of test strips of £180 per patient. Contact time across all HCPs peaked in the year following insulin initiation. There was an absolute increase of 8 contacts per patient in the 3 years post insulin initiation, representing an additional cost of £103 per patient. **CONCLUSIONS:** Insulin initiation increases the cost of care not only because of the insulin costs, but because of the package of resources that insulin requires. The estimated cost of insulin, insulin pens, needles and test strips is £609 per patient. The analysis suggests divergence from the NICE Clinical Guidelines 87 recommendation that first-line insulin therapy should be intermediate NPH insulin.

PDB37

INJECTION OF LONG-ACTING SOMATOSTATIN ANALOGS: A COST CONSEQUENCE ANALYSIS FOR THREE EUROPEAN COUNTRIES

Marty R[1], Roze S[1], Kurth H[2]
[1]HEVA, Lyon, France, [2]IPSEN, Boulogne Billancourt, France

OBJECTIVES: Long-acting somatostatin analogs (SSA) with product-specific formulation and means of administration are injected periodically in acromegaly and neuroendocrine tumor (NET) patients. The ready-to-use device Somatuline Autogel/Depot® reduces drug administration time by 80%. Its prefilled syringe also avoids the risk of clogging reported for octreotide LAR. A simple decision-analytic model aimed at estimating cost savings due to these differences in administration was developed for the UK, France and Germany. **METHODS:** The decision tree simulated four scenarios for SSAs Somatuline Autogel/Depot® and Sandostatin LAR®, injected by either hospital- or community-based nurses. Injection success depended on clogging event occurrence. In the case of clogging, the first dose was assumed to be lost and a second injection performed. Administration costs were valued based on average hourly nurse wages in addition to country-specific retail drug costs. Several simulations were run depending on the baseline risk of clogging, administration time, and their respective relative reduction due to use of Somatuline Autogel/Depot®. **RESULTS:** Costs per successful injection were less for Somatuline Autogel/Depot®, ranging from EUR 13 to EUR 44, EUR 52 to EUR 150 and EUR 107 to EUR 127 respectively for France, Germany and the UK. As the prices for both long-acting SSAs were the same in France, cost savings came 100% from differences other than drug prices. For Germany and UK, the proportions of savings due to lower clogging and administration time was estimated around 32% and 20%, respectively. Based on low and high country-specific patient cohort size estimations for acromegaly and NETs, these costs savings per patient could lead to overall annual savings up to one million euros for France, six million euros for Germany, and four million euros for the UK. **CONCLUSIONS:** Widespread usage of the new pre-filled Somatuline device for injection of SSA might lead to substantial savings for healthcare providers across Europe.

PDB38

ECONOMIC EVALUATION OF RANIBIZUMAB IN THE TREATMENT OF VISUAL IMPAIRMENT DUE TO DIABETIC MACULAR EDEMA IN AUSTRIA

Brennig C[1], Schöllbauer V[1], Walter E[1], Gallagher M[2], Knudsen MS[3]
[1]Institute for Pharmaeconomic Research, Vienna, Austria, [2]Novartis Pharma AG, Basel, Switzerland, [3]IMS Health, London, London, UK

OBJECTIVES: Diabetic macular edema (DME) is an ophthalmological complication of diabetes that may lead to visual impairment and blindness if left untreated, and even despite treatment with the current standard of care, laser coagulation. Currently, an estimated 2% of diabetics suffer from DME with vision loss. The aim of the study was to evaluate the cost-effectiveness of ranibizumab versus laser coagulation in the treatment of visual impairment due to DME. **METHODS:** A cost-effectiveness analysis was simulated using a Markov model adapted for Austria. The model is based on the PHIII-RESTORE trial. Outcome measures were 'Vision Years' and QALY. Costs are year 2010 values. Direct medical costs comprise all treatment costs due to diabetic macular edema. The cost of blindness was incorporated using data from an Austrian cost-of-illness-analysis. The model time horizon was lifetime. The analysis was performed from the perspective of the Austrian health care system according to the Austrian Guidelines for Health Economic Evaluations. **RESULTS:** The model assumes 7 injections of ranibizumab in the first year and 4 injections in the second year, as well as 2 treatments with laser coagulation in the first year and one treatment in the second year. Lifetime costs amount to €17,417 for ranibizumab and to €16,286 for laser coagulation. The ICER is €5354 (incremental QALYs gain with ranibizumab of 0.22). The number of vision years is 10.19 for ranibizumab and 8.57 for coagulation; the incremental cost per additional vision year gained is €701. **CONCLUSIONS:** The study suggests that in Austria, ranibizumab treatment for visual impairment resulting from DME is a cost-effective strategy versus the current standard of care, laser coagulation.

PDB39

COST-EFFECTIVENESS OF SAXAGLIPTIN COMPARED TO SITAGLIPTIN FOR THE TREATMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM)

Hutchings A[1], Tolley K[2], Achana F[3], Brereton NJ[4], Lebmeier M[5], Mesa OA[6]
[1]GMAS, London, UK, [2]Tolley Health Economics, Buxton, UK, [3]University of Leicester, Leicester, UK, [4]BresMed Health Solutions, Sheffield, South Yorkshire, UK, [5]Bristol-Myers Squibb, Uxbridge, Middlesex, UK, [6]Bristol-Myers Squibb Pharmaceuticals Ltd, Uxbridge, Middlesex, UK

OBJECTIVES: Saxagliptin (Onglyza®) and sitagliptin (Januvia®) are DPP-4 inhibitors licensed for the treatment of T2DM. The two treatments have been investigated as an add-on to metformin in an 18-week, non-inferiority, RCT in 801 patients with T2DM who failed to achieve adequate glycaemic control on metformin alone. Results showed that the newer treatment, saxagliptin, was noninferior to sitagliptin, with a similar tolerability profile. Saxagliptin has a lower acquisition price, hence this analysis sought to assess cost effectiveness of saxagliptin+metformin versus sitagliptin+metformin using a cost utility analysis (CUA) framework from a UK healthcare perspective. **METHODS:** The CUA utilised a validated model using UKPDS risk equations to estimate long run micro/macro-vascular complications and mortality over a 40 year time horizon. Clinical parameters in the model included HbA_{1c} levels for treatment effect, weight gain and incidence of hypoglycaemic adverse events. Parameter estimates were obtained from a mixed treatment comparison (MTC) of saxagliptin and sitagliptin, which included the head-to-head study. Treatment costs were based upon UK published list prices. Established costs and disutilities associated with long-term diabetic outcomes were used, based upon a UKPDS sub study. Univariate/probabalistic sensitivity analysis was conducted. **RESULTS:** The annual drug cost per patient for saxagliptin was £411.93 versus £433.57 for sitagliptin. In the base case, total discounted healthcare costs over the 40 year time horizon were £9,907 with saxagliptin and £10,035 with sitagliptin, with the same discounted QALY outcomes (10.49). Saxagliptin was therefore cost saving in the base case analysis. This finding was consistent across a range of sensitivity analyses, with the exception of lower 95% credible intervals for saxagliptin efficacy which resulted in a small incremental cost for saxagliptin (£29). **CONCLUSIONS:** Saxagliptin and sitagliptin have been shown to have comparable therapeutic profiles in a head-to-head study and MTC, but lower healthcare costs driven by a 5% lower drug acquisition cost.

PDB40

ECONOMIC ANALYSIS OF DIABETES TREATMENT GOALS DEFINED BY POLISH DIABETES ASSOCIATION: HOW MUCH DOES COST-EFFECTIVE TREATMENT COST?

Szmurlo D[1], Schubert A[2], Kostrzewska K[1], Rys P[1], Skrzekowska-Baran I[2]
[1]HTA Consulting, Krakow, Poland, [2]Novo Nordisk Pharma Sp z.o.o., Warsaw, Poland

OBJECTIVES: Clinical guidelines for diabetes management issued by Polish Diabetes Association (PDA) describe therapeutical goals in patients with diabetes. The aim of this analysis was to determine additional costs that may be incurred for treatment along with PDA recommendations (as compared with current treatment practice), so that the growth of treatment-related expenses would remain cost-effective in Polish setting. **METHODS:** Two hypothetical patients were defined: John and Peter, whose clinical characteristics correspond to those of newly diagnosed patients with diabetes mellitus type 2 (DM2) in Poland. Diabetes progression was modelled assuming that John is treated in line with current clinical practice and Peter is treated along with PDA recommendations (HbA1c, LDL, HDL, SBP are

maintained within PDA-defined limits). Simulations were conducted in CORE diabetes model, which is a Markov model built on the base of published clinical trials and encompasses over a dozen of diabetes complications. The model was extensively validated and allows for reliable estimation of costs and outcomes associated with diabetes. Model inputs were adapted to Polish setting. Economic analysis was conducted in lifetime horizon, costs and outcomes were discounted (5% and 3,5%, respectively). Cost acceptability threshold in Poland is 25 511 euro per QALY gained. **RESULTS:** John's QALY is 0,3 lower that QALY of Peter. Treatment of John's complications is 400 euro more expensive as compared to Peter. If willingness to pay (WTP) equals to €7500 euro per QALY, yearly costs of Peter's treatment may be 250 euro higher that John's. If WTP is €15,000, Peter's treatment may be €450 more expensive that John's and if WTP is €25,000 the difference in treatment costs may be as high as 725 euro. **CONCLUSIONS:** DM2 treatment along with PDA recommendations may be cost-effective provided additional costs do not exceed €725 per year.

PDB41

THE COST-EFFECTIVENESS OF GETTING TO GLUCOSE, BLOOD PRESSURE, AND LIPID GOALS IN PATIENTS NEWLY DIAGNOSED WITH TYPE 2 DIABETES MELLITUS (T2DM) AND YOUNGER THAN FIFTY IN SWEDEN

He J[1], Neslusan C[1], Willis M[2], Worbes-Cerezo M[3]
[1]*Janssen Global Services LLC, Raritan, NJ, USA,* [2]*IHE, Lund, Sweden,* [3]*Janssen-Cilag S.A., Madrid, Spain*

INTRODUCTION: Good T2DM management requires not only good control of blood glucose, but also blood pressure and serum lipid levels. Although data from the Swedish National Diabetes Registry indicates that more patients have attained recommended levels of these biomarkers over time, a sizable proportion fails to meet all of these goals. **OBJECTIVES:** Assess the cost-effectiveness of intensifying therapy to achieve Swedish-specific treatment goals for HbA1c, systolic blood pressure (SBP), and LDL versus usual care for patients newly diagnosed with T2DM and younger than fifty. **METHODS:** We used the Economic and Health Outcomes (ECHO)-T2DM model, a Markov-based micro-simulation model, to simulate the lifetimes of 500 cohorts of 500 hypothetical patients under two different scenarios: 1) treatment to maintain target goals for HbA1c, SBP and LDL; and 2) treatment to maintain levels observed empirically in Sweden. Pharmacotherapy treatment pathways for the control of hyperglycemia, hypertension and dyslipidemia followed Swedish guidelines and were identical in the two scenarios. The costs of pharmacotherapy and medical events were obtained from Swedish data. **RESULTS:** Treatment to HbA1c, SBP and LDL goals versus treatment to observed levels in Sweden resulted in a small QALY gain (0.13) and medical cost-savings of SEK 3552(€395). Spending on glucose-lowering agents, anti-hypertensives, and lipid-lowering agents was increased by SEK 4136(€460), SEK 4864(€540) and SEK 2390(€265), respectively. Costs due to micro- and macrovascular complications were reduced by SEK 5731(€637) and SEK 9522(€1058), respectively. **CONCLUSIONS:** For patients newly diagnosed with T2DM and younger than fifty in Sweden, intensifying therapy to maintain target glucose, blood pressure, and lipid levels resulted in increased spending on pharmacotherapy, however, spending on micro- and macrovascular events was reduced by a greater degree. These results suggest that allocating more resources toward the attainment of these goals may be welfare-improving.

PDB42

ECONOMIC EVALUATION OF RECOMBINANT HUMAN FSH IN COMPARISON WITH URINARY HMG IN ASSISTED REPRODUCTION IN THE GREEK SETTING

Fragoulakis V[1], Tarlatzis B[2], Mastrominas M[3], Maniadakis N[1]
[1]*National School of Public Health, Athens, Greece,* [2]*Medical School, Aristotle University of Thessaloniki, Thessaloniki, Greece,* [3]*Embryogenesis Centre for Reproductive and Fertility Studies, Athens, Greece*

OBJECTIVES: To compare the cost-effectiveness of Follitropin Alpha (Gonal-F®), which is a recombinant FSH, with a urinary highly purified hp-FSH (Menopur®) used in assisted reproduction in Greece. **METHODS:** A decision tree in combination with a Markov model was constructed to assess the clinical and economical impact of comparators for three consecutives cycles. Transition probabilities for all stages of a treatment cycle (i.e, cancelled ovum retrieval, successful recovery of oocytes etc) were derived from literature and validated by clinical experts. Cost components such as "initial treatment cost", cost of "oocytes", "oocyte pick-up", "fertilization", "transfer", "cryo preservation" and "frozen- thawed embryo transfer (FET)" were derived from the electronic databases of selected private and public clinics. The average number of units used per IVF and the rate of adverse events were based on the literature. Drug prices and reimbursement tariffs, were obtained from the "Government Gazette" and valued at 2011 prices. A probabilistic sensitivity analysis was performed to deal with uncertainty and to construct variability measures. **RESULTS:** There was a statistically significant difference in favor of the r-FSH arm compared to hp-HMG, which is associated with 52 more life births (95%CI: 26-78, p-value<0.001) per 1,000 patients. The cost per life birth was estimated at €16,906 (95%CI: €16,347 – €17,516) and €17,286 (95%CI: €16,740 – €17,845) in the r-FSH and hp-HMG arms, respectively. The cost per IVF was estimated at €4,365 (95%CI: €4,205 – €4,506) in the r-FSH and €3,815 (95%CI: €3,661 – €3,953) in hp-HMG arm, indicating a difference at €550 (95%CI: €365 – €730, p-value<0.001). The incremental cost per life birth (ICER) for r-FSH versus hp-HMG was estimated at €14,540 (95%CI: €10,509 – €21,868), while the incremental cost per life year was estimated at €4,153 (95%CI: €2,038 – €6,233). **CONCLUSIONS:** r-FSH may represent a cost-effective choice compared with a urinary hp-FSH (Menopur®) used for ovarian stimulation in the Greek setting.

PDB43

THE ECONOMIC IMPACT OF WEIGHT LOSS IN PATIENTS NEWLY DIAGNOSED WITH TYPE 2 DIABETES MELLITUS (T2DM) AND YOUNGER THAN FIFTY IN SWEDEN

Willis M[1], Neslusan C[2], He J[2], Worbes-Cerezo M[3]
[1]*IHE, Lund, Sweden,* [2]*Janssen Global Services LLC, raritan, NJ, USA,* [3]*Janssen-Cilag S.A., Madrid, Spain*

OBJECTIVES: This study estimated the effect of weight reduction on long-term outcomes and associated direct medical costs for patients newly diagnosed with T2DM and less than fifty years old in Sweden. **METHODS:** We simulated the lifetimes of 500 cohorts of 1000 patients with characteristics based on the Swedish National Diabetes Register using the Economic and Health Outcomes (ECHO)-T2DM model. All patients were assumed to increase weight over time (0.23 kg per year) however, half of the patients were assumed to lose 5 kg in the first year, so that a 5 kg differential was maintained. The effect of weight on T2DM complications was modeled using risk equations from the UK Prospective Diabetes Study, wherein weight is only a direct determinant of the risk of congestive heart failure (CHF). The risks of stroke and myocardial infarction are affected only indirectly via their linkage with CHF, and mortality risk is affected only indirectly via macrovascular event history. Weight change was assumed to impact QALYs by an amount reported in the T2DM-specific CODE-2 study. Pharmacotherapy was administered according to Swedish recommendations and Swedish cost data was used for medical events and pharmacotherapy. **RESULTS:** A weight loss of 5 kg resulted in cost-savings of SEK 654 (€69) over an average of 17.1 years, mainly attributable to reductions in CHF incidence. Life years increased marginally; QALYs, however, increased more substantially (0.18). **CONCLUSIONS:** At a relatively conservative willingness-to-pay threshold of SEK 250,000 (€26,540), an intervention that resulted in a one-time weight loss of 5 kg would be welfare improving at a cost of up to SEK 45,654 (€4,846) over 17.1 years. As this simulation conservatively excluded a number of other benefits of weight loss (e.g., effects via improved lipids, blood pressure and reductions in other weight-related illnesses), the true economic value is likely greater.

PDB44

AN ECONOMIC EVALUATION OF THE USE OF PIOGLITAZONE IN ITALY USING PROACTIVE

Gladwell D[1], Capri S[2], Fionda A[3], Massi-Beneddeti M[4]
[1]*Takeda Global Research and Development Europe, London, UK,* [2]*Institute of Economics, Castellanza, Italy,* [3]*Takeda Italia Farmaceutici S.P.A, Rome, Italy,* [4]*University of Perugia, Perugia, Italy*

OBJECTIVES: The aim of this economic evaluation was to test the hypothesis that the clinical benefits observed with pioglitazone in the PROactive Study will lead to economic benefits in terms of reduced macrovascular complications costs and insulin treatment in Italy (the trial compared standard of care + pioglitazone versus standard of care alone). **METHODS:** Two analyses were undertaken; within trial analysis and life-time simulation. The PROactive study provided the clinical and resource utilization data to estimate the cost-effectiveness of pioglitazone in the within trial analysis and was the basis for the secondary analysis which undertook a life time simulation using a modified version of the validated CORE diabetes model. CODE-II utility values were used for the base case. Due to the distribution system of pioglitazone in Italy, two different prices were used; the public price paid by the retail market (€2.11 per patient per day) and the ex-factory price discounted by 25% (€ 0.96 per patient per day). Costs and health gains were discounted at the joint rate of 3%. **RESULTS:** The incremental utility gain in within trial analyses was 0.0191, the incremental event and medication costs in the public price scenario were €842 leading to an ICER of €43,996 per QALY. In the lifetime simulation model the incremental utility gain was 0.149, the incremental event and medication costs in the public price scenario were €3,783 leading to an ICER of €25,426 per QALY. In the ex-factory price discounted by 25% scenario the medication costs were lower leading to the inclusion of pioglitazone in treatment being dominant in both analyses. **CONCLUSIONS:** In the Italian setting reduced costs for macrovascular complications and insulin treatment leads to the inclusion of pioglitazone in treatment being within standard cost-utility thresholds and is therefore an effective use of health resources.

PDB45

COST-EFFECTIVENESS OF TRANSFERRING TYPE 2 DIABETIC PATIENTS FROM NEUTRAL PROTAMINE HAGEDORN (NPH) TO DETEMIR IN PORTUGAL SETTINGS

Carvalho D[1], Lindner L[2], Kozarzewski M[3]
[1]*São João Hospital, Porto, Porto, Portugal,* [2]*IMS Health, Barcelona, Cataluña, Spain,* [3]*Novo Nordisk Portugal, Lisboa, Lisboa, Portugal*

OBJECTIVES: To estimate the long-term cost-effectiveness of transferring type 2 diabetes patients to an insulin detemir regimen therapy from a Neutral Protamine Hagedorn (NPH) insulin regimen in the Portuguese routine clinical practice. **METHODS:** A computer simulation model "CORE Diabetes Model" was used to make long-term projections of clinical outcomes and direct medical costs based on short term findings from the European cohort in the PREDICTIVE trial. Therapy conversion to insulin detemir was associated with a reduction in glycosylated haemoglobin (HbA_{1c}) by 0.2% ($p < 0.05$), mean body weight was reduced by 0.7 kg ($p<0.01$) and the incidence of total hypoglycaemia decreased from 11.7 to 3.0 episodes per patient/year ($p < 0.0001$). Events were projected for a time horizon of 30 years. The cost analysis takes the perspective of the Portuguese National Health System. **RESULTS:** Therapy conversion to insulin detemir plus OADs improves life expectancy by 0.056 years and quality-adjusted life years (QALY) by 0.462 compared to NPH insulin plus OAD. The incremental cost effectiveness ratio cost per life years gained and per QALY gained with insulin detemir plus OADs treatment as compared to NPH insulin plus OADs is 3,239€ and 393€ respectively. Type 2 diabetes

complications treatment costs were the main cost driver, accounting for 67% and 77% of total direct costs of the insulin detemir therapy and NPH insulin therapy respectively. Due to a better reduction from baseline of HbA_{1c} the development and progression of complications was delayed, and the cumulative incidence of diabetes complications decreased for insulin detemir plus OADs therapy versus NPH insulin plus OADs therapy. **CONCLUSIONS:** The results of this study demonstrate that insulin detemir is a very cost-effective option for the treatment of type 2 diabetes compared to NPH insulin in Portugal.

PDB46

COST-EFFECTIVENESS OF ANGIOTENSIN CONVERTING ENZYME INHIBITORS FOR THE PREVENTION OF DIABETIC NEPHROPATHY IN THE NETHERLANDS - A MARKOV MODEL

Adarkwah CC[1], Evers S[1], Akkerman M[2], Gandjour A[3]
[1]*Maastricht University, Maastricht, The Netherlands,* [2]*RWTH University Aachen, Aachen, Germany,* [3]*Pennington Biomedical Research Center/Louisiana State University, Baton Rouge, LA, USA*

OBJECTIVES: Type 2 diabetes is the main cause of end-stage renal disease (ESRD) in Europe and the USA. Angiotensin-converting enzyme (ACE) inhibitors slow down the progression of renal disease and therefore provide a renal-protective effect. The aim of our study was to assess the most cost-effective time to start an ACE inhibitor (or an angiotensin II receptor blocker (ARB) if coughing as a side effect occurs) in patients with newly diagnosed type 2 diabetes in the The Netherlands. **METHODS:** Three strategies were compared: treating all patients at the time of diagnosing type 2 diabetes, screening for microalbuminuria, and screening for macroalbuminuria. A lifetime Markov decision model with simulated 50-year-old patients with newly diagnosed diabetes mellitus was developed using published data on costs and health outcomes and simulating the progression of renal disease. A health insurance perspective was adopted. **RESULTS:** In the base-case analysis, the treat-all strategy is associated with the lowest costs and highest benefit and therefore dominates screening both for macroalbuminuria and microalbuminuria. A multivariate sensitivity analysis shows that the probability of savings is 70%. Treating all patients with an ARB would also be a dominant strategy despite the fact that ARBs are a much more expensive alternative. **CONCLUSIONS:** Patients with type 2 diabetes should receive an ACE inhibitor immediately after diagnosis if they do not have contraindications. An ARB should be considered for those patients developing a dry cough under ACE inhibitor therapy. The potential for cost savings would be even larger if the prevention of cardiovascular events were considered.

PDB47

UNDERSTANDING THE IMPLICATIONS OF INCORPORATING THE UKPDS GLYCAEMIC LEGACY EFFECT INTO EVALUATING THE COST-EFFECTIVENESS OF TYPE 2 DIABETES THERAPIES

McEwan P[1], Prettyjohns M[2], Bergenheim K[3]
[1]*HEOR Consulting, Monmouth, Monmouthshire, UK,* [2]*Cardiff Research Consortium Ltd, Cardiff, UK,* [3]*AstraZeneca, Mölndal, Sweden*

OBJECTIVES: The UK Prospective Diabetes Study (UKPDS) reported a persistence in risk reduction of diabetes-related events associated with improved glycaemic control observed between intensive and conventional therapy groups beyond the intervention period. This has important implications for projecting short-term clinical trial results over long-term time horizons. The aim of this study was to reproduce the UKPDS legacy effect and assess the impact on long-term cost-effectiveness. **METHODS:** The Cardiff Type 2 Diabetes Model was initiated with cohort profiles consistent with reported intensive versus conventional control groups within UKPDS; initial HbA1c treatment effects were applied and modelled over time assuming two scenarios: a loss of antihyperglycaemia benefit at year 10 or maintenance of clinical benefit (the legacy effect). Under both scenarios, risk reductions and cost-effectiveness of sulphonylurea (SU) versus insulin were assessed over a 40-year time horizon using UK 2010 costs. Both costs and health benefits were discounted at 3.5%. **RESULTS:** The risk ratio (RR) of any diabetes-related end point predicted by the model was consistent with that reported by UKPDS when incorporating the legacy effect (RR of 0.90 versus 0.91 in the model and UKPDS, respectively). Ignoring the legacy effect resulted in a RR of 0.99 at year 30 and a cost per quality-adjusted life-year (QALY) of £162,400, compared with £22,565 when including the legacy effect. **CONCLUSIONS:** The legacy effect of intensive glucose-lowering strategies has important implications when assessing the cost-effectiveness of new therapies. Failure to include such a legacy effect, as seen in UKPDS, may result in new therapies for managing glycaemic control appearing less cost-effective than they actually are.

PDB48

SHORT-TERM COST-EFFECTIVENESS OF INSULIN DETEMIR VERSUS NPH INSULIN IN INSULIN-NAÏVE SUBJECTS WITH TYPE 2 DIABETES IN SWEDEN

Ridderstråle M[1], Ericsson Å[2], Jensen MM[3]
[1]*Department of Endocrinology, Skåne University Hospital and Department of Clinical Sciences, University Hospital of Lund, Malmö, Sweden,* [2]*Novo Nordisk Scandinavia AB, Malmö, Sweden,* [3]*Novo Nordisk Scandinavia AB, Copenhagen, Denmark*

OBJECTIVES: To estimate short-term cost-effectiveness of insulin detemir versus Neutral Protamine Hagedorn (NPH) insulin based on incidence of self-treated hypoglycaemia and body-weight gain in insulin-naïve subjects with type 2 diabetes in Sweden. **METHODS:** A short-term (one year) cost-effectiveness model was developed in Microsoft Excel® 2003. Hypoglycaemia incidence rates were based on UKHSG data. Relative risk (RR) of hypoglycaemia, weight change and insulin doses were obtained from randomized clinical trial data. Resource use (health care contacts, blood glucose tests) and sick-leave following hypoglycaemia were estimated from survey data. Effectiveness was expressed as quality adjusted life-years (QALYs). Direct and indirect costs were in Swedish Kronor (SEK 1 ≈ €0.10, 2010 values) with unit costs from official sources. Probabilistic sensitivity analyses were performed. **RESULTS:** Treatment with detemir was associated with fewer self-treated hypoglycaemic events compared with NPH (RR: 0.47 [CI 0.25:0.88]) and lower weight gain (mean difference -0.91 kg [CI -1.53;-0.28]), leading to an average gain of 0.011 QALYs per year. Annual costs were SEK6,505 for detemir versus SEK5,008 for NPH with an incremental cost-effectiveness ratio (ICER) of SEK139,665 per QALY gained for detemir versus NPH from a societal perspective. From a health care perspective, annual costs were SEK5,809 for detemir and SEK3,527 for NPH with an ICER of SEK212,909 per QALY gained for detemir versus NPH. **CONCLUSIONS:** Insulin detemir can be considered cost-effective versus NPH insulin in insulin-naïve subjects with type 2 diabetes in Sweden already in the first year of treatment, both from a health care and a societal perspective, based on reductions in self-treated hypoglycemia and superior weight management. Given the non-significant differences in HbA1c control, results of the short-term analyses is not expected to deviate substantially if longer time horizons are applied. Higher pharmacy costs with insulin detemir should not be a barrier to therapy based on these findings.

PDB49

RESOURCE USE IN PATIENTS WITH TYPE 2 DIABETES (T2D) WHO INITIATED EXENATIDE BID (EXBID) OR STARTER INSULIN (INS) THERAPY: 6-MONTH DATA FROM CHOICE

Theodorakis M[1], Reaney MD[2], Bruhn D[3], Matthaei S[4], Mathieu C[5], Kiljanski J[6], Guerci B[7], Sapin H[8], Östenson CG[9], Salaun-Martin C[8], Krarup T[10]
[1]*University of Athens School of Medicine, Athens, Greece,* [2]*Eli Lilly and Company, Windlesham, Surrey, UK,* [3]*Eli Lilly and Company, Indianapolis, IN, USA,* [4]*Diabetes Centre Quakenbrück, Quakenbrück, Germany,* [5]*UZ Gasthuisberg, Leuven, Belgium,* [6]*Eli Lilly & Company Ltd, Warsaw, Poland,* [7]*Hôpital Jeanne d'Arc, Dommartin-lès-Toul, France,* [8]*Eli Lilly and Company, Paris, France,* [9]*Karolinska Institutet, Stockholm, Sweden,* [10]*Bispebjerg Hospital, Copenhagen, Denmark*

OBJECTIVES: This analysis of CHOICE presents resource use data from the six months pre and post initiation of adult patients' first injectable therapy for the treatment of T2D (ExBID or INS). CHOICE is an ongoing European 6 country prospective observational study. **METHODS:** Patient data are collected immediately before (baseline), and 3, 6, 12, 18 and 24 months after, initiation of injectable therapy. **RESULTS:** Important baseline differences between the ExBID and INS cohorts prevent direct comparison of outcome data. In the ExBID cohort (baseline n=1177; 6 months n=1073) 78.8% patients self-monitored their blood glucose (SMBG) at baseline; 81.6% at 6 months. Mean (SD) tests/week (past 4 weeks) were 9.28 (7.93) and 8.24 (6.41) respectively. Mean (SD) number of oral antihyperglycaemic medications used was 1.20 (0.75) at baseline and 1.42 (0.73) at 6 months. 93.4% patients had ≥1 contact with a health care professional (HCP) in 6 months before ExBID initiation (mean [SD] 7.75 [7.49] visits); 89.1% in 6 months post initiation (7.55 [7.41]). In the INS cohort (baseline n=1315; 6 months n=1235), 79.8% patients SMBG at baseline; 92.4% at 6 months. Mean (SD) tests/week were 9.91 (8.58) and 13.08 (8.46) respectively. Mean (SD) number of oral antihyperglycaemic medications used was 0.96 (0.76) at baseline and 0.98 (0.77) at 6 months. 93.8% patients had ≥1 contact with a HCP in 6 months before INS initiation (mean [SD] 8.45 [9.19] visits); 93.2% in 6 months post initiation (11.11 [16.75]). Mean doses of both ExBID and INS increased during the first 6 months post initiation. In both ExBID and INS cohorts, between-country variability was found. **CONCLUSIONS:** Mean resource utilisation increased following initiation of injectable therapy. Increases in mean test strip use/week (+32%) and mean number of contacts with HCPs (+31%) were observed in the INS cohort. Respective observations for ExBID cohort were -12.7% and -2.7%.

PDB50

REDUCTION IN COMORBIDITIES AND COST SAVINGS ASSOCIATED WITH BIOCHEMICAL CONTROL IN PATIENTS WITH CUSHING'S DISEASE: A LITERATURE-BASED ANALYSIS

Patel D[1], Stephens JM[1], Wiegand P[1], Pulgar S[2]
[1]*Pharmerit North America LLC, Bethesda, MD, USA,* [2]*Novartis, Florham Park, NJ, USA*

OBJECTIVES: Hypercortisolism in Cushing's Disease (CD) is associated with significant comorbidities, which improve and in some cases are reversed with biochemical control (BC). The purpose of this study was to capture data describing comorbidity reductions with BC and estimate the potential cost savings associated with reversal. **METHODS:** Comorbidity reductions with BC were identified through a comprehensive literature search using CD AND epidemiology, morbidity, complications, BC and treatment outcomes as search terms. Selected clinical studies detailed the relationship between comorbidity and BC in adults. In the cost analysis, comorbidities were selected if reported in patients achieving BC. Literature-based cost estimates were identified for CD-related comorbidities from the US payer perspective, and inflated to 2010 USD. Cost ranges were reported as the difference between expected comorbidity costs in uncontrolled and controlled patients. Sensitivity analyses were conducted to also include possibly reversible comorbidities. **RESULTS:** Patients with CD experience comorbidities ranging from back pain (86%) to psychosis (1.4%). Of 16 comorbidities identified in this study, seven were certainly reversible in CD patients achieving BC. Hypertension and diabetes mellitus were reversed in 44% and 40% of patients achieving BC at 1 year. Psychiatric illness and nephrolithiasis were resolved in 76% and ~50% of CD patients. In CD patients with reported impaired glucose tolerance and overweight/obesity, 60% and 37% of cases were resolved with BC. The application of cost estimates to prevalence of each reversible comorbidity before BC yielded a total per-patient cost of $19,239-$27,600. With BC, expected comorbidity costs ranged from $12,448-$18,312, representing a cost savings of $6,790-$9,288. Sensitivity analysis including possibly reversible comorbidities (like back pain, osteoporosis and vertebral fractures) produced estimated total cost savings of $10,571-$14,806 (incre-

mental cost savings, $3,780-$5,518). **CONCLUSIONS:** Comorbidity improvement and resolution in CD can be achieved with BC, which confers a commensurate cost savings to the health care payer.

Diabetes/Endocrine Disorders – Patient-Reported Outcomes & Preference-Based Studies

PDB51

A COMPARISON OF INSULIN ADHERENCE IN PATIENTS WITH TYPE 2 DIABETES INITIATING THERAPY WITH INSULIN DETEMIR FLEXPEN® OR NPH INSULIN IN A VIAL

Buysman E[1], Aagren M[2], Liu F[3], Bouchard J[4], Conner C[5]
[1]*I3 Innovus, Eden Prairie, MN, USA,* [2]*Novo Nordisk Inc., Princeton, NJ, USA,* [3]*i3Innovus, Eden Prairie, MN, USA,* [4]*Novo Nordisk, Inc., Princeton, NJ, USA,* [5]*Novo Nordisk, Inc., Redmond, WA, USA*

OBJECTIVES: Non-adherence to insulin therapy in patients with type 2 diabetes presents a serious challenge. Potential explanations for non adherence may include aversion to insulin self-injection and fear of hypoglycemic events. In clinical trails, insulin analogs have shown to reduce the risk of hypoglycemic events versus human insulins, and a recent review suggests that insulin delivered via a pen device may result in greater adherence versus vial and syringe. This study was conducted to compare the adherence rates of patients initiating basal insulin therapy with insulin detemir (IDet) FlexPen® versus those initiating basal insulin therapy with NPH via vial and syringe. **METHODS:** Data were gathered from a large US national payer retrospective claims database, and included only patients with type 2 diabetes that initiated basal insulin therapy with either IDet FlexPen® or NPH in vials. Patients with claims for any other type of insulin, other than the index insulin formulations during the 12-month observation period were excluded. Patients were defined as being adherent to therapy if they had a medication possession ration (MPR) of at least 0.80 in the 12-month follow up period. **RESULTS:** The IDet FlexPen® cohort (n=1082) and the NPH vial cohort (n=794) were of similar age (54.06 vs. 53.13, p=0.134); however, the IDet FlexPen® cohort had a lower proportion of female patients (44% vs. 55%, p<0.001) and fewer patients without a history of pre-index OADs (9% vs 45%, p<0.001), than the NPH vial cohort. After controlling for important confounders, patients initiating insulin therapy with IDet FlexPen® were 39% more likely to achieve an MPR of 0.80 or greater versus patients initiating insulin therapy with NPH vial (95% CI: 1.04-1.85). **CONCLUSIONS:** These results suggest that adherence may be improved for patients initiating basal insulin therapy with IDet in the FlexPen® versus NPH in a vial.

PDB52

ADHERENCE WITH ORAL MEDICATIONS FOR DIABETES AMONG BRAZILIAN PATIENTS: A SYSTEMATIC REVIEW OF NATIONAL LITERATURE

Takemoto MLS, Fernandes RA, Tolentino ACM, Takemoto MMS, Cukier FN, Cruz RB, Santos PML, Ribeiro ACP, Fernandes RRA, Moretti AIP
ANOVA - Knowledge Translation, Rio de Janeiro, Brazil

OBJECTIVES: To identify studies examining adherence with oral diabetes mellitus (DM) medication and the potential association between adherence rates and glycemic control among Brazilian patients. **METHODS:** A systematic literature search was performed by two independent reviewers using MEDLINE via Pubmed and LILACS databases (until May 2011) without limits for time or language. Specific filters to identify studies assessing Brazilian population were not used in the search strategy and this assessment was conducted by reviewers. Publications were included only if adequate documentation of adherence and population could be abstracted (adherence outcomes, thresholds used, and characteristics of the populations). **RESULTS:** The search strategy identified 289 records (Pubmed=174 and LILACS=115), from which only 2 cross-sectional studies met the eligibility criteria and were included in the systematic review. The most recent study (Araujo 2010) was conducted in 2007 and evaluated 79 DM patients using the 4-item Morisky-Green Test. Gimenes 2006 (n=31) was designed to investigate if DM patients have proper knowledge of their prescription and assessed adherence through self-reported patient compliance with medication schedule. Araujo 2010 found that 54.4% of DM patients were considered non-compliant according to the Morisky-Green Test. Taking medication in the wrong schedule and skipping doses were referred by 54.5% and 34% of patients, respectively. Gimenes 2006 observed that 48.4% of patients reported taking medication in the wrong schedule and 71% of them were classified as having unsatisfactory knowledge about their prescription. Studies examining the association between adherence and glycemic control were not found. **CONCLUSIONS:** This review reinforced the lack of adherence data for Brazilian DM population, but the included studies confirmed that a significant group of DM patients were poor compliers with treatment, although their findings should be interpreted with some concerning given the small sample size and explanatory nature.

PDB53

DIABETES MEDICATION ADHERENCE AND GLYCEMIC CONTROL IN PENANG, MALAYSIA

Al-Qazaz HK[1], Syed Sulaiman SA[2], Hassali MA[3], Shafie AA[4], Sundram S[5], Saleem F[1]
[1]*Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia,* [2]*School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM), Penang, Malaysia,* [3]*Discipline of Social & Administrative Pharmacy, Universiti Sains Malaysia, Pinang, Palau Pinang, Malaysia,* [4]*Universiti Sains Malaysia (USM), Penang, Penang, Malaysia,* [5]*Hospital Balik Pulau, Balik Pulau, P.Penang, Malaysia*

OBJECTIVES: To evaluate the patient's adherence to diabetic medications and the association between medication adherence and diabetic control outcome. **METHODS:** A cross-sectional, investigational study using a convenient sampling method for data collection was employed. A cohort of 540 diabetic patients attending diabetes clinic of Hospital Pulau Pinang, Malaysia was identified. A previously validated Malaysian version of Morisky Medication Adherence Scale (MMAS) was used for the assessment of medication adherence. Medical records were reviewed for Hemoglobin A1C (HbA1C) levels and other diabetes related information. **RESULTS:** Only 505 patients were included in the final analysis. The mean age of the patients was 58.16 years (SD=9.16), with 50.7% males and the mean diabetes duration was 9.68 years (SD=6.31). The mean MMAS scores was 6.11 (SD= 1.66) in which 42.2% were low, 36.4% were medium and only 21.4% were in high adherence group and the mean HbA1C was 7.94 (SD=1.61). Significant association between medication adherence and different educational level, diabetes duration, medication number, self monitoring of blood glucose and glycemic control was found. Higher MMAS score was found in patients with lower HbA1c levels, less number of medications per day, longer diabetes duration, with self monitoring of blood glucose and higher level of education. MMAS scores correlates significantly with HbA1c (- 0.505, p < 0.001). **CONCLUSIONS:** The lower HbA1C results in patients with higher medication adherence can be the result of other factors but this study revealed that adherence is among the modifiable factors that are associated with better glycemic control. The study results reinforce the recommendation for the periodic assessment of medication adherence and the use of educational programs to improve the self-management ability of patients and enhance patients' awareness about glycemic control with diabetes.

PDB54

HRQOL AND CLINICAL IMPACT OF MILD PATIENT-REPORTED HYPOGLYCAEMIC EPISODES IN FIVE EUROPEAN COUNTRIES: EXTENT OF AGREEMENT BETWEEN PHYSICIAN- AND PATIENT-REPORTED HYPOGLYCAEMIC EPISODES

Gruenberger JB[1], Bader G[1], Benford M[2], Pike J[2]
[1]*Novartis, Basel, Switzerland,* [2]*Adelphi Real World, Macclesfield, Cheshire, UK*

OBJECTIVES: To describe the clinical and health-related quality of life (HRQoL) impact of patient-reported mild hypoglycaemic episodes and quantify the extent of physician-reported agreement with patient-reported mild hypoglycaemic episodes in patients with type 2 diabetes mellitus (T2DM). **METHODS:** We have used data from the Adelphi Diabetes VII (2010) Disease Specific Programme (DSP) which collected data from 379 Primary Care physicians (PCPs) across 5 EU countries - France, Germany, Italy, Spain and UK- for patients receiving at least one oral antidiabetic with or without insulin. This generated 1145 physician-completed patient record forms (PRFs) that could be matched directly to patient-completed questionnaires (PSCs). Patients were asked: "How often do you have mild low blood sugar experiences (those you have treated by eating some fruit, fruit juice or a sweet)", while physicians were asked to capture "How often does the patient experience mild (self treated) hypoglycaemic episodes"? **RESULTS:** 88 patients out of 1093 (8.05%) reported hypoglycaemic episodes, whereas physicians reported that only 39 patients (3.57%) suffered hypoglycaemic episodes. Physician and patient did not agree in 55 cases. The Fisher's test suggests that the physician-reported prevalence of hypoglycaemic episodes was not influenced by whether or not the patient completed a PSC (p=0.374). Multivariate regression analysis including age, gender, BMI, and duration of T2DM as covariates shows that the utility decrement (HRQoL) is -0.0687 (p<0.01) between the patients who had experienced hypoglycaemic episodes and those who had not. Patients who reported hypoglycaemic episodes also had a significantly higher HbA_{1c} +0.374 (p<0.01) than those who did not report hypoglycaemia. **CONCLUSIONS:** PCPs in Europe may underestimate the true incidence rate of mild hypoglycaemia as their treated patients report over twice as many as they do. The occurrence of patient-reported hypoglycaemic episodes is associated with lower HRQoL and significantly higher HbA_{1c} and hence has substantial clinical impact.

PDB55

TRANSLATION AND VALIDATION STUDY OF 14-ITEM MICHIGAN DIABETES KNOWLEDGE TEST (MDKT): THE URDU VERSION

Saleem F[1], Hassali MA[2], Shafie AA[3], Al-Qazaz HK[1], Atif M[4], Haq N[1], Ahmad N[1], Asif M[5]
[1]*Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia,* [2]*Universiti Sains Malaysia, Minden, Penang, Malaysia,* [3]*Universiti Sains Malaysia (USM), Penang, Penang, Malaysia,* [4]*Universiti Sains Malaysia (USM), Pinang, Malaysia,* [5]*The Islamia University of Bahawalpur, Bahawalpur, Punjab, Pakistan*

OBJECTIVES: This study aimed to translate the Michigan Diabetes Knowledge Test (MDKT) into Pakistani (Urdu) language, and to examine the psychometric properties of the Urdu version. **METHODS:** A standard procedure of "forward-backward" translation procedure was used to create the Urdu version of the MDKT from the original English version. A convenience sample of 325 outpatients with type 2 diabetes was approached between June and November 2010. All data were collected from Bolan Medical College Hospital, Quetta, Pakistan. In addition to MDKT, socio-demographic data of the patients was also collected. Patient medical records were explored to get clinical and hemoglobin A1c data. For the purpose of test-rest analysis, Spearman's rho coefficient was used and data was available from 51 patients. Internal consistency was used as a measurement of reliability using Cronbach's alpha. Known group validity was also measured to ensure the consistency of the MDKT. **RESULTS:** By using the recommended scoring methods of MDKT, the mean ± SD of MDKT scores was reported as 7.56±2.98. Cronbach's alpha value was 0.702 showing good internal consistency. Test-retest reliability value was 0.812 (p < 0.001). Significant relationship between MDKT categories and HbA1c categories (chi-square = 20.555; p < 0.001) was found for known group validity. **CONCLUSIONS:** The findings of this validation study reveal that that the Pakistani (Urdu) version of the MDKT is a reliable and valid measure of diabetes knowledge that can be used in clinical and research practice of Pakistani health care system.

PDB56

DEVELOPMENT OF A NEW MEASURE FOR ASSESSING HEALTH RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WITH PRIMARY HYPERPARATHYROIDISM (PHPQOL)

Farrerons J[1], Muñoz M[2], Puig M[3], Villabona C[4], Webb S[5], Badia X[6]
[1]Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, [2]Hospital San Cecilio, Granada, Spain, [3]Hospital Germans Trias i Pujol, Badalona, Spain, [4]Hospital Universitari de Bellvitge, Hospitalet del Llobregat, Spain, [5]Hospital de la Santa Creu i Sant Pau and CIBERER 747, Barcelona, Spain, [6]IMS Health S.A, Barcelona, Spain

OBJECTIVES: Few studies in recent years, have evaluated the health related quality of life (HRQoL) of patients with hyperparathyroidism (PHP) using validated instruments. Only one specific questionnaire has been used to assess the HRQoL in these patients but is more focused on the severity of associated symptoms than on the impact of PHP on HRQoL. A new specific questionnaire to assess the HRQoL of patients with PHP has been developed using a standardized methodology. **METHODS:** The objective of the questionnaire is to capture all the relevant aspects; a literature review and a meeting with five endocrinologist experts were carried out. To assess the impact on HRQoL of symptoms related to PHP in this population, a semi-structured interview of 24 PHP patients was carried out. From these interviews a group of items were identified. Each item was subsequently scored by the group of experts, according to clarity, frequency and importance in order to perform a qualitative reduction of the items. The final items were edited in a questionnaire format and administered to a sample of 67 PHP patients. A factorial analysis and a Rasch analysis were performed to obtain the final pilot questionnaire before initiating the validation study. **RESULTS:** After qualitative reduction, 34 items were obtained. Factor analysis identified two dimensions with a total variance explained of 51.5%. Rash analysis was used to exclude those items with inadequate adjustment (INFIT or OUTFIT>1.30 and <0.70) or those which were redundant. The resultant scale was composed of 16 items (the final questionnaire, PHPQoL). **CONCLUSIONS:** PHPQoL questionnaire will allow, once the validation phase is completed and the psychometric properties (validity, feasibility and responsiveness to change) are assessed, to learn more on the impact of PHP in usual clinical practice and clinical studies.

PDB57

POLISH HEALTH CARE SYSTEM FOR DIABETIC PATIENTS: THE ANALYSIS OF CURRENT HEALTH CARE SYSTEM AND THE NEED OF COMMUNITY PHARMACY IMPLEMENTATION

Rzeszotarska O[1], Hermanowski TR[1], Rdzanek M[2]
[1]Medical University of Warsaw, Warsaw, Poland, [2]AstraZeneca, Warsaw, Poland

The diabetes disease entity is a serious threat to society, becoming already the epidemic of the twenty-first century. It currently affects over 220 million people worldwide. In many countries, including Poland, this incurable disease is one of the biggest challenges for health care. **OBJECTIVES:** The aim of this study is to determine the place of pharmaceutical care for a diabetic patient in the current health care system in Poland, to examine the need for actual implementation of such initiatives and the possible benefits arising from them. **METHODS:** 1) The analysis of the currently functioning system of care for diabetic patients, and 2) The study of the quality of life of people with diabetes and their educational needs (carried out through a questionnaire). **RESULTS:** Data from 59 people were analyzed (55.9% men). The significant amount of surveyed diabetes patients (62,71%) declares, that is covered by community pharmacy. The respondents when asked for some clarification regarding their perception and definition of community pharmacy listed elements that are not perceived as such by the theoretical scope of this kind of care. Almost 95% of respondents claims, that the improved knowledge regarding diabetes contributes to manage with the disease. More than 83% of respondents express the willingness to explore in more depth their knowledge regarding the topic. The average value of quality of life among population is 67,31 (with reference to EQ-VAS scale). **CONCLUSIONS:** Polish health care system among diabetic patients is still on the low level. Patients face many limitations when attempting to access the medical benefits and they lack education in the topic. The need for the knowledge extension and the belief in its efficacy are on a very high level. In spite of many premises of implementation community pharmacy services in Poland, still the role of pharmacists is in many cases omitted.

PDB58

HOW MUCH DO PATIENTS WITH TYPE 2 DIABETES VALUE IMPROVEMENTS IN DOSING CONVENIENCE? RESULTS FROM A CONJOINT STUDY

Hauber AB[1], Han S[2], Yang JC[1], Gantz I[3], Tunceli K[2], Gonzalez JM[1], Brodovicz K[2], Alexander C[3], Davies M[2], Lento K[2], Zhang Q[2], Radican L[2]
[1]RTI Health Solutions, Research Triangle Park, NC, USA, [2]Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA, [3]Merck, Whitehouse Station, NJ, USA

Fixed-dose combinations of antihyperglycaemic therapies were developed to reduce pill burden and improve convenience and adherence in patients with type 2 diabetes (T2DM). **OBJECTIVES:** To quantify the relative importance of dosing schedules to T2DM patients and to estimate patients' willingness to pay (WTP) for improvements in dosing schedules. **METHODS:** Participants were US patients (age ≥18 years) with T2DM who were on oral antihyperglycaemic therapy. Each patient completed a web-enabled, conjoint survey that presented a series of 8 choice questions, each including a pair of hypothetical oral antihyperglycaemic therapy profiles. Each profile was defined by reductions in average glucose, daily-dosing schedule, chance of mild-to-moderate stomach problems, frequency of hypoglycaemia, weight change, incremental treatment-related risk of congestive heart failure (CHF), and out-of-pocket cost. Choice questions were based on predetermined experimental design. Random-parameters logit was used to estimate the relative importance of each attribute and to calculate patients' WTP for improvements in daily dosing. **RESULTS:** Of the 2080 patients invited to participate in the study, 1115 patients completed the survey. Over the ranges of attribute levels in the survey, out-of-pocket cost was the most important attribute. The remaining attributes were ranked in order of importance as: glucose control, hypoglycaemia, chance of mild-to-moderate stomach problems, weight change, incremental chance of CHF, and daily-dosing schedule. On average, patients were willing to pay $35.52 (95% CI: 25.65, 44.89) monthly to move from three pills twice daily to one pill twice daily. Patients were willing to pay $30.72 (95% CI: 21.18, 40.05) monthly to move from three pills twice daily to two pills once daily. **CONCLUSIONS:** Although less important than other factors associated with oral antihyperglycaemic therapy, reducing pill burden through reductions in the frequency of dosing or number of pills per dose is of value to T2DM patients.

PDB59

NOCTURNAL HYPOGLYCEMIC EVENTS: IMPACTS ON PATIENTS FUNCTIOING, WELL-BEING AND DIABETES MANAGEMENT

Brod M[1], Wolden M[2], Pohlman B[1], Christensen T[3]
[1]The Brod Group, Mill Valley, CA, USA, [2]Novo Nordisk A/S, Søborg, Denmark, [3]Novo Nordisk A/S, Virum, Denmark

OBJECTIVES: Approximately 60% of people with diabetes experience non-severe hypoglycemic events, the most troubling of which are non-severe nocturnal events (NSNHE). Unfortunately, little is known about the specific impacts of NSNHEs on functioning, well-being and diabetes management. **METHODS:** Nine focus groups were conducted in the US and Europe (France, Germany, UK). Transcriptions were coded based on modified grounded theoretical approach and a theoretical model of the impact of NSNHEs derived. **RESULTS:** Seventy-seven people participated: mean age 46.5 (20 to 65), (26 type 1, 51 type 2), 66.2% on insulin with on average 4.1 (range 1-25) NSNHEs per month. Analysis generated domains of: symptoms, corrective diabetes management actions taken, sleep disruption, social and work impacts. Participants reported awakening with sweating, shaking, dizziness, odd dreams, and vision disturbances. The majority of participants noted difficulty in returning to sleep following the NSNHE and many did not return to sleep for the remainder of the night. As a result, most participants reported feeling fatigue and being physically ill (e.g. headaches) the next day, negatively impacting a wide range of daily activities. This impact lasted well into the next day and sometimes for as much as 48 hours. Corrective actions often included a reduction in insulin dose and increased blood glucose monitoring in subsequent days. At work, participants reported calling in sick, arriving late, concentration problems, or reduced effort. They described canceling social event and coping with irritability that affected their interactions with family and friends. Additionally, sleep quality of partners was also disrupted due to the event. NSNHEs were considered by most to be more frightening, dangerous and anxiety provoking than daytime events. Findings were similar across all countries. **CONCLUSIONS:** NSNHEs have a significant negative impact and require further study. Reducing their frequency may help improve diabetes management and patient quality of life.

PDB60

HEALTH RELATED QUALITY OF LIFE OF DIABETICS IN SINDH

Khowaja MA
Aga Khan University, Karachi, Sindh, Pakistan

OBJECTIVES: Globally the prevalence of diabetes is increasing and it is expected that about 370 million people will live with the condition by 2030. Based on this expectation the public awareness about this disease remains quite low. Diabetes strongly affects the health-related quality of life (HRQOL) especially along with co-morbidities and complications. The aim of this study was to examine the HRQoL of diabetics living in temporary camps of flood affected compared to controls living in similar conditions. **METHODS:** We conducted a cross-sectional survey in five camps in a rural district of Sindh between August and October 2010. In total, 169 persons with diabetes and 136 age and sex matched controls living in the same camps were randomly selected from these camps. World Health Organization Quality of Life questionnaire (WHOQOL-BREF) was used to assess HRQoL. Four domain scores (physical health, psychological, social relations and environment) were compared for cases (diabetics) and controls (non-diabetics) and the impact of socio-economic factors was evaluated in both groups. **RESULTS:** Overall, the mean (SD) age of study subjects was 51(14.9) years. The mean duration of diabetes among respondents was 7.7±4.1 years. All WHOQOL domains were strongly reduced in diabetic patients as compared to controls, with strongest effects in physical health (39 versus 78 points of the 0 – 100 score) and psychological domains (29 versus 71) and weaker effects in social relationships (57 versus 69) and environment domains (32 versus 41). The impact of diabetes on HRQoL was especially severe among females and older subjects. Diabetics with low literacy levels had significantly weaker effects ($p<0.001$) on the different domains compared to educated subjects. **CONCLUSIONS:** Based on these findings, a public health intervention and information campaign is needed to be launched in the flood affected camps for regular disease monitoring of persons with diabetes to prevent them from developing co-morbidities and complications.

PDB61

ASSESSMENT OF QUALITY OF LIFE IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES MELLITUS

Moreira S[1], Almeida A[1], Guerra P[2]
[1]Universidade da Beira Interior, Covilhã, Portugal, [2]Unidade Local de Saúde da Guarda, E.P.E., Guarda, Portugal

OBJECTIVES: The aim of this study is to characterize the children and the adolescents from Centro Hospitalar da Cova da Beira with Type 1 Diabetes Mellitus, to understand better which factors influence the level of Health-related Quality of Life

and the implications that this entails. **METHODS:** It is presented as a cross-sectional research, drafted in a descriptive and analytical component of data. It is based on the application of an anonymous questionnaire to these patients, which consists of three parts: 1) socio-demografic, clinical and disease's characterization data; 2) Pediatric Quality of Life Inventory Version 4.0 – PedsQLTM 4.0 and 3) Diabetes Quality of Life questionnaire – DQOL. The data was analyzed using SPSSâ software – version 17 and were considered significant at p-value <0,10. **RESULTS:** In total, 17 (68%) children and adolescents between 11-18 years, with an average number of years with disease of 6,29 years, participated in this study. The dimensions of PedsQLTM 4.0 "Emotional Functioning" and the "School Functioning" and the sub-scales of DQOL "Worries about Diabetes" and "Satisfaction with treatment" imply worst results in Health-related Quality of Life. It is observed that the variables gender, location, school performance and employment status of mother and father can influence the level of quality of life. Moreover, this level is more satisfactory in the presence of records related to more appropriate Body Mass index, fewer years of disease, lower values of glycated hemoglobin type A1c and lower number of insulin injections per day. **CONCLUSIONS:** It is recognized that this work offers a partial view of the disease, but contributes to understand some implicated factors in its control and in the level of quality of life of diabetic children and adolescents. It is recommended that such assessments should be made regularly, within a multi-disciplinary team which should be responsible for monitoring these patients

Diabetes/Endocrine Disorders – Health Care Use & Policy Studies

PDB62

THE IMPACT OF CLINICAL INERTIA IN THE TREATMENT OF TYPE 2 DIABETES

McEwan P[1], Prettyjohns M[2], Ketsetzis G[3], Evans LM[4], Bergenheim K[5]
[1]*HEOR Consulting, Monmouth, Monmouthshire, UK,* [2]*Cardiff Research Consortium Ltd, Cardiff, UK,* [3]*Cardiff Research Consortium Ltd, Cardiff, South Glamorgan, UK,* [4]*University Hospital Llandough, Cardiff, UK,* [5]*AstraZeneca, Mölndal, Sweden*

OBJECTIVES: Following the introduction of the Quality and Outcomes Framework (QOF) in the UK there has been an increase in the number of patients below-target HbA1c levels (HbA1c <7.5%) from 39.7% to 52.1% between 2006 and 2008. However, a substantial number of patients with type 2 diabetes mellitus (T2DM) remain poorly controlled. This study quantifies the effect of poorly controlled T2DM on the average number of microvascular and macrovascular events. **METHODS:** The Cardiff Type 2 Diabetes Model was initiated with cohort profiles consistent with current UK clinical practice in patients newly diagnosed with T2DM. HbA1c treatment effects were modelled to correspond with the intensive and conventional control groups in the UKPDS over a 20-year time horizon assuming: 1) patients achieve and maintain target control ("controlled"), and 2) patients fail to achieve target control ("uncontrolled") having HbA1c levels of 7.5-9.0%. Data from primary care (THIN) were used to categorise the number of patients by HbA1c level in those on first-line therapy or diet and exercise whose duration of diabetes was <2 years. **RESULTS:** Data from THIN demonstrated that 50% of patients had HbA1c below 7%. Of the remaining, 20%, 13%, 7% and 10% had HbA1c readings in the following ranges: 7-7.4%; 7.5-7.9; 8-8.4 and ≥8.5% respectively. Compared to those controlled subjects, with an HbA1c <7%, the model predicts 92, 115, 138 and 162 excess macrovascular and microvascular complications in those in the 7-7.4%; 7.5-7.9; 8-8.4 and ≥ 8.5% HbA1c groups respectively. **CONCLUSIONS:** Given current budgetary constraints, an ageing population, and increasing obesity, it is imperative that patients with T2DM are optimally managed in routine clinical practice from the outset. Failure to manage patients appropriately will have substantial implications for both patients and the healthcare system.

PDB63

ANTI-DIABETIC THERAPEUTIC STRATEGIES FOR TYPE 2 DIABETES PATIENTS WITH CHRONIC KIDNEY DISEASE IN FRANCE

Amalric F[1], Attali C[2], Joly D[3], Simon D[4], Verges B[5], Grandfils N[6], Briand Y[7]
[1]*IMS Health, PUTEAUX, France,* [2]*Cabinet Médical des Docteurs Attali - Chemoul - Cherqui - Le Roux, Epinay sous sénart, France,* [3]*Hopital Necker, PARIS, France,* [4]*Hôpital de la Pitié, Paris, France,* [5]*CHU de Dijon, DIJON, France,* [6]*IMS Health, Paris, France,* [7]*Boehringer Ingelheim France, Paris, France*

OBJECTIVES: To assess how general practitioners (GPs) in France adapt their anti-diabetic therapeutic strategies among type 2 diabetes mellitus (T2DM) patients who also had chronic kidney disease (CKD). **METHODS:** A multi-centric cross-sectional and retrospective study was undertaken, investigating patient characteristics, disease severity, therapeutic strategies, reasons for changes thereof through questionnaires filled by GPs, coupled with drug treatments extracted from the IMS Disease Analyser database. **RESULTS:** The study sample included 120 T2DM patients (median age = 76.0, 45% men): 37 with stage 3a CKD (45≤GFR<60 ml/min, median age = 75.1, 57% men) and 83 with stage 3b or severe CKD (GFR <45 ml/min, median age = 76.4, 38% men). Oral anti-diabetic treatments were widely prescribed among CKD patients: of those with stage 3a and 3b, respectively 37.5% and 39.3% had oral monotherapy, while 40.6% and 28.6% had oral double or triple therapy. 21.9% and 32.1% had insulin therapy (3 a and 3 b, respectively). 65% of patients were treated with an anti-diabetic drug which is either contraindicated or not recommended for CKD patients; GPs adapted the anti-diabetic strategy during the previous year for 43% patients, 53% of the time due to CKD. Mean HbA1c was 7.1% and 7.2% among CKD stage 3a and 3b patients, respectively; with 58% (3a) and 54% (3b) having HbA1c<7. Only 23% of patients achieved control of diabetes (GP assessment), with treatment that does not include a drug either contraindicated or not recommended for this patient group; 2/3 of these patients received insulin. **CONCLUSIONS:** Treating T2DM patients with CKD remains a challenge for GPs: data suggest that GPs are favouring glycemic control over safety by using anti-diabetic drugs that are either contraindicated or not recommended for CKD patients. New oral treatments that would allow physicians to control glycemia while appropriately considering impaired renal function are needed.

PDB64

CRITERIA FOR REFERRAL OF TYPE 2 DIABETES PATIENTS FROM PRIMARY CARE TO SPECIALIZED CARE AND VICE VERSA IN SPAIN. PATHWAYS STUDY

Font B[1], Lahoz R[1], Casamor R[1], Escalada FJ[2], Ezkurra P[3], Ferrer JC[4], Ortega C[5]
[1]*Novartis Farmacéutica S.A., Barcelona, Spain,* [2]*Clínica Universidad de Navarra, Pamplona, Navarra, Spain,* [3]*Centro de Salud Zumaia, Zumaia, Guipuzcoa, Spain,* [4]*Hospital General Universitario de Valencia, Valencia, Spain,* [5]*Centro de Salud Pozoblanco, Córdoba, Spain*

OBJECTIVES: To assess the causes for referral of type 2 diabetes (T2DM) patients from primary care (PC) to specialized care (SC) in Spain. To assess the degree of compliance with referral quality markers established in national guidelines/recommendations. **METHODS:** Observational, cross-sectional, multicentre national study, in PC and SC. Each physician provided data on usual practice for T2DM patient referral and clinical status of patients with T2DM for 6 referred patients. Inclusion criteria for patients were: written consent, previous T2DM diagnosis and age over 18; exclusion criteria: T1DM, MODY, LADA and secondary diabetes. Recommendations of the Spanish Society for Endocrinology and Nutrition (SEEN) and the National Health System (SNS), were used as reference documents to assess compliance. **RESULTS:** Data from clinical practice of 143 endocrinologists and 641 general practitioners (GPs), and from referrals of 805 patients to PC and 3624 to SC are presented. PC to SC referrals: 31.8% of GPs reported the existence of a coordination protocol with endocrinologists. The most frequent communication tool with SC was Consultation Report (89.2%). The referral criterion that most GPs reported to apply in usual practice was Metabolic Instability (80.5%). The most frequent cause for referral among the patients studied was Reassessment (48.4%), a criterion not included in national guidelines. 46.8% of GPs applied in usual practice all SNS, 3.9% all SEEN referral criteria. SC to PC referrals: 46.2% of endocrinologists reported the existence of a coordination protocol with PC. The most frequent communication channel with PC was Medical History (47.2%). The referral criterion reported by a higher number of endocrinologists (96.5%) was Goal Achievement, most frequent cause for referral also among the patients studied. **CONCLUSIONS:** These findings emphasise the need of improving coordination processes to optimize and homogenize referrals. The number of reported coordination protocols is low, and the compliance with national guidelines poor.

PDB65

UNMET NEED AND DRUG MANAGEMENT CHALLENEGES IN ELDERLY TYPE 2 DIABETES MEDICARE PART D POPULATION

Kuan R[1], Schwartz EL[2], Davis EA[2], Schnecker AM[3]
[1]*PriceSpective, El Segundo, CA, USA,* [2]*PriceSpective, San Diego, CA, USA,* [3]*PriceSpective, San Diego , CA, USA*

OBJECTIVES: To identify patient barriers, clinical management concerns, and drug coverage issues for elderly type 2 diabetes patients in the Medicare Part D population **METHODS:** A literature review was conducted using PubMed with searches limited to studies published in the last 2 years, in English, and in aged 65+. Searches included combinations of the following terms: diabetes mellitus, mortality, prevention and control, Medicare, diabetes management, treatment guidelines, control. Hand searching of clinical management guidelines and diabetes conferences (2007-present) was conducted to identify further issues pertaining to the research questions of interest. **RESULTS:** The literature search by key word yielded 141 relevant articles, 42 of which were included after abstract review for relevance. Literature on clinical management challenges identified a high prevalence of untreated disease in this patient population due to a significantly large number of elderly type 2 diabetes patients being undiagnosed. Adherence to treatment guidelines in this patient population is challenging due to the high level of co-morbidities that may complicate the goal of intensive glucose management. As more oral antidiabetic agents become available as treatment options, patients become more likely to change therapies with more elderly patients switching from single-agent to combination therapy. Literature on cost-sharing in Medicare Part D and the current coverage gap suggest that patients covered under the benefit face a high out of pocket burden for treatment and that such costs lead to medication non-adherence and physician switching to less efficacious alternatives **CONCLUSIONS:** Clinical management challenges and economic barriers to access are more pronounced for elderly Medicare Part D than in the general population of type 2 diabetes patients. Further insight and research are needed to explore how policy changes for coverage and treatment guidelines may be able to address these concerns.

PDB66

ACHIEVEMENT OF GLYCEMIC CONTROL AND RELAPSE AMONG PATIENTS INITIATING BASAL INSULIN FROM A GEOGRAPHICALLY-DIVERSE US ELECTRONIC MEDICAL RECORD (EMR) DATABASE

Aargen M[1], Wu N[2], Boulanger L[2], Lamothe K[2]
[1]*Novo Nordisk Inc., Princeton, NJ, USA,* [2]*United BioSource Corporation, Lexington, MA, USA*

OBJECTIVES: To describe demographic and clinical characteristics of diabetic patients who initiated basal insulin and assess their glycemic control. **METHODS:** Physician encounters recorded in the General Electric EMR Database (2005-2010) were assessed. Patients with type II diabetes (T2DM) who initiated basal insulin between February 2006 and August 2009 were selected, with initiation defined as no prescription record of insulin in prior 15 months. Patients were followed for an average of 2.5 years after insulin initiation, and the proportion achieving A1C≤7% ("goal") and time to achieving goal were assessed. Among patients who reached

goal, the proportion of and time to A1C increasing above 7% (relapse) were analyzed. Cox proportional hazard models were estimated to identify demographic and clinical predictors of A1C goal achievement and relapse. **RESULTS:** Basal insulin initiators with T2DM (n=13,373) were on average 60 years old, 50.5% were females, 59.5% had A1C>8%, 59.7% were obese, and more than half used metformin (52.7%) or sulfonylureas (53.4%) before insulin initiation. A total of 5844 (44%) patients reached goal within one year since initiation, and 7699 (58%) reached goal during the ~2.5-year follow-up. The median time to reaching goal was 536 days (95% CI: 510-562). Older age, being white or male, lower baseline A1C values and no OAD use before insulin initiation were associated with significantly higher rates of reaching goal. Among the patients who reached goal, 57.6% relapsed, and the median time from reaching the goal to relapse was 398 days (95% CL: 383-417). Being Hispanic, higher baseline A1C values and OAD use at baseline were associated with significantly higher rates of relapse. **CONCLUSIONS:** A high proportion of T2DM patients did not have adequate glycemic control after initiating basal insulin. Various factors existing prior to insulin initiation were related to successful treatment of T2DM. Further research into how to improve glycemic control is encouraged.

PDB67

TREATMENT PATTERNS AND HEALTH OUTCOMES AMONG TYPE 2 DIABETES WITH COMORBID OBESITY IN FRANCE, GERMANY, AND UK

DiBonaventura MD[1], Isherwood G[2], Le Pautremat V[3], Eschwège E[4]
[1]*Kantar Health, New York, NY, USA,* [2]*Kantar Health, Epsom, Surrey, UK,* [3]*Kantar Health, Montrouge, France,* [4]*INSERM, Villejuif, France*

OBJECTIVES: The aim of the current study was to examine patient characteristics, treatment patterns, and burden of type 2 diabetes (T2D) adult patients with and without comorbid obesity in France, Germany, and UK. **METHODS:** Data from the EU National Health and Wellness Survey were used. Demographics, HbA1c levels, prevalence of hypertension, high cholesterol, T2D current treatments, and health outcomes (SF-12) were assessed for all T2D patients (France: n=642, Germany: n=1,019, UK: n=932). Patients with and without obesity (BMI≥30) were also compared. **RESULTS:** Obesity rates within T2D were 47%, 51%, and 56% in France, Germany, and UK, respectively. Pooling countries, T2D patients had 2.6 greater odds of obesity than non-T2D patients and the proportion of obese T2D patients increased from 44% to 51 % (2006 to 2010). The rates of being uncontrolled (HbA1c ≥7%) were higher among obese T2D (20% vs. 17%, p<.05), but the difference was only significant in Germany (24% vs. 19%, p<.05). The use of insulin was significantly higher (23% vs. 16%, p<.05) among obese patients, but this difference was only significant in Germany and UK and not in France. Hypertension and high cholesterol were significantly more prevalent in obeseT2D patients (65% vs. 51% and 40% vs. 35%, respectively, ps<.05). Hypertension differences were significant for all countries while high cholesterol differences were only significant in Germany. Obesity was associated with significantly worse physical quality of life (France: 40 vs. 44; Germany: 39 vs. 44; UK: 37 vs. 42, respectively p<.05). **CONCLUSIONS:** A substantial number of T2D patients are obese. Obesity was associated with worse quality of life, and worse health outcomes including poor glycemic control (in the case of Germany), hypertension and high cholesterol; all these factors are CV disease risk factors. Improving obesity management will be the key to improve health and outcomes in T2D.

PDB68

THE IMPACT OF IMPLEMENTING A DRUG PREAUTHORIZATION POLICY IN A PRIMARY CARE SETTING

Triki N[1], Shani S[1], Mossinson D[2], Greenberg D[1]
[1]*Ben-Gurion University of the Negev, Beer-Sheva, Israel,* [2]*Maccabi Healthcare services, Tel Aviv, Israel*

OBJECTIVES: We analyzed the impact of implementing a preauthorization policy for Rosiglitazone (an anti-diabetic drug) use on the eligibility requirements (treatment initiation and discontinuation) and patients' HbA1c levels. **METHODS:** We compared treatment patterns of diabetic patients prior to and after an implementation of a preauthorization policy for Rosiglitazone use. Data were obtained from the Maccabi Healthcare Services' (the second largest HMO in Israel) registry of diabetic patients. We compared adherence to eligibility criteria in a group of patients who received Rosiglitazone without preauthorization (N=1362) and patients who received the medication with preauthorization (N=824). The criteria for receiving Rosiglitazone in both groups were identical and included prior medication [experienced patients who received drug from the sulphonylurea class in combination with Metformin for at least a three months period], and laboratory criterion [HbA1c levels higher than 8% during the past three months]. Treatment should be continued only if within three months from treatment initiation, the patient acquired at least three packages of Rosiglitazone and a decrease of >0.8% in HbA1c values was observed. **RESULTS:** Implementing preauthorization policy increased the fulfillment of the eligibility criteria (medication and laboratory) for drug use by 41% [from 25% of patients without preauthorization to 35% with preauthorization (p<0.001)]. With regard to meeting the requirements for treatment continuation after a three month period, there was an increase of only 6.4% in the fulfillment of both requirements (from 37.6% to 40.0% prior and after preauthorization, respectively). The average decrease in patients' HbA1c levels was 0.6% and was similar in both patients with and without preauthorization. **CONCLUSIONS:** Implementing preauthorization for Rosigitazone resulted in an increase in meeting the requirements for treatment initiation and a marginal change in treatment continuation criteria, but this increase was insufficient to achieve HbA1c target levels. However, patients' health was not negatively affected by this policy.

PDB69

PRESCRIPTION PATTERN STUDY OF TYPE 2 DIABETES MELLITUS IN IRAN

Soleymani F[1], Farshchi A[1], Haerizadeh M[2]
[1]*Tehran University of Medical Sciences, Tehran, Iran,* [2]*Minitry of Health, tehran, Iran*

OBJECTIVES: Type 2 diabetes, is a disease with a rising prevalence worldwide. A major burden of this disease would be shared by developing countries like Iran. Medications for diabetes mellitus need to be taken for the entire life and factors like efficacy, side effects, drug interactions and cost of therapy should be consider. This study was designed to evaluate the prescription pattern of anti-diabetic drugs in T2DM patients from 2006 to 2009 in Iran. **METHODS:** A retrospective study was undertaken on insured prescriptions during 4 years. All insured prescriptions which were collected in special software called Rx Analyst during the study period in the NCRUD were reviewed for prescriptions included anti-diabetic drugs. The brand names of drugs in prescriptions were decoded to generic names, according to standard Iran drug list. **RESULTS:** A total of 261,110,666 prescriptions were assessed in which 11,637,224 were detected to be included at least one dosage form of anti-diabetic medications. From all, 1,376,750 prescriptions had at least one injection form of Insulin and 10,260,474 of oral anti diabetic drugs. Trend evaluation of prescribing showed that the total number anti-diabetic medications were increased from 16,158,375 in 2006 to 4,268,444 in 2009. The portion of prescriptions with Insulin was 8%, 9%, 13% and 9% and for oral anti-diabetic drugs, it was 59%, 66%, 71% and 72%in 2006, 2007, 2008 and 2009, respectively. The total cost of Insulin during study period was 17,134,032 US$ and for oral anti-diabetic drugs was 84,682,039 US$ from national sales data. **CONCLUSIONS:** According to national sales data, total cost of anti-diabetic medications is about 100,00 times more than cost of these drugs in prescriptions. This huge gap shows irrational use of such medications. A multi interventional policy including educational, regulatory, managerial and financial strategies for professions and public should be planed to promote rational use of anti-diabetic medications.

PDB70

LOW-DOSE PIOGLITAZONE UTILISATION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN THE UNITED KINGDOM

Zhao C, Zhang Q, Davies MJ, Steinberg H
Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA

OBJECTIVES: To evaluate the distribution of pioglitazone (PIO) daily dose prescribed by physicians for patients with type 2 diabetes mellitus (T2DM). **METHODS:** In a retrospective cohort study using the UK MediPlus database, patients with diagnosed T2DM who received PIO prescription between July 2008– June 2009 (observation period) were included. Medical records from 07/2007–06/2008 were used to assess baseline conditions. Patients were grouped, according to prescriptions in the observation period, as low-dose users who received PIO prescriptions of 15-mg daily dose only or were down-titrated to 15 mg from a higher daily dose, and high-dose users for the rest who received a 30 mg or higher daily dose. **RESULTS:** Of 1813 patients with T2DM who received a PIO prescription, 48% received at least one 15 mg prescription during the observation period. Among all PIO prescriptions, 39%, 40%, and 21% were in 15, 30, and 45 mg or higher daily dose, respectively. Per study definitions 38% of the patients were classified as low-dose users and 62% as high-dose users. Low-dose users were more likely to be female (56% vs. 40%) and had a lower baseline prevalence of diabetic nephropathy (0% vs. 1%), compared to high-dose users (p<0.05). Low-dose PIO use was not associated with baseline prevalence of congestive heart failure, coronary artery disease, or bone fractures. **CONCLUSIONS:** Low-dose PIO was prescribed in greater than one-third of PIO prescriptions, regardless of patient age and major comorbidities. The reason(s) why patients received low-dose PIO warrants further investigation.

PDB71

CROSS-SECTIONAL ANALYSIS OF AMBULATORY CARE EXPENDITURE AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) ACCORDING TO TREATMENT STAGE AND RENAL FUNCTION IN FRANCE USING EGB DATABASE (ECHANTILLON GENERALISTE DE BENEFICIAIRES)

Guelfucci F[1], Clay E[1], Aballea S[2], Toumi M[3], Lassalle R[4]
[1]*Creativ Research, Paris, France,* [2]*Creativ Ceutical, Paris, Ile de France, France,* [3]*University Claude Bernard Lyon 1, Lyon, France,* [4]*Université de Bordeaux, Bordeaux, France*

OBJECTIVES: This retrospective study compares annual expenditures among T2DM patients according to treatment stage and renal function status (RFS) and identifies determinants of costs. **METHODS:** T2DM patients' records were extracted from the EGB database, which contains ambulatory care claims for a representative sample of the French population. Patients were classified according to treatment stage: oral / GLP1 monotherapy, double therapy, triple therapy or insulin therapy (either associated or not with other antidiabetics), and according to RFS (identified using pharmacy, lab and consultation claims). Costs were estimated from the national insurance perspective and included all reimbursements except for hospitalisations. Annual expenditures were assessed by year (from 2005 to 2010), by treatment stage and by RFS. Effects of treatment stages and RFS on expenditures by year were analysed by means of generalised linear models, with matching on age and gender. **RESULTS:** The number of patients ranged from 9,682 to 11,772 between 2005 and 2010. Annual average total reimbursements in 2010 were €3,279 (standard error: 65.5) for monotherapy, €3,592 ±92.1 for double therapy, €3,803 ±157.2 for triple therapy and €7,729 ±180.8 for insulin therapy. The same cost pattern was found in previous years. The regression model showed that costs increased by a ratio of 2.31 (p<0.001) from monotherapy to insulin therapy, adjusted for sociodemographic characteristics and co-treatments. Excess costs for insulin therapy were mainly related to nursing care (increasing by a ratio of 12.16, p<0.001), med-

ical devices and pharmacy costs. Reimbursements for patients with declining renal function were estimated at €4,933 ±368.9 for monotherapy, €4,521 ±350.8 for double therapy, €4,191 ±497.9 for triple therapy and €13,768 ±1106.2 for insulin therapy. **CONCLUSIONS:** Overall, ambulatory care costs increase with treatment escalation and declining renal function amongst T2DM patients. Insulin therapy is associated with substantial increased costs, related to pharmacy, nursing care and medical device utilization.

PDB72

THE BURDEN OF HYPOGLYCAEMIA IN SECONDARY CARE IN ENGLAND

Heller S[1], Tilling C[2]
[1]University of Sheffield, Sheffield, Yorkshire, UK, [2]Sanofi-Aventis, Guildford, Surrey, UK

OBJECTIVES: Hypoglycaemia is a common adverse event associated with the management of both type 1 and type 2 diabetes. While many hypoglycaemic episodes can be self-treated, more severe episodes can require emergency treatment and hospitalisation. The objective of our study was to evaluate the burden of hypoglycaemia on secondary care costs in England. **METHODS:** Data captured in Hospital Episode Statistics (HES)* for the period between 2006 and 2009 was analysed to estimate the trends in hospital episodes. The associated costs were estimated using Hospital Resource Group (HRG) tariff prices in England for the respective years. **RESULTS:** There were a total of 11,330 inpatient spells assigned an HRG for hypoglycaemia in 2009, an increase of 17.0% from 2006 when there were 9,682 inpatient spells. In 2006 the average inpatient length of stay was 5.7 days, but by 2009 this figure had risen by 21.1% to 6.9 days. In 2006 the cost of hypoglycaemia due to hospitalisation was £13.57 million. In 2009 this figure was £16.04 million, representing an 18.2% increase in cost burden. In 2009 the average inpatient cost was £1635, up 8.7% from 2006 when the average cost was £1504. Over the four year period 2006-2009 there were a total of 41,717 inpatient spells due to hypoglycaemia at a total cost of £58.44 million. **CONCLUSIONS:** Hypoglycaemia represents a significant and increasing burden on hospital care in England. Given current cost constraints in the NHS, prescribers should seek to use medications that reduce the risk of hospitalisation due to hypoglycaemia.

PDB73

IMPACT OF EPIDEMIOLOGICAL AND ECONOMIC FACTORS ON INSULIN TOTAL SALES IN THE UK DIABETIC MARKET

Mehta P[1], Zhang J[2], Walker SA[1], Ramadan F[1]
[1]IHS Global Insight, London, UK, [2]IHS Global Insight, Eddystone, PA, USA

OBJECTIVES: Diabetes affects 3%-5% of total UK population and insulin is the largest drug-class category used to treat the disease. A greater understanding of the impact of different economic and epidemiological variables on total insulin sales will help the healthcare system and pharmaceutical industry be more responsive to demand and cost. **METHODS:** Generalized least squares regression with period random effects was used on a pooled yearly data set (2001 to 2010) of variables. The dependent variable was total yearly sales for insulin. The explanatory variables included - size of population; incidence and prevalence of diabetes; estimated total prescription (Rx) for insulin; and employee compensation per capita. The analysis used yearly pooled, cross-sectional data from IDF and IHS Forecasting Database at different time points to account for the variation in different variables. The total population was obtained from OECD. The prevalence and incidence rates were obtained from IDF for 2001, 2003, 2007 and 2010; average of previous year's datapoints were used for years in which no data was provided. The main independent variable was the total yearly prescription rate for insulin, calculated from data derived from intrinsic Patient Flow Model. **RESULTS:** A direct correlation was found between estimated total Rx for insulin, total population, and prevalence rates for diabetes. The results can be summarized as: For every 1% rise in total estimated Rx for Insulin and total population there is a 71% and 48% increase in insulin sales, respectively. **CONCLUSIONS:** Based on our model, total Rx plays a major role in determining the total sales for insulin. From a policy perspective, it will support UK government's diabetes related initiatives focusing on effective cost management.

PDB74

TITLE: IMPLEMENTATION OF DIABETES PROGRAMME BUDGET MARGINAL ANALYSIS (PBMA) EXERCISE IN AN ENGLISH PRIMARY CARE TRUST (PCT)

Lim M[1], Anderson PM[2]
[1]East of England Specialised Commissioning Group, Stansted , UK, [2]Swansea University, Swansea, UK

OBJECTIVES: To undertake resource re-allocation for improvements in service and patient outcomes within a diabetes programme using PBMA. **METHODS:** UK National Health Service organisations have to manage severe budget pressures. If health outcomes for patients are to be maintained and improved, resources must be (re)allocated efficiently and some disinvestment is inevitable. PBMA is an ideal framework for these tasks as it is based on opportunity costs and maximisation of benefits. The pilot PBMA exercise reported was undertaken in an English PCT in 2010. Data on the inputs and outputs of diabetes care received by patients was collected and evaluated by a multidisciplinary group of commissioners, healthcare staff and patient representatives. Through comparison of the data with other PCTs, and a review of the literature concerning the effectiveness and cost-effectiveness of current and proposed interventions within the programme, the multidisciplinary group identified opportunities for resource reallocation. **RESULTS:** In comparisons, the PCT had near average spending but with poor HbA1c outcomes, use of glucose blood testing reagents was high - the third most costly prescribed item and of overall drug spending. Reducing unnecessary spending on these in type II diabetes patients freed resource for specialist nurses to coach patients in optimal diabetes control. **CONCLUSIONS:** Literature reporting successful implementation of PBMA is uncommon and factors associated with success are setting, individuals leading the initiative and buy-in of participants to the process. In this exercise using detailed financial and outcomes data, implementing PBMA and gaining buy-in of stakeholders resulted in a successful disinvestment decision, resource reallocation and re-investment in diabetes services. The next important step is to use PBMA to make a disinvestment decision alone and improve the process; reducing the burden of this complex, data-intensive decision-making framework, maintaining transparency, equity and ethics. This may increase the adoption and successful execution of PBMA.

PDB75

ANALYSIS OF THE MEDICINES PRICING PROCEDURE IN THE REPUBLIC OF MACEDONIA

Angelovska B[1], Ivanovska V[1], Manova M[2], Petrova G[3]
[1]Faculty of Medical Sciences, University ">Goce Delchev" Shtip, Republic of Macedonia, Stip, Macedonia, [2]Medical University Sofia, Faculty of Pharmacy, Sofia, Bulgaria, [3]Medical University, Faculty of Pharmacy, Sofia, Bulgaria

OBJECTIVES: To analyze the development in the medicines pricing regulation in Republic of Macedonia during 2005 to 2010 and its impact on medicines affordability. **METHODS:** Regulatory analysis of the changes in the medicines prices regulation for the period 2005 to 2010 was applied. The affordability of the medicines to the population was explored before the after the new regulation introduction. Affordability was evaluated through the comparison of the cost of therapy of the most frequent diseases with the inhabitants wages. For comparison purposes, the average monthly wages in January 2005 (7.999,00 MKD) and in January 2010 (14.914,00 MKD) were used as announced by the UJP (Public Revenue Office of Macedonia). The statistical test used was Wilcoxon Matched Pais Test. **RESULTS:** The unified medicines prices were established in 2007 based on ex-factory price, wholesale mark-ups and pharmacy mark-ups. The Health Insurance Fund carried out the supply of medicines on the Positive list by international tenders until 2005. The reference pricing was introduced in 2007 and it took into consideration the Purchasing Parity Power. The statistical analysis of the cost of treatment for selected health conditions compared with the average monthly wages, expressed as working hours shows that less working hours are needed to purchase medicines for all clinical conditions in 2010 compared to 2005. There is statistically significant difference in the working hours needed to purchase medicines between 2010 and 2005 (Wilcoxon Matched Pairs Test: Z = 2240, p = 0, 0250). The better financial affordability of medicines in 2010 is a result of partly lower medicines prices, but predominantly a result of higher monthly wages. **CONCLUSIONS:** The analysis reveals the positive impact of medicines price control and reference pricing on medicines affordability. The number of working hours needed to purchase a month of treatment decreased.

PDB76

KNOWLEDGE, MEDICATION ADHERENCE AND GLYCEMIC CONTROL AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS

Al-Qazaz HK[1], Syed Sulaiman SA[2], Hassali MA[3], Shafie AA[4], Sundram S[5], Saleem F[1]
[1]Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia, [2]School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM), Penang, Malaysia, [3]Discipline of Social & Administrative Pharmacy, Universiti Sains Malaysia, Pinang, Palau Pinang, Malaysia, [4]Universiti Sains Malaysia (USM), Penang, Penang, Malaysia, [5]Hospital Balik Pulau, Balik Pulau, P.Penang, Malaysia

OBJECTIVES: To evaluate the association of knowledge and medication adherence with glycemic control in patients with diabetes mellitus type 2. **METHODS:** The research was shaped as a cross-sectional, investigational study. Convenient sampling was done to identify a cohort of 540 diabetic patients attending diabetes clinic of Hospital Pulau Pinang, Penang, Malaysia. A previously validated knowledge test and medication adherence scale was used for data collection. Patients' medical records were reviewed for haemoglobin A1C (HbA1C) levels and other disease-related information. **RESULTS:** Five hundred five patients were included in the final analysis, with a mean age of 58.15 years (SD=9.16) with 50.7% males having mean HbA1C of 7.94 (SD=1.61). Knowledge scores ranged from 0 to 14, with mean scores of 7.44 (SD=3.08). Medication adherence scores ranged from 0 to 8 with mean scores of 6.11 (SD=1.66). HbA1C was found to be significantly lower in patients with higher level knowledge and higher level of medication adherence ($p<0.05$). Significant correlations were found between the three variables HbA1C, Knowledge and adherence ($p<0.05$). Combined therapy, higher diabetes knowledge and higher medication adherence were statistically predictors of good glycemic control. **CONCLUSIONS:** There is a high prevalence of poor glycemic control among patients in this study. This study revealed that knowledge and adherence are among the modifiable factors that are associated with better glycemic control.

PDB77

IMPACT OF KNOWLEDGE ON MEDICATION ADHERENCE AMONG TYPE 2 DIABETES PATIENTS

Al-Qazaz HK[1], Syed Sulaiman SA[2], Hassali MA[3], Shafie AA[4], Sundram S[5], Saleem F[1]
[1]Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia, [2]School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM), Penang, Malaysia, [3]Discipline of Social & Administrative Pharmacy, Universiti Sains Malaysia, Pinang, Palau Pinang, Malaysia, [4]Universiti Sains Malaysia (USM), Penang, Penang, Malaysia, [5]Hospital Balik Pulau, Balik Pulau, P.Penang, Malaysia

OBJECTIVES: To evaluate the medication adherence and general diabetes knowledge among patients with type 2 diabetes and to assess the relationship of knowledge with medication adherence of patients. **METHODS:** A cross-sectional study design was conducted among convenience sample of 505 type 2 diabetic outpatients in the Diabetes Clinic of the Penang General Hospital, Penang, Malaysia from November 2009 to April 2010. Patients with diabetes type 2 were asked to complete

a short questionnaire about socio-demographic data, adherence (Morisky Medication Adherence Scale) and knowledge (Michigan Diabetes Knowledge Test) while medical records were reviewed for diabetes-related data. **RESULTS:** The mean age was 58.16 years (SD=9.16) with around 50% males. The mean MMAS score of the patients was 6.11 (SD= 1.66) and the total mean score of MDKT was 7.44 (SD=3.08). A significant positive correlation between MMAS and MDKT scores were found (n = 505, $r_s = 0.456$, $p < 0.001$). A significant association between knowledge levels and adherence levels was found ($p<0.05$). The correlation coefficient between HbA1C and total knowledge score was – 0.39 ($p< 0.001$). Higher diabetes knowledge was a significant predictor of higher medication adherence (OR = 1.381, $p < 0.001$). **CONCLUSIONS:** Medication adherence is moderately related with diabetes knowledge. Deficiencies in patients' knowledge may be the greatest barriers to improving adherence and improvement of patients' knowledge could result in better medication adherence.

PDB78

REASONS OF UK GENERAL PRACTITIONERS FOR PRESCRIBING 15- OR 30-MG OF PIOGLITAZONE IN COMBINATION WITH OTHER ORAL ANTIHYPERGLYCAEMIC AGENTS

Tunceli K[1], Lento K[1], Zhang Q[1], Jameson K[2], Meiler S[3], Davies MJ[1], Steinberg H[1], Brodovicz K[1], Radican L[1], Sinclair A[4]
[1]*Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA,* [2]*MSD Ltd., Hoddesdon, UK,* [3]*Kantar Health GmbH, Munich, Germany,* [4]*Beds & Herts Postgraduate Medical School, Luton, not applicable, UK*

OBJECTIVES: To evaluate the general practitioners' (GPs) reasons for prescribing pioglitazone 15 or 30 mg and characterise the patients on these doses. **METHODS:** An internet-based survey was conducted among 245 UK GPs who selected reasons for prescribing pioglitazone 15 or 30 mg/day for their patients. Eligible patients were ≥18 years at type 2 diabetes mellitus (T2DM) diagnosis and currently on pioglitazone (15 or 30 mg) with other oral antihyperglycaemic agents for ≥3 months. GPs provided clinical data for ≥1 patient on each pioglitazone dose. The 29 potential reasons for prescribing the current pioglitazone dose were classified into 4 categories: sufficient glycaemic control, poor tolerability and/or side effects associated with pioglitazone, comorbidity/polypharmacy, and patient-related factors. **RESULTS:** Of the 1456 patients provided by GPs, 739 were on pioglitazone 15 mg and 717 on 30 mg. Compared with the 30-mg group, patients in the 15-mg group had a shorter duration of T2DM (median 7.3 vs. 8.3 years) and the same median HbA_{1c} level (7.2%). Collectively, reasons in the sufficient glycaemic control category were selected most for both groups; however, they were selected more often for 15 than 30 mg (85 vs. 75%, $p<0.0001$). Specifically, "new user" was selected for 26% on 15 mg and 11% on 30 mg ($p<0.0001$). No significant differences between groups were seen within the other categories. Overall, 37% of GPs selected reasons related to poor tolerability and/or side effects, 42% for comorbidity/polypharmacy, and 30% for patient-related factors. GPs indicated they had no plans to change the current pioglitazone dose for 58% on 15 mg and 66% on 30 mg. **CONCLUSIONS:** UK GPs in this study appear comfortable with their current pioglitazone dose choice for their patients and a majority of GPs planned to have their patients continue on their current pioglitazone dose in combination therapy.

Diabetes/Endocrine Disorders – Research On Methods

PDB79

APPLICATION OF THE SUBGROUP IDENTIFICATION TOOL USING A HEALTH CARE DATABASE: TREATMENT RESPONSE HETEROGENEITY IN TYPE II DIABETES

Chen L[1], Buesching D[1], Curtis B[1], Zagar A[1], Rotelli M[1], Delisle F[2], Lipkovich I[1], Peng X[1]
[1]*Eli Lilly & Company, Indianapolis, IN, USA,* [2]*Delisle Associates Ltd, Indianapolis, IN, USA*

OBJECTIVES: To explore the utility of a novel Subgroup Identification Tool (SIT) in a healthcare database; specifically to identify which patient subgroup would achieve better outcome from which treatment option. **METHODS:** For the purposes of this study, two cohorts of patients with type II diabetes were extracted from the UK General Practice Research Database. Study patients were ≥40 years old, were newly prescribed with antidiabetics Drug A or Drug B, and had at least 6-month pre-index and 12-month post-index history. The index date was defined as the date of first prescription for Drug A or Drug B. The outcome was the average HbA1c from 3 months post-index to the end of 12-month follow-up. Subgroups were constructed using the SIT, which employs a novel SIDES (subgroup identification based on differential effect search) methodology. **RESULTS:** A total of 4824 patients were identified initiating Drug A and 1007 patients initiating Drug B. Slightly more patients achieved HbA1c ≤7% for Drug A (46.4%) compared with Drug B (42.6%), translating to the number needed to treat (NNT) of 26 in favor of Drug A. The SIT identified a subgroup (male, ≤ 71 years old without a prescription for antihypertensives) where the Drug A patients responded more favorably than Drug B in terms of achieving HbA1c ≤7% (NNT= 8 in favor of Drug A); and a subgroup (female, low density cholesterol <120mg/dl with a prescription for angiotensin-converting enzyme inhibitors) where the Drug-B patients responded more favorably (NNT= 10 in favor of Drug B). **CONCLUSIONS:** This study indicates that the SIT can be useful when applied to healthcare data to identify subgroups that are more likely to achieve better outcome from one of the two comparative treatment options. The results from the SIT could be used for hypothesis generation. Validation using independent data is warranted.

PDB80

VALIDATION OF THE UPDATED CHARLSON COMORBIDITY INDEX (CCI) FOR USE IN PATIENTS WITH DIABETES OR ASTHMA: A COMPARISON STUDY

Cheng LI, Rascati KL
University of Texas at Austin, Austin, TX, USA

OBJECTIVES: To validate the recently updated Charlson Comorbidity Index (CCI) for the prediction of healthcare utilization and to compare its predictive power in patients with diabetes or asthma. **METHODS:** Data were retrieved from the Medical Expenditure Panel Survey (MEPS) Panel 12 (2007-2008) for this retrospective cohort study. The original CCI (CCI-1) and updated CCI (CCI-2) scores were calculated for patients who had diabetes or asthma in 2007. Adjusted R2 from linear regression models were used for the estimation of log-transformed healthcare expenditures (COST) in 2008. C statistics from logistic regression models were used to compare the predictive power of the risk of hospitalizations (≥ 1 admission), risk of emergency department visits (≥ 1 visit), and high expenditures (≥ 90th percentile of COST) in 2008. **RESULTS:** 833 diabetic patients and 704 asthmatic patients were included in the study. The diabetes cohort had a mean age of 59.7 years (SD: 15.3), and 54% were female; the asthma cohort had a mean age of 37.8 years (SD: 23.6), and 59% were female. In the linear regressions, the CCI-2 explained more variance in COST in diabetic patients than in asthmatic patients (adjusted R2 = 17.4% vs. 14.1%), adjusting for demographics. The CCI-2 was a better predictor of high COST (c = 0.881 vs. 0.816) and the risk of hospitalization (c = 0.713 vs. 0.682) but a poorer predictor of the risk for an emergency department visit (c = 0.583 vs. 0.653) in the diabetes cohort than in the asthma cohort. In both cohorts, the CCI-2 (c = 0.583 to 0.881) exhibited consistently better predictive power than the CCI-1 (c = 0.576 to 0.839). **CONCLUSIONS:** The predictive power of CCI varies depending on the outcomes of interest in patients with diabetes or asthma. The updated CCI showed improved predictive performance compared to the original CCI.

PDB81

ASSESSMENT OF DRUG ADHERENCE FOR TYPE 2 DIABETES PATIENTS USING VIAL OR PEN FORM INSULIN: A METHOD TO ADJUST THE TRADITIONAL MEDICATION POSSESSION RATIO

Wang L[1], Xie L[2], Baser O[3]
[1]*STATinMED Research, Dallas, TX, USA,* [2]*STATinMED Research, Ann Arbor, MI, USA,* [3]*STATinMED Research/The University of Michigan, Ann Arbor, MI, USA*

OBJECTIVES: To develop a method to adjust the medication possession ratio (MPR) for type 2 diabetes patients who used a vial or pen form of insulin. **METHODS:** Using a retrospective analysis of large US health claims data from 2003 to 2008, diabetes patients who had at least two insulin prescription fills during the pre-index period were selected. The index date was the date of the first fill of insulin during the identification period from 2004 to 2007. One year of pre- and post-index continuous enrollment was required. Patients were excluded from the study if they switched to another form of insulin during the post-index period or had a diagnosis of gestational diabetes during the pre- or post-index period. MPR was calculated as a measure of drug adherence for patients who used vial insulin (&#x0018;Vial Cohort&#x0019;), and for those who used pen form insulin ('Pen Cohort'). Since insulin is a multi-dose treatment and is available in several package sizes, traditional MPR calculation is not suitable for this study. We adjusted the MPR by multiplying the traditional MPR by (average days between prescription refills/average days' supply) for patients in both cohorts. **RESULTS:** The unadjusted MPR during the post-index period for patients who used the pen device is lower than for patients who used a vial (0.55 vs. 0.60, p=0.0082). After controlling for baseline patient characteristics as well as the differences in package size between the pen and vial insulin using the new calculation method, the adjusted MPR for patients in the 'Pen Cohort' was higher than for patients in the 'Vial cohort' (0.22 vs. 0.13, p=0.001). **CONCLUSIONS:** After modifying the traditional MPR by adjusting the package size of the pen or vial insulin device, the adjusted MPR showed that pen insulin users had a significant advantage in drug adherence over vial users.

PDB82

DEVELOPMENT OF A HEALTH ECONOMIC MODEL TO COMPARE THE PREVENTION, TREATMENT AND MANAGEMENT STRATEGIES OF TYPE 2 DIABETES

Nagy B[1], Nagyjanosi L[2], Nagyistok S[2], Józwiak-Hagymásy J[2], Dessewffy Z[3], Kalo Z[4], Vokó Z[1]
[1]*Eötvös Loránd University, Budapest, Hungary,* [2]*Syreon Research Institute, Budapest, Hungary,* [3]*Novartis Hungary, Budapest, Hungary,* [4]*Eötvös Loránd University, Budapest, Hungary*

OBJECTIVES: The growing prevalence of diabetes mellitus highlights the conflict between the burden of disease and sustainability of health care systems, especially in Central-Eastern European middle income countries. Open access health economic models that calculate the effects of health policy programs and public interventions can improve the appropriateness of decisions. Our objective was to develop a long term economic model for type 2 diabetes and make it available for public sector decision-makers to support evidence based health policy decisions. **METHODS:** The health economic model projects outcomes for selected patient populations, taking into account baseline patient characteristics, history of complications, changes in physiological parameters over time, diabetes treatment and management strategies, and screening programs. First section of the model examines secondary prevention strategies of type 2 diabetes in a decision tree structure. The second section simulates patients through interconnected Markov sub-models that replicate important complications of diabetes (ischemic heart disease, retinopathy, hypoglycaemia, nephropathy, neuropathy, foot ulcer, peripherial vascular disease, stroke and ketoacidosis). Treatment and management strategies are taken into account when modeling patient pathways. The model includes a wide range of economic and clinical input data to support adaptability, country- or provider-specific outcomes and the analysis of different policy and treatment strategies. **RESULTS:** In this paper we present the methodological approach, the model structure, main scientific evidences applied and the choice of policy or treatment strategies that can be examined. **CONCLUSIONS:** Evidence based health pol-

icy can be implemented only if decision-makers have the access to analytical tools to address different policy scenarios. It requires initial investment, which pays off in better decisions.

PDB83

THE EPIDEMIOLOGY AND BURDEN OF OBESITY AND DIABETES IN FRANCE: A METHODOLOGICAL COMPARISON

Moisan C[1], Eschwège E[2], Basdevant A[3], Charles MA[2], DiBonaventura MD[4], Bonnélye G[5]
[1]ROCHE, Neuilly sur Seine Cedex, France, [2]INSERM, Villejuif, France, [3]Assistance Publique-Hôpitaux de Paris, Paris, France, [4]Kantar Health, New York, NY, USA, [5]Kantar Health, Montrouge , France

OBJECTIVES: The aim of the current study is to utilize two different methodologies to estimate the prevalence and burden of type 2 diabetes (T2D) and obesity among the adult population in France. **METHODS:** Two separate representative data sources were used for the adult French population. Data from the French respondents of the EU National Health and Wellness Survey (NHWS) (N=15,051) and the OBEPI survey (N=25,286) were used. The NHWS is an internet-based annual survey and the OBEPI is a mailed survey conducted every three years, validated by the French authorities. Prevalence information for T2D, comorbid treatments, and BMI were analyzed using both data sources. The humanistic and economic burden of T2D was analyzed only from the NHWS data. **RESULTS:** From NHWS, 44.3% of respondents from France were male and the average age was 45.1 years (SD=15.5). From OBEPI, 47.8% were male and the average age was 48.2 years (SD=17.8). A total of 30.5% (OBEPI=31.9%) and 15.6% (OBEPI=14.5%) of the French population were estimated to be overweight and obese, respectively. A total of 4.4% (from NHWS) and 4.8% (from OBEPI) of the adult French population reported suffering from T2D. Among these patients, 15.1% and 80.5% were taking an insulin and oral treatment, respectively (12.4% by OHA+insulin and 76.0% by OHA only as estimated by OBEPI). From NHWS, a significant burden was observed among patients with T2D as they reported significantly lower levels physical quality of life (using the SF-12v2; 42.6 vs. 50.1, $p<.05$) and significantly greater work impairment (26.7% vs. 18.2%, $p<.05$) and physician visits (8.7 vs. 5.5, $p<.05$). **CONCLUSIONS:** Both internet and mailed survey methodologies provided consistent prevalence estimates of diabetes and obesity among the French population. Further, despite the high prevalence of treatment, significant effects are observed on health outcomes among T2D patients, highlighting the unmet need.

Respiratory-Related Disorders – Clinical Outcomes Studies

PRS1

COST-EFFECTIVENESS OF VARENICLINE VERSUS EXISTING SMOKING CESSATION STRATEGIES IN BRAZIL FROM THE PUBLIC PERSPECTIVE, USING THE BENESCO MODEL

Fujii RK[1], Correia EA[2], Mould JF[3]
[1]Pfizer Pharmaceutics inc., São Paulo, São Paulo, Brazil, [2]Pfizer Parmaceutics Inc., São Paulo, São Paulo, Brazil, [3]Pfizer, Inc., New York, NY, USA

OBJECTIVES: According to DATASUS, from 1996 to 2005, there were more than 1 million hospitalizations related to smoking, with total costs sum of half billion dollars. The aim of this study was to assess the cost-effectiveness of varenicline compared to other existing strategies for smoking cessation in an adult population cohort from the public payer's perspective. **METHODS:** The Benefits of Smoking Cessation on Outcomes (BENESCO) simulation model was used for an 18 years of age and older cohort of 557,881 smokers, within a lifetime time horizon. Smoking cessation therapies in comparison were: varenicline (0.5–2 mg/day), bupropion (300 mg/day), nicotine replacement therapy (NRT) (5-10 mg/day), and unaided cessation. Relapse rates were considered as 6.3% for the first 5 years after cessation, 2% for years 6 to 10 and 1% for subsequent years. Effectiveness measure was Life-Year gained (LYG). Smoking and smoking-related heath condition's prevalence, resource use and costs data were obtained from DATASUS, INCA (National Cancer Institute), INCOR (Heart Institute) and DECIT (Science and Technology Department of Brazil). The model used a 5% discount rate for health outcomes and costs were expressed in 2010 USD. **RESULTS:** LYG for varenicline was 7310 compared to 7295 from bupropion, 7294 from nicotine replacement therapy and 7273 for untreated treatment. Compared to untreated patients, varenicline reduced smoking-related morbidity by 10,757 events, prevented 8,612 early deaths due to smoking related events, representing savings for US$139.602.241,20 from heathcare expenses. The net average cost per additional quitter showed that varenicline was cost-saving against bupropion (- USD 1.122,00) and nicotine replacement therapy (- US$ 46.184,40). **CONCLUSIONS:** Smoking cessation therapy with varenicline is cost-saving for Brazil. These results could help to reduce the tobacco related disease burden while agreeing with cost-containment policies.

PRS2

THE ROLE OF RX DATA IN COMPARATIVE EFFECTIVENESS RESEARCH

Varasteh L, Pedan A, Asumeng-Denteh E
inVentiv Health, Burlington, MA, USA

OBJECTIVES: To demonstrate Rx data application in relation to comparative effectiveness of inhaled corticosteroids (ICS) through evaluation of the rate of adherence to drug therapy and consumption of rescue medications in respiratory impaired patients. **METHODS:** Participants: A total of 533,382 patients age 18 or older who filled a prescription for ICS drugs. Setting: More than 12,153 community pharmacies nationwide. Data were from computerized pharmacy records. Design: The persistency analysis included prescription data for ICS dispensed during a 4-month period. Patient prescription activity was followed for 360 days. Patients were monitored for consumption of short acting beta agonist (SABA) medication in combination with their index ICS for 360 days from their ICS index fill date. An average SABA consumption in days for each index ICS drug was calculated. **RESULTS:** Persistence with ICS is generally poor; about 60% to 78% of patients drop off therapy within the first 30 days of therapy. Fluticasone/salmeterol (F/S) combination shows the best persistence and budesonide the worst persistence. Children were more persistent with mometasone whereas patients 19-60 and 60+ were more persistent with F/S. Budesonide and triamcinolone had the worst persistence with all age groups. The same results were seen in patients with multiple co-morbidities. Persistency with ICS across different co-morbid condition was consistent. On average 67% to 91% of ICS users took a SABA concomitantly. Budesonide (N=69,432) patients on average used fewer days of SABA therapy (higher control), whereas budesonide/formeterol combination (N=25,763) patients used more days of SABA therapy (lower control). **CONCLUSIONS:** Rx data can be used to compare effectiveness of drugs in a class across different population segments. Our analysis showed that different ICSs have different effectiveness, as indicated by the rate of adherence to therapy and use of rescue medication, in different individuals.

PRS3

THE EFFECT OF AAT REPLACEMENT THERAPY ON PATIENT LENGTH AND QUALITY OF LIFE - A MARKOV MODEL

Batty AJ[1], Tolley K[2], Jain M[3], Ruebesam T[4], Winn B[1]
[1]BresMed Health Solutions, Sheffield, South Yorkshire, UK, [2]Tolley Health Economics, Buxton, UK, [3]Talecris Biotherapeutics GmbH, Frankfurt am Main, Germany, [4]Talecris Biotherapeutics, Frankfurt am Main, Germany

OBJECTIVES: To model the outcomes associated with alpha-1-antitrypsin deficiency (AATD) related emphysema, an orphan disease, through the use of a Markov cohort model. **METHODS:** A simulated cohort of 773 patients (the number predicted patients in the UK) were transitioned between seven health states: mild, moderate, severe, very severe, lung transplantation, post lung transplantation and death, according to transition probabilities calculated from pooled randomised controlled trials. Computed tomography (CT) is accepted to be a more sensitive and correct measure of progression of disease in AATD-related emphysema, whereas FEV1 is a more recognised measure of lung function for clinical management of pulmonary disorders. Thus to model disease progression, CT decline from the randomised trials was converted to FEV1 decline through two different mapping algorithms, and transition probabilities calculated accordingly. Health-Related Quality of Life decreases as disease progresses, with utility values taken from the literature. At the stage where FEV1 % predicted fell below an eligible threshold, patients underwent lung transplantation. A predefined limitation on the number of lungs available reflected the competition for lung transplantation in the healthcare system. The model outputs include Life Years, QALYs, Lung transplantations, and disease specific mortality. All values were discounted at 3.5%. **RESULTS:** AAT replacement therapy resulted in an increase of 0.32 life years (6.93 vs. 6.61), with an estimated gain of 0.28 QALYs per patient (4.64 vs. 4.27) over best supportive care. For a cohort of 773 patients over a lifetime horizon, 19 AAT deficiency deaths and 6 lung transplantations were avoided when patients were treated with AAT compared to best standard care. **CONCLUSIONS:** Treatment with AAT slows decline in lung function and delays death associated with AATD. By slowing lung function decline, patients experience improved health related quality of life, while fewer lung transplantations are required, increasing the number of donor organs available for use in other diseases.

PRS4

EFFECTIVENESS OF A MULTIFACTORIAL INTERVENTION TO IMPROVE ADHERENCE IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) ICEPOC STUDY

Leiva-Fernandez F[1], Barnestein-Fonseca P[1], Leiva- Fernandez J[2], Vidal-España F[1], García-Ruiz A[3], Prados-Torres D[1]
[1]Distrito Sanitario Málaga (SAS), Málaga, Spain, [2]Área Sanitaria Málaga-Este Axarquía (SAS), Málaga, Spain, [3]Malaga Unversity, Malaga, Spain

OBJECTIVES: To assess the effectiveness on treatment adherence of a multifactorial intervention in patients with COPD. **METHODS:** Design: Randomized Control Trial (ISRCTN 15106246) Patients: 146 subjects randomly allocated (random blocks of 4 patients) in two groups (intervention group: IG, control group: CG). Intervention components: 1) Motivational aspects related with adherence: beliefs-behaviour about COPD (group and individual interviews); 2) Cognitive aspects: information about illness; and 3) Skills: inhaling techniques training. Follow-up: 1 year, 5 visits/group: 1) V0 random allocation, all variables were measured; 2) V0C adherence was measured; 3) V1-V2 (3-6 moths after start/intervention) adherence and variable changes were measured; and 4) V3 (one year after start/intervention) all variables were measured. Primary Outcome: adherence (doses recount); Secondary Outcomes: functional status (spirometry), quality of life (Saint George Respiratory Questionnaire-SGRQ); Independent variables: age, sex, educational level, comorbidity, COPD severity stage (SEPAR guidelines), prescribed medication. **RESULTS:** Predominace of males (91.8%), mean age 69.01 years (CI95%, 67.58-70.44); low cultural level (78.1%), 32.2% current smokers (29.36 cigarettes/day [CI 95%, 26.03-32.7]) overweight (Body Mass Index 30.78 kg/m2 [CI 95%, 28.78-32.78]), 81.2% mild-moderate severity stage, predominance of obstructive respiratory pattern; FEV1 (mean)=68.76% (CI 95%, 65.23-72.29), 0.87 exacerbations/year [CI95%, 0.68-1.06]. Pharmacological treatment: inhaled-anticholinergic (77.4%); inhaled-beta2-adrenérgic (80.1%); inhaled-corticosteroids (70.5%); xantins (8.2%); oxygen therapy (4.8%); oral-corticosteroids (0.7%); mucolytics (11.6%). All these measurements were similar in both groups. Adherence was 41% (41.2CG/40.8IG). 93 patients (63.7%) completed follow-up. Adherence in follow-up V1=61.8% (58.9CG/65.2IG), V2=66.3% (63.2CG/71.1IG), V3=56.8% (43.1CG/72.7IG). Significative differences between study groups (p=0.004). NNT for intervention:6,8 .Multivariate analysis (Adherence): (specificity = 87.5%, sensibility = 60.4%): intervention [OR=6.066 (IC95%,

2.075-17.734) p=0.001], age [OR=0.93(IC95%, 0.87-0.994) p=0.032]. inhaled-beta2-adrenérgic [OR=0.101 (IC95%, 0.017-0.589) p=0.021] SGRQ-Impact scale [OR=1.064 (IC95%, 1.014-1.117) p=0.012], SGRQ-Activity scale [OR=0.96 (IC95%, 0.924-0.997) p=0.034]. **CONCLUSIONS:** The performed intervention improves adherence in patients with COPD.

PRS5

ANALYSIS OF EFFICACY AND SAFETY OF DORNASE ALFA IN THE TREATMENT OF CYSTIC FIBROSIS

Kaczor M[1], Wojcik R[1], Rolka M[1], Banas P[1], Niewiara L[1], Kaczynski L[1], Russel-Szymczyk M[2], Szkultecka-Debek M[2]
[1]*Aestimo s.c., Cracow, Poland,* [2]*Roche Polska Sp. z o.o., Warsaw, Poland*

OBJECTIVES: To assess efficacy and safety of dornase alfa in the treatment of cystic fibrosis (CF) in children and adults. **METHODS:** Systematic review of Medline, EmBase, CENTRAL and clinicaltrials.gov databases was conducted. The references from relevant articles and abstracts from conferences were also examined to identify any additional studies. Each full-text article was critically appraised with use of the Jadad Scale. Clinical practice and CF treatment procedures in Poland were consulted with clinical experts. Placebo and treatment without dornase were identified as potential comparators. Changes in FEV_1, FVC, and $FEF_{25\%-75\%}$, exacerbation of respiratory symptoms, body mass change, use of drugs, number of days spent at home due to CF, hospitalizations (number and length), ambulatory visits, quality of life, mortality rate, treatment acceptance by patient and safety were assessed and compared based on the review results. **RESULTS:** Among 294 reports found, 17 publications concerning 12 randomized clinical trials were included in the analysis. The meta-analysis of available data regarding changes in FEV_1 after 1, 3, 6 months and 1 and 2 years showed better results with dornase therapy. The use of dornase also improved pulmonary function measured in FVC. Exacerbations of respiratory symptoms were less frequent (by 20% when dornase alpha was administered once daily and by 34% when administered twice daily), which resulted in fewer hospitalizations. Patients treated with dornase required less frequent courses of intravenous antibiotics and spent fewer days at home due to CF. Safety analysis showed a higher risk of rash, voice alteration and pharyngitis with dornase. Mortality was similar among groups. **CONCLUSIONS:** Dornase alfa is an effective (improves respiratory function, reduces CF symptoms, dyspnea and respiratory system exacerbations) and safe therapeutic option.

PRS6

MORTALITY TRENDS IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE: DATA FROM A STRUCTURED LITERATURE REVIEW

Rycroft C[1], Heyes A[1], Lanza L[2], Becker K[3]
[1]*RTI Health Solutions, Manchester, UK,* [2]*RTI Health Solutions, Waltham, MA, USA,* [3]*Boehringer Ingelheim GmbH, Ingelheim/Rhein, Germany*

OBJECTIVES: Chronic obstructive pulmonary disease (COPD) is a chronic respiratory disease characterised by a decline in lung function over time. The objectives of this literature review were to quantify COPD burden worldwide in terms of incidence, prevalence, mortality and identify trends in these data over time, in eleven countries: Australia, Canada, France, Germany, Italy, Japan, The Netherlands, Spain, Sweden, the UK, and the United States. Here, we focus on mortality in COPD. **METHODS:** A structured literature search (January 2000-September 2011) of PubMed, and EMBASE was conducted to identify English-language articles reporting prevalence, incidence and/or mortality of COPD. Of 2,838 articles identified, 299 full-text articles were reviewed, and data extracted from 133 publications. **RESULTS:** Mortality data were extracted from 58 articles (numbers include 7 multi-country studies that provide data for specific countries): Australia (n=6); Canada (n=6); France (n=3); Germany (n=1); Italy (n=2); Japan (n=2); The Netherlands (n=4); Spain (n=5); Sweden (n=7); UK (n=4); USA (n=30). In Sweden and the UK, patients with COPD were reported to have a mortality rate almost double that of the general population, and COPD mortality was two to three times greater in females than males in the The Netherlands, Italy and Germany. More recently, one retrospective US study conducted in 2000-2005, reported an increase in mortality rate in women (54.4 to 56.0 per 100,000) but a decrease in men (83.8 to 77.3 per 100,000). **CONCLUSIONS:** This is the first structured literature review to compile data on COPD mortality. Although COPD mortality rates have increased over time, more recently rates have declined, indicating improvements in COPD management. However, the mortality rate in women with COPD has increased, while it has decreased in men. This can probably be explained by the relative differences in smoking patterns between men and women.

PRS7

EFFICACY AND SAFETY OF SILDENAFIL ABOVE 60 MG DAILY IN PULMONARY ARTERIAL HYPERTENSION TREATMENT - A SYSTEMATIC LITERATURE REVIEW

Cukier FN[1], Fernandes RA[1], Takemoto MLS[1], Takemoto MMS[1], Fujii RK[2], Mould JF[3]
[1]*ANOVA - Knowledge Translation, Rio de Janeiro, Brazil,* [2]*Pfizer Pharmaceutics inc., São Paulo, São Paulo, Brazil,* [3]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: Maximum sildenafil dose dispensed by the Brazilian public healthcare system for pulmonary arterial hypertension (PAH) treatment is 60 mg daily. According to clinical practice, higher doses have been prescribed by most physicians. This systematic review aims to evaluate sildenafil efficacy and safety in doses above 60mg daily in PAH treatment. **METHODS:** A systematic review was conducted in May 2011 through Cochrane Collaboration, Medline, EMBASE, and Lilacs databases. Inclusion criteria's considered were meta-analysis, systematic reviews, randomized clinical trials, and observational studies using sildenafil above 60mg for any etiology PAH on WHO/NYHA functional classes II-IV patients over 12 years old. The exclusion criteria's were sample size below 10. Only sildenafil as monotherapy was considered. Outcome measures were distance walked in six minutes (6MWD), functional classification, and satisfactory adverse events profile, defined as similar to doses up to 60mg daily. Two independent reviewers selected articles qualitatively rated according to Oxford Center for Evidence-Based Medicine classification. **RESULTS:** Of 337 titles found, 45 articles evaluated and 16 selected (1 meta-analysis, 5 randomized trials and 10 observational studies). All but one demonstrated the benefit of sildenafil higher doses in 6MWD with satisfactory safety profile . In a 3-year follow up (SUPER 2), 46% of patients increased 6MWD and 60% maintained or improved their functional classification with 240mg daily compared to lower doses baseline. Two studies evaluated optimal sildenafil dose. Chocklingman (2005) found that 100mg daily improved 6MWD (234±44 vs. 377±128 meters, p=0.001) and WHO/NYHA class (3.8±0.4 vs. 2.4±0.5, p=0.002), from baseline. Garg (2007) tested from 37.5mg to 300mg daily and 6MWD increased from 247.4±74.4 to 366.3±93.8 meters (p=0.0001). Optimal dose appeared to be 150mg daily, with some additional benefit by increasing up to 225mg. **CONCLUSIONS:** Literature review supports that sildenafil in doses above 60mg daily is safe and may provide additional benefit to patients with PAH functional classes II-IV.

PRS8

PREDICTED SURVIVAL FOR NORTH AMERICAN PATIENTS WITH CYSTIC FIBROSIS ADJUSTED FOR COHORT SPECIFIC COVARIATES

Becker CC[1], Li H[1], Harrow B[1], Liou TG[2]
[1]*Vertex Pharmaceuticals Incorporated, Cambridge, MA, USA,* [2]*University of Utah, Salt Lake City, UT, USA*

BACKGROUND: Cystic Fibrosis (CF), the most common hereditary disease in Americans of European descent, affects 30,000 children and adults in the US. An important measure of the effectiveness of a new medicine for CF is its ability to extend survival past the result expected with the current standard-of-care. However, predicting what the natural median survival is for a cohort is not simple. Patient cohorts that have lived long enough that the median survival can be directly observed are not relevant to people born in the past twenty years as the standard-of-care has advanced significantly. On the other hand, with the resulting improvements in survival, post-1990 cohorts still have greater than 90% survival and it will take several decades before the median survival can be directly observed. **OBJECTIVES:** To estimate median survival for average North American patients with CF as a function of covariates, including age, gender, weight-for-age z-score, infection status and lung function. **METHODS:** A review of survival curves published by Canadian and US CF registries yielded 19 survival curves representing different birth cohorts. A Weibull function was fitted to the data. Using odds ratios the average survival curve could be adjusted to accommodate cohorts with non-average characteristics. **RESULTS:** A closed form equation was developed that estimates the survival function of cohorts with different clinical and demographic characteristics. It predicts, on average, patients with CF born today may live past forty years. **CONCLUSIONS:** The estimated survival function agreed well with historic data. By translating clinical results into survival, we believe the model can aid in evaluation of the value of new therapies. Supported by Vertex Pharmaceuticals Incorporated.

Respiratory-Related Disorders – Cost Studies

PRS9

BUDGET IMPACT ANALYSIS OF IMMUNOTHERAPY IN PATIENTS WITH GRASS POLLEN ALLERGIC RHINITIS

Westerhout KY[1], Verheggen BG[1], Schreder CH[2], Doering C[2], Augustin M[3]
[1]*Pharmerit International, Rotterdam, The Netherlands,* [2]*Stallergenes GmbH, Kamp-Lintfort, Germany,* [3]*University Clinics of Hamburg, Hamburg, Germany*

OBJECTIVES: A budget impact analysis was conducted to estimate the impact of Oralair® on a market of selected number of relevant grass allergens. **METHODS:** In this analysis the hypothetical market for grass allergens consisted of those compounds for which efficacy data of comparable high-quality evidence have been published. These compounds were Oralair®, Grazax® and ALK Depot SQ®. Actual German market data from 2008-2010 served as a basis for future estimates of market share development. Future predictions were made on market uptake and market dynamics (i.e. which drug increases their market share at the expense of another drug). German drug acquisition costs were taken from the Lauer-Taxe; average annual treatment related costs have been extracted from a supportive cost-effectiveness analysis. The analysis perspective was that of the German Statutory Health insurance (SHI). Three scenario analyses were conducted over a 5-year time horizon. **RESULTS:** The total market budget in 2010 for these 3 therapies was estimated at €48,209,211. The budget decreased with €7,049,756 over a 5-year period in the first scenario, when the annual uptake of Oralair® was set at +5% with market dynamics of 10%/90% (Grazax®/ ALK Depot SQ®). These savings represent 2.9% of the total cumulative reference budget varying from 1.0% in 2011 to 4.8% in 2015. In the second scenario market uptake for Oralair® was varied from +2% to +6% annually. Accordingly, the budget was reduced by €2,819,902 to €8,549,707. In the final scenario, shifting market dynamics from 0%/100% to 20%/80% (Grazax®/ ALK Depot SQ®) showed a reduction of €5,389,170 to €8,710,342. **CONCLUSIONS:** In all scenarios, an increase of Oralair's® market share at the expense of Grazax® and ALK Depot SQ® was estimated to result in a decrease of the budget varying from €2,819,902 to €8,710,342 over 5 years. This results in Oralair® being a budget-saving treatment option.

PRS10

A COMPARATIVE HEALTH ECONOMIC EVALUATION OF TWO TREATMENTS FOR GRASS POLLEN INDUCED ALLERGIC RHINOCONJUNCTIVITIS

Ronborg SM[1], Svendsen UG[2], Micheelsen JS[3], Ytte L[4], Andreasen JN[5], Ehlers L[6]

[1]The Pulmonology and Allergy Clinic of Copenhagen, Copenhagen, Denmark, [2]Bispebjeg Hospital, Copenhagen, Denmark, [3]Private ENT practice Birkerød, Birkerød, Denmark, [4]GP, Humlebæk, Denmark, [5]ALK-Abello A/S, Hørsholm, Denmark, [6]Department of Business Studies, Aalborg, Denmark

OBJECTIVES: Grass pollen induced allergic rhinoconjunctivitis (ARC) constitutes a large burden for the society. The prevalence is increasing and up to 20% of the European and US populations suffer from respiratory allergies including grass pollen induced ARC. The majority of patients are treated with symptomatic medications; however a large proportion remains uncontrolled despite the use of such treatments. Specific immunotherapy (SIT) is the only treatment documented to target the underlying cause of the allergic disease leading to a sustained effect after treatment completion. The aim of this study was to compare the economic consequences of treatment of patients with ARC with a grass allergy immunotherapy tablet (AIT) and the clinical practice of subcutaneous immunotherapy (SCIT). **METHODS:** A cost-minimisation analysis (CMA) was applied comparing the SQ-standardised grass AIT (Grazax, Phleum pratense, 75,000 SQ-T/2,800 BAU, ALK, Denmark) with SCIT (Alutard, Phleum pratense, 100,000 SQ-U/ml, ALK, Denmark). The CMA included health care utilisation measured in physical units based on national guidelines, literature reviews and expert opinions, as well as valuation in unit costs based on drug tariffs, physician fee structures and wage statistics. The CMA was conducted from a Danish societal and health care perspective. **RESULTS:** Treating patients with ARC with the grass AIT instead of grass SCIT results in a significantly reduced number of physician visits leading to a total reduction in direct treatment costs, direct patient costs as well as in indirect costs of €3526 per patient during a treatment course. A one-way sensitivity analysis confirmed the robustness of these results. **CONCLUSIONS:** The cost minimisation analyse shows that grass AIT is a cost-saving alternative to SCIT when treating patients suffering from grass pollen induced ARC.

PRS11

BUDGET IMPACT ANALYSIS OF IMMUNOTHERAPY IN PATIENTS WITH BIRCH ALLERGIC RHINITIS

Westerhout KY[1], Verheggen BG[1], Schreder CH[2], Doering C[2], Reich K[3]
[1]Pharmerit International, Rotterdam, The Netherlands, [2]Stallergenes GmbH, Kamp-Lintfort, Germany, [3]Dermatologikum Hamburg, Hamburg, Germany

OBJECTIVES: A budget impact analysis was conducted to estimate the impact of Staloral Birch® on a market of selected number of relevant birch allergens. **METHODS:** The hypothetical market for birch allergens consisted of 3 compounds; Staloral Birch®, ALK Depot SQ® and SLITone®. Randomized controlled trials have been performed to estimate safety and efficacy of Staloral Birch® and ALK Depot SQ®; however, for SLITone® no comparable evidence-based information is available. Actual German market data from 2008-2010 served as a basis for future estimates of market share development. Future predictions were made on market uptake and market dynamics (i.e. which drug increases their market share at the expense of another drug). German drug acquisition costs were taken from the Lauer-Taxe; average annual treatment related costs have been extracted from a recent cost-effectiveness analysis for grass allergens. The analysis perspective was that of the German payer (i.e. Statutory Health Insurance). Three different scenario analyses were conducted over a 5-year time horizon. **RESULTS:** The total market budget in 2010 for these 3 therapies was estimated to be € 36,485,362. It decreased with €2,263,694 over a 5-year period in the first scenario, when the annual uptake of Staloral Birch® was set at +6.9% with market dynamics of 80%/20% (ALK Depot SQ®/SLITone®). These savings represent 1.2% of the cumulative reference budget varying from 0.4% in 2011 to 2.1% in 2015. In the second scenario market uptake for Staloral Birch® was varied from +2% to +8% annually. Accordingly, the budget was reduced by €656,143 to €2,624,573. In the final scenario, shifting market dynamics from 90%/10% to 70%/30% (ALK Depot SQ®/SLITone ®) showed a reduction of €136,675 to €4,390,713. **CONCLUSIONS:** Increasing Staloral Birch® market share was estimated to result in a stable, if not decreasing budget with more patients treated using an evidence-based compound.

PRS12

A BUDGET IMPACT ANALYSIS TO ESTIMATE THE ECONOMIC IMPACT OF BECLOMETHASONE/FORMOTEROL FOR THE TREATMENT OF MODERATE TO SEVERE PERSISTENT ASTHMA IN SIX SPANISH REGIONS

Darba J[1], Kaskens L[2]
[1]Universitat de Barcelona, Barcelona, Spain, [2]BCN Health, Barcelona, Spain

OBJECTIVES: To assess the economic impact of introducing beclomethasone/formoterol extrafine for the treatment of moderate to severe persistent asthma in six Spanish regions including Andalusia, Bask Country, Catalonia, Galicia, Madrid and Valencia. **METHODS:** A budget impact model was developed using the perspective of the Spanish regional healthcare services with a 5-year time horizon. The model was populated with regional data on disease prevalence, population growth, drug tariffs, healthcare resource utilization, unit costs and market shares. Drugs considered in the study were fluticasone/salmeterol, budesonide/formoterol and beclomethasone/formoterol extrafine. Costs considered included drug costs, diagnostic tests, physician visits, hospitalisation and adverse effects treatment costs. All costs referred to EUR 2010, using a 5% annual discount rate. Total annual healthcare costs were estimated based on mean costs per patient for each treatment before and after the introduction of beclomethasone/formoterol extrafine. **RESULTS:** Based upon the Spanish adult population data and asthma prevalence, the treated population with moderate to severe persistent asthma in 2010 was estimated at 110,346 in Andalusia, at 16,369 in the Bask Country, at 31,118 in Catalonia, at 30,506 in Galicia, at 21,800 in Madrid and at 37,316 in Valencia versus populations of 140,684, 19,893, 38,378, 37,753, 27,660 and 46,789 respectively in 2015. The annual mean cost per patient was €996 before the introduction of beclomethasone/formoterol extrafine and €990 after its introduction. Total annual health care costs over the next 5 years for all six regions range between €95,7 and €661,6 million for the Bask Country and Andalucia before the introduction of beclomethasone/formoterol extrafine and €95,1 and €657,9 million after its introduction, respectively. **CONCLUSIONS:** The introduction of beclomethasone/formoterol extrafine for the treatment of moderate to severe persistent asthma showed to reduce the budget impact for each of the regional health care services by showing net savings for all six regions over the next 5 years.

PRS13

SPECIFIC IMMUNOTHERAPY AND THE ECONOMIC IMPLICATIONS FROM THE PERSPECTIVE OF GERMAN STATUTORY HEALTH INSURANCE - A BUDGET-IMPACT MODELING APPROACH

Reinhold T[1], Willich SN[2], Brüggenjürgen BH[3]
[1]Charite University Medical Center Berlin, Germany, Berlin, Germany, [2]University Medicine Berlin, Charité, Berlin, Berlin, Germany, [3]University of Berlin, Berlin, Germany

OBJECTIVES: Specific immunotherapy (SIT) is the only potentially curative therapy in patients with allergic rhinitis (AR) and allergic asthma (AA). The present study examined the effects of specific immunotherapy (SIT) on the financial situation of the German statutory health insurance systems (SHI). **METHODS:** Taking population projections of the German Statistical Federal Office, the number of expected new cases (AR, AA) was calculated until 2050. Based on assumptions about the proportion of patients who received SIT in the future, age cohorts passed cost-effectiveness models that were based on Markov chains. For determining the cost situation of SIT remedies, we used selling prices for Allergovit® depot suspensions. All future costs are discounted at a rate of 2%. Data on effectiveness were extracted from published literature. The model calculation was supplemented by a Delphi panel and additional probabilistic sensitivity analysis. **RESULTS:** Based on the current situation, a total annual economic burden of € 1 billion is expected for care of patients with pollen-induced AR and AA in Germany. Several realistic scenarios have shown, that despite higher initial expenses, savings of up to 10% of the average total annual cost are realizable. That would mainly driven by a reduced number of patients suffering from AA. The size of this cost reduction is mainly affected by the starting point of therapy: If SIT is applied at an early disease stage without asthma symptoms, the expected number of asthma sufferers is up to 35% lower compared to status quo. **CONCLUSIONS:** From the perspective of statutory health insurance companies, SIT could be a useful strategic option to prevent future allergic disease cases and to reduce associated medical expenses.

PRS14

ESTIMATING THE BUDGET IMPACT OF INTRODUCING INDACATEROL IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) FROM THE PUBLIC PAYER PERSPECTIVE IN SÃO PAULO

Suzuki C[1], Silva NL[2]
[1]Novartis Biociências SA, São Paulo, Brazil, [2]Novartis Biociências SA, Sao Paulo, Brazil

OBJECTIVES: To estimate the budget impact of introducing indacaterol in the treatment of COPD over a 5-year time horizon in patients eligible for treatment with long-acting maintenance therapy. **METHODS:** An Excel-based budget impact model was developed to calculate the budget impact based on local epidemiological and drug costs data. The number of patients eligible for treatment with long-acting maintenance therapy was estimated considering: 1) the local adult population (>40 years old) of approximately 14.5 millions; 2) proportion of population using the public healthcare system services and medications around 77%; 3) prevalence of local COPD patients about 15.8%; 4) 18% of these patients are diagnosed and receiving treatment; 5) 1.05% of annual population growth rate; 6) the same patient distribution in each disease severity across all years was assumed as 64% of mild, 29% of moderate, 6% of severe and 1% of very severe; 7) only patients in moderate, severe and very severe groups were considered as eligible for treatment with long-acting maintenance therapy; and 8) 53% of annual treatment persistence rate was applied. The ex-factory price with 24.38% of discount was used for indacaterol costs and 5% of annual discount rate was applied on the costs. Indacaterol 150μg uptake was assumed to be: 10%, 15%, 20%, 23%, 25%, over 5 years consecutively. **RESULTS:** The number of patients eligible for treatment with long-acting maintenance therapy in São Paulo was estimated to be around 60,754 in the first year. The annual net budget impact of indacaterol was negative through the years around: -88K, -1.7M, -3.2M, -4.2M and -4.4M (BRL) consecutively. **CONCLUSIONS:** The budget impact results show that indacaterol has potential to reduce costs on the budget of State health care system.

PRS15

ESTIMATING THE BUDGET IMPACT OF INTRODUCING INDACATEROL IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) FROM THE BRAZILIAN PUBLIC HEALTH CARE SYSTEM (SUS) PERSPECTIVE

Suzuki C[1], Silva NL[2]
[1]Novartis Biociências SA, São Paulo, Brazil, [2]Novartis Biociências SA, Sao Paulo, Brazil

OBJECTIVES: To estimate the budget impact of introducing indacaterol in the treatment of COPD over a 5-year time horizon in patients eligible for treatment with long-acting maintenance therapy. **METHODS:** An Excel-based budget impact model was developed to calculate the budget impact based on local epidemiological and drug costs data. The number of patients eligible for treatment with long-acting maintenance therapy was estimated considering: 1) the local adult population (>40 years old) of approximately 61 millions; 2) proportion of population using the public healthcare system services and medications around 77%; 3) prevalence of local COPD patients about 15.8%; 4) 18% of these patients are diagnosed and receiving treatment; 5) 1.05% of annual population growth rate; 6) the same patient distribution in each disease severity across all years was assumed as 64% of mild,

29% of moderate, 6% of severe and 1% of very severe; 7) only patients in moderate, severe and very severe groups were considered as eligible for treatment with long-acting maintenance therapy; and 8) 53% of annual treatment persistence rate was applied. The ex-factory price with 24.38% of discount was used for indacaterol costs and 5% of annual discount rate was applied on the costs. Indacaterol 150μg uptake was assumed to be: 9%, 13%, 17%, 19%, 21%; and for indacaterol 300μg: 1%, 2%, 3%, 4%, 4%, over 5 years consecutively. **RESULTS:** The number of patients eligible for treatment with long-acting maintenance therapy in Brazil was estimated to be around 256,040 in the first year. The annual budget impact of indacaterol through the years was approximately: 20M, 30M, 38M, 42M and 44M (BRL) consecutively. **CONCLUSIONS:** Currently none drugs are reimbursed for COPD maintenance therapy by SUS. According to this analysis, considering only the costs with indacaterol, it should have a small impact on the Ministry of Health's budget.

PRS16

COST ANALYSIS OF HAEMOSTATIC TREATMENT WITH A FIBRIN-BASED SPONGE VERSUS FIBRIN SEALANT IN LUNG SURGERY AND LIVER RESECTION IN A SPANISH SETTING

Darba J[1], Kaskens L[2], Perez-Alvarez N[2]
[1]*Universitat de Barcelona, Barcelona, Spain,* [2]*BCN Health, Barcelona, Spain*

OBJECTIVES: To assess the health care resources used and estimate the costs associated with the use of a collagen sponge coated with human fibrinogen and thrombin compared with fibrin sealant to improve haemostasis in lung surgery and liver resection. **METHODS:** A cost-analysis of the healthcare resources used with the administration of a fibrin-based sponge and fibrin sealant was performed. Health care resource utilisation and unit costs associated with both treatments in lung surgery and liver resection was obtained from literature research. Costs included for lung surgery were drug costs, preparation and administration time and additional hospitalisation due to post-surgery pulmonary air leakage. Costs for liver resection included drug costs, preparation and administration time, drainage and hospitalisation days at ward or an intensive care unit. Drug costs were obtained from Spanish medication databases. All costs were referred to EUR 2010. Based on the healthcare resource use the mean cost per patient for each treatment was estimated. A two-way sensitivity analysis was performed determining minimum and maximum mean costs per patient. **RESULTS:** Mean drug costs for the fibrin-based sponge and fibrin sealant in lung surgery resulted in €275 and €345, respectively. Total treatment costs per patient were estimated at €376 and at €509 for the fibrin-based sponge and fibrin sealant. In liver resection mean drug costs resulted in €550 for the fibrin-based sponge and in €690 for fibrin sealant, respectively. The associated total treatment costs per patient added up to approximately €5725 for the fibrin-based sponge and €6148 for fibrin sealant. **CONCLUSIONS:** The use of a fibrin-based sponge showed benefits over the use of fibrin sealant in lung surgery and liver resection. Less use of health care resources with the application of fibrin-based sponges versus fibrin sealant resulted in lower associated treatment costs per patient.

PRS17

PREVALENCE AND COST OF SEVERE CHRONIC HAND ECZEMA REFRACTORY TO TOPICAL POTENT CORTICOSTEROIDS

Cortesi PA[1], Scalone L[1], De Pità O[2], Angelini G[3], Cristaudo A[4], Girolomoni G[5], Gola M[6], Ayala F[7], Cannavò SP[8], Satta R[9], Gallo R[10], Lisi P[11], Peserico A[12], Pigatto P[13], Mantovani LG[14], Belisari A[15], Giannetti A[16]
[1]*University of Milano - Bicocca, Monza, Italy,* [2]*Istituto Dermopatico dell'Immacolata (IDI)-IRCCS, Roma, Italy,* [3]*University of Bari, Bari, Italy,* [4]*Istituto Dermatologico San Gallicano IRCCS, Roma, Italy,* [5]*University of Verona, Verona, Italy,* [6]*University of Florence, Florence, Italy,* [7]*University Federico II of Naples, Napoli, Italy,* [8]*University of Messina, Messina, Italy,* [9]*University of Sassari, Sassari, Italy,* [10]*Di.S.E.M., University of Genoa, Genoa, Italy,* [11]*University of Perugia, Perugia, Italy,* [12]*University of Padua, Padua, Italy,* [13]*University of Milan, Milano, Italy,* [14]*Federico II University of Naples, Naples, Italy,* [15]*CHARTA Foundation, Milano, Italy,* [16]*University of Modena, Modena, Italy*

OBJECTIVES: Earlier research has shown that Hand Eczema (HE) is often work-related, widespread, potentially disabling and costly, but often misdiagnosed and mistreated. Severe Chronic Hand Eczema (CHE) can be particularly burdensome, especially among severe patients refractory to therapy. We assessed cost-of-illness of severe CHE patients refractory to topical potent corticosteroids and their prevalence among HE patients accessing dermatology centres. **METHODS:** a naturalistic, multicentre study was conducted in 14 Italian dermatology centers. HE patients aged ≥18 years, consecutively accessing the participating centers through a 6-month period were enrolled. Socio-demographic and clinical data were collected for all patients, while direct, indirect costs and HRQol data were collected on severe refractory CHE patients. HRQoL was collected with the EQ-5D and the condition-specific Dermatology-Life-Quality-Index (DLQI, having a summary score ranging from 0 to 30, higher score corresponds to more impaired HRQoL). Direct and indirect costs data were collected through a retrospective 8-week time horizon, using the societal perspective. **RESULTS:** in total 981 HE patients were enrolled (mean age+SD=39.1+15.1, 35.9% male), 11.0% had severe refractory CHE. DLQI mean+SD sum score was 11.3+6.3. With EQ-5D 96.2% of patients reported moderate or severe pain/discomfort, 73.1% problems with usual activities, 55.8% anxiety/depression and 52.9% problems with self-care. VAS mean+SD=60.4+23.3. On average hospitalizations cost 67.3€/patient-month, travels cost 43.4€/patient-month, specialist visits cost 41.0€/patient-month, other products (gloves, gauze bandage, vacuum cleaner, cosmetics) cost 27.2€/patient-month, diagnostic exams cost 19.6€/patient-month, non pharmacological therapy (emollients, galenic products, soap, UV-therapy) cost 18.7€/patient-month, pharmacological therapy cost 18.2€/patient-month. Patients lost on average 4.9 workdays/patient-month for reasons attributable to their disease. **CONCLUSIONS:** Approximately one tenth of HE patients accessing dermatology centers have severe refractory CHE. These generate high costs to manage their condition, and have a significant productivity loss and a poor HRQoL. An appropriate diagnosis and treatment is necessary to efficiently manage the disease.

PRS18

ECONOMIC BURDEN OF CYSTIC FIBROSIS IN THE US: COSTS OF CARE BY DISEASE SEVERITY AND AGE

Becker CC[1], Clements K[2], DeLong K[2], Harrow B[1], O'Sullivan A[2]
[1]*Vertex Pharmaceuticals Incorporated, Cambridge, MA, USA,* [2]*OptumInsight, Eden Prarie, MN, USA*

Cystic fibrosis (CF) is a genetic disease characterized by progressive lung disease. In the US, the median age of death is 27 years. Published studies of the cost of CF by severity are outdated and do not report costs stratified jointly by age and FEV_1. **OBJECTIVES:** To gain understanding of the current economic burden of disease, we estimated the cost of CF by severity and age group. **METHODS:** We used an administrative claims database from a large US health plan to estimate mean annual total costs for patients with CF by age category (in 5-year increments) for patients ages 5 and older from 2004 to 2008. As claims data do not contain information on FEV_1, we derived the proportions of patients with mild (FEV_1 ≥70% predicted), moderate (40-69% predicted), and severe (<40% predicted) CF by age category using data from the CF Foundation Registry. We then estimated the ratios of costs for moderate and severe patients relative to mild patients using data from Lieu et al. (1999). Finally, we estimated treatment costs for patients with CF by age and FEV_1 using proportions of patients in each FEV_1 category, relationships between cost and disease severity, and costs by age from the database analysis. **RESULTS:** Preliminary estimated annual costs of care were $30,000, $57,000, and $215,000 for patients with mild, moderate, and severe disease, respectively. For all severity groups, costs were highest among children 10-14 years, and decreased with increasing age through age 45 years. Estimated annual costs of care for patients with CF ranged from $15,600 for mild patients aged 40-44 years to $343,900 for severe patients aged 10-14 years. **CONCLUSIONS:** Annual costs of CF care are highly variable by age and disease severity. Interventions that keep patients out of the severe disease state may save costs.

PRS19

QUALITY OF LIFE AND ECONOMICS OF ASTHMA CONTROL IN FRANCE AND SPAIN: FINAL RESULTS OF THE EU-COAST STUDY

Brosa M[1], Com-ruelle L[2], Calvo E[3], Chouaid C[4], Robert J[5], Doz M[5], Decuypere L[6], Huerta A[7], Pribil C[8], Detournay B[9]
[1]*Oblikue Consulting, Barcelona, Spain,* [2]*IRDES,, paris, France,* [3]*Universidad Autónoma de Madrid., Madrid, Spain,* [4]*Service of Pneumology, Paris, France,* [5]*Cemka-Eval, Bourg la Reine, France,* [6]*GlaxoSmithKline, Marly le Roi, France,* [7]*GlaxoSmithKline, Tres Cantos, Madrid, Spain,* [8]*GSK France, Marly le Roi, France, France,* [9]*Cemka, Bourg la Reine, France*

OBJECTIVES: Current asthma management guidelines are based on the level of asthma control. This study was designed to estimate quality of life and health care costs according to the patients' level of asthma control in France and in Spain in real-life setting. **METHODS:** On a 1-month and a 3-months period. An observational retrospective bottom-up cost of illness study (XX2113553) was conducted simultaneously in both countries among adults with asthma. Patients were recruited by samples of general practitioners during four quarterly waves throughout the year 2010 avoiding thus a seasonal bias. Asthma control was evaluated using the autotest Asthma Control Test (ACTTM) for a one month period and 2009 GINA's asthma control criteria for a three months period. Quality of life (QoL) was assessed using EQ-5D profile. Costs (direct and indirect) were evaluated from a societal perspective. **RESULTS:** A total of 2671 patients (France: 1154; Spain: 1517) were enrolled in the survey. Asthma was determined to be well-controlled (ACT ≥ 20) in 54.2% [IC 95%: 50.9% - 57.7%] and 58.8% [IC95: 56.2% - 61.3%] of French and Spanish patients respectively. In both countries, average EQ-5D scores were higher for patients with well-controlled asthma (France: 0.9 vs. 0.7, p<0.0001; Spain: 0.9 vs. 0.6, p<0.0001). Total costs of asthma varied accordingly to asthma control in both countries. The average total cost (Euros/month/patient) of well-controlled asthma was 57 € (±467) in France and 82 € (±171) in Spain compared with 111 € (±618) (p<0.0001) and 221 € (±323) (p <0.0001) respectively for not well-controlled asthma. Similar variations were observed using the GINA's criteria on a 3-months period. **CONCLUSIONS:** Results suggested that a poor asthma control is associated with higher costs and lower QoL in patients with asthma in both countries. Improving the control of asthma could eventually be associated to a decrease of the burden of asthma.

PRS20

COSTS OF COPD BY DISEASE SEVERITY - A COMPARISON OVER 10 YEARS

Jansson SA, Backman H, Lindberg A, Rönmark E, Lundbäck B
The OLIN Studies, Luleå, Sweden

OBJECTIVES: To examine the relationship between costs and severity of COPD, and to up-date the economical burden of COPD for the Swedish society. **METHODS:** The study sample was identified in 2009 from earlier clinical examinations of general population cohorts within the OLIN (Obstructive Lung Disease in Northern Sweden) studies. A number of 993 subjects were identified as having COPD (GOLD spirometric criteria). In 2009-2010, telephone interviews on resource utilization were made to a sample of 244 subjects, stratified by disease severity. Interviews were performed quarterly to minimize the risk of recall bias. Costs were calculated by applying unit costs from 2010. The prevalence for each disease severity was multiplied with the mean costs in order to calculate total societal costs. Non-parametric tests were used for testing the influence of COPD severity on costs in 2010, and when comparing the results with a previous study in 1999. **RESULTS:** A highly significant relationship was found between disease severity and costs. The mean

annual total cost per subject in relation to disease severity (GOLD) was: €783 (mild), €2,567 (moderate), €6,818 (severe), and €19,927 (very severe). Indirect costs were higher than direct costs in all severity stages. For direct costs, main cost drivers were hospitalizations in severe and very severe disease, and drugs in mild and moderate COPD, respectively. The main cost driver in indirect costs was productivity loss due to early retirement, except in mild disease where the driver was sick-leave. In comparison with a similar study performed in 1999 a numerical increase in mean annual total costs per subject was observed (ns). The total costs of COPD in 2010 could be estimated to about €1212-1469 million, with indirect costs accounting for about 70% of the total costs. **CONCLUSIONS:** The costs of COPD are still high in Sweden, and the costs increase considerably by disease severity.

PRS21

RESOURCE UTILIZATION AND ASSOCIATED COSTS OF COMMUNITY ACQUIRED PNEUMONIA (CAP) IN ADULTS: OBSERVATIONAL STUDY IN A POPULATION SETTING IN A WELL DEFINED AREA OF BARCELONA (BADALONA, SPAIN)

Sicras-Mainar A[1], Guijarro P[2], de Salas-Cansado M[2], Cifuentes-Otero I[2], Navarro-Artieda R[3]
[1]*Directorate of Planning, Badalona Serveis Assistencials, Badalona, Barcelona, Spain,* [2]*Pfizer Spain, Alcobendas, Madrid, Spain,* [3]*Hospital Universitari Germans Trias i Pujol, Barcelona, Spain*

OBJECTIVES: This study aimed to assess the economical impact of the CAP patients identified through the study period. **METHODS:** Retrospective review of medical records of all patients ≥18 years old diagnosed with CAP from January 1, 2008 to December 31, 2009 belonging to Badalona (population ≥ 18 years: 90,315) and attended by 6 primary care centres and 2 hospitals (68,274 patients seen throughout the study period, 6 months). Economical analysis (resource utilization and direct/indirect associated cost) is presented. Statistical analysis was performed through a regression model and Bonferoni-adjusted ANCOVA; $p<0.05$. **RESULTS:** Among the 581 patients identified [55.6% males, mean age 57.5 (SD 19,1)], 41.5% (241) were hospitalized. Total cost per patient was 1365.97€ (85.2% related to health care direct costs and 14.8% to non-health care costs due to sick leaves). Ambulatory care accounted for 154.24€ (13.25%) and hospital care 1010.25€ (86.75%) of the direct costs; $p<0.001$. Greater impact was due to hospitalization length of stay (71.47%), primary care pharmacological costs (13.24%) and specialist visits (11.42%). CAP costs were related to age ($r=0.303$); Fine scale score ($r=0.437$) and re-hospitalization ($r=0.667$); $p<0.001$. Overall cost per patient increased with age (1138€ in patients < 65 year-old vs. 1716€ in ≥ 65 year-old; $p<0.001$). **CONCLUSIONS:** CAP is still associated with high economic burden in our country which is mainly due to hospital care cost (almost one out of two patients were hospitalized). New preventive measures under development could reduce this impact.

PRS22

ESTIMATION OF DIRECT AND INDERCT COSTS OF COPD IN UKRAINE: THE PILOT STUDY RESULTS

Tolubaiev V[1], Zalis'ka O[1], Ostrovskyy M[2], Korzh G[2], Yakovenko O[3], Holovatyuk I[4]
[1]*Danylo Halytsky Lviv National Medical University, Lviv, Ukraine,* [2]*Ivano-Frankivsk National Medical University, Ivano-Frankivsk , Ukraine,* [3]*Volyn Regional Clinical Hospital, Lutsk, Ukraine,* [4]*O.O. Bohomolets National Medical University, Kyiv, Ukraine*

OBJECTIVES: The first official data on COPD prevalence, morbidity and mortality in Ukraine were introduced in 2009 report of National Center of Medical Statistics (2010). Nevertheless, there were no information on a number of specialists' consultations, a number of disability days and hospitalizations' frequency in Ukrainian COPD patient cohort. **METHODS:** Real-life 12 previous month's data from the personal medical cards (90%) and interview-lists (10%) of II-III severity stage COPD patients were analyzed retrospectively. The study was conducted in three regional clinical centers Bila-Tserkva (Kiev region), Ivano-Frankivsk, Lutsk (Volyn' region). Costs of COPD were calculated through the analysis of a number of GPs' and pulmonologists' consultations, a number of lost working days due to COPD, and COPD related hospitalizations frequency during the last 12 months. Direct medical costs included outpatient costs (specialists' consultations, control spirometry once a year) and inpatient costs (diagnostic measures and hospital-service costs), indirect costs included productivity loss (absenteeism and presenteeism) and disability compensations. The 2010-2011 medical service inflation (11.45%), salary growth rate (25%), social tax (18.6%) and Value Added Tax (17%) discounted the calculations. Exchange rate: 1EUR = 11.42UAH on 18.06.2011. **RESULTS:** The total study sample contained 132 patients, aged from 24 to 65 (mean age 49.49±10.02), males - 60.61 %. The number of GPs' and Pulmonologists' consultations per COPD patient was 2.63 and 1.18 per year respectively. The number of lost working days due to COPD was 12.63 per patient annually and a frequency of COPD related hospitalizations was 0.56 per 12 months. The total COPD costs in Ukraine in 2009 were €38870506 (103.03 per patient) with €28448213 (73.8%) direct medical costs and €10422293 (26.82%) indirect costs. **CONCLUSIONS:** The pilot study results showed that costs per COPD patient in Ukraine are large and could correspond with costs in several EU countries. Nevertheless, COPD in Ukraine is underdiagnosed and underestimated.

PRS23

HIGH COST CYSTIC FIBROSIS PATIENTS AS IDENTIFIED IN A US CLAIMS DATABASE: A CLOSER LOOK AT THE TAIL

Harrow B[1], Becker CC[1], Buikema A[2]
[1]*Vertex Pharmaceuticals Incorporated, Cambridge, MA, USA,* [2]*OptumInsight, Eden Prarie, MN, USA*

OBJECTIVES: Cystic fibrosis (CF) is an inherited disease that leads to progressive damage to the respiratory system, the digestive system, and other organs. Medical care utilization for patients with CF can be substantial. Recent studies of privately insured patients with CF in the US have been fairly consistent in their estimates of annual costs for the average or median patient with CF. However, the variation in cost is considerable and those patients in the tail of the distribution are also those with the most severe disease. **METHODS:** A national employer based claims database for the years 2004 to 2008 was used to identify patients with a valid CF diagnosis using multiple criteria. There were a total of 5019 unique patients with CF who had at least 1 year of continuous enrollment in the health plan. Annual all cause costs were calculated in total and by different settings and type of cost. The distribution of total costs was examined and the top 2.5 percentile (111 patients) were identified as high cost users. **RESULTS:** While the average annual cost was approximately $50,000 for patients in our data, the average for the high cost users was over tenfold higher and ranged between $270,000 and $3.1 million. The vast majority of these costs were for inpatient stays with the average number of days spent in the hospital of 87 days. **CONCLUSIONS:** In this study we used a US administrative claims database to take a closer look at the most resource intensive patients with CF. A greater understanding of this group can help inform stakeholders of the level of expenses to be incurred in the treatment of severe illness and aid in cost-analysis of treatments.

PRS24

IMPACT OF AGE AND PATIENT CO-MORBIDITIES ON COMMUNITY ACQUIRED PNEUMONIA (CAP) RELATED COSTS AT THE HOSPITAL SETTING IN A WELL DEFINED AREA OF BARCELONA (BADALONA, SPAIN)

Sicras-Mainar A[1], Guijarro P[2], de Salas-Cansado M[2], Cifuentes-Otero I[2], Navarro-Artieda R[3]
[1]*Directorate of Planning, Badalona Serveis Assistencials, Badalona, Barcelona, Spain,* [2]*Pfizer Spain, Alcobendas, Madrid, Spain,* [3]*Hospital Universitari Germans Trias i Pujol, Barcelona, Spain*

OBJECTIVES: This study aimed to assess the economical impact of the hospitalized CAP patients identified through the study period. **METHODS:** Retrospective review of medical records of all patients ≥18 years old diagnosed with CAP from January 1, 2008 to December 31, 2009 belonging to Badalona (population ≥ 18 years: 90,315) and attended by 6 primary care centres and 2 hospitals (68,274 patients seen throughout the study period). Economical analysis of hospitalized CAP (resource utilization and direct/indirect associated cost) is presented. Statistical analysis was performed through a regression model and Bonferoni-adjusted ANCOVA; $p<0.05$. **RESULTS:** Among the 518 patients diagnosed with CAP included, 241 were hospitalized (41.5%), mean age 66.6 (SD 16.4) years-old, 55.6% males. Adjusted mean total cost per patient was 2,332.4€ (sick leaves: 191.6€ and health care costs: 2,140.8€). Healthcare cost was mainly caused by hospital length of stay and specialist visits costs. Likelihood of inpatient admission increased with liver disease (OR=5.9), stroke (OR=3.6), dementia (OR=3.5), COPD (OR=2.9), diabetes mellitus (OR=1.9) and age (OR= 1.1); $p<0.002$. Patient suffering from these co-morbidities (except dementia) had higher hospital related costs: liver disease (2896.6€); stroke (2960.2€), COPD (2701.9€) and diabetes mellitus (3,057.7€); $p<0.001$. Direct hospital costs per patient increased with patient age (805€ in patients < 65 year-old vs. 1,716€ in ≥ 65 year-old; $p<0.001$). Streptococcus pneumoniae was the most prevalent pathogen identified [82/114 culture-positive inpatients (71.9%)]. Patients with confirmed pneumococcal pneumonia had greater overall mean cost (2864.7€ vs. 2259.8€; $p=0.041$) and healthcare cost (2722.1€ vs. 2,153.6€; $p=0.047$) than those not-confirmed. **CONCLUSIONS:** CAP caused great hospital resource utilization, mainly due to hospitalization days. Those patients older and/or suffering from co-morbidities had greater likelihood for inpatient admission and higher hospital related costs.

PRS25

SYSTEMATIC LITERATURE REVIEW OF ECONOMIC AND HUMANISTIC BURDEN OF DYSPNOEA IN COPD

Priedane E[1], van Nooten F[2], Tabberer M[3], Gonzalez McQuire S[4]
[1]*United BioSource Corporation, London , UK,* [2]*United BioSource Corporation, London, UK,* [3]*GlaxoSmithKline, Uxbridge, UK,* [4]*GlaxoSmithKline, Uxbridge, UK*

OBJECTIVES: To review published evidence on the economic and humanistic (health related quality of life (HRQoL)) burden of dyspnoea in patients with chronic obstructive pulmonary disease (COPD). **METHODS:** A systematic literature search was performed using PubMed and Embase databases. Search terms identified studies on economic and humanistic burden of dyspnoea in patients with COPD published since 2000 in English. **RESULTS:** Two articles for economic burden and six for humanistic burden were identified. The economic studies used different methodology; one a cohort study and another chart review. Both studies showed that dyspnoea within COPD is associated with higher costs. Five quantitative and one qualitative study were identified for humanistic burden. The quantitative studies concluded there is a correlation between dyspnoea and QoL. Although considerable variation was observed around the parameters used to define dyspnoea, including forced expiratory volume in one second (FEV_1) forced vital capacity (FVC), baseline dyspnoea index (BDI) and transitional dyspnoea index (TDI) and instruments used to assess QoL, including the World Health Organisation quality of life – BREF (WHOQOL-BREF), Borg scale and chronic respiratory disease questionnaire (CRQ). The qualitative study was based on interviews. Patients identified breathlessness as the worst COPD symptom, affecting nutritional intake and an association with anxiety. Overall, humanistic burden studies showed dyspnoea has a significant impact on the QoL. The main limitations of the reviewed studies were variation in instruments used to assess QoL and dyspnoea and small sample size (range: n=10-n=130). **CONCLUSIONS:** Studies identified in this review varied in methodological approach and were based on relatively small patient populations. The findings of this review suggest dyspnoea may be an important predictor of health related quality of life and economic burden in COPD. There are significant limitations in the current evidence base, further research is required before firmer conclusions can be drawn.

PRS26

DIRECT COSTS OF PNEUMONIA IN THE UNITED STATES: AN ANALYSIS OF 2008 MEDICAL EXPENDITURE PANEL SURVEY (MEPS) DATA

Parkv H, Rascati KL
The University of Texas at Austin, Austin, TX, USA

OBJECTIVES: To estimate annual health care utilization and costs of pneumonia across age cohorts in the United State (US) from an all-payer perspective. **METHODS:** A retrospective cross-sectional study was conducted using the 2008 Medical Expenditure Panel Survey (MEPS) database, a nationally representative annual survey of the civilian non-institutionalized population of the US. Pneumonia patients were identified as those with a Clinical Classification Code for pneumonia (code with 122). Resources used and expenditures incurred by patients with pneumonia that were directly attributable to pneumonia treatment (physician office visits, emergency room visits, outpatients visits, inpatient visits, other medical visits, and medications) were estimated. Health care costs per year per person (PYPP) were assessed across five age cohorts (<5, 5-<18, 18-<50, 50-<64, and ≥65 years old) and reported in 2008 US dollars. **RESULTS:** A total of 297 patients (representing 3.1 million persons) reported using medical resources or incurring expenditures due to pneumonia. Direct medical costs attributable to pneumonia were estimated at $2,763 (standard error [SE] ± 344) per patient. Approximately 86% ($2,394) of this estimate was generated by inpatient hospitalizations for pneumonia, which were experienced by 26.9% of pneumonia patients, with an average of 0.31 admissions per patient. Physician office visits and home health visits were the next largest categories of expenditure, contributing $153 (5.5%) and $113 (4.1%), respectively. By age cohort, mean attributable costs PYPP for patients <5 (n=47), 5-<18 (n=38), 18-<50 (n=41), 50-<64 (n=108), and ≥65 years old (n=63) were $2,166 (±1043), $579 (±119), $1,747 (±$888), $2,983 (±556), and $4,201 (±553), respectively (p< 0.05). **CONCLUSIONS:** This study provides an overview of clinical and economic burden of pneumonia in the US. Pneumonia-attributable expenditures were considerable, strongly driven by high inpatient hospitalization cost. In addition, patients aged ≥ 65 years had highest expenditures of pneumonia among all age cohort.

PRS27

TRENDS IN UK SMOKING CESSATION PRESCRIPTION EXPENDITURE OVER TIME - A THIN DATABASE STUDY

Blak BT, Lee J, Dungarwalla M
Cegedim Strategic Data Medical Research Ltd, London, UK

OBJECTIVES: In the UK, smoking cessation prescriptions (SCPs) include bupropion, nicotine replacement therapy (NRT) and varenicline, where NRT and bupropion were available around 2000 and varenicline in 2006, with NRT being relatively less expensive. This study evaluates the trends in SCP expenditure from the national payer perspective. **METHODS:** From patients >18 years, annual SCPs were obtained between January 1, 2000 - December 31, 2009 from The Health Improvement Network (THIN) database, which holds anonymised longitudinal UK primary care data from >500 practices. Drug prices came from the British National Formulary March 2010 to estimate real growth in expenditure. Expenditure trends were disaggregated by prescription frequency; treatment prevalence, defined as the number of patients receiving a SCP in THIN; SCPs per patient treated; and average drug expenditure per SCP. Sensitivity of 5% was applied towards expenditure. **RESULTS:** Total number of SCPs was 9,706 in 2000 and estimated 131,466 in 2009. SCP expenditure were estimated at 7,416,741£ (range:7,045,904-£;7,787,578£) in 2000 (2010 £ values) and 77,904,026£ in 2009 (range:74,008,825-£; 81,799,228£) reflecting a 950.4% real rate of increase. Bupropion prescription frequency was 70.8% in 2000 decreasing to 2.2% in 2009, NRT frequency was 29.2% in 2000 peaking at 94.4% in 2006 and declining to 65.1% in 2009, and varenicline frequency was 16.8% in 2007 increasing to 32.8% in 2009. Treatment prevalence rose from 0.3% in 2000 to 2.0% in 2009, while the average annual SCPs per patient treated increased from 1.5 to 3.0. The average SCP expenditure per SCP decreased to 22.2£ in 2006, however increased to 25.8£ in 2009. **CONCLUSIONS:** The expenditure increase reflects increase in treatment prevalence and average annual SCPs per patient treated. Furthermore, the introduction of varenicline may have impacted recent expenditures as the average SCP expenditure per SCP increased at varenicline introduction, suggesting a product shift towards more expensive SCPs.

PRS28

ADHERENCE TO CURRENT GUIDELINES FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN SUBJECTS TREATED WITH COMBINATION OF LONG-ACTING B2-AGONIST (LABA), LONG-ACTING MUSCARINIC ANTAGONIST (LAMA) OR INHALED CORTICOSTEROIDS (ICS)

Asche C[1], Leader S[2], Plauschinat C[3], Raparla S[4], Ye X[4], Yan M[4], Young D[4]
[1]*University of Illinois College of Medicine, Peoria, IL, USA,* [2]*Novartis, East Hanover, NJ, USA,* [3]*Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA,* [4]*University of Utah College of Pharmacy, Salt Lake City, UT, USA*

OBJECTIVES: To estimate the potential cost savings and reduction in exacerbations by following guideline recommendations in subjects being treated for COPD with the combination of LABA, LAMA or ICS. **METHODS:** Subjects were identified with a diagnosis for COPD using ICD-9 codes between January 1, 2004 to December 31, 2007. The index date was based on first prescription of a LAMA+LABA, LAMA+LABA/ICS, or LABA+ICS. Based on pulmonary function test (PFT) data within 30 days of the index date, subjects were classified as adhering or non-adhering to guidelines. Chi-square and t-test were conducted to determine the differences among cohorts. **RESULTS:** A total of 365 subjects were identified as adhering or non-adherent to guidelines based on their PFT data. Oxygen were significantly higher in LAMA plus LABA/ICS and lower in LABA/ICS as compared to LAMA plus LABA cohort (p<0.05). Also, number of office visits and hospital admissions were significantly higher in LAMA plus LABA/ICS compared to LAMA plus LABA cohort. The mean number of prescriptions for antibiotics and prednisone was higher in LAMA plus LABA/ICS cohort. The highest mean number of baseline exacerbations was observed in LAMA plus LABA/ICS group (12.9) with 6.06 in LABA plus ICS group and 7.76 in LAMA plus LABA group. 31% of the subgroup received COPD medications consistent with guidelines was associated with cost savings of $5,889 for LAMA plus LABA, $3,330 for LABA+ICS, and $10,217 for LAMA plus LABA/ICS cohorts. The LAMA plus LABA (1.3 vs. 2.9) LABA plus ICS (2.78 vs. 3.57), and LAMA plus LABA/ICS (-0.82 vs. 3.62) cohorts had lower mean change in exacerbations in adhering group versus non-adhering group. **CONCLUSIONS:** Adherence to current GOLD guidelines is associated with lower costs and fewer exacerbations in subjects with moderate to severe COPD for LAMA plus LABA, LABA plus ICS and LAMA plus LABA/ICS groups. AbstractsAbstracts

PRS29 EVALUATION OF STABLE COPD MEDICATION COSTS IN UKRAINE BASED ON GPS' PRESCRIPTIONS HABITS SURVEY RESULTS

HolovatyukI[1]Zalis'kaO[2]TolubaievV[2]
[1]*O.O. Bohomolets National Medical University, Kyiv, Ukraine,* [2]*Danylo Halytsky Lviv National Medical University, Lviv, Ukraine*

OBJECTIVES: Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic morbidity and mortality throughout the world. There was not any reliable information about its prevalence, morbidity and mortality in Ukraine until 2009. **METHODS:** We analyzed the data about COPD from the first report of Ukrainian Center of Medical Statistics. Than we calculated, the number of COPD cases needed the basis in 2009 and the approximate costs for COPD basis therapy based on data from the survey of Ukrainian GP's prescription habits in treatment of stable COPD. **RESULTS:** According to the Ukrainian Center's of Medical Statistics data in 2009 prevalence of COPD in Ukraine amounted to 998.7 per 100,000 (377,267 persons), morbidity – 79.2 per 100,000 (29,928 persons), mortality – 29.5 per 100,000 (11,121 persons). The number of persons with COPD needed the basis were 336,218 (total number of cases excluding new patients and deaths). According to our survey of Ukrainian GP's prescription habits for stable COPD basis 56.8% of COPD patients were given by fenoterol/ipratropium with annual costs per patient €120, 10.2% - tiotropium with €606.2 annually, 9.1% - fenoterol with €103.3, 7.9% - salbutamol with €27.5, 7.2% - fluticazone/salmeterol with €185, 6.8% - theophylline with €48.7, 2% - budesonide/formoterol €187.5 per patient annually. Therefore, in 2009 in Ukraine the expenditures for basis treatment of 336,218 COPD patients' with fenoterol/ipratropium, tiotropium, fenoterol, salbutamol, fluticazone/salmeterol, theophylline budesonide/formoterol were €22,916,618.88, €20,789,165.86, €3,160,550.07, €730,433.61, €4,478,423.76, €1,113,419.53, €1,260,817.50, respectively. Moreover, the total basis medications costs in 2009 could be €54,449,429.20 (€161.94 per patient). **CONCLUSIONS:** The study results showed that basis medication costs per COPD patient in Ukraine could correspond with costs in several EU countries. And we need to provide comparative cost studies for medications reimbursement-system creation.

PRS30

IDENTIFYING THE PATIENT POPULATION WHERE TREATMENT OF SEVERE ALLERGIC ASTHMA WITH OMALIZUMAB (XOLAIR®) EXHIBITS OPTIMAL COST-EFFECTIVENESS IN AUSTRALIA

Tilden D[1], Cottrell S[1], Tocchini L[1], Frenzel C[2], Bonney MA[2]
[1]*THEMA Consulting Pty Ltd, Pyrmont, NSW, Australia,* [2]*Novartis Pharmaceuticals Australia, North Ryde, NSW, Australia*

OBJECTIVES: In Australia omalizumab (OM) is indicated for moderate-to-severe allergic asthma. Two randomised controlled trials conducted in patients with severe asthma compared optimised asthma therapy (OAT) (includes maximal inhaled therapy) versus OM+OAT. This analysis was to identify a patient subgroup in which clinical need, comparative costs and effectiveness of OM is greatest. **METHODS:** A Markov model incorporating local treatment algorithms and data from the trials was developed. Patient subgroups were defined according to baseline use of maintenance oral corticosteroids (MOCS), Asthma Control Questionnaire (ACQ-5) and Asthma Quality-of-Life Questionnaire (AQLQ) scores, FEV&rtf-inf-start;1&rtf-inf-end;, exacerbation history and combinations of these. Costs and effectiveness of OM+OAT were compared with OAT alone. OM was continued only while patients exhibited treatment response. Various definitions of response were examined to optimise continuation criteria. Model parameters included: clinically significant asthma exacerbations; hospital admissions; emergency visits; change in MOCS dose; impact of MOCS on risk of certain chronic conditions; ACQ-5, AQLQ and EQ5D utility index scores. The model estimated numbers of clinically significant severe asthma exacerbations, deaths, life-years and QALYs gained due to OM. **RESULTS:** OM+OAT showed optimal cost-effectiveness in patients uncontrolled on or intolerant to MOCS, with a baseline ACQ-5 ≥2.0 or AQLQ ≤5.0. Response for OM continuation was optimally defined as a reduction in ACQ-5 ≥0.5 or ≥25% reduction in MOCS dose without deterioration in ACQ-5. These patients benefitted most from OM because they had severe disease, and were able to reduce exacerbations and MOCS dose and associated MOCS risks. The low baseline AQLQ score

meant these patients had greatest propensity for quality-of-life improvements and QALY gains, resulting in the public subsidy recommendation in this patient subgroup by the PBAC in Australia. **CONCLUSIONS:** Patients using MOCS with a baseline ACQ-5 ≥2.0 or AQLQ ≤5.0 are those in whom OM shows optimal cost-effectiveness in the Australian healthcare environment.

PRS31

ECONOMIC EVALUATION OF INDACATEROL IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) FROM THE PUBLIC PAYER PERSPECTIVE IN BRAZIL

Suzuki C[1], Silva NL[2]
[1]*Novartis Biociências SA, São Paulo, Brazil,* [2]*Novartis Biociências SA, Sao Paulo, Brazil*

OBJECTIVES: To assess the cost-effectiveness of indacaterol in comparison to tiotropium and formoterol from Brazilian public healthcare system perspective. **METHODS:** A Markov model was designed to project costs and outcomes associated with disease progression of patients with COPD over 3-years time horizon. The model health states are divided by severity of COPD (mild, moderate, severe and very severe) with each of these states divided into three states: no exacerbation, non-severe and severe exacerbations. The target population consists of patients with moderate or severe COPD, and the health states for mild and very severe COPD are included to account for those who improve in first cycle to the mild state and those who progress to very severe state over time. Efficacy data and exacerbation rates were obtained from the pivotal trials. Mortality data for COPD-specific states are based on study by Rutten-van Mölken et al. COPD related medical resource utilization patterns were assessed through clinical experts' panel. Unit costs were extracted from Brazilian official lists. Outcomes are expressed as life years gained (LYG). One-way sensitivity analysis was performed. Annual discount rate of 5% was applied both to costs and outcomes. **RESULTS:** Base case analysis estimated incremental LYG for indacaterol of 0.010 vs. formoterol and 0.006 vs. tiotropium. Indacaterol was cost-saving as compared to tiotropium (incremental cost of -2,667BRL). Comparing to formoterol, the projected ICER was 25,458BRL per LYG. The variables that most influenced the results were time horizon, mortality rates and baseline population. **CONCLUSIONS:** Indacaterol is a valuable alternative for COPD patients, being a cost-saving treatment vs. tiotropium with incremental clinical benefits and lower costs. Versus formoterol, indacaterol has incremental benefit, at a reasonable incremental cost.

PRS32

COST-EFFECTIVENESS OF OMALIZUMAB IN SEVERE UNCONTROLLED ALLERGIC ASTHMA USING RCT AND REAL-WORLD EVIDENCE IN THE DUTCH SETTING

Stern S[1], van Nooten F[2], Groot M[3], Brown R[1]
[1]*United BioSource Corporation, Bethesda, MD, USA,* [2]*United BioSource Corporation, London, UK,* [3]*Novartis Pharma B.V., Arnhem, The Netherlands*

OBJECTIVES: The objective of this analysis was to compare results of two cost-effectiveness analyses for omalizumab added to standard therapy in severe allergic asthma patients using an RCT (INNOVATE) compared to a real-world, prospective observational study (EXPERIENCE). **METHODS:** A Markov model was developed to examine the cost-effectiveness of add-on omalizumab versus standard care from the perspective of the Dutch health care system over a patient's lifetime. Efficacy data for clinically significant (CS) exacerbations and resource use (hospital admissions, unscheduled physician visits and emergency visits) were derived from INNOVATE or Dutch patients enrolled in EXPERIENCE. Data from each were projected to lifetime with discounted future costs (4%) and outcomes (1.5%). **RESULTS:** For the EXPERIENCE study, the modelled direct medical costs for patients on standard therapy were €77,615, of which 75% was for exacerbation control versus €133,475 for standard therapy + omalizumab, of which 38% was for exacerbation control. Patients on omalizumab had more QALYs than those on standard therapy alone, 12.05 versus 10.47. The resulting ICER was €35,257/QALY for the EXPERIENCE study. The INNOVATE costs were lower in both treatment arms: €22,499 for standard therapy and €58,666 for standard therapy + omalizumab. Costs were lower due to lower rate of CS exacerbations in the RCT where patients had been under best possible control at trial entry. QALYs were similar to the EXPERIENCE study 12.05 and 10.91, respectively; resulting in €31,802/QALY. **CONCLUSIONS:** Decision-makers are often presented with cost-effectiveness evidence from RCTs although they prefer to base decisions on real-world data are preferred. This study is one the first to include both in a re-evaluation dossier. It showed differences in patient characteristics (exacerbation rates and resource use) between the RCT and observational study. However it confirmed the value of omalizumab with similar ICERs, indicating that omalizumab is cost effective in both settings.

PRS33

A COST-EFFECTIVENESS ANALYSIS OF VARENICLINE VERSUS BUPROPRION AND NICOTINE REPLACEMENT THERAPY IN GREECE

Athanasakis K[1], Igoumenidis M[1], Karampli E[1], Vitsou E[2], Kyriopoulos J[1]
[1]*National School of Public Health, Athens, Greece,* [2]*Pfizer Hellas, Athens, Greece*

OBJECTIVES: To evaluate the cost-effectiveness of varenicline compared to bupropion and nicotine-replacement therapy (NRT) from a third-party payer (Social Insurance Fund) perspective in Greece. **METHODS:** The Benefits of Smoking Cessation on Outcomes (BENESCO) Markov model was applied to calculate the long-term health and economic benefits of smoking cessation, simulating the incidence and outcomes of smoking-related morbidities to a hypothetical cohort of patients (age- and gender-representative of the Greek population) making a single quit attempt. Demographic, epidemiological, treatment efficacy and economic inputs for the modelled cohort were obtained from the literature and publicly available data from public healthcare databases. The model calculated costs and outcomes for a lifetime perspective, discounted at a 3% discount rate and reported in year 2011 fees and prices. Extensive probabilistic sensitivity analysis was performed to test the robustness of the results. **RESULTS:** The cohort consisted of 819,709 current smokers making a quit attempt. The respective 1year continuous abstinence rates were 22.5%, 15.5% and 15.4% for quitters under varenicline, NRT and bupropion. For a lifetime horizon, varenicline prevented in total 7652 and 7609 additional cases of smoking-related disease (coronary heart disease, stroke, lung cancer, chronic obstructive pulmonary disease) versus NRT and bupropion, respectively. Moreover, varenicline led to a gain of 21,219 QALYs (16,955 life years) and 21,099 QALYs (16,859 life years) for the cohort, compared to NRT and bupropion. Taking direct costs into account, varenicline produced cost-savings against both comparators for the lifetime as well as for shorter (20year) timeframes of analysis. The probabilistic sensitivity analysis corroborated the study outcomes. **CONCLUSIONS:** Taking into account the Social Security perspective in Greece, varenicline was a dominant smoking cessation strategy compared to NRT and bupropion, reducing both treatment costs and smoking-related morbidity.

PRS34

COST-EFFECTIVENESS OF ROFLUMILAST (DAXAS®) IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN SPAIN

Lindner L[1], Camins de Valdenebro L[2], Aparicio Martinez J[2]
[1]*IMS Health, Barcelona, Cataluña, Spain,* [2]*Nycomed Pharma S.A., Madrid, Madrid, Spain*

OBJECTIVES: To estimate the cost-effectiveness of roflumilast (Daxas®) versus the most prescribed drug combination in Spain in the treatment of adult patients with severe chronic obstructive pulmonary disease (COPD) with a history of frequent exacerbations. **METHODS:** A Markov model was constructed to estimate the life time cost-effectiveness of roflumilast plus a long acting muscarinic antagonist (roflumilast + LAMA) versus the combination of LAMA with a long-acting beta agonist plus and an inhaled corticosteroid (LAMA+LABA/ICS). Outcomes were expressed as the incremental cost per exacerbation avoided from the Spanish National Health System perspective using a life-time horizon (30 years). Other health outcomes in the model include quality-adjusted life year (QALY) gained and life years (LY) gained. The key inputs to the model are based on roflumilast pivotal clinical trials and published epidemiological and population data. Uncertainty in the model's parameters was examined by sensitivity analysis. **RESULTS:** The results of the economic analysis have demonstrated that over the lifetime of the treatment of patients with severe COPD and associated chronic bronchitis with a history of frequent exacerbations, the roflumilast + LAMA strategy will cost 3468 € less than using LAMA + LABA/ICS. Over a lifetime a patient treated with a roflumilast + LAMA is estimated to have 1.23 exacerbations less and 0.129 more QALYs that a patient treated with LAMA + LABA/ICS. Therefore, the roflumilast treatment arm appears to be the dominating option. The sensitivity analyses showed that the variable that has the most impact on the ICER results is the relative risk of exacerbations. **CONCLUSIONS:** Roflumilast + LAMA offers a cost-effective option for the maintenance treatment of severe COPD associated with chronic bronchitis in patients with a history of frequent exacerbations compared with LAMA + LABA/ICS.

PRS35

ECONOMIC EVALUATION OF INDACATEROL VERSUS TIOTROPIUM OR FORMOTEROL FOR PATIENTS WITH MODERATE TO SEVERE COPD IN GREECE

Geitona M[1], Hatzikou M[2], Bania E[2]
[1]*University of Peloponnese, Athens, Greece,* [2]*Novartis Hellas, Metamorfosis, Greece*

OBJECTIVES: Evaluate the cost-effectiveness of indacaterol (Onbrez Breezhaler, 150μg & 300μg) against tiotropium (Spiriva, 18μg) or formoterol (Foradil, 12μg twice daily) respectively. **METHODS:** A Markov model was developed describing each COPD disease severity stage based on pre-bronchodilator FEV_1 measurements reported in the indacaterol clinical trials (INVOLVE & INHANCE). The outcomes assessment criteria were Quality-Adjusted Life-Years (QALYs), Life Years Gained (LYG) and exacerbation rates. A 3-year time horizon was used for the cost-utility analysis (CUA) and a lifetime (25 year) time horizon was used for the cost-effectiveness analysis (CEA). Discount rates of 3.5% were set for both costs and outcomes and univariate sensitivity analyses were conducted. Resource utilization was based on Greek published data and relevant costs on official NHS prices. **RESULTS:** The mean number of QALYs per patient in the three-year CUA was 2.152 in the indacaterol 150μg arm and 2.144 in the tiotropium arm, resulting in 0.0078 QALYs in favor of indacaterol; the total costs per patient were €9,717 in the indacaterol arm and €9,853 in the tiotropium arm, resulting in €136 savings in favor of indacaterol, gaining the dominant position (lower total costs, better outcomes). The CEA over the lifetime is similarly dominant with 10.213 LYG for indacaterol and 10.119 LYG for tiotropium and a lower cost per patient for indacaterol. The CUA comparing indacaterol 300μg and formoterol also resulted in indacaterol dominating formoterol with an incremental QALY of 0.017 (2.149 and 2.132 respectively) and a cost saving of €48.23 compared to formoterol over 3 years. Similarly, indacaterol dominates the CEA over a life time. Regarding exacerbation rates, although very similar outcomes appeared among treatments, COPD treatment was less costly with indacaterol against all other comparators. **CONCLUSIONS:** For patients with moderate to severe COPD, indacaterol represents a cost-effective treatment and is potentially cost saving for the Greek NHS.

PRS36

THE COST-EFFECTIVENESS OF STEP DOWN FROM HIGH DOSE ICS/LABA COMBINATION THERAPY IN ASTHMA IN THE UK SETTING

Paggiaro P[1], Buseghin G[2], Nicolini G[2], Patel S[2], Iannazzo S[3], Zaniolo O[3], Papi A[4]
[1]*University of Pisa, Pisa, Italy,* [2]*Chiesi Farmaceutici, Parma, Italy,* [3]*AdRes HE&OR, Turin, Italy,* [4]*University of Ferrara, Ferrara, Italy*

OBJECTIVES: According to international guidelines on the management of asthma (GINA), step down to the lowest dose of treatment that maintains control should be considered for controlled patients. The aim of this analysis was to estimate the costs and health outcomes associated with step down of controlled patients on high dose fluticasone/salmeterol (FP/S 1000/100μg daily) dry powder to either extrafine beclometasone/formoterol (BDP/F 400/24μg) pMDI or medium dose FP/S (500/100μg) dry powder in the UK setting. **METHODS:** A patient-level simulation Markov model was defined to perform the simulation of a cohort of patients along three comparative arms (FP/S 1000/100, FP/S 500/100, BDP/F 400/24). Transition probabilities and healthcare resources costs were derived from patient-level data of a recent multinational clinical trial comparing the three treatments. Direct costs and health state utilities were sourced from published literature and UK current prices and tariffs. The analysis was conducted from the UK National Healthcare System perspective, over a six–month time horizon. Probabilistic sensitivity analysis was conducted. **RESULTS:** The analysis showed an ICER (Incremental Cost-Effectiveness Ratio) of 57,300 GBP/QALY (Quality Adjusted Life Year) associated with high dose FP/S 1000/100μg versus extrafine BDP/F 400/24μg and an ICER of approximately 86,300 GBP/QALY associated with medium dose FP/S 500/100μg versus BDP/F 400/24μg. **CONCLUSIONS:** International guidelines recommend that when asthma control is achieved and stabilized, treatment can be stepped down to the lowest possible dose maintaining control. This analysis shows that maintaining controlled patients on high dose FP/S is not a cost-effective strategy. Extrafine BDP/F 400/24μg daily can be considered to be a cost-effective option in the UK to maintain control of asthmatic patients stepped down from high dose FP/S 1000/100μg daily.

PRS37

THE IMPACT OF REGIONAL DATA ON COST-EFFECTIVENESS RESULTS OF SALMETEROL/
FLUTICASONE PROPIONATE (SAL/FP) + FENOTEROL/IPRATROPIUM BROMIDE (FEN/IB) VERSUS FEN/IB ONLY IN COPD TREATMENT

Yagudina R[1], Kulikov A[1], Chuchalin AG[2], Belevsky A[3], Demko IV[4], Lomakin A[5], Shchurov D[6]
[1]*I.M. Sechenov First Moscow State Medical University, Moscow, Russia,* [2]*SRI of Pulmonology, Moscow, Russia,* [3]*Russian State Medical University, Moscow, Russia,* [4]*Krasnoyarsk State Medical University, Krasnoyarsk, Krasnoyarsk, Russia,* [5]*GlaxoSmithKline Russia, Moscow, Russia,* [6]*GlaxoSmithKline, Moscow, Russia*

OBJECTIVES: In order to assess cost-effectiveness of SAL/FP + Fen/IB versus Fen/IB only in chronic obstructive pulmonary disease (COPD) treatment in different Russian regions we developed PHACTOR pharmacoeconomic model. **METHODS:** Our model was based on the constant disease-specific data such as number of COPD exacerbations and health care resource utilization data obtained from PHACTOR (multicenter observational research of severe and very severe COPD). The methodology of PHACTOR research was published in 13th ISPOR Annual European Congress (Research Abstract #PRS31). The following region-specific input data were taken into account: drug prices (from the List of Vital and Essential Pharmaceuticals), medical tariffs (from regional government regulations), gross domestic product (GDP) per capita and average salary (from statistics service). SAL/FP + Fen/IB was compared with Fen/IB only. ICERs (cost per COPD exacerbation avoided) were calculated for all 83 Russian regions. Regional willingness to pay (WTP) was assumed as three regional GDP per capita. **RESULTS:** Average yearly drug costs varied from 29,539 RUR (Belgorod) to 35,264 RUR (Yakutia) for SAL/FP + Fen/IB treatment and from 7,877 RUR (Altai Republic) to 9,442 RUR (Yakutia) for Fen/IB treatment. Estimated yearly costs of COPD exacerbation treatment significantly varied from 6,552 RUR (Evreyskaya AO) to 63,053 RUR (Chukotka) for SAL/FP + Fen/IB treatment and from 12,592 RUR (Evreyskaya AO) to 109,019 RUR (Chukotka) for Fen/IB treatment. SAL/FP + Fen/IB treatment was cost-saving (dominating) in 9 regions and cost-effective in 74 regions (ICER < WTP; in this regions ICERs were from 74 RUR to 4,605 RUR per COPD exacerbation avoided). **CONCLUSIONS:** This analysis demonstrated that regional data had the biggest impact on final cost-effectiveness results. In general case SAL/FP + Fen/IB treatment was cost-effective in most Russian regions and cost-saving in some regions.

PRS38

THE COST-EFFECTIVENESS OF ROFLUMILAST FOR COPD IN SWEDEN

Engström A
Nycomed, Stockholm, Sweden

OBJECTIVES: Daxas (roflumilast) is a new PDE4-inhibitor which targets the underlying inflammation in COPD. It is indicated for treating severe and very severe COPD associated with chronic bronchitis and a history of frequent exacerbations. The objective was to assess the incremental cost-effectiveness of using roflumilast in a Swedish health care setting.The clinical trials for roflumilast have shown that it consistently reduces exacerbations by approx. 20% and that it also provides a lung function benefit of between 46-81 mL in addition to long-acting bronchodilators. **METHODS:** A Markov model with a life time time horizon, one month cycles and a discount rate of 3% was constructed using Treeage and an Excel interface. The model uses comparator treatments relevant to Swedish guidelines including long acting β-2 agonist (LABA), inhaled corticosteroids (ICS) and long-acting muscarinic antagonists(LAMA). All input parameters on costs and epidemiology were from Swedish sources. Clinical effectiveness was based on results from clinical trials along with indirect comparisons to address other comparators relevant to the reimbursement authorities. The analysis had a societal perspective and included lost productivity using a human capital approach. Outcomes were measured in QALYs. Uncertainty was addressed both through probabilistic sensitivity analysis and one-way analyses of central variables. **RESULTS:** Treatment with roflumilast (ROFL) as an add-on to LABA resulted in an incremental gain of 0.35 QALY. From a societal perspective the ICER for LABA+ROFLU versus LABA was €18,000 per QALY. The probability that LABA+ROFLU was cost-effective using a €50 000 threshold was 97%. The ICER for LABA+ROFLU vs LABA+ICS was €14,500. ROFLU+LAMA+LABA+ICS vs LAMA+LABA+ICS was €19,000. **CONCLUSIONS:** The ICERs calculated were all well below commonly accepted willingness to pay for a QALY in Sweden for all different comparator scenarios. The results were stable when central variables were varied. Roflumilast is a cost-effective treatment for severe and very severe COPD.

PRS39

COST-EFFECTIVENESS OF ROFLUMILAST IN COMBINATION WITH BRONCHODILATOR THERAPIES IN PATIENTS WITH SEVERE AND VERY SEVERE COPD IN SWITZERLAND

Samyshkin Y[1], Radford M[1], Schlunegger M[2], Gooss A[2]
[1]*IMS Health, London, UK,* [2]*Nycomed Pharma AG, Dübendorf, Switzerland*

OBJECTIVES: Chronic obstructive pulmonary disease (COPD) represents a considerable burden on patients and health systems. Frequent exacerbations in patients with COPD result in high healthcare costs. Roflumilast, an oral, selective phosphodiesterase-4 inhibitor, has been shown to reduce exacerbation rates and improve lung function in patients with severe COPD. The objective of this analysis is to estimate the long-term cost and outcomes of roflumilast added to several bronchodilator regimens in management of severe COPD from a health payer perspective in Switzerland. **METHODS:** A Markov cohort model was constructed to simulate the progression of disease, mortality, and exacerbation rates in patients with COPD. Transition probabilities between severe and very severe COPD were determined from the published literature. Background mortality was expressed through the risk of death in the general population and standardised mortality ratios (SMR); hospital mortality was based on the published literature. A cost-effectiveness analysis was conducted for roflumilast as add-on treatment to LAMA, LABA/ICS and LAMA+LABA/ICS, with the relative ratios of exacerbations rates derived from a recently published multiple-treatment-comparison. Direct costs were sourced from published Swiss data; utilities and disutilities of exacerbations were based on published data. Analysis was conducted from the payer perspective in Switzerland, for a lifetime horizon, with costs and outcomes discounted at 2.5% pa. A range of sensitivity analyses were conducted. **RESULTS:** The added quality-adjusted life years (QALY) and exacerbations avoided were: (0.275 and 2.56); (0.289 and 2.69); and (0.278 and 2.59) for roflumilast added to LAMA, LABA/ICS, and LAMA+LABA/ICS respectively. The incremental cost-effectiveness ratios (ICER) were CHF 18,512 per QALY in LAMA+roflumilast vs. LAMA, CHF 17,083 per QALY in LABA/ICS+roflumilast vs. LABA/ICS, and CHF 19,470 per QALY in LAMA+LABA/ICS+roflumilast vs. LAMA+LABA/ICS. **CONCLUSIONS:** For patients with severe COPD who continue to exacerbate in clinical practice in Switzerland roflumilast can be a cost-effective treatment option.

PRS40

COST-UTILITY OF FLUTICASONE COMPARED WITH BECLOMETHASONE AND BUDESONID IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN POLAND

Bolisega D[1], Dziewiatka M[1], Fedyna M[1], Ziobro M[1], Rutkowski J[1], Haldas M[1], Barlog D[2], Dziurda D[2], Glogowski C[2], Rys P[1], Plisko R[1]
[1]*HTA Consulting, Krakow, Poland,* [2]*GSK, Warszawa, Poland*

OBJECTIVES: To evaluate cost-utility of fluticasone compared with beclomethasone and budesonide in COPD treatment in Poland. **METHODS:** A discreet event simulation (DES) model was used to estimate utilities and costs of treatment (medicines, standard hospitalization, ambulatory visit cost for patients with COPD) on fluticasone therapy in comparison to beclometasone and budesonide. Analysis was performed from public payer's perspective with a time horizon of 10 years. Measures of medical effects of the therapies were obtained from a systematic review of RCTs. The range of possible outcomes in the model included: exacerbation, death, FEV_1. Based on the systematic review fluticasone is more effective than beclomethasone and budesonide in terms of FEV_1 improvement. Differences in costs and effects are presented per individual patient, described as statistically significant (SS) or non-significant (NS) and discounted at 5% and 3.5% respectively. Probabilistic sensitivity analysis was performed to estimate the probability that fluticasone is cost-effective in Polish conditions (threshold about 105,000 PLN/QALY). **RESULTS:** The QALY difference between fluticasone and beclomethasone was 0.136 QALY (SS), and the cost difference was 4544 PLN (NS). In deterministic analysis incremental cost per QALY for fluticasone compared with beclometasone was 33,333 PLN. The probability of fluticasone being cost-effective was 88.1%. The QALY difference between fluticasone and budesonide in 10 years perspective was 0.071 (NS). The cost difference was 9,027 PLN (SS). In deterministic analysis incremental cost per QALY for fluticasone compared with budesonide was 127,190 PLN and exceeded the threshold. There was 44.9% chance that the fluticasone therapy was cost-effective in comparison with budesonide therapy. **CONCLUSIONS:** Fluticasone therapy is more effective than beclomethasone (SS) and budesonide (NS). It offers to patients with COPD an additional, pay-off therapeutic option.

PRS41

COST-EFFECTIVENESS ANALYSIS OF IMMUNOTHERAPY IN PATIENTS WITH GRASS POLLEN ALLERGIC RHINITIS

Westerhout KY[1], Verheggen BG[1], Schreder CH[2], Sieber J[2], Augustin M[3]
[1]*Pharmerit International, Rotterdam, The Netherlands,* [2]*Stallergenes GmbH, Kamp-Lintfort, Germany,* [3]*University Clinics of Hamburg, Hamburg, Germany*

OBJECTIVES: To assess the relative effects and costs of Oralair® versus Grazax®, ALK Depot SQ® (alongside symptomatic medication) and symptomatic treatment alone for grass pollen allergic rhinitis; based on a systematic literature review, meta-analysis and cost-effectiveness analysis. **METHODS:** The costs and effects of three year treatment were assessed for a period of 9 years using a Markov model. Efficacy was estimated using an indirect comparison of available clinical trials. Estimates for immunotherapy discontinuation, occurrence of asthma, health state utilities, drug acquisition costs, resource use and other medical costs were derived from published sources. The analysis was conducted from the German payer's perspective, including Statutory Health Insurance (SHI) payments and co-payments by insurants. Effects were reported as quality adjusted life years (QALYs) and symptom-free days (SFDs). The uncertainty around the incremental model outcomes was tested by means of extensive deterministic univariate and probabilistic sensitivity analyses; various scenario analyses were also conducted. **RESULTS:** In the base case analysis the model predicted a cost-utility ratio of Oralair® versus symptomatic treatment of €14,728 per QALY: incremental costs were €1,356 (95%CI: €1,230;€1,484) and incremental QALYs 0.092 (95%CI: 0.052;0.140). Oralair® was the dominant strategy compared to Grazax® and ALK Depot SQ®, with estimated incremental costs of -€1,142 (95%CI: -€1,255;-€1,038) and -€ 54 (95%CI: -€188;€85) and incremental QALYs of 0.015 (95%CI: -0.025;0.056) and 0.027 (95%CI: -0.022;0.075), respectively. At a willingness-to-pay threshold of €20,000, the probability of Oralair® being the most cost-effective treatment was predicted to be 79%. The univariate sensitivity analyses show that the results were especially sensitive to changes in transition probabilities of immunotherapy discontinuation and efficacy estimates. Calculations on SFDs showed a comparable cost-effectiveness trend. **CONCLUSIONS:** The analysis suggests Oralair® to be cost-effective compared to Grazax®, ALK Depot SQ® and symptomatic treatment. The robustness of these statements has been confirmed in extensive sensitivity analyses.

PRS42

PHARMACOECONOMIC ANALYSIS OF METHYLPREDNISOLONE ACEPONATE FOR TREATMENT OF ATOPIC DERMATITIS AND ECZEMA

Omelyanovsky V[1], Avxentyeva M[1], Krysanov I[1], Margieva A[1], Hajlov P[1], Korsunskaja I[2]
[1]*Research center for clinical and economic evaluation and pharmacoeconomics, Russian State Medical University, Moscow, Russia,* [2]*Center of theoretical problems of physico-chemical pharmacology, Russian academy of SCIENCES, Moscow, Russia*

OBJECTIVES: To conduct comparative pharmacoeconomic analysis of Methylprednisolone aceponate (MA) and Betamethasone valerate (BV, brand name drug) for treatment of atopic dermatitis and eczema in adults. **METHODS:** Review of the published studies has been conducted to evaluate the comparative efficacy and safety of studied drugs. The cost-minimization analysis was used further. The pharmaceutical costs were calculated on the basis of average wholesale prices (according to RMBC/IMS database for the 3d quarter of 2010) and average retail prices in Moscow drugstores on 15.12.2010. The dosing regimen for both drugs was 1 g per 30 cm2 for 10 days, MA once a day, BV twice daily. **RESULTS:** A review of clinical efficacy and safety of topical corticosteroids studies has not revealed significant differences between MA and BV, though the experts consider MA to have more favorable therapeutic index (combination of high anti-inflammatory activity with reliable safety profile) compared to BV. With the retail price the costs of atopic dermatitis and eczema treatment were almost equal for MA and brand name drug of BV: MA cream - 257,85 ± 19,83 RUB (9,15 ± 0,70 $), BV cream - 265,61 ± 33,34 RUB (9,43 ± 1,18 $), MA ointment- 257,85 ± 19,83 RUB (9,15 ± 0,70 $), BV ointment - 265,61 ± 33,34 RUB (9,43 ± 1,18 $). **CONCLUSIONS:** Costs of MA and brand name BV for treating atopic dermatitis and eczema in adults are identical in both retail and wholesale market segments. Thus MA may be considered as a preferable option being a medication with the better therapeutic index compared to BV.

PRS43

PHARMACOECONOMIC EVALUATION OF ANTIBIOTIC THERAPY OF COMMUNITY-ACQUIRED INFECTIONS OF THE LOWER RESPIRATORY TRACTS BY THE USE OF MOXIFLOXACIN VERSUS CLARITHROMYCIN IN UKRAINE

Mishchenko O[1], Iakovlieva L[1], Matyashova N[2]
[1]*National University of Pharmacy, Kharkiv, Ukraine,* [2]*National University of Pharmacy, Kharkiv, Ukraine*

OBJECTIVES: The community-acquired respiratory tract infections (CARTI) are the most frequent indicators for antibacterial preparations prescription, that requires significant costs. Traditionally, penicillins and macrolids are used for it. Certain perspectives of CARTI treatment are connected with the new generation "respiratory" fluoroquinolones use, that have high antibacterial activity in relation to S. pneumoniae, but are rather expensive, especially in Ukraine. The aim of this work was comparative evaluation of costs efficiency for patients treatment with community-acquired pneumonia (CAP) and exacerbations of chronic bronchitis (ECT) with antibacterial preparations such as fluoroquinolone moxifloxacin versus macrolid clarithromycin for the optimal use of patient's or state's financial expenses grounding. **METHODS:** cost-minimization and sensitive analysis. **RESULTS:** The results of G. Hoffken, H.P. Meyer, K. Sprenger et al.(1999) have been used for pharmacoeconomic evaluation. In the trial 531 patients took place and it lasted 10 days. The treatment regimes were: moxifloxacin (200 mg / day); moxifloxacin (400 mg / day); clarithromycin (500 mg / two times a day). For pharmacoeconomic evaluation of ECT treatment the results of trial (R. Wilson, R. Kubin, I. Ballin et al., 1999) have been used: 649 patients took part in trial. The trial lasted 7 days. The treatment regimes were: moxifloxacin (400 mg / one time a day) for 5 days, clarithromycin (500 mg / two times a day) for 7 days. Efficacy of moxifloxacin and clarithromycin for CAP and ECT was equal. **CONCLUSIONS:** The results of "cost-minimization" analysis are sensitive to prices for drugs changing, and it does not create stable advantages for clarithromycin. In case of maximal price for drugs, it is moxifloxacin that has advantages.

PRS44

COST UTILITY ANALYSIS OF OMALIZUMAB THERAPY FOR SEVERE ASTHMA PATIENTS IN THAILAND

Sakul-isariyaporn C, Lertiendumrong J, Vasavid C, Pachanee K
International Health Policy Program, Nonthaburi, Thailand

OBJECTIVES: Asthma is a common chronic disease affecting approximately 4 million or 6.2% of Thais. Most asthmatic patients under the universal health coverage (UC) scheme are poor, and cannot access to appropriate treatments due to geographical barriers, and high costs of medications. Severe asthmatic patients not improved with inhaled corticosteroids (ICS) and long acting beta agonists (LABA) rarely access to Omalizumab, an anti IgE medication, because of its high costs, and exclusion from the UC benefit package. This study explores cost-utility analysis in societal perspective between Omalizumab and standard medical treatments (ICS, LABA, or oral corticosteroid) for severe asthmatic patients. **METHODS:** A mathematical model using variables and data from comprehensive literature reviews and asthma policy model were employed. Data on costs of medication and health service use were computed from existing reports of the Ministry of Public Health. The quality of life of asthma patients was assessed by the Asthma Quality of Life Questionnaire (AQLQ). **RESULTS:** Results from the mathematical model indicate that using Omalizumab compared to other standard medical treatments would achieve 231 quality-adjusted years (QALY) with additional costs of 95 million Baht (approximately US$ 3 million) for 100 severe asthmatic patients. The incremental cost-effectiveness ratio (ICER) of Omalizumab is approximately 414,503 Baht (US$13,371) per QALY gained. This ICER exceeds 1 GDP per capita which is the criteria for including new health interventions into the UC benefit package. **CONCLUSIONS:** Omalizumab is not cost-effective for severe asthma patients in Thailand. It is recommended that improving access to ICS and LABA and maintenance systemic steroid should be the priority of medial care for asthma patients in Thailand, prior to including Omalizumab into the UC benefit package. Omalizumab will be considered to be cost-effective if its cost decreases significantly and used for severe asthmatic patients only.

PRS45

FULLY INCREMENTAL COST-EFFECTIVENESS ANALYSIS OF AVAILABLE TREATMENT OPTIONS IN THE MANAGEMENT OF SEVERE COPD IN THE UK SETTING

Kotchie R[1], Samyshkin Y[1], Hertel N[1], Radford M[1], Jameson K[2], Humphreys S[2]
[1]*IMS Health, London, UK,* [2]*MSD Ltd, Hoddesdon, UK*

OBJECTIVES: Despite availability of current treatments, patients with chronic obstructive pulmonary disease (COPD), associated with chronic bronchitis, often experience life-threatening and costly exacerbations. The aim of this analysis was to assess the long-term costs and outcomes associated with different treatment options for the management of severe COPD in the UK. **METHODS:** A Markov cohort model was constructed to simulate decline from severe to very severe COPD (as defined by the NICE/GOLD guidelines), treatment regimen changes, and death. Community- and hospital-treated exacerbations were modelled as events within each health-state. A fully incremental cost-effectiveness analysis was conducted for LABA, LAMA, PDE-4 inhibitors, and ICS in various combinations. Transition probabilities for COPD progression were derived from published epidemiological sources. Relative rate ratios of exacerbations were taken from a recently published mixed treatment comparison. Direct costs were sourced from UK data, and health state utilities and exacerbation disutilities from the published literature. Analyses were conducted from the UK NHS perspective, based on a 30-year time horizon, with costs and outcomes discounted at 3.5% p.a. One-way and probabilistic sensitivity analyses were conducted. **RESULTS:** The cost-efficiency frontier suggests LAMA as the most effective monotherapy (£22,370, 5.421 QALYs). If patients continue to exacerbate, LAMA+LABA/ICS is a cost-effective second line option (£22,816, 5.484 QALYs, ICER £7,045/QALY), followed by LAMA+LABA/ICS+roflumilast (£23,230, 5.509 QALYs, ICER £16,566/QALY). For patients who are intolerant to (or decline) ICS, the addition of roflumilast to LAMA+LABA is a cost-effective treatment option (ICER £13,764/QALY). The results were consistent under a variety of assumptions. **CONCLUSIONS:** For severe COPD patients who continue to exacerbate, despite current standard of care, the addition of roflumilast to the treatment regimen is cost-effective in UK clinical practice. The addition of roflumilast in this manner is consistent with the step-wise treatment paradigm recommended in NICE guidelines.

PRS46

EFFECTIVENESS AND COST-UTILITY ESTIMATES OF TIOTROPIUM TREATMENT AND PULMONARY REHABILITATION PROGRAMS IN FRENCH PATIENTS WITH CHRONIC OBSTRUCTIVE PULOMONARY DISEASE

Atsou K[1], Hejblum G[2], Chouaid C[3]
[1]*UPMC Univ Paris 06, Paris, FRANCE, France,* [2]*INSERM, Paris, FRANCE, France,* [3]*Assistance Publique Hopitaux de Paris, Paris, France*

OBJECTIVES: Chronic obstructive pulmonary disease (COPD) is a progressive (and non-completely reversible) inflammatory lung disease. Disease progression is associated with increasing morbidity, mortality and economic burden. As compared to usual care, tiotropium treatment and pulmonary rehabilitation programs have been reported to improve the health of COPD patients in terms of exacerbations, quality of life, and mortality. However, to date, the cost-effectiveness/utility of these therapies in French settings have not been reported. We estimated the cost-utility/effectiveness of these therapies in a patient population recruited from French general practitioners and lung specialists. **METHODS:** A Markov model of

the disease was developed and the study adopted society's perspective while the horizon time considered was patient's remaining lifespan. Cohorts of COPD patients treated with Tiotropium or cohorts of patients undergoing pulmonary rehabilitation programs were simulated (Monte-Carlo simulations in TreeAge software) and compared to identical cohorts of patients subjected to usual care. Life expectancies, quality adjusted life-years (QALY), disease-related costs, and incremental cost-utility ratios were estimated. **RESULTS:** At the horizon of a patient's remaining lifetime (14.29 life years in average, considering a population combining moderate to very severe patients), tiotropium would result in 0.12 life years and 0.58 QALY gained (mean estimates), induce an additional cost of 5380 €/patient in the disease-related costs, with a corresponding incremental cost-utility ratio of 8853 €/QALY. For pulmonary rehabilitation programs, these estimates were 0 life years, 0.31 QALY, 2,969 €, and 12,000 €/QALY, respectively. Results were mostly sensitive to the utility changes associated with exacerbations. **CONCLUSIONS:** Tiotropium treatment and pulmonary rehabilitation programs were estimated as worth interventions in the studied population, below the usual threshold used for declaring procedures as cost effective. Nevertheless, the modest gains in health issued from the study emphasize the need of research for developing more effective COPD-related therapies.

PRS47

OPTIMA MODEL-BASED COST-UTILITY ANALYSIS OF FIXED COMBINATION SALMETEROL/FLUTICASONE VERSUS NON-FIXED COMBINATION BUDESONIDE/FORMOTEROL IN ONE PACK FOR BRONCHIAL ASTHMA TREATMENT

Yagudina R[1], Kulikov A[1], Chuchalin AG[2], Ogorodova LM[3], Demko IV[4], Lomakin A[5], Shchurov D[6]
[1]*I.M. Sechenov First Moscow State Medical University, Moscow, Russia,* [2]*SRI of Pulmonology, Moscow, Russia,* [3]*Siberian State Medical University, Tomsk, Russia,* [4]*Krasnoyarsk State Medical University, Krasnoyarsk, Krasnoyarsk, Russia,* [5]*GlaxoSmithKline Russia, Moscow, Russia,* [6]*GlaxoSmithKline, Moscow, Russia*

OBJECTIVES: To assess costs, utilities and cost-utility of fixed combination salmeterol/fluticasone (SAL/FP maintenance treatment) versus non-fixed combination budesonide + formoterol in one pack (BUD+FORM maintenance treatment) in the management of patients with bronchial asthma by means of an OPTIMA model. **METHODS:** In this analysis we used the following data: drug prices (from List of Maximum Permissible Manufacturer Prices for Vital and Essential Drugs) and drug dosage proportion (from MRC Pharmexpert, 4Q 2010); number of inhalations per day (from instructions); QOL and number of health care resources for controlled and uncontrolled asthma (from published sources); resource unit costs (from 2010 health care insurance program). Work-off day costs included tax deficiency, GDP underproduction and sick pay. Frequency of controlled asthma was obtained from ARROW study (Ogorodova et al., 2009) for SAL/FP (73%) and from FACET trial (O'Byrne et al. 2008) for BUD+FORM (62%). Conceptual formula of analysis was: cost of drugs + % controlled * cost of controlled + % uncontrolled * cost of uncontrolled. One-way sensitivity analysis was conducted to assess the robustness of the results. **RESULTS:** Average monthly costs of drugs were 1,677 RUR/€42 and 2,023 RUR/€51 for SAL/FP and BUD+FORM respectively. Medical costs and QOL measures were 378 RUR/€9 and 0.75 for controlled asthma; 88,295/€2,207 RUR and 0.49 for uncontrolled asthma. Yearly total costs per patient were higher for BUD+FORM than for SAL/FP (58,057/€1,451 RUR vs. 44,244 RUR/€1,106). Compared to BUD+FORM, SAL/FP was associated to an expected increase of QALYs per patient (0.68 QALYs vs. 0.65 QALYs). The cost-utility analysis showed that SAL/FP was dominant (less costly and more effective in terms of QALYs gained). Results were sensitive to all the parameters varied in the sensitivity analysis, especially health care costs. **CONCLUSIONS:** Treatment of patients with bronchial asthma with SAL/FP is a dominant strategy in comparison with non-fixed combination BUD+FORM in one pack.

PRS48

COST-UTILITY ANALYSIS OF VARENICLINE VS EXISTING SMOKING CESSATION STRATEGIES IN EL SALVADOR

Lutz MA[1], Lovato P[2], Morales G[2], Cuesta G[2]
[1]*Pfizer S.A., Escazú, San Jose, Costa Rica,* [2]*Pfizer Central America and the Caribbean, Escazú, San Jose, Costa Rica*

OBJECTIVES: Smoking is the leading cause of preventable death in El Salvador (50%) and results in many serious comorbidities, including lung cancer, coronary heart disease, stroke and chronic respiratory disease. The aim of this study was to evaluate the cost-utility of varenicline compared to other existing strategies for smoking cessation within a 5-year time horizon in El Salvador using the healthcare payer's perspective. **METHODS:** The Benefits of Smoking Cessation on Outcomes (BENESCO) simulation model was used for an adult cohort (n=4,537,803). Diseases included were: stroke, lung cancer, coronary heart disease and chronic obstructive pulmonary disease. Smoking cessation therapies compared were: varenicline (0.5 – 2 mg/day), bupropion (300 mg/day), nicotine replacement treatment (NRT) (5-10 mg/day) and unaided cessation. Effectiveness measure was: quality-adjusted life year gained (QALY's), which was obtained from published literature. Resource use and costs data were obtained from El Salvador's Ministry of Health and Social Security official databases (2010). The model used a 3% discount rate for costs (expressed in 2010 US dollars) and QALYs. Probabilistic sensitivity analyses (PSA) were conducted and acceptability curves were constructed. **RESULTS:** Varenicline reduced smoking related morbidity, mortality and healthcare costs. After 5 years, Varenicline gained 306,158 QALYs, which represents 73, 94 and 178 more QALYs than bupropion, NRT and unaided cessation, respectively. Overall costs showed varenicline as the least expensive option against bupropion (+US$328,558), NRT (+US$412,730) and unaided cessation (+US$777,124). Cost-effectiveness analyses showed that varenicline was the dominant strategy. Acceptability curves showed that varenicline would be cost-effective within <3 GDP per capita threshold. PSA results support the robustness of the findings. **CONCLUSIONS:** Smoking cessation therapy with varenicline is cost-saving in El Salvador. These results could help to reduce the tobacco related disease burden and align cost-containment policies.

PRS49

ECONOMIC BURDEN ATTRIBUTABLE TO OBESITY IN ADULT PATIENTS WITH ASTHMA IN THE UNITED STATES

Suh DC[1], La HO[2], Barone J[3], Chang CW[3], Kim CM[2]
[1]*College of Pharmacy, Chung-Ang University, Seoul, NJ, South Korea,* [2]*Catholic University College of Medicine, Seoul, South Korea,* [3]*Rutgers University, Piscataway, NJ, USA*

OBJECTIVES: To estimate annual medical and productivity costs attributable to obesity in adult patients with asthma in the US. **METHODS:** This study used the 2003-2008 Medical Expenditure Panel Survey. Asthma patients(18-64 years) were identified using ICD-9-CM code 493, clinical classification code-128, or physician diagnosis. Patients were classified as normal(BMI:18.5-<25 kg/m2), overweight-(BMI:25-<30 kg/m2) or obese(BMI:≥30 kg/m2). Medical costs were estimated using a generalized linear model(GLM) with a log link function and gamma distribution. Costs associated with productivity loss were calculated based on missed working days due to illness and average hourly wage using a two part model. In the first part, logistic regression was used to estimate the probability of having missed working days due to illness. In the second part, among patients with missed working days, GLM was used with the estimated probability from first part of model to estimate the cost associated with productivity loss. The costs attributable to obesity were estimated by differences between the observed and estimated cost in obese patients, using a distribution of covariates obtained from normal patients. All costs were converted to 2010 US dollars using price indices. **RESULTS:** A total of 8775 adults were identified with asthma. The average treatment cost and lost productivity costs of normal patients were $3154(95%CI:$2689-$3620) and $327(95%CI:$279-$375), and those of obese patients were $5720(95%CI:$5314-$6129) and $699(95%CI:$608-$790), respectively. Obese patients had 38% higher medical cost and 53% higher lost productivity costs after adjusting for other study variable.Additional medical costs attributable to obesity were calculated at $1087 (95%CI:$687-$1487) and lost productivity costs attributable to obesity were $279(95%CI:$191-$368). **CONCLUSIONS:** The economic burden of asthma among US adults is substantial which is only further amplified by the presence of obesity. This study highlights the importance of obesity control to reduce the cost of treating asthma patients and enhance productivity.

PRS50

THE DUTCH 1-YEAR RESOURCE USE RESULTS FROM THE EXPERIENCE STUDY, AN INTERNATIONAL REGISTRY OF REAL-WORLD OUTCOMES FOR ASTHMA PATIENTS TREATED WITH OMALIZUMAB

van Nooten F[1], Thompson C[2], Brown R[2], Groot M[3]
[1]*United BioSource Corporation, London, UK,* [2]*United BioSource Corporation, Bethesda, MD, USA,* [3]*Novartis Pharma B.V., Arnhem, The Netherlands*

OBJECTIVES: The objective is to describe the healthcare resource utilization and cost patterns associated with severe uncontrolled allergic asthma, based on data from Dutch patients collected in the EXPERIENCE study. **METHODS:** EXPERIENCE was a prospective, open-label, observational, multicenter, multicountry study in patients with severe persistent allergic asthma treated with omalizumab. The Global Evaluation of Treatment Effectiveness (GETE) was used to evaluate patient response. Healthcare resource use and number of exacerbations were captured for one year prior to the start of the study for all patients and continued for 104 weeks until end of the study. Hospitalizations, specialist visits and medications were included in this analysis for year before study and first year of study. Unit cost prices taken from 2010. **RESULTS:** A total of 154 subjects were included in ITT population. There were 2.5 clinically significant (CS) exacerbations/patient year prior compared to 0.90 CS exacerbations/patient for year of study on omalizumab. The total number of CS severe (CSS) exacerbation was 0.95 CCS exacerbations/patient for year prior and 0.26 CSS exacerbations/patient for year of study. The results indicate that patients in this study have an average cost of €4257/patient in the year prior to the study and €2583/patient cost during the study year, excluding omalizumab costs. The biggest cost drivers are hospitalization, work days lost and other asthma medications. The total omalizumab costs were €12,652/patient plus €1,171/patient for administration cost. **CONCLUSIONS:** This study reflects real life clinical practice and associated costs for omalizumab treatment of severe allergic asthma patients. It indicates a reduction in CS and CSS exacerbation rates of 64% and 73%, respectively associated with a 40% reduction in treatment costs when using omalizumab. Keeping in mind the study limitations associated with the observational setting, it provides estimated costs for patients with severe uncontrolled allergic asthma based on 'real-world' Dutch practice patterns.

Respiratory-Related Disorders – Patient-Reported Outcomes & Preference-Based Studies

PRS51

THE DEVELOPMENT OF THE EARLY MORNING SYMPTOMS OF COPD INSTRUMENT (EMSCI)

Palsgrove A[1], Houghton K[2], Hareendran A[3], Schaefer M[1], Setyawan J[4], Mocarski M[5], Carson R[5], Make B[6]
[1]*United BioSource Corporation, Bethesda, MD, USA,* [2]*RTI Health Solutions, Manchester, UK,* [3]*United BioSource Corporation, London, UK,* [4]*Shire Pharmaceuticals, Wayne, PA, USA,* [5]*Forest Research Institute, Jersey City, NJ, USA,* [6]*National Jewish Health, Denver, CO, USA*

OBJECTIVES: To develop a self-administered patient reported outcome (PRO) instrument to evaluate patients' experience of early morning symptoms of Chronic Obstructive Pulmonary Disease (COPD). **METHODS:** A literature review and interviews with six clinical experts were performed to identify concepts for the evaluation of early morning symptoms of COPD and to develop a focus group discussion guide. Four focus groups were conducted with a total of 27 COPD patients who experienced COPD symptoms at night or in the early morning. Qualitative data was analyzed using ATLAS.ti to identify key concepts and patient terminology which were then used to create a conceptual framework and to generate items and response options for the new PRO instrument. One-on-one cognitive debriefing interviews were conducted with 10 COPD patients to assess item readability, comprehensiveness, and content validity. **RESULTS:** Focus group participants had a mean age of 68.1 years, were 51.9% female, and had a range of COPD severity levels: 7.4% GOLD I (mild), 55.6% GOLD II (moderate), 14.8% GOLD III (severe), 22.2% GOLD IV (very severe). Most of the participants experienced COPD symptoms in the early morning (n=25, 92.6%). Patients noted symptoms such as cough and impacts such as restricted morning activities. Cognitive debriefing interviews demonstrated that the items were comprehensive, relevant and interpreted as intended. A few items were edited to improve clarity based on feedback from the patients. **CONCLUSIONS:** The Early Morning Symptoms of COPD Instrument (EMSCI) is a PRO instrument developed to evaluate the full range of early morning symptoms of COPD. The instrument was developed based on patients' experiences to support content validity. The EMSCI can be used to characterize COPD patients' experience of early morning symptoms for clinical decision making and for the evaluation of new treatments.

PRS52

INPATIENT HOSPITAL CARE OR HOSPITAL-AT-HOME FOR COPD EXACERBATIONS: A DISCRETE CHOICE EXPERIMENT

Goossens L, Rutten-Van Mölken M
Erasmus University, Rotterdam, The Netherlands

OBJECTIVES: Hospital-at-home programs for COPD exacerbations aim to provide care efficiently by shortening or avoiding hospital admissions. The objective was to quantify Dutch patient and informal caregiver preferences for different aspects of hospital-at-home. **METHODS:** In a discrete-choice experiment, respondents made 14 choices between regular hospital admission (7 days) and two programs in which 3 hospital days were followed by a 4-day treatment at home. The home treatment was described by a set of attributes (see results). Hospital treatment was constant across choice sets. Respondents were patients and their informal care givers who participated in an RCT on the cost-effectiveness of hospital-at-home versus regular hospital care. The data were analyzed in latent-class conditional logit models, which allowed for heterogeneity across groups. **RESULTS:** A total of 202 questionnaires were returned. 25% of patients and caregivers always opted for hospital treatment, 46% always chose hospital-at-home. For both groups, the best fit was provided by a model with four latent classes, depending on preference for hospital and caregiver burden. All attributes had the expected sign and a significant effect on choices, except for number of home visits. Attribute levels with the strongest impact were hospital preference (for patients, coefficients (depending on class): -5.62 to +3.3), a 5h/day caregiver burden (-3.5 to -0.11) and co-payment of €100 (1.11). Also influential were specialized training for the homecare nurse (0.52), visits by many different nurses (-0.43), high readmission risk (-0.41), GP instead of hospital as contact for emergencies (-0.63), €50 co-payment (-0.48), 3h/day caregiver burden (-0.32), medium readmission risk (-0.24). Results were similar for informal care givers. **CONCLUSIONS:** A considerable proportion of patients and caregivers have a fixed preference for either admission or hospital-at-home, regardless of the specifics of the program. When choosing between hospital-at home programs, co-payments and the burden on informal caregivers are the principal attributes.

PRS53

FURTHER DEVELOPMENTS OF THE ASTHMA LIFE IMPACT SCALE (ALIS)

Crawford SR[1], McKenna S[2], Twiss J[1], Tammaru M[3], Oprandi NC[4]
[1]*Galen Research Ltd, Manchester, UK,* [2]*Galen Research Ltd, Manchester, UK, UK,* [3]*University of Tartu, Tartu, Estonia,* [4]*University of Verona, Verona, Italy*

OBJECTIVES: The Asthma Life Impact Scale (ALIS) is a disease-specific measure used to assess the quality of life of people with Asthma. It was developed in parallel in the UK and US and has proven to be acceptable to patients, to have good psychometric properties and to be unidimensional. The objective of this study was to adapt and validate the ALIS for use in Italy and Russia. **METHODS:** The dual panel methodology was used to translate the ALIS for both cultures. Patient interviews were conducted to test the new language versions to ensure their face and content validity. A test-retest postal survey was conducted in both countries to assess the psychometric properties of the new adaptations. **RESULTS:** The translation process proved straightforward. Cognitive debriefing interviews conducted in Italy (n=15) and Russia (n=9) indicated that patients found the new versions of the ALIS easy to complete and relevant. Validation data were available from postal surveys in Italy (n=61) and Russia (n=71). Both new versions of the ALIS had good internal consistency (0.92) and high test-retest correlation coefficients (Italian = 0.86; Russian = 0.94) indicating good reproducibility. The Russian ALIS showed strong correlations with a measure of fatigue (CAFS; 0.87) and sleep (CASIS; 0.85). The Italian ALIS had a moderate correlation with the Nottingham Health Profile Energy level scale (0.63). Both adaptations of the ALIS were able to distinguish between patients based on their self-rated general health and asthma severity. **CONCLUSIONS:** The ALIS was successfully adapted for use in Italy and Russia. The psychometric properties of these new adaptations matched those of the original UK and US versions. The new instruments represent valid and reliable tools for measuring QoL in international clinical trials and for use in routine clinical practice.

PRS54

TESTING OF A CONCEPTUAL MODEL OF ASTHMA IN ADOLESCENTS

Bright N[1], Maguire L[1], Arbuckle R[1], Tabberer M[2], Dale P[2]
[1]*Mapi Values, Bollington, Cheshire, UK,* [2]*GlaxoSmithKline, Uxbridge, Middlesex, UK*

OBJECTIVES: Conceptual Models (CM) are useful for characterising domains of Symptoms, Functioning and Treatment Satisfaction. Previously a Conceptual Model (CM) of asthma was developed and relevance to patients confirmed through qualitative interviews with 15 asthmatic adults. The aim of this research was to test the model in adolescents. **METHODS:** Twenty semi-structured interviews were conducted with asthmatic adolescents (aged 12-16) in the US. Cards were used to elicit feedback from the patients on their understanding and experience of different concepts included in the CM (symptoms and functioning/disability). Patients used the cards to rank the importance of symptoms and impacts. Treatment satisfaction was also discussed and the Asthma Control Test (ACT) completed. **RESULTS:** Based on the ACT 40% (8/20) of adolescents had poorly controlled asthma compared with 13% (2/15) of adults in the previous study. Most adolescents reported experiencing all four core symptoms of asthma; breathlessness (n=20), tight chest (n=19), cough (n=18) and wheeze (n=20). Additional symptoms reported by the adolescents were light-headedness (n=7), shaking (n=6), congestion (n=5), feeling as if about to pass out (n=2), vomiting (n=2) and an uncomfortable feeling in the ribcage (n=2). Breathlessness was the most important and bothersome symptom for both adolescents and adults. The functioning/disability concepts relevant to adolescents were the same as for adults. 'Spending time with friends/family' was the impact ranked as most important by adolescents (n=5). Understanding of terms and definitions was good for all core symptoms and impacts. The term 'rescue inhaler' was not familiar to a minority (3/12, 25%) of younger adolescents. **CONCLUSIONS:** Qualitative analysis of the interviews found evidence supporting all concepts in the CM. New symptoms reported by adolescents were distal symptoms experienced due to poorly controlled asthma or rescue medication overuse. No changes to the CM for asthma are needed for adolescents.

PRS55

FURTHER DEVELOPMENTS OF THE LIVING WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (LCOPD)

Crawford SR[1], McKenna S[2], Twiss J[1], Oprandi NC[3], Tammaru M[4]
[1]*Galen Research Ltd, Manchester, UK,* [2]*Galen Research Ltd, Manchester, UK, UK,* [3]*University of Verona, Verona, Italy,* [4]*University of Tartu, Tartu, Estonia*

OBJECTIVES: The Living with Chronic Obstructive Pulmonary Disease (LCOPD) scale is a disease-specific measure used to assess quality of life of people with COPD. The measure was developed in parallel in the UK and US and was shown to be highly acceptable to patients, unidimensional and have very good psychometric properties. The objective of this study was to adapt and validate the LCOPD for use in Italy, Spain and Russia. **METHODS:** Translated versions were produced using dual panel methodology. The translated versions were tested with patients to ensure face and content validity. Test-retest postal surveys were conducted to establish internal consistency, reproducibility and construct validity. **RESULTS:** The translation process proved successful for the new language versions. Cognitive debriefing interviews conducted in Italy (n=15), Spain (n=14) and Russia (n=8) indicated that patients found the new versions of the LCOPD acceptable and easy to comprehend. Validation data was generated from postal surveys in Italy (n=51), Spain (n=142) and Russia (n=69). All three versions showed good internal consistency ranging from 0.94-0.95, and good reproducibility was evident from the high test-retest correlation scores (Italian=0.96, Russian=0.94, Spanish=0.85). The Russian LCOPD had strong correlations with a measure of fatigue (CAFS; 0.87) and sleep (CASIS; 0.76). The Spanish LCOPD had a moderate correlation with the CAFS (0.66) and a strong correlation with the CASIS (0.75). The Italian LCOPD had strong correlations with three of the sub-scales of the Nottingham Health Profile (0.83) and with the NHP-D (0.86). The new adaptations of the LCOPD were all able to distinguish between patients based on their self-rated general health and COPD severity. **CONCLUSIONS:** The LCOPD was successfully adapted for use in Italy, Spain and Russia. These results were similar to those found for the original UK and US versions.

PRS56

ASSESSING PATIENT REPORT OF FUNCTION: CONTENT VALIDITY OF THE FUNCTIONAL PERFORMANCE INVENTORY-SHORT FORM (FPI-SF) IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Leidy N[1], McCormack J[1], Hamilton A[2], Becker K[3]
[1]*United BioSource Corporation, Bethesda, MD, USA,* [2]*Boehringer Ingelheim (Canada) Ltd., Burlington, ON, Canada,* [3]*Boehringer Ingelheim GmbH, Ingelheim/Rhein, Germany*

OBJECTIVES: The performance of daily activities is a major challenge for people with chronic obstructive pulmonary disease (COPD). The 65-item Functional Performance Inventory (FPI) was developed to quantify these difficulties in naturalistic studies and clinical trials. The instrument was based on an analytical framework of functional status and qualitative interviews; it was reduced to a 32-item short form (FPI-SF) through a systematic process of item reduction and testing and re-formatted for greater clarity and ease of use. This study assessed the content validity of the FPI-SF. **METHODS:** Qualitative cognitive interviews were performed with men and women with COPD recruited through pulmonary clinics in the United States. Interviews were conducted in-person by a trained interviewer using a semi-structured interview guide and continued to saturation. Qualitative data analyses included the following: 1) comprehensiveness; 2) clarity of instructions, items, and response options; 3) respondent interpretation of the instructions, items, and re-

sponse options; 4) ease of completing the questionnaire; 5) relevancy of the items; 6) formatting (e.g., design and placement of instructions, font, placement of items on page); and 7) identification of new concepts (e.g., functional areas or activities that patients consider relevant and not represented by existing items). **RESULTS:** Twenty COPD patients were interviewed: 12 (60%) males; mean age = 63.0 ± 11.3 years; 14 (70%) Caucasian; 12 (60%) retired; mean FEV_1 = 1.5 ± 0.5 liter; FEV_1% predicted = 48.4 ± 13.1. Content of the FPI-SF was seen as comprehensive and represented activities participants found important and often difficult to perform. Participants understood the instructions, items, and response options as intended. No new concepts were identified. Two minor formatting changes were suggested to improve clarity. **CONCLUSIONS:** These results, together with its development history and previously tested quantitative properties, suggest the FPI-SF is content valid for use in clinical studies of COPD.

PRS57

PATIENT REPORTED BURDEN OF ASTHMA BRONCHIALE IN THE SLOVAK REPUBLIC

Tomek D[1], Bielik J[2], Visnansky M[3], Helbich M[4], Hroncova D[5]
[1]*Pharmaceutical Faculty at Comenius University, Bratislava, Slovak Republic,* [2]*Trencin University, Trencin, Slovak Republic,* [3]*Slovak Society for Pharmacoeconomics, Bratislava, Slovak Republic,* [4]*Caldera ltd., Banská Štiavnica, Slovak Republic,* [5]*Mediforum, Non-commercial Educational Center of GSK, Bratislava, Slovak Republic*

OBJECTIVES: Over the past few decades the treatment of asthma bronchiale has experienced huge progress. Hospitalizations and emergency visits almost disappeared and majority of patients with severe asthma are active in work and leisure activities. However asthma still presents significant burden on patient's daily living. Objective of the study was to explore the burden of asthma on everyday life from the patient's perspective. **METHODS:** From May till September 2010, 506 patients were enrolled in a prospective 6 months study in the Slovak Republic with moderate and severe persistent asthma. A total of 461 patients returned valid diaries recording everyday asthma related symptoms and use of treatment over period of 3 months. Clinical and treatment data have been recorded by the physician for the period of 6 months. **RESULTS:** The mean age of patients is 50 yrs with disease duration of 12 years. Majority of patients are women (71%) and with moderate asthma (88%). Most patients are active at work or study (85%) with 11% disabled and only 4% unemployed. 31% patients have ever experienced a negative impact of asthma on their employment opportunities. The impact of asthma on everyday life is still large. According to patient diaries the patients suffer from asthma symptoms (% of days with symptom of all severities/severe symptoms): any of the monitored symptoms (67/19), dyspnoe (46/8), cough (49/10), wheezing (32/6), limitation of daily activities (37/8), sleep disturbance (30/9), limitation of work activities (25/2.5). The need for medical services such as unscheduled visits (0.53/person year) or hospitalizations (0.036/person year) is less frequent. **CONCLUSIONS:** The data demonstrate that asthma is still present in most of patient days including the presence of symptoms and impact on personal and work life of patients. Patient insight is very valuable and should be incorporated more within the routine treatment in order to get asthma under better control.

PRS58

TREATMENT OUTCOMES OF NEW SMEAR POSITIVE PULMONARY TUBERCULOSIS PATIENTS IN NORTH EAST LIBYA

Solliman MM[1], Hassali MA[2], Shafie AA[3], Atif M[4], Saleem F[5], Al-Haddad MS[6], Hadidan M[7]
[1]*Universiti Sains Malaysia, P.Penang, Malaysia,* [2]*Universiti Sains Malaysia, Minden, Penang, Malaysia,* [3]*Universiti Sains Malaysia (USM), Penang, Penang, Malaysia,* [4]*Universiti Sains Malaysia (USM), Pinang, Malaysia,* [5]*Universiti Sains Malaysia (USM), Pinang, Penang, Malaysia,* [6]*Universiti Sains Malaysia, Gelugor, P.Penang, Malaysia,* [7]*Alfatih Medical Sciences University, Tripoli, Tripoli, Libya*

OBJECTIVES: This study was designed to evaluate treatment outcome of pulmonary tuberculosis patients by using WHO/IUATLD classification and investigate factors associated with unsuccessful outcome. **METHODS:** The study was designed as a retrospective evaluation of patients with smear confirmed pulmonary tuberculosis visiting two specialized hospitals in North East Libya. All patients who registered during 2008-2009 were enrolled. Standardized protocol was used to collect the required data. Descriptive analysis was computed for demographic and clinical characteristics. Chi-square test with significance level of 0.05 was used to determine association between variables. Data was analyzed by Statistical Package for the Social Sciences version 16.02. **RESULTS:** Three hundred and twenty seven patients were notified during the study period. Using the WHO/IUATLD criteria, cure and treatment completion rate was 1.2% and 57.5%, respectively. Treatment failure occurred in 7(2.1%) cases. Ninety (27.5%) patients defaulted treatment, 11 (3.4%) died and 26 (8%) transferred out. Nationality, sex, educational level, area of residence and smoking were associated with unsuccessful treatment outcome. **CONCLUSIONS:** Improving clinical and laboratory infrastructure in peripheral areas, educating defaulters about benefits of completing therapy and stratifying foreigners as high risk groups could improve success rate. Measures should be taken to improve professional commitment and expertise of health care professionals.

PRS59

QUALITY OF LIFE IN SEVERE PERSISTENT UNCONTROLLED ASTHMA: PATIENTS AND CAREGIVERS IN THE SPANISH PEDIATRIC POPULATION: A PREX STUDY

Galera J[1], Lahoz R[1], Herráez L[1], Casafont J[1], Plaza A[2], Vennera M[3]
[1]*Novartis Farmacéutica, S.A., Barcelona, Spain,* [2]*Hospital Sant Joan de Déu, Esplugues de Llobregat, Spain,* [3]*Hospital Clínic de Barcelona, Barcelona, Spain*

OBJECTIVES: To assess the quality of life (QoL) in patients with severe persistent uncontrolled asthma and their caregivers, in the asthmatic Spanish pediatric population in specialist consultation. **METHODS:** An observational, cross-sectional, multicenter (pneumology and allergy) study was done. Inclusion criteria were: male and female patients, 6> years old ≤14, diagnosed with severe persistent asthma [controlled and uncontrolled (ratio 5:2), according to physician criteria], with data of clinical history and spirometry in the last 6 months. QoL in pediatric patients and caregivers using PAQLQ and PACQLQ questionnaires, respectively, and diagnostic concordance between physician criteria and GEMA, were determined. **RESULTS:** A total of 207 patients were included, 33.8% with severe persistent uncontrolled asthma and mean age ± SD of 10.4 ± 2.3 vs. 11.5 ± 2.1 years in patients controlled ($p = 0.0015$). Of all patients, 61.4% were male, BMI were 19.4 ± 3.8 kg/m2 and time from diagnosis was 5.5 ± 3.4 years. Uncontrolled patients had a higher number of exacerbations (7.4 ± 5.2 vs. 3.2 ± 2.8, $p < 0.0001$), emergency room visits number (2.4 ± 3.3 vs 1.0 ± 1.3, $p < 0.0001$), FVC and FEV1 percentage <80% (28.4% vs 18.5%, $p < 0.0270$ and 47.5% vs 28.6%, $p < 0.0069$, respectively). QoL in uncontrolled patients (114.2 ± 30.2 vs 137.8 ± 25.6) and their caregivers (64.2 ± 17.3 vs 74.7 ± 17.9) was worse compared to controlled patients ($p < 0.0001$, both). Concordance between physician versus GEMA asthma control evaluation was moderate, showing that 34.3% of patients with poor controlled asthma according to GEMA would be considered controlled according physician criteria (k: 0.4, 95% CI: 0.3-0.6). **CONCLUSIONS:** Uncontrolled asthma patients have worse QoL, affecting their caregivers. One third of physicians underestimate patients with uncontrolled asthma.

PRS60

THE IMPACT OF SEVERE POOR-CONTROLLED ASTHMA ON PATIENTS' QUALITY OF LIFE CONTROL STUDY

Galera J[1], Lahoz R[1], Herráez L[1], Casafont J[1], Vennera M[2], Picado C[2]
[1]*Novartis Farmacéutica, S.A., Barcelona, Spain,* [2]*Hospital Clínic de Barcelona, Barcelona, Spain*

OBJECTIVES: Asthma symptoms can lead to physical and social activities limitations, deteriorating the quality of life (QoL) of patients. Given the high percentage of asthmatic uncontrolled patients, it is important to assess how the lack of control affects the QoL. **METHODS:** An observational, cross-sectional and multicenter study with severe persistent asthma patients according to GEMA, in specialist consultation (pneumology and allergy) was done. QoL was assessed using Mini-AQLQ questionnaire (domains: daily activity limitation, symptoms, emotions and environment) according to GEMA and physician criteria, and patients' perception. Anxiety and depression according to GEMA criteria and patient's perception, and hyperventilation were assessed using the Hospital Anxiety and Depression scale and the Nijmegen questionnaire, respectively. **RESULTS:** A total of 343 patients were enrolled, being the mostly women (67.6%). Uncontrolled patients had worse QoL scores according to GEMA, physician criteria and patient perception [4.4 (1.3) versus 6.1 (1.0), 4.2 (1.2) versus 5.7 (1.2), 3.9 (1.1) versus 5.5 (1.2), respectively, $p<0.0001$ in all cases]. These patterns were also observed in the different dimensions of QoL assessed ($p<0.0001$ in all cases). The anxiety was associated with a poor control asthma according to the GEMA [7.7 (4.4) versus 4.9 (3.1), $p=0.0003$] and patient perception [8.4 (4.4) versus 6.1 (3.9), $p<0.0001$]. Depression also showed significant association with poor control according to GEMA and patient perception [4 (4.3) versus 2.3 (2.7) and 6.2 (4.1) versus 3.5 (3.9), respectively, $p<0.0001$ in both cases]. Similarly, the degree of hyperventilation was higher in uncontrolled patients according to GEMA and patients perception [19.2 (10.0) versus 9.6 (8.5) and 21.9 (9.3) versus 13.5 (9.5), respectively, $p<0.0001$ in both cases]. **CONCLUSIONS:** Uncontrolled asthma patients have worse quality of life, showing a greater degree of anxiety, depression and hyperventilation.

PRS61

AGE HAS NO SIGNIFICANT IMPACT ON HEALTH-RELATED QUALITY OF LIFE IN PATIENTS HOSPITALIZED FOR COPD EXACERBATIONS

Antoniu SA[1], Puiu A[2], Zaharia BG[3], Azoicai D[4]
[1]*University of Medicine and Pharmacy, Iasi, Romania,* [2]*Sf Spiridon University Hospital, Iasi, Romania,* [3]*Sf Ioan Emergency University Hospital, Iasi, Romania,* [4]*University of Medicine and Pharmacy , Iasi, Romania*

OBJECTIVES: To evaluate the impact of age on health related quality of life in patients hospitalized for COPD exacerbations, given the fact that little is known on this aspect. **METHODS:** Analysis of data from patients with COPD exacerbation admitted in an university hospital between March and November 2008. Elderly patients were defined as having an age of at least 65 years. Lung function, dyspnea level at hospital admission, and health-related quality of life (CCQ, WHO-Five Well -being Index-WHO-5) were among the variables analyzed comparatively in elderly (E) and younger (Y) patients respectively. **RESULTS:** Included in the analysis were 72 patients, 42 (58.3%) were ex smokers, and there were 45 E patients and 27 Y patients. Elderly patients had more severe dyspnea at admission, more impaired lung function during hospitalization, and required longer hospitalizations. E patients had a more impaired health-related quality of life at admission as compared to Y patients but this was not significantly altered (at admission WHO-5 score 19.28 E versus 22.81 Y, $p=0.49$; CCQ symptoms score 3.64 for E and 3.26 for Y, $p=0.23$; CCQ functional score 3.63 for E and 3.25 for Y, $p=0.27$, CCQ mental score 3.75 for E and 3.40 for Y, $p=0.4$, CCQ total score 3.66 for E and 3.30 for Y, $p=0.19$). Health-related quality of life at discharge was found to be slightly and non significantly impaired in E patients as compared to Y patients. **CONCLUSIONS:** This analysis demonstrated that elderly patients hospitalised for a COPD exacerbation had a more impaired health-related quality of life even if no statistically significant differences were detected.

PRS62

COMPARISON OF GENERIC AND DISEASE SPECIFIC QUALITY OF LIFE MEASURES IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Agh T, Inotai A, Meszaros A
Semmelweis University, Budapest, Hungary

OBJECTIVES: Chronic obstructive pulmonary disease (COPD) has a great impact on patient's health-related quality of life (HRQoL). The aims of this study were: 1) to assess the generic and disease specific HRQoL of COPD patients, and 2) to evaluate the influence of age and lung function on the patient's HRQoL. **METHODS:** In this observational, cross-sectional study the following information was obtained: age, lung function (post-bronchodilator forced expiratory volume in one second [FEV_1]) and HRQoL (generic: EuroQol five-dimension questionnaire [EQ-5D], disease specific: St. George's Respiratory Questionnaire [SGRQ]). Multiple linear regression model was applied to analyze the effect of age and FEV_1 on the HRQoL. **RESULTS:** Data collected from 170 patients (mean age 63.8 years, 41.8% male) were analyzed. The mean EQ-5D score was 0,55 (SD=0,21) and the mean SGRQ total score was 56,22% (SD=16,19). The multiple linear regression model was successfully applied to describe the effect of age and FEV_1 on the patient's HRQoL measured by either EQ-5D (R2=0,47) or SGRQ (R2=0,64). Both generic and disease-specific HRQoL were related with age and lung function ($p<0.005$). **CONCLUSIONS:** SGRQ and EQ-5D appear to be reliable and valid for the assessment of HRQoL in COPD patients and may be used as a non-invasive patient-centered monitoring system as a guide for the management of COPD. Due to the simplicity of EQ-5D, the use of this instrument can be recommended within routine clinical practice.

PRS63

FACILIATORS AND BARRIERS ASSOCIATED WITH THE USE OF PHARMACOLOGICAL – BEHAVIORAL COMBINATION THERAPY TO SMOKING CESSATION

Uttiyung R[1], Layton MR[2]
[1]*Chiang Mai Drug Dependent Treatment Center, Chiang Mai, Thailand,* [2]*Khon Kaen University, Khon Kaen, Khon Kaen, Thailand*

OBJECTIVES: We aimed to explore patients' perceived positive and negative factors associated with the use of pharmacological-behavioral combination therapy to smoking cessation. **METHODS:** Each patient who visited a drug dependent treatment center was assessed using structured clinical interviews and the Fagerström Test for Nicotine Dependence (FTND). In-depth interviews were conducted with patients who agreed to participate in the study. These patients were treated with behavioral therapy combined with bupropion or nicotine gum and followed up for three consecutive months. The interview responses were recorded, transcribed and organized thematically based on emerging codes using an inductive analysis. **RESULTS:** Seventeen key informants participated in this study and the mean age was 38.2 years. Their FTND score varied from 3.0-5.0 and the number of cigarettes smoked was 3-40 per day. Among these patients 11.8% were able to quit smoking within 1 month, 29.4% within 2 months, 29.4% within 3 months, and 29.4% could not quit smoking in any period of the study. Supportive factors to smoking cessation included supports from family and colleagues, poorer health, role model for acquaintances, household cost saving, practical advice from encouraging physicians, fear of social blame, smoking-free policy at workplace, and the patients' proactive strategies to avoid smoking temptation. Nevertheless, some barriers to smoking cessation were lacking in initiative and readiness to quit smoking; lacking of family support; incompliance to pharmacological-behavioral therapy; gaining weight; triggers such as nicotine withdrawal symptoms, stress, being in a party with smokers; using tobacco as a substitute of other substance; and inconvenient service time and facility at the treatment center. **CONCLUSIONS:** This study provides a framework of interrelated social factors associated with the use of pharmacological-behavioral combination therapy to smoking cessation. There is a need for developing tobacco dependence treatment programs and enabling factors tailored to meet the needs of patients.

PRS64

EXPLORING THE REASONS SMOKERS DROPPED OUT AFTER ENROLLING AT THE QUIT SMOKING CLINIC (QSC) IN MALAYSIA

Lee ML, Hassali MA, Shafie AA
Universiti Sains Malaysia, Penang, Malaysia

OBJECTIVES: Most studies assumed defaulters to be similar to smokers in smoking cessation programmes. Thus, the objective of this qualitative study was to explore perceptions held by QSC defaulters towards QSC service provision. This study also examined the smoking and smoking cessation beliefs among the defaulters. **METHODS:** Drawing from the patients' register at two different QSC settings; one being managed by a team of physicians, medical assistants and nurses while another is managed by the pharmacists, 14 current adult smokers were interviewed face-to-face, from May 2010 to March 2011. Interviews were audio-recorded and transcribed verbatim. The data were analyzed using thematic analysis to generate codes, categories and subsequently themes. **RESULTS:** This heterogeneous subgroup of smokers revealed shared ambivalence towards smoking and smoking cessation, indicating the underlying unreadiness to quit smoking and low self-efficacy. The dynamic interaction between components of the QSC such as the degree of relationship established between the health care providers and the efficacy and availability of smoking cessation aids (SCA) were being perceived as extrinsic motivational cues to enable these smokers to quit smoking. Overall these smokers described the barriers encountered mirrored the unmet expectation; comprising of the lack of expected skills and poor attitudes in the health care providers and the perceived unavailability and ineffective formal smoking cessation aids provided at the QSC. **CONCLUSIONS:** It is necessary to optimize the interplay of extrinsic motivational cues (health care provider and SCA's factors) in order to steer these smokers to quit smoking using the QSC approach. This study serves to underline the need to address a tailored stepped-care approach in these smokers in relation to gender, socio-economic status and nicotine dependence level, encompassing a wider stance in the tobacco control policy.

Respiratory-Related Disorders – Health Care Use & Policy Studies

PRS65

THE EFFECT OF OMALIZUMAB ON UNSCHEDULED HEALTHCARE RESOURCE UTILISATION AND HEALTH-RELATED QUALITY OF LIFE IN UK CLINICAL PRACTICE: THE APEX STUDY

Barnes N[1], Radwan A[2], Percival F[3]
[1]*Barts and The London NHS Trust, London, UK,* [2]*Novartis Pharmaceuticals UK Limited, Surrey, UK,* [3]*pH Associates, Marlow, UK*

OBJECTIVES: The efficacy and safety of omalizumab for the treatment of severe persistent allergic asthma have been demonstrated in randomised controlled clinical trials. However, there are limited 'real world' data on its effects on healthcare resource utilisation or health-related quality of life (QoL) in UK clinical practice. **METHODS:** A 10 centre retrospective observational study (APEX) compared 12 months pre- versus 12 months post-omalizumab initiation in patients aged ≥12 years with severe persistent allergic asthma. All patients received ≥1 dose of omalizumab. Hospital records were reviewed to obtain data on hospital resource use and routinely used QoL measures e.g. Asthma Quality of Life Questionnaire (AQLQ) at baseline (pre-omalizumab), 16 weeks and up to 12 months following omalizumab initiation. **RESULTS:** Mean Accident and Emergency department attendances fell by 70% from 1.52 per patient in the 12 months pre-omalizumab to 0.46 in the 12 months post-omalizumab ($p<0.001$). Similarly, mean in-patient hospital admissions fell by 61% from 1.30 to 0.51 ($p<0.001$) and mean in-patient bed days fell by 70% from 9.10 to 2.74 ($p<0.001$) per patient. In the subgroup of patients hospitalised for asthma in the 12-months pre-omalizumab (n=81), mean in-patient hospital admissions fell by 70% from 2.19 to 0.65 ($p<0.001$) and mean in-patient bed days fell by 74% from 14.86 to 3.83 ($p<0.001$) per patient. Other resource use, such as outpatient attendances (excluding visits made solely for omalizumab administration), nurse appointments and telephone consultations remained unchanged following omalizumab initiation. QoL data were not available for all patients at every time point. However, where data were available, mean AQLQ scores increased from 3.09 at baseline to 5.01 at 16 weeks (n=90) and to 5.22 at 12 months (n=29). **CONCLUSIONS:** Treatment with omalizumab is associated with a significant reduction in unplanned hospital resource utilisation and significant improvements in patients' QoL.

PRS66

DRUG USE REVIEW IN PATIENTS WITH BRONCHIAL ASTHMA - THE INTRODUCTION OF THE OPTIMIZATION PROGRAM OF THERAPY

Oskina E
Samara Medical University, Samara, Russia

OBJECTIVES: Drug use review for the treatment of asthma and assess the impact of the administrative program to optimize the use of drugs in the Samara region in 2008-2010. **METHODS:** In 2008 retrospective analysis of drug use in ambulatory practice based on a database of 90,196 paid prescriptions patients with bronchial asthma in the Samara region. An analysis of 155 history of 15 clinics. Data on the consumption of drugs were presented with the ATC/DDD methodology in the form of DDD/1000 inhabitants day. After the analysis has developed a program that includes training, administrative controls over the discharge of drugs, medications, and form a formal application form. In 2009, the evaluation of the implementation of the optimization program by re-examining the consumption of drugs (105 318 prescriptions paid for) and analysis of hospital records (143 history) **RESULTS:** Use of basic products in 2008 amounted to 380, including inhaled corticosteroids (ICS) was 286, medications to relieve symptoms - 485 DDD 1000 inhabitants/day. In 2009, use of basic drugs increased by 1.6 times to 621, the consumption of inhaled corticosteroids has increased by 1.7 times to 502 DDD per 1000 inhabitants/day, ($p<0.001$). In 2009 compared to 2008 the number of patients with nocturnal symptoms dropped from 52% to 37%; of hospitalization from 47% to 25%; ambulance call from 40% to 23%, respectively ($p<0.001$). **CONCLUSIONS:** The introduction of a rational program for the use of drugs with the use of administrative controls in 2009 allowed the drug to optimize the consumption of patients with asthma to improve asthma control in clinical practice and to reduce the costs of the use of medical resources.

PRS67

CONSUMPTION PATTERNS AND IN VITRO RESISTANCE OF S. PNEUMONIAE TO FLUOROQUINOLONES

Simoens S[1], Verhaegen J[2], Van Bleyenbergh P[2], Peetermans W[2], Decramer M[2]
[1]*K.U. Leuven, Leuven, Belgium,* [2]*University Hospitals Leuven, Leuven, Belgium*

OBJECTIVES: This study analyses consumption patterns of fluoroquinolones and documents *in vitro* resistance of *S. pneumoniae* to fluoroquinolones in ambulatory care in Belgium. **METHODS:** Data on fluoroquinolone consumption were derived from IMS Health. Volume of consumption was expressed in terms of the number of defined daily doses per 1,000 inhabitants per day (DID). Consumption was valued at public prices pertaining to the year or month of consumption. Respiratory blood isolates were taken from adults to test *in vitro* susceptibility of *S. pneumoniae* to levofloxacin and moxifloxacin. The *S. pneumoniae* strains were isolated in 15 clinical laboratories throughout Belgium. A hundred blood isolates per year were at random selected from 2004 to 2009. Susceptibility and resistance of *S. pneumoniae* was expressed using the Clinical and Laboratory Standards Institute breakpoints. **RESULTS:** Fluoroquinolone consumption increased from 24.1 million € in 1993 to a maximum of 44.4 million € in 2002, and then decreased to 35.0 million € in 2009. The volume of fluoroquinolone consumption has fallen consistently from 3.00 DIDs in 2003 to 2.66 DIDs in 2009. Fluoroquinolones were primarily used to treat urinary tract infections (36% of consumption, volume of 0.95 DIDs) and lower respiratory tract infections (26% of consumption, volume of 0.70 DIDs). The minimum inhibi-

tory concentration (MIC) distribution of moxifloxacin and levofloxacin in *S. pneumoniae* isolates remained stable during 2004-2009 and resistance to moxifloxacin and levofloxacin was low (≤1%). Moxifloxacin was the most potent fluoroquinolone available for treatment of *S. pneumoniae* infections in Belgium with MIC90 of 0.19 mg/L. **CONCLUSIONS:** The volume of fluoroquinolone use remains well controlled and fluoroquinolones were primarily used in those indications where they have been shown to yield clinical benefit. The use of fluoroquinolones has not led, to date, to an increase in the rate of pneumococcal resistance to fluoroquinolones.

PRS68

A SYSTEMATIC REVIEW OF CHRONIC RHINOSINUSITIS IN ASIA-PACFIC AND THE ROLE OF BALLOON SINUPLASTY

McElroy HJ[1], Belarbi S[2], Foteff C[1], Metz L[2], Chung L[3], Levine HL[4], O'Leary BA[1]
[1]*Covance Pty Ltd, North Ryde, NSW, Australia,* [2]*Johnson and Johnson Medical Asia-Pacific, Singapore,* [3]*Covance (Asia) Pte Ltd, Singapore,* [4]*Acclarent, Menlo Park, CA, USA*

OBJECTIVES: Chronic rhinosinusitis (CRS) is a debilitating chronic condition with substantial burden of illness. The purpose of this study was to obtain information to inform a budget impact model for balloon sinuplasty (BSP) in CRS in Asia Pacific (Australia, China, India, Japan, South Korea). **METHODS:** Three systematic reviews of the literature were undertaken (October 2010 – February 2011) using Medline, Embase and Cochrane to identify prevalence of CRS in the region, clinical evidence for BSP and economic evidence for CRS. Manual searching, including HTA databases and interviews with clinicians in each country, supplemented the review. **RESULTS:** A total of 171 epidemiological, 50 clinical and 95 economic articles were identified. After title/abstract and full text review, 14 epidemiological, 14 clinical and 6 economic articles remained. However, population-based prevalence of CRS was only reported for Japan (0.05%) and Korea (1% to 7%), with the remainder of the articles discussing risk factors or subcategories of the disease. Manual searching of key country specific journals, published articles and guidelines, the internet (including Mandarin search) and secondary data sources identified prevalence of CRS for Australia (9%) and India (8%), but not China. Two comparative (non-randomised) studies of BSP and nine case-series (n≥10 patients) were identified. BSP was reported to be favourable in terms of safety and efficacy with high ostia patency, shorter recovery time, improved symptoms and patient satisfaction. Economic studies confirmed the high economic burden of CRS. One economic study on BSP was identified which, from a USA payer perspective, demonstrated lower cost than conventional endoscopic sinus surgery predominantly due to the lower cost of revision surgery and associated shorter surgical time. **CONCLUSIONS:** Traditional data sources provide limited information on prevalence of CRS in Asia-Pacific. BSP appears to have value both clinically and economically, however further research is required to accurately quantify these benefits.

PRS69

SOCIOECONOMIC DETERMINANTS OF SMOKING STATUS IN GREECE

Athanasakis K, Zavras D, Pavi E, Kyriopoulos J
National School of Public Health, Athens, Greece

OBJECTIVES: To identify factors that affect smoking status in Greece. **METHODS:** A strictly-structured questionnaire-based telephone survey was conducted to a sample of 6559 individuals, >18 years, representative of the Greek population and stratified according to age, sex and place of residence. Participants were requested to answer to questions, regarding, among others, smoking status, family/marital status, self-reported quality-of-life, presence of a health problem, level of education, family income and type of occupancy. The survey took place from January to March 2011. A logistic regression analysis was conducted to identify the factors that influence smoking status (non-smokers vs. smokers, ex- vs. current smokers). **RESULTS:** Distinguishing between non-smokers vs. smokers, higher income (Odds Ratio: 1.08, 95% Confidence Interval: 1.03-1.13), absence of a health problem (OR: 1.31, 95%CI: 1.14-1.50) and living single (ORs: 1.46, 1.18 and 2.25 for singles, widows/widowers and divorcees, respectively) were associated with a greater risk of smoking. Female gender, enhanced quality-of-life status, and higher levels of education had a protective influence on the probability of smoking (ORs: 0.69, 0.79, 0.91). Comparing ex- and current smokers, the regression showed that the probability of quitting was associated with higher levels of education (OR: 0.91, 95%CI: 0.88-0.95), increasing age (OR: 0.97, 95%CI: 0.95-0.97) and enhanced quality-of-life (OR: 0.88, 95%CI: 0.80-0.98), whereas, women (OR: 1.81, 95%CI: 1.46-2.24), people without health-related problems (OR: 1.62, 95%CI: 1.32-1.99) and those with a higher income (OR: 1.05, 95%CI: 1.01-1.13) had increased probability of being current smokers. Pensioners and students were more likely to have quitted smoking than other occupational groups. All reported values are statistically significant ($p<0.05$). **CONCLUSIONS:** Socioeconomic factors significantly influence smoking status and the decision to quit. In Greece, as in other countries with a high prevalence of smoking, evidence like the aforementioned can serve as important inputs in the health policy decision-making process.

PRS70

REAL WORLD EVALUATION OF DIFFERENT SMOKING CESSATION SERVICE MODELS IN ENGLAND

Mardle T[1], Merrett S[2], Wright J[3], Percival F[4], Lockhart I[5], Marshall S[4]
[1]*South Essex Stop Smoking Service, Rayleigh, Essex, UK,* [2]*Bournemouth and Poole Teaching PCT, Poole, Dorset, UK,* [3]*Warwickshire PCT, Warwick, Warwickshire, UK,* [4]*pH Associates, Marlow, Buckinghamshire, UK,* [5]*Pfizer UK, Tadworth, Surrey, UK*

OBJECTIVES: NHS Stop Smoking Services provide various options for support and counselling. Most services have evolved to suit local needs without any retrospective evaluation of their efficiency. Objective was to describe the structure and outcomes associated with different services. **METHODS:** Local service evaluations were done in three primary Care Trusts (PCTs) by conducting standardised interviews with key personnel in addition to extraction and analysis of data from 400 clients accessing the service after 1st April 2008 in each PCT. **RESULTS:** The PCTs varied in geography, population size and quit rate (47%-63%). Services were delivered by PCT-led specialist teams (PCT1), community-based health care providers (PCT3) and a combination of the two (PCT2) with varying resources and interventions in each. Group support resulted in the highest quit rates (64.3% for closed groups v 42.6% for one-to-one support (PCT1)). Quit rates were higher for PCT (75%) versus GP (60%) and pharmacist-delivered care (40%) where all existed in the same model (PCT2). The most-prescribed therapy was NRT (56%-65%), followed by varenicline (25%-34%), counselling alone (6%-8%) and bupropion (2%-4%). Quit rates for NRT at 4 weeks were 43%-55% across the 3 PCTs; 60% -81% for varenicline and 38%-91% for bupropion. **CONCLUSIONS:** The results suggest that service structure, method of support, healthcare professional involved and pharmacotherapy all play a role in a successful quit. Services must be tailored to support individual needs with patient choice and access to varied services being key factors.

PRS71

EVALUATION OF THE GETQUIT CLINICS FOR SMOKING CESSATION

Pokras SM[1], Ferrufino CP[1], Galaznik A[2], Zou K[2], Chapman R[1]
[1]*IMS Consulting Group, Alexandria, VA, USA,* [2]*Pfizer Global Pharmaceuticals, New York, NY, USA*

OBJECTIVES: GETQUIT clinics (GQCs) are free, US-based, 1-hour workshops sponsored by Pfizer, and designed to support smokers planning to quit. The clinics are hosted by physicians and tobacco-treatment specialists. We evaluated the impact of the GQCs on attendees' knowledge around developing a quit plan, readiness to change, and intent-to-act regarding smoking cessation. **METHODS:** Subjects pre-enrolled at GQCs between March-November 2010 were invited to a pre-clinic telephone interview and, within 7 days of attendance, to a post-clinic telephone interview. A survey was administered at both interviews to compare changes in responses. Incentives were offered to subjects completing both interviews. Change in subject knowledge was assessed by comparing pre- vs. post-clinic level of agreement with seven statements on developing a quit plan. Readiness-to-change was based on the proportion of subjects progressing ≥1 stage on the Transtheoretical Model Stages of Change-Short Form. Intent to act was assessed post-clinic only. Subject demographics, smoking history and nicotine dependence were also obtained. **RESULTS:** Of 3147 persons contacted, 369 completed both interviews. Mean age was 51.4y, 69% were female. All knowledge endpoints showed significant improvement post-clinic ($p<0.0001$ for all). Although there was no significant improvement in readiness-to-change overall, there were larger improvements among those in earlier stages of change pre-clinic (Contemplators 25% improvement vs. Preparation 5%). Post-clinic, 38% of attendees had contacted their doctor about quitting smoking and 44% of the remainder intended to do so within the next 2 weeks. Approximately 90% agreed or strongly agreed that they viewed their health care provider as a partner in managing their overall health since attending the GETQUIT clinic. **CONCLUSIONS:** Effecting successful behavior change requires sustained effort and multiple techniques. The GQCs, although brief, significantly improved attendees' knowledge on how to quit successfully. Additionally, more than a third of attendees reported engaging with their doctors about quitting after attending.

PRS72

HOW MUCH WOULD THE UNIVERSAL UPTAKE OF GOLD RECOMMENDATIONS FOR ITALIAN COPD PATIENTS COST?

Zaniolo O[1], Bettoncelli G[2], Bosio G[3], Mantovani LG[4], Pistelli R[5], Vaghi A[6], Villa M[7], Iannazzo S[1], Bamfi F[8], Pitrelli A[8], Frizzo V[8], Dal Negro R[9]
[1]*AdRes HE&OR, Turin, Italy,* [2]*SIMG, Ospitaletto, Italy,* [3]*A.O. Istituti Ospedalieri di Cremona, Cremona, Italy,* [4]*Federico II University of Naples, Naples, Italy,* [5]*Università Cattolica Sacro Cuore, Rome, Italy,* [6]*A.O. Salvini, Garbagnate Milanese (Mi), Italy,* [7]*ASL Provincia di Cremona, Cremona, Italy,* [8]*GlaxoSmithKline, Verona, Italy,* [9]*ASL 22 Ospedale Orlandi, Bussolengo (VE), Italy*

OBJECTIVES: To estimate the economic consequences of an ameliorated adherence to GOLD guidelines recommendations for Chronic Obstructive Pulmonary Disease (COPD) management in the Italian clinical practice. **METHODS:** A Markov model compares the current approach for COPD treatment (CURRENT strategy) with a strategy of care (GOLD GL strategy) mainly consisting of universal spirometry-based staging, alignment of the pharmacological therapy to guideline recommendations implemented by expert opinion. Drug consumption of the CURRENT strategy is based on data of 3113 patients collected by three Local Health Units. The consumption of other health resources, i.e. medical visits and inpatient care, is estimated from a multicentre observational Italian study, from which also their variation as a consequence of the improved adherence to GOLD is derived. Costs are calculated from the National Health Service perspective, based on published analyses and current prices and tariffs. **RESULTS:** The adoption of the GOLD GL strategy for the treatment of the over 1250,000 prevalent Italian COPD patients results in a cost increase of 19 million Euros for the restaging and of 100 million Euros for the redefinition of the clinical management strategy, compared to the CURRENT strategy. Furthermore, the adaptation of the pharmacological therapy to GOLD recommendations, (essentially a higher usage of long-acting beta agonist/corticosteroid combinations), increases costs by more than 320 million Euros. On the other side, the consumption of other health care resources is reduced by 44%, an estimated cost saving of more than 850 million Euros. The net cost saving associated with the improved GOLD guideline adoption results in 410 million Euros. **CONCLUSIONS:** The model estimates that the adoption of GOLD guidelines in the Italian clinical practice is associated to an increase of expenses for pharmaceuti-

cals and diagnostic (or staging) tests, more than offset by cost savings related to lower consumption of other health care resources.

PRS73

SYSTEMATIC REVIEW OF THE GUIDELINES ON THE PREVENTION OF ALLERGIC MANIFESTATIONS IN CHILDREN

Iskedjian M[1], Berbari J[2], Navarro V[1], Heil-Ruess M[3], Detzel P[4], Spieldenner J[4]
[1]PharmIdeas Europe SAS, Lyon, France, [2]PharmIdeas Research and Consulting, Ottawa, ON, Canada, [3]MHR - Nutrition Marketing Services, Lausanne, Switzerland, [4]Nestlé Nutrition Institute, Vevey, Switzerland

OBJECTIVES: A systematic review of the literature was performed to gather all official recommendations on the prevention in infants of allergic manifestations (AM), and, more specifically, atopic dermatitis (AD), by using hydrolyzed infant formulas (HF) such as partially or extensively hydrolyzed formula (PHF; EHF). **METHODS:** OVID MEDLINE® and the grey literature were searched by two reviewers using the keywords AM, AD, prevention and guidelines. A third person acted as adjudicator in case of disagreement. Of interest were recommendations pertaining to the prevention of AM issued by national or regional associations of medical professionals. **RESULTS:** This review yielded 11 sets of guidelines published for Australia, France, Germany, Spain, Switzerland (all n=1), Europe and the US (both n=3) between 1999 and 2010. Most guidelines included AD either specifically (n=3) or in the broad context of AMs. Six guidelines (of which 2 recommended PHF over EHF) endorsed the use of HFs for the prevention of AM in "at risk" infants when exclusive breastfeeding was not or no longer possible. Two other publications did not explicitly recommend HFs, but rather formulas with a documented reduced allergenicity. The need for an appropriate level of nutritional support was stressed in one publication. Five guidelines acknowledged that not all HFs have the same protective benefit. . Four publications underlined the importance of sound clinical evidence when determining the preventive efficacy of HFs. None of the guidelines based their recommendations on recent evidence from meta-analyses focusing on a specific brand of PHF NAN-HA®. **CONCLUSIONS:** HFs and specifically PHFs are endorsed for the prevention of AMs. The need for a strong validity and universality of the clinical evidence and methodology is acknowledged by national or regional medical associations. Hence, recent evidence regarding the preventive efficacy of a specific brand of PHF, NAN-HA®, should provide the basis for new recommendations.

Respiratory-Related Disorders – Research On Methods

PRS74

MEASUREMENT OF A POSSIBLE PATCH TESTING OUTCOME INDICATOR

Gallo R, Signori A, Cinotti E, Parodi A
University of Genoa, Genoa, Italy

OBJECTIVES: Patch testing is a well-established method to determine whether contact sensitization to certain agents has occurred and it can directly influence the clinical outcome of patients with allergic contact dermatitis (ACD) where detection of causative allergens is crucial for appropriate prevention and treatment. Its positive predictive value, however, is influenced by many variables. In particular, not all patients referred for patch testing actually have ACD and not all positive reactions are clinically relevant. The objective of our study was to develop an outcome indicator of patch testing. **METHODS:** We identified and measured as a possible indicator the ratio of patients with allergic and/or photo-allergic contact dermatitis clinically cured/improved as a result of identification of relevant allergens. Patients with positive reactions considered relevant to their current dermatitis were interviewed by telephone 2 months after patch/photo-patch testing in order to assess their clinical outcome in relation to the recommended elimination of supposedly relevant allergens. We parallely evaluated the prevalence of referral diagnosis different from ACD in patients whose test results were negative/non-relevant. **RESULTS:** Over a 4-year period positive reactions were seen in 1397 out of 2857 tested patients. Relevance was considered current in 578 subjects, and 506 of them were interviewed. Remission/significant improvement following allergen(s) contact avoidance was reported by 431 patients, the outcome indicator (431/506) thus scoring 85.2%. Among the 75 patients who reported no improvement, 41 had not avoided contact with the offending substance(s), 17 had other persistent concomitant skin conditions, and 17 were unchanged despite elimination of the alleged relevant allergens. The likely diagnoses of patients whose test results were negative/non-relevant were: non-eczematous diseases (39% of total patients), endogenous eczema (22%), irritant contact dermatitis (10%), unknown (5%), possible ACD from unidentified haptens (4%). **CONCLUSIONS:** The ratio of relevantly patch-test-positive patients resolved/improved after allergen avoidance is a useful patch-testing outcome indicator.

PRS75

HEALTH TECHNOLOGY APPRAISAL OF NEW DRUGS: ARE WE GETTING IT RIGHT?

Gordon J[1], Karnon J[2]
[1]University of Adelaide, Adelaide, SA, Australia, [2]University of Adelaide, Adelaide, South Australia, Australia

OBJECTIVES: A particular challenge for economic evaluation of new pharmaceuticals is to address the potential for conflict between 1) the available evidence that informs decisions about reimbursement coverage, and 2) the reality of how products are used in clinical practice. The aim of this study is to explore the issue of divergence between actual and evaluated drug pathways and resultant consequences for the appropriateness of technology appraisals and reimbursement coverage decisions. **METHODS:** We develop a generic decision analytic model to illustrate the issue of divergence between actual and evaluated drug pathways arising from a new product changing the number of lines of therapy available to patients, rather than displacing existing therapies. Under this generic model, incremental costs and effects are potentially affected by response to therapy and the clinical decision to maintain or switch treatment. The potential effects on the estimated cost-effectiveness of new drugs from the misspecification of the drug pathway are illustrated using COPD as a case study disease area and prescription utilisation data from Australia. **RESULTS:** In the case of treatments for COPD, cost-effectiveness of new therapies is overestimated when displacement is assumed, but the real-world utilisation of new products involves additions to reimbursement schedules without displacement and when effect size decreases with therapy line. We define this as *pathway misspecification bias* and consider that it may arise in all disease areas and drug classes. We demonstrate that the size of the bias is positively related to the proportion of non-responders. **CONCLUSIONS:** We demonstrate that without provision to withdraw funding from existing lines of therapy, cost-effectiveness analysis to inform reimbursement decision-making should be expanded to include further routine modelling of the likely use of products in clinical practice. We demonstrate that providing for the withdrawal of funding for existing technologies may provide for more efficient funding decisions.

PRS76

SYSTEMATIC LITERATURE REVIEW OF CONCEPTUAL MODELS TO INFORM ECONOMIC MODELLING IN COPD

Gonzalez McQuire S[1], Tabberer M[2], Chambers M[1]
[1]GlaxoSmithKline, Uxbridge, UK, [2]GlaxoSmithKline, Uxbridge , UK

OBJECTIVES: To identify evidence gaps for future economic modelling of Chronic Obstructive Pulmonary Disease (COPD) by reviewing published Conceptual Models and studies reporting associations between end-points and disease outcomes. **METHODS:** A systematic literature search was undertaken to identify English language publications since 2000 in Medline and Embase describing Conceptual Models of COPD and studies reporting associations between end-points and disease outcomes. Studies were reviewed against inclusion/exclusion criteria and those including therapeutic interventions were excluded at screening. **RESULTS:** Forty-one published papers were identified: 7 conceptual models of COPD and 34 articles on associations between endpoints and disease outcomes. Of the 7 conceptual models, 6 described single aspects of COPD (cognitive function, dyspnoea, brain function, design of patient related interventions, activity and functional performance). Only 1 described a broader set of determinants of health status in COPD patients (physiological functioning, patient complaints, functional impairment and quality of life.) 2 review papers on cognitive function and functional performance and 1 reporting determinants of functional performance and dyspnoea based on patient/expert interviews were identified. 31 studies using regression analyses to estimate associations between relevant parameters in COPD, including symptoms (mainly dyspnoea), health status, exercise, lung function, exacerbations, quality of life, biomarkers, co-morbidities, mortality and healthcare utilization were found. No studies on the use of conceptual models for economic modelling in COPD were identified. None of the studies presented a comprehensive set of determinants of disease progression and outcomes. **CONCLUSIONS:** It is recommended that models used to support economic evaluations of health care interventions are based on conceptual models capturing all relevant aspects of the disease and outcomes of value. The available evidence does not provide a full spectrum of relationships between diagnosis, disease progression and outcomes needed for a comprehensive disease based economic model in COPD.

PRS77

APPLICATION OF INNOVATIVE METHODS TO IDENTIFY AND CHARACTERIZE DIFFERENTIAL RESPONDERS IN CLINICAL TRIALS OF COPD: THE USE OF MIXTURE MODELS

Stull DE[1], Houghton K[1], Gale R[2], Wiklund I[3], Capkun-Niggli G[4], Jones P[5]
[1]RTI Health Solutions, Manchester, UK, [2]Novartis, Horsham, UK, [3]United BioSource Corporation, London, UK, [4]Novartis Pharma AG, Basel, Switzerland, [5]St. George's, University of London, London, UK

OBJECTIVES: Applying innovative methods to clinical trial data to identify and characterize unobserved subgroups of differential responders. **METHODS:** Data from three COPD clinical trials was retrospectively analysed using Growth Mixture Models (GMMs): INHANCE (indacaterol 150μg and 300μg vs tiotropium 18μg and placebo); INLIGHT-2 (indacaterol 150μg vs salmeterol 50μg and placebo); and INVOLVE (indacaterol 300μg and 600μg vs formoterol 12μg and placebo). GMMs were conducted on SGRQ Symptoms Domain data at baseline, 12 weeks, and six months to identify unobserved subgroups. Baseline characteristics were compared between emergent subgroups of differential responders in *post hoc* analyses. **RESULTS:** Within INHANCE and INLIGHT-2, two subgroups of patients emerged per treatment arm: responders (improvement) and non-responders (little change/deterioration). Within INOLVE, three subgroups of patients emerged per treatment arm: responders, non-responders, and partial-responders. When responders were analysed separately, mean treatment effects in terms of SGRQ Symptom scores were generally larger than when all patients were included: INHANCE responder improvements ranged from 8 -12 units compared with 7-14 for all patients; INLIGHT-2 responder improvements were 3 -13 units versus 3 -8 for all patients; INVOLVE responder improvements were 5 -17 units vs 3 -11 for all patients. Within each trial, responders made up the largest proportion of the sample (55% - 82%) but non-/partial-responder groups were large enough and different enough to dampen treatment effects when group means were analyzed as a whole. Responders had significantly better baseline SGRQ Symptom scores than non-responders. Further significant differences were found between non-responders, partial-responders and responders in terms of smoking history, age, and breathlessness.

CONCLUSIONS: GMMs have the potential to increase understanding of treatment effects and identify patients more likely to benefit from treatment. The ability of baseline characteristics to predict responders/non-responders needs to be tested prospectively.

Sensory Systems Disorders – Clinical Outcomes Studies

PSS1

OCULAR DISCOMFORT, COMPLIANCE AND INTRA-OCULAR PRESSURE (IOP) CONTROL IN PATIENTS TREATED FOR GLAUCOMA

Lafuma A[1], Robert J[2], Berdeaux G[3]
[1]*CEMKA-EVAL, Bourg la Reine, France,* [2]*Cemka Eval, Bourg la Reine, France,* [3]*Alcon France, Rueil-Malmaison, France*

OBJECTIVES: To investigate the associations between ocular discomfort, compliance and efficacy of IOP lowering drugs. **METHODS:** This was a prospective observational survey. Centres were selected at random from the CEGEDIM list. Consecutive patients treated with an IOP lowering fixed combination drug (prostaglandin analogues excluded) were included. IOP was collected at two visits (delay fixed by the investigator). Self-reported compliance measured by validated questionnaires (EDSQ, TSQM and TEO) and self-reported ocular discomfort (13 items with a focus at instillation and during the day) based on a questionnaire developed according to international patient reported outcome recommendations were collected at the last visit. Patients were classified into 3 groups of compliance (good, minor and major issues) using the TEO published algorithm. Comparisons between compliance groups were made by ANOVA and chi-square tests. Adjustments were made for confounding variable unbalances. **RESULTS:** 410 patients (66 years old, 237 females, 101 ocular hypertensions) were included. 32.9% reported good compliance, 55.9% minor and 11.2% major compliance issues. Patients reporting either red eyes (P=0.02), stinging (P=0.007), feeling of sand in the eyes (P=0.0009), dry eye (P=0.02), or blurry vision (P=0.002) were more likely to report compliance issues. Patients in the good compliance group reported 3.2 ocular discomfort concerns, 4.5 in the minor and 5.2 in the major compliance issue group (P=0.0002). The probabilities to report no concern were 24.2%, 12.7% and 11.9% (P=0.02), respectively. An association between IOP control and compliance was reported in the group of patients that did not have a change in treatment at the first visit: patients in the good compliance group had an IOP decrease of 0.9 mmHg, 0.3 mmHg in the minor and a 0.2 mmHg increase in the major compliance issue group. **CONCLUSIONS:** Ocular discomfort issues reported by patients might impact compliance leading to poor IOP control.

PSS2

PREVALENCE, DEMOGRAPHICS AND TREATMENT CHARACTERISTICS OF VISUAL IMPAIRMENT DUE TO DIABETIC MACULAR EDEMA IN A REPRESENTATIVE CANADIAN COHORT

Petrella RJ[1], Blouin J[2], Davies B[2], Barbeau M[2]
[1]*Lawson Health Research Institute, indivisual health outcomes inc, London, ON, Canada,* [2]*Novartis Pharmaceuticals Canada Inc, Dorval, QC, Canada*

OBJECTIVES: To determine the prevalence, demographics and treatment characteristics of patients with visual impairment (VI) due to diabetic macular edema (DME) in a real-world Canadian setting. **METHODS:** Records from a longitudinal population-based database of more than 170,000 patients in 53 family practice clinics in southwestern Ontario, Canada were analyzed between January 1, 2008 to December 31, 2009. Patient records were limited to those aged 18 years of age and older. These records contained chart-abstracted information such as visit diagnosis, medications and consultation notes. Initial extractions of control, diabetic and DME patients with VI, defined as best corrected visual acuity ≤20/40 in the DME eye, were accomplished utilizing International Classification of Disease codes (ICD9/ICD10); reviewing patient charts for text entries of symptoms that supported a diagnosis of diabetes and DME and concomitant comorbidity; and reviewing patient treatment records unique to DME with VI including consultation notes and hospital discharge summaries. Demographic characteristics, comorbidities, and treatment were reported. **RESULTS:** 8368 patients with type 1 or 2 diabetes and a control cohort of 76,077 patients were extracted for this analysis. Among diabetic patients, prevalence of DME was 15.7%. Average duration of diabetes among patients with DME was 19 years. More patients with DME had hypertension (66%), or vascular disease (28%) than the control cohort ($p<0.05$). The prevalence of VI due to DME was 2.56%. Mean age was 64±17. In patients with VI due to DME, 53% had focal and 47% had diffuse edema. For both focal and diffuse edema, the most common treatment was laser monotherapy, used in 62% and 53% of cases, respectively. **CONCLUSIONS:** : In a real-world setting, among patients with diabetes, we observed the prevalence of VI due to DME at 2.56% . Laser monotherapy was the most common treatment.

PSS3

INCIDENCE AND CHARACTERISTICS OF PATIENTS WITH MACULAR EDEMA SECONDARY TO RETINAL VEIN OCCLUSION IN A REPRESENTATIVE CANADIAN COHORT

Petrella RJ[1], Blouin J[2], Davies B[2], Barbeau M[2]
[1]*Lawson Health Research Institute, indivisual health outcomes inc, London, ON, Canada,* [2]*Novartis Pharmaceuticals Canada Inc, Dorval, QC, Canada*

OBJECTIVES: Retinal vein occlusion (RVO) has an abrupt onset and is an important cause of visual morbidity. Macular edema (ME) is the most common cause of visual impairment (VI) in patients with RVO. The Canadian incidence of VI due to ME secondary to RVO is unknown. This study aimed to determine the annual incidence and characteristics of patients with ME secondary to branch RVO (BRVO) and central RVO (CRVO) in a real-world Canadian setting. **METHODS:** Records from a longitudinal population-based database of more than 170,000 patients in 53 family practice clinics in southwestern Ontario, Canada were analyzed between January 1, 2008 and December 31, 2009. These records contained chart-abstracted information such as visit diagnosis, medications and consultation notes. Initial extractions of control cohort and RVO patients with ME and VI (defined as best corrected visual acuity ≤20/40 in the RVO eye), were accomplished utilizing International Classification of Disease codes (ICD9/ICD10); reviewing patient charts for text entries of symptoms that supported a diagnosis of RVO and concomitant comorbidity; and reviewing patient treatment records unique to RVO including consultation notes and hospital discharge summaries. Demographic characteristics and comorbidities were reported. **RESULTS:** Seventy-three (53 with BRVO and 20 with CRVO) of 47,166 patients over 40 years (mean age 61±17 years) with new diagnosis of RVO and a control cohort of 76,077 patients were extracted for this analysis. The annual incidence of VI due to ME secondary to BRVO and CRVO was 0.056% and 0.021%, respectively. More RVO patients had hypertension (68 vs. 18%) or dyslipidemia (16 vs. 10%) than control cohort ($p<0.05$). One-quarter of RVO patients had a history of vascular disease, primarily MI and stroke. **CONCLUSIONS:** In a real-world setting, the annual incidence of VI due to ME secondary to BRVO and CRVO was 0.056% and 0.021%, respectively. RVO is associated with several vascular comorbidities.

PSS4

LONGER TERM PATIENT BENEFITS OF POLYQUAD® PRESERVATIVE INSTEAD OF BENZALKONIUM CHLORIDE IN PROSTAGLANDIN EYE DROPS: A MICROSIMULATION MODEL IN OCULAR HYPERTENSION AND OPEN-ANGLE GLAUCOMA

Gerlier L[1], Lamotte M[1], Berdeaux G[2], Verboven Y[3], Pfeiffer N[4]
[1]*IMS Consulting Group, Vilvoorde, Belgium,* [2]*ALCON RESEARCH LTD, RUEIL-MALMAISON, France,* [3]*Alcon Research Ltd, Puurs, Belgium,* [4]*University Medical Centre, Mainz, Germany*

OBJECTIVES: The presence of the preservative benzalkonium chloride (BAK) at 0.01% concentration in commercialized prostaglandin eye drops for glaucoma is known to increase the risk of ocular surface disease (OSD), which worsens with the extent of exposure to BAK. We aimed to estimate longer term clinical outcomes with travoprost preserved with Polyquad® 0.001% instead of BAK. **METHODS:** A Markov microsimulation model was developed (TreeAge) to assess the development of OSD and disease progression (Mean Defect [MD], in db) over 10 years, in patients initiating travoprost with Polyquad® followed by travoprost/beta-blocker fixed combination vs. the same sequence using BAK-preserved drops. Initial patient's characteristics came from distributions on age (normal), sex, OSD presence, disease stage (uniform) and anticipated progression rates (triangular). The risk of developing OSD in aging population was derived from a US incidence study, multiplied by independent risk factors (age, sex, duration and amount of BAK-containing drops received). Rates of disease progression (db/year) came from landmark studies in OHT/glaucoma, multiplied by independent accelerating factors (disease stage, treatment line, OSD severity, non-compliance). Compliance was expected by experts to be 20% (absolute) better with Polyquad® vs. BAK-preserved drops. **RESULTS:** Using 3000 trials (mean age 57 years, 57% female, 14% with initial OSD, mean MD -4db), 47.6% [41.5-53.6%] of patients receiving in first and second line BAK-preserved travoprost treatments are expected to have OSD at 10 years versus 31.7% [28.5-35.1%] with Polyquad®. In OHT/early glaucoma patients, the model predicted the progression to advanced glaucoma (MD<-12db) of 13.2% [12.0-14.4%] with Polyquad® versus 18.1% [16.7-19.5%] with BAK. In patients diagnosed with moderate glaucoma, 1.9% [1.4-2.4%] versus 5.6% [4.8-6.4%] progressed to blindness (MD<-24db) respectively. **CONCLUSIONS:** The model estimated that OSD incidence was reduced by 33% and glaucoma disease progression was significantly less frequent after 10 years of use of Polyquad® versus BAK-containing travoprost eye drops.

PSS5

VISUAL FIELD EVOLUTION IN GLAUCOMA PATIENTS PRESENTING WITH DIFFERENT DISEASE STAGES: RESULTS FROM AN OBSERVATIONAL STUDY

Gerlier L[1], Shlaen R[2], Wolfram C[3], Lamotte M[1], Verboven Y[4]
[1]*IMS Consulting Group, Vilvoorde, Belgium,* [2]*IMS Health, Munich, Germany,* [3]*Medical University Center, Mainz, Germany,* [4]*Alcon Research Ltd, Puurs, Belgium*

OBJECTIVES: The progression of glaucoma is measured by a Mean Defect (MD) of the perimetry in decibels (db), from an early disease stage (<6db loss), until moderate (6-12db loss), advanced stages (12-24db loss) and eventually blindness (>24db loss). The rate of disease progression is highly variable between individuals and hard to predict. The objective of this study was to analyze the change in MD of glaucoma patients in a real-life setting in Germany. **METHODS:** We analyzed patient-level data from a German observational study in ocular hypertension (OHT) and glaucoma, with retrospective collection of MD measures (db). Descriptive statistics were derived on the rate of disease progression (db loss/year, obtained by dividing the change in MD by the duration of observation). The change in MD in best eye between the time of first treatment until last MD measure was included in a generalized linear regression, adjusting for age, sex, presence of cataract, time since first treatment, initial MD and initial glaucoma stage (OHT, early/moderate or advanced). **RESULTS:** MD data was available for 57 patients (53% female, mean age 67 +/−12 years). The mean (SD) time from first treatment until last MD measure was 7.0 (3.7) years. The mean (SD) MD was -4.5db (4.7) at first treatment and -6.0db (6.8) at last assessment (i.e. average rate of progression of -0.21db/year, all stages). In 12 OHT patients, 50% had no MD worsening, while 50% lost on average -0.26db/year. Based on the adjusted analysis, the initial diagnosis was significantly associated with the amount of db loss over time (early/moderate glaucoma -0.19db/year +/−0.13, advanced -0.66db/year +/−0.22, p=0.038). **CONCLUSIONS:** The rates of disease progression measured over more than 7 years in glaucoma patients was

significantly increasing with their initial disease severity. Amount of db loss per year were in line with previously published prospective studies.

PSS6

EPIDEMIOLOGY, DISEASE BURDEN, SYMPTOMATOLOGY, TREATMENT PATTERN, AND QUALITY OF LIFE IN MACULAR DEGENERATION IN KOREA: SYSTEMATIC LITERATURE REVIEW BASED ON KOREAN EVIDENCE

Sohn HS
Sookmyung Women's University, Seoul, South Korea

OBJECTIVES: The objective of this study was to summarize epidemiology, disease burden, symptomatology, treatment pattern, and quality of life in macular degeneration (MD) in the Korean population through a systematic literature review. **METHODS:** Literature searches were conducted through Korean databases(RISS, KMBase, KoreaMed, NDSL, National Assembly Library), national statistics portals and ophthalmology journals for the period to April 2011, using "macular degeneration" as a keyword. Publications were selected according to pre-defined selection criteria. **RESULTS:** Forty-three studies were identified and included in the review. Most (40) described clinical characteristics and treatment pattern. 4 described epidemiology and 2 focused on quality of life. No study estimated economic burden. In summary, 1) MD characterizes exudative form, subretinal neovascularization or retinal pigment epithelial detachment, and equal distribution of circular and geographic atrophy; 2) MD is a major reason of low vision/visual impairment; 3) Drug therapy such as bevacizumab or ranibizumab presents effects on decrease of central macular thickness and preservation of visual acuity, but optimized patients have to be identified. Photodynamic therapy is relatively safe, and pneumatic displacement or radiation therapy is somehow effective on visual acuity even though being a risk of vision loss. Concurrent drug and non-drug therapies have been tried as well clinically; 4) Prevalence of MD is higher in elderly over 65 years with 13.3% rate and higher proportion of exudative form than western countries; and 5) Quality of life is decreased in patients with MD or low vision. **CONCLUSIONS:** This study describes lack of local information especially disease burden and quality of life. In the era growing sharply aging population, prevent and treat MD are crucial for preserving vision and improving quality of life. Therefore future studies are needed.

PSS7

PREVALENCE ASSESSMENT OF DIABETIC MACULAR EDEMA WITH VISUAL IMPAIRMENT IN SPAIN: A PREVAIL STUDY

Andres I[1], Balañá M[1], Gallagher M[2], Riera M[3], Pareja A[4], Barrot J[5], Orozco D[6], Roura M[1]
[1]*Medical Department. Novartis Farmacéutica S.A., Barcelona, Barcelona, Spain,* [2]*Novartis Pharma A.G., Basel, -, Switzerland,* [3]*Market Access Department. Novartis Farmacéutica S.A., Barcelona, Barcelona, Spain,* [4]*Hospital Universitario Insular de Gran Canaria, Las Palmas de Gran Canaria, ., Spain,* [5]*Centro Atención Primaria, Salt, Girona, Spain,* [6]*C.S. Petrer II, Alicante, ., Spain*

OBJECTIVES: Diabetic macular edema (DME) is the main cause of visual impairment (VI) in diabetic patients. The prevalence of DME is estimated to be 5.4% in Europe, but there is no observational evidence currently available. The objective was to determinate the prevalence of DME and DME with VI from Belgium, France, Germany, Italy, The Netherlands, Spain and UK, in an epidemiological study. Reported here are the results from Spain. **METHODS:** Patients with diabetes mellitus types 1 and 2 (DM1 and DM2) were consecutively recruited by General Practitioners (GPs) across Spain. Diagnosis and severity of DME, related VI, sociodemographics, general and ophthalmic comorbidities, HbA1c, antidiabetic and DME treatment were documented. Patients with retinitis pigmentosa, epiretinal membrane, or active uveitis were excluded from the calculation of VI due to DME. **RESULTS:** A total of 26 GPs recruited 445 eligible patients (38 DM1, 411 DM2) from July 2010 to April 2011, 51.2% male, mean (SD) age of 66.2 (12.8) years, 37.2% smokers or exsmokers. Patients with DME diagnosis showed a longer length of time since onset of diabetes (14.55 y vs 9.64). The prevalence of DME was estimated to be 4% (18/445 patients) (95%CI 2.2-5.8%) and VI due to DME was 2% (9/445) (95%CI 0.7-3.3%). Poor diabetic control (HbA1c $\geq$7%) was reported in 219 (48.8%) of all patients, being higher in those with DME (66.7%). Ocular comorbidities, such as cataract or glaucoma, were present in 17 (94.4%) DME patients. 15 (83.3%) patients received DME treatment, mainly laser photocoagulation (77.8%), alone or in combination with vitrectomy and/or pharmacological treatment. **CONCLUSIONS:** ME affects 4% of the diabetic patients in Spain, and 2% of them suffer VI due to DME. Results suggest that poor diabetic control and long time since diabetis onset are associated with development of DME. This study was sponsored by Novartis Pharma AG.

PSS8

ADVANCED CUTANEOUS MELANOMA IN THE UK: A SYSTEMATIC REVIEW

Poku E[1], Cooper K[1], Wang Q[2], Bapat U[2], Lebmeier M[2]
[1]*University of Sheffield, Sheffield, South Yorkshire, UK,* [2]*Bristol-Myers Squibb, Uxbridge, Middlesex, UK*

OBJECTIVES: Cutaneous malignant melanoma (CMM) is an uncommon yet aggressive form of skin cancer. In 2008, CMM was found to be the sixth most common cancer in the UK. The aim of this review was to identify the incidence of advanced CMM in the UK (UK). The definition of advanced CMM was stage IIIc and stage IV disease in affected patients. **METHODS:** Multiple sources including the Cochrane Library, MEDLINE, EMBASE and CINAHL were searched between December 2010 and March 2011. Searches were also conducted by scanning the websites of the Office of National Statistics, Cancer Research UK as well as the Welsh Cancer Intelligence and Surveillance Unit. A narrative synthesis was undertaken due to heterogeneity in included studies. **RESULTS:** Of the three included studies, 2 were conducted in Scotland while one was undertaken in the East Anglia region of England. Although all patients had a confirmed diagnosis of CMM, variations in staging methods and unclear or insufficient reporting made it challenging to identify patients with stage IIIc and stage IV disease. Both studies undertaken in Scotland at different periods reported that 2% of all melanoma patients had advanced CMM at the time of diagnosis. However, the definitions of advanced CMM were not similar in each study. The incidence of stage IV CMM reported in 3,971 patients from East Anglia decreased from 0.42 to 0.13 per 100,000 population per year between 1991 and 2004. **CONCLUSIONS:** This review highlighted the lack of, and need for primary studies to estimate the incidence of advanced CMM in the UK. In order to examine trends across UK as well as identify patients for targeted treatment, we suggest that researchers must clearly define this sub-group in future studies.

Sensory Systems Disorders – Cost Studies

PSS9

THE BURDEN OF AGE-RELATED MACULAR DEGENERATION IN THE NETHERLANDS

Boland MRS[1], Vingerling J[2], Groot M[3], Hakkaart-van Roijen L[1]
[1]*Erasmus University, Rotterdam, The Netherlands,* [2]*Erasmus Medical Center, Rotterdam, Rotterdam, The Netherlands,* [3]*Novartis Pharma B.V., Arnhem, The Netherlands*

OBJECTIVES: Age-Related Macular Degeneration (AMD) is a disorder of the central area of the retina resulting in a significant loss of visual acuity. AMD is the leading cause of incurable blindness and visual impairment in industrialized countries. Consequently AMD leads to decrease of Quality of Life (QoL) and increased health care costs. For the The Netherlands no information on the burden of AMD was available. The main aim of this study was to assess the burden of AMD patients in the The Netherlands in terms of health care costs and QoL from a societal perspective. **METHODS:** AMD cost parameters were identified and the 'AMD cost and impact questionnaire' was developed. Members of the Dutch Macular Degeneration Patient Organization with a disease severity ranging from normal vision to legally blind were invited to enter the study during regional meetings. The EuroQol 5D was used for measuring QoL. Data on resource use and QoL were collected through telephone interviews. **RESULTS:** Seventy-five patients completed the questionnaire. The average total annual cost for AMD was €5651 per person (95% CI: 4252 - 7051). Home help was the major cost component (€2507 p.p.). Total costs were significantly higher for individuals with more severe AMD and the QoL significantly lower for individuals with more severe AMD ($P<0.05$). The average utility of AMD was 0.792 (95% CI: 0.771-0.812) significantly lower than the average 50+ Dutch population (0.850). The respondents reported 'usual activities' as the area with the most problems. **CONCLUSIONS:** Increased visual impairment leads to significantly higher annual costs and lower overall QoL.

PSS10

ECONOMIC OUTCOMES OF GLAUCOMA TREATMENT WITH PROSTAGLANDIN EYE DROPS PRESERVED WITH POLYQUAD® INSTEAD OF BENZALKONIUM CHLORIDE IN GERMANY

Gerlier L[1], Lamotte M[1], Lorenz K[2], Berdeaux G[3], Verboven Y[4], Pfeiffer N[2]
[1]*IMS Consulting Group, Vilvoorde, Belgium,* [2]*University Medical Centre, Mainz, Germany,* [3]*ALCON RESEARCH LTD, RUEIL-MALMAISON, France,* [4]*Alcon Research Ltd, Puurs, Belgium*

OBJECTIVES: In glaucoma patients, the long term use of prostaglandin eye drops containing benzalkonium chloride (BAK) increases the risk of developing an ocular surface disease (OSD). Polyquad® preserved prostaglandins are now available, among which travoprost proved similar in efficacy and safety compared to BAK-preserved formulations. We aimed to estimate the impact of Polyquad® instead of BAK on glaucoma management cost. **METHODS:** A Markov microsimulation model was developed in TreeAge, including 5 health states corresponding to 4 treatment lines plus death, in representative, treatment-naive patients at different OHT/glaucoma stages. The sequence travoprost-travoprost+timolol fixed combination preserved with Polyquad® was compared to BAK-preserved latanoprost-latanoprost+timolol (LAT) and bimatoprost-bimatoprost+timolol (BIM). The model events were: onset of OSD (risk factors: age, sex, BAK exposure; sources: US incidence study [Moss 2005], Erb 2008), need for treatment change including surgery/laser (risk factors: treatment line, disease stage, OSD presence, BAK exposure; sources: persistence studies in UK GPRD [Lafuma 2007] and US claims database [Schmier 2010]), and disease progression (risk factors: treatment line, OSD severity, non-compliance; sources: large prospective studies in OHT/glaucoma). Costs data came from a German observational study in OHT/glaucoma with 5-year retrospective collection of medical resources used (Statutory Health Insurance perspective + patient co-payments; 2011 drug costs, other costs 2010). The 95% confidence intervals came from a probabilistic sensitivity analysis. **RESULTS:** After 10 years, the total management cost in the travoprost with Polyquad® arm was €4677 [4378; 5013] compared to €5196 [4904;5482] with LAT and €5342 [5069;5664] with BIM. More patients required eye surgery/laser procedures with BAK-preserved sequences (LAT: 4.7% [3.2;6.4%], BIM: 6.0% [4.0;8.3%]) compared to travoprost with Polyquad® (1.8% [0.9;2.9%]). **CONCLUSIONS:** At 10 years, prostaglandin treatment with Polyquad® is expected to reduce the cost of glaucoma treatment by 10-15% from both individual and societal perspectives, and have lower surgery/laser rates compared to BAK-preserved treatments.

PSS11

RANIBIZUMAB AND BEVACIZUMAB FOR THE TREATMENT OF AGE-RELATED MACULAR DEGENERATION: A SYSTEMATIC REVIEW AND ECONOMIC EVALUATION

Martinez Ferez IM, Flores Moreno S
Andalussian Agency for Health Technology assesment, Sevilla, Spain

OBJECTIVES: To evaluate and comparate the efficacy, safety and cost of the bevacizumab and ranibizumab intravitreous injections for the treatment of age related

macular degeneration (AMD). **METHODS:** A systematic review of literature was conducted. The bibliographic search covered the period between January 1996 and January 2011. The search was run on MEDLINE, EMBASE, Cochrane library, INAHTA and ECRI. The criteria employed to select the papers were: population (AMD patients), treatment (Ranibizumab or Bevacizumab), comparison (placebo or other active treatments). To assess the efficacy, it was decided to include systematic reviews and randomised clinical trials (RCT). For the safety, it was considered any type of study. **RESULTS:** The bibliographical search retrieved 731 references of articles and 51 papers were finally included: 4 were controlled clinical trials: two on Ranibizumab and two on Bevacizumab. Efficacy: Ranibizumab and Bevacizumab, as compared to placebo as to Verteporfin, gets results in terms of AMD stabilization (between 0 and 1.2% of severe visual losses as opposed to 13-16% in the control groups), in terms of reduction in the lesion size and it even achieves improvement in visual acuity in some cases. Safety: The adverse effects (of any magnitude) were more frequent in the groups treated with Ranibizumab and Bevacizumab than in the control groups (placebo and Verteporfin). The data's synthesis showed adverse effects similar in both drugs. Economic Evaluation: Drug costs for 1 year of treatment were estimated as 2.330€ for Ranibizumab and 53€ for Bevacizumab. **CONCLUSIONS:** : Both drugs provide startling benefits in the treatment of age-related macular degeneration (AMD). Cost effectiveness analysis of bevacizumab makes this intervention highly cost effective versus ranibizumab. The price of ranibizumab would have to be drastically reduced for it to be cost effective. Public pressure may be the most potent weapon in persuading Genentech to license bevacizumab for AMD.

PSS12

C-REALITY (CANADIAN BURDEN OF DIABETIC MACULAR EDEMA OBSERVATIONAL STUDY): THREE-MONTH FINDINGS

Barbeau M[1], Gonder J[2], Walker V[3], Maschio M[3], Zaour N[1], Li R[1]
[1]*Novartis Pharmaceuticals Canada Inc, Dorval, QC, Canada,* [2]*Ivey Eye Institute, London, ON, Canada,* [3]*OptumInsight, Burlington, ON, Canada*

OBJECTIVES: To characterize the economic and societal burden of Diabetic Macular Edema (DME) in Canada. **METHODS:** Patients with clinically significant macular edema (CSME) were enrolled by ophthalmologists or retinal specialists across Canada. Patients are followed over a 6-month period to combine prospective data collected during monthly telephone interviews and at sites at months 0, 3 and 6. Visual acuity (VA) is measured and DME-related health care resource information is collected. Patient health-related quality of life is measured using the National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25), and the EuroQol Five Dimensions (EQ-5D). The 3-month results are available and presented here. **RESULTS:** A total of 145 patients [mean age 63.8 years (range: 30-86 yrs); 52% male; 81% Type 2 diabetes; mean duration of diabetes 18 years (range: 1-62 yrs); 72% bilateral CSME] were enrolled from 17 sites across 6 provinces in Canada. At baseline, the mean VA was 20/60 (range: 20/20-20/800) across all eyes diagnosed with CSME (249 eyes). Sixty-eight percent of patients had VA severity in the worse seeing eye of normal/mild vision loss (VA 20/10 to $\leq$ 20/80), 19% moderate vision loss (VA $>$ 20/80 to $\leq$ 20/200), and 13% severe vision loss/nearly blind (VA $>$ 20/200). At month 3, the mean NEI VFQ-25 composite score was 79.9, the mean EQ-5D utility score was 0.79, and the EQ visual analogue scale score was 70.6. The average 3-month DME-related cost per patient was $1,487 across all patients (95% confidence interval: $1,164 to $1,810). The cost was $1,390 for patients with normal/mild vision loss, $1,831 for patients with moderate vision loss, and $1,467 for patients with severe vision loss/nearly blind. **CONCLUSIONS:** DME is associated with limitations in functional ability and quality of life. In addition, the DME-related cost is substantial to the Canadian health care system.

PSS13

ECONOMIC BURDEN OF PSORIASIS AND DIABETES IN PATIENTS WITH PSORIASIS IN THE UNITED STATES

Guerin A[1], Latremouille-Viau D[1], Day R[2], Khan Z[2], Zhang F[2]
[1]*Analysis Group, Ltee., Montreal, QC, Canada,* [2]*Celgene Corporation, Summit, NJ, USA*

OBJECTIVES: Psoriasis, an immune mediated disorder with skin manifestations and comorbidities, has high resource requirement. Specifically, diabetes is highly prevalent in psoriasis patients and may represent a substantial incremental economic burden. This retrospective study aimed to estimate the incremental costs of psoriasis and diabetes in psoriasis patients. **METHODS:** Adult patients with psoriasis (i.e., $\geq$2 psoriasis diagnoses ICD-9 codes:696.1x) were selected from a large US administrative claims database. Psoriasis-free controls were matched with the psoriasis sample by age and gender in a 1:1 ratio. All patients were followed for one year to assess their healthcare costs. Incremental total healthcare costs (USD 2010) associated with psoriasis and diabetes in a psoriasis population, measured from a third-party payer perspective, were estimated using regression models controlling for age and gender. **RESULTS:** A total of 106,128 matched pairs were studied. Among psoriasis patients, 16% had diabetes compared to 13% of the psoriasis-free controls ($p<.001$). Psoriasis was associated with a $4,523 adjusted increment total health care costs among patients without diabetes ($10,017 vs. $5,539; $p<.001$), compared to $5,984 among patients with diabetes ($19,536 vs. $13,589; $p<.001$). In the psoriasis population, diabetes presented a $8,337 adjusted incremental cost compared to the psoriasis patients without diabetes ($19,536 vs. $10,017; $p<.001$). This was $1,460 more than the adjusted incremental costs from diabetes among controls without psoriasis ($p<.001$), representing an interaction of psoriasis and diabetes conditions, which significantly increases the health care costs. **CONCLUSIONS:** Both psoriasis and diabetes are expensive conditions to treat. The incremental economic burden of patients having both diseases is significantly higher than each condition individually, potentially due to the complexity of managing both conditions at the same time.

PSS14

BURDEN OF DISEASE IN PATIENTS WITH SEVERE CHRONIC HAND ECZEMA IN GERMANY

Diepgen TL[1], Purwins S[2], Posthumus J[3], Kuessner D[3], Augustin M[2]
[1]*University Heidelberg, Heidelberg, Germany,* [2]*University Clinics of Hamburg, Hamburg, Germany,* [3]*Basilea Pharmaceutica International Ltd., Basel, Switzerland*

OBJECTIVES: Analyse the burden of chronic hand eczema (CHE) patients with episodes of severe disease preceding the availability of the first approved systemic treatment in 2008. **METHODS:** In this cost-of-illness study, 310 patients with CHE refractory to topical steroids in Germany were analyzed (patients with coverage by statutory (GKV) or occupational health insurances (BG)). The cross-sectional survey instrument collected data on patient characteristics, clinical status (i.e. max. severity in past year and at inclusion) and resource use. Only patients with severe disease (photographic guide) in the year preceding this study were selected for this analysis. The following aspects were investigated: resource use, costs, clinical status (at inclusion) and quality of life (DLQI). **RESULTS:** A total of 161 (52 %) of the CHE patients had severe CHE during the last 12 months (similar fractions in both insurances categories) and 74 % of these patients reported a moderate/severe disease status (Physician global assessment (PGA)) at inclusion. The average DLQI score at inclusion was 8.1 (moderate effect on patient's life). Approximately half of the patients received only topical treatments, while the remaining patients received a combination of topical therapies with UV-therapy (68 %) and/or systemic therapies (36%). The yearly health care costs of these patients were €2221 (GKV patients) and €3961 (BG). **CONCLUSIONS:** Among these CHE patients refractory to topical corticosteroids, half of the patients had severe disease during the year prior to the survey. Despite the extensive usage of health care resources (incl. UV-therapy, off-label systemic therapies and hospitalization), the CHE disease severity state did not change considerably for most patients. It remains to be seen whether the availability of the first approved systemic treatment (alitretinoin) for severe CHE will change the dynamics seen in this disease and therefore, further prospective studies are warranted to clarify this aspect.

PSS15

BURDEN OF CHRONIC TINNITUS IN HUNGARY

Kiss Z
United BioSource Corporation, London, London, UK

OBJECTIVES: Tinnitus has a major effect on quality of life when it occurs for a longer period of time. It is a conservative estimate that 10% of the general population experiences spontaneous prolonged tinnitus. The aim of this study is to estimate the burden and cost of tinnitus in Hungary from three different perspectives, as no publicly available cost or burden of illness study has been found in this field. The objective is to fill this gap in the Hungarian setting. **METHODS:** The present study identified both the costs that are made and the resources that are lost in the form of direct medical and nonmedical costs and indirect costs associated with tinnitus. An expert panel based estimate was used to identify probabilities for the different paths and resource use, due to lack of information in the literature. Direct medical costs were observed from the National Health Insurer's (NHI) database, while the indirect costs were estimated according to the human capital approach. The cost estimates were based on a model structured by a decision tree. **RESULTS:** An annual cost of 91,891Ft (€ 328) has been estimated for a newly diagnosed tinnitus patient. The average treatment cost borne by the NHI is 6,363Ft (€ 23), while a 37,534Ft (€ 134) cost was assigned to the diagnosis of a typical patient attending an ENT specialist. Indirect cost consist of sick leave cost which is 861Ft (€3.1), 3,118Ft (€11) and 8,743Ft (€31) in the different cost categories of NHI costs, out of pocket costs and societal costs, respectively. **CONCLUSIONS:** From the societal perspective, the annual cost of tinnitus amounted for 0.01% of the Hungarian GDP in 2009 which is almost evenly borne by the NHI and the population with tinnitus. There is little information in either the Hungarian or the international literature to validate the model against.

PSS16

COST OF BLINDNESS IN AUSTRIA

Brennig C, Schöllbauer V, Walter E
Institute for Pharmaeconomic Research, Vienna, Austria

OBJECTIVES: Literature concerning epidemiology of blindness and with these disease patterns associated economic consequences is very rare. The aim of this analysis was to close this research deficit for Austria by evaluating the whole economic impact of blindness for the Austrian society using the incidence approach. **METHODS:** A model that captures all causes of blindness (AMD, glaucoma, diabetic retinopathy, cataract, and other causes) was developed. We differentiated between age groups as well. Cost of illness comprises direct medical cost (treatment, consultations, devices, cost of depression, hip fractures etc.) and direct non-medical cost (adaption of housing facilities). Indirect cost are allowance for nursing care, cost for assisted living and productivity loss. The analysis was performed from a society's perspective. Cost are calculated from onset of blindness until death (reduced life expectancy due to blindness) (dicount rate 5%). The analysis was performed according to the Austrian Guidelines for Healtheconomic evaluations. **RESULTS:** In Austria every year 1160 (Incidence) people go blind. Total cost (direct and indirect) of blindness over all age groups value €105.71 Mio. (incl. allowance for nursing care) over lifetime. Direct cost account for 3% of total cost (€3.61 Mio.) and indirect cost for 97% (€102.09 Mio.). Highest cost of blindness over lifetime can be found within the groups ‚opticusatrophy' (18-39-year-old-patients) with 11.77 Mio., diabetic retinopathy' (60-79-year-old-patients) with cost of €7.02

Mio, and, other causes' (18-39 year old patients) with €33.80 Mio. **CONCLUSIONS:** A multitude of causes for blindness affects primarily older people. Demographic development will lead to an increase in blind people and therefore to a costly public health problem. Loosing eyesight is connected to high cost on the one hand and to a lower QOL for patients on the other hand. The analysis shows the high cost of blindness for the whole society in Austria.

PSS17

SOCIETAL BURDEN OF BLINDNESS IN HUNGARY

Németh J[1], Nagyjanosi L[2], Nagyistok S[2], Tolnayné Csattos M[3], Szabóné Berta I[3], Kincse É[3], Szulyák E[3], Boér I[4], Hundzsa G[5], Kalo Z[6], Berta A[7]
[1]*Semmelweis University, Budapest, Budapest, Hungary,* [2]*Syreon Research Institute, Budapest, Hungary,* [3]*National Institute of Blind, Budapest, Hungary,* [4]*Novartis Hungária Kft., Budapest, Hungary,* [5]*Hungarian Retina Association, Budapest, Hungary,* [6]*Eötvös Loránd University, Budapest, Hungary,* [7]*University of Debrecen, Debrecen, Hungary*

OBJECTIVES: Blindness represents significant burden of disease worldwide. The aim of this research is to estimate medical and non medical expenses related to blindness of elderly patients (>60 years) in Hungary so that results can be used for further policy analyses. **METHODS:** Inputs for burden of disease model were derived from the published literature, statistical databases and structured interviews with relevant experts. We divided the burden of elderly blindness into public and private medical and non medical costs. In addition to direct costs (social care and subvention, conduct recourse, medical costs) indirect costs and lost revenues (unemployment, support to activities of daily living) were also calculated. **RESULTS:** The social burden of 6051 elderly blind patients was estimated 53.35 million USD in 2009, 0.03% of the Hungarian GDP (1 USD = 128.19 HUF in purchasing power parity exchange rate). Social care and subventions (20.04 million USD), support to daily living activities (15.91 million USD) and healthcare costs (6.68 million USD) represented the largest proportion of expenses. 55% of total burden were derived from public sector and within public burden social care and subventions represented two-third of expenses. **CONCLUSIONS:** The societal burden of elderly blindness is significant even without measuring its impact on mortality and quality of life. It is important to redefine the necessary health and social policy objectives of prevention, health care and social integration of elderly blindness. Further research is needed to measure the impact of medical and non-medical interventions to reduce the societal burden of elderly blindness

PSS18

DIRECT ECONOMIC BURDEN OF REGULAR INTRAVITREAL INJECTIONS FOR THE TREATMENT OF RETINA DISEASES IN THREE EUROPEAN COUNTRIES

Johnson MK[1], Lara N[2]
[1]*Allergan EAME, Parkway, Marlow, Bucks SL7 1YL, UK,* [2]*IMS Health, Barcelona, Barcelona, Spain*

OBJECTIVES: Retina disease (RD) is a leading cause of blindness in Europe with significant clinical and economic consequences. The research objective was to assess the direct health care resource use of patients receiving regular intravitreal injections (rIVI) to treat RD in France, Spain and the UK (UK). **METHODS:** Three focus group sessions were performed with at least 6 retina specialists who treated RD patients with rIVIs (defined as IVIs every 4 to 6 weeks). A specific questionnaire assessed resource use including medical visits, diagnostic/monitoring tests and procedures, drugs administered, IVI adverse event treatment, surgery and transport. Costs were quantified using official and bibliographical sources from each national health care system perspective over a one-year time horizon. All costs are expressed in 2010 euros and pound sterling. **RESULTS:** The annual total direct health care cost per patient treated with rIVI was €14,725 in France, €10,027 in Spain and £9,647 to £13,759 in the UK (depending on the setting of care: outpatient or day case). In all countries, pharmacological costs accounted for the largest proportion of overall costs (50-80%). Ranibizumab was the most used drug except some countries that reported off-label use of bevacizumab. Non-pharmacological costs, including follow-up visits, tests and administration costs, were €2353, €2918 and £3000-£9096 in France, Spain and the UK, respectively. **CONCLUSIONS:** Treatment with rIVIs is costly to health care systems. While drug costs account for a large portion of costs, required monitoring is a key cost driver and affects health care systems' capacity to treat RD patients. Any strategy to reduce the number of rIVIs per year would assist in reducing the burden on health care systems. Furthermore, to assess the full cost of treatment, a study assessing direct cost to patients and caregivers and indirect cost is also needed.

PSS19

GLAUCOMA MANAGEMENT COST AS A FUNCTION OF DISEASE STAGE AND TREATMENT CHANGES

Gerlier L[1], Shlaen R[2], Lorenz K[3], Lamotte M[1], Verboven Y[4], Pfeiffer N[3]
[1]*IMS Consulting Group, Vilvoorde, Belgium,* [2]*IMS Health, Munich, Germany,* [3]*University Medical Centre, Mainz, Germany,* [4]*Alcon Research Ltd, Puurs, Belgium*

OBJECTIVES: Ocular hypertension (OHT) and primary open-angle glaucoma (POAG) are chronic eye conditions that progress over time, potentially leading to blindness. Glaucoma management costs increase with disease severity and treatment switches, drugs and surgical treatments being cost drivers. Our study aimed to estimate this glaucoma management costs as a function of the disease stage and the number of treatment changes in Germany. **METHODS:** We analyzed patient-level data from an observational study with retrospective collection of medical resources used by German glaucoma patients over a 5-year period. Associated costs were derived for drug treatment, medical/surgical procedures, exams/tests and hospitalizations (Statutory Health Insurance, 2009 costs). A linear regression was performed on the total management costs and drug costs, with two independent variables: the current disease stage (OHT [reference], early, moderate, advanced POAG), and the number of treatment changes (0 [reference], 1, 2, ≥3 changes). Costs were estimated against the reference category (OHT-No change). **RESULTS:** Data from 154 OHT/POAG patients (57% female, mean age 67 +/−11 years) was analyzed. OHT patients without treatment change had a mean (SD) total management cost of €123 (121) per year, which increased by €71 ($p>0.05$), €153 ($p>0.05$) and €398 ($p=0.004$) in disease stages early, moderate and advanced POAG respectively. Each treatment line change (1, 2, ≥3) also resulted in increase in cost of €45 ($p>0.05$), €177 ($p<0.05$) and €451 ($p<0.0001$) compared to the reference cost, respectively. The drug cost followed the same pattern, with a mean (SD) reference cost of €83 (33) per year and increases by €70 ($p>0.05$), €88 ($p=0.022$) and €160 ($p<0.0001$) with the disease stage, and €22 ($p>0.05$), €76 ($p=0.044$) and €146 ($p<0.0001$) with each treatment change. **CONCLUSIONS:** The analysis of observational data showed a significant increase of the glaucoma management costs with both the disease severity and the number of treatment changes.

PSS20

ANNUAL COST OF BIOLOGICAL THERAPIES FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS IN SPAIN

Domínguez-Gil A[1], Moreno D[2], Garcia D[3], Campo C[3]
[1]*Hospital Clínico Universitario de Salamanca, Salamanca, Spain,* [2]*Hospital Universitario Virgen Macarena, Sevilla, Spain,* [3]*Abbott Laboratories S.A., Madrid, Spain*

OBJECTIVES: To estimate the mean annual cost of the different biological agents licensed for the treatment of patients with moderate to severe plaque psoriasis during the first year of treatment and maintenance, according to the daily clinical practice in Spain. **METHODS:** Data were obtained from case notes of a sequential patient cohort with psoriasis attending a tertiary referral severe psoriasis service and initiated on biologics for treatment of their psoriasis at least 12 months before to the cut-off date (November 2010). Data on drug usage (dose and dosage, starting and changing dates), that patients have experienced throughout the treatment, were collected To estimate the annual drug cost for each patient, two periods of time were considered in the analysis: first year after initiation of biologic therapy and the year before the cut-off as maintenance period. Specific assumptions regarding the dosage, interruption, or switching to other biological after initiation of treatment were set out. Only the cost of biological agents was considered, regardless of any other associated expenses, dismissing those subjects who have been on therapy less than 3 months before switching to other biological drug. **RESULTS:** The primary analysis population comprised a total of 760 patients: adalimumab (n=212), etanercept (n=214), infliximab (n=145), and ustekinumab (n=189). These subgroups were comparable in age, gender, weight, type of psoriasis, severity, joint affectation and concomitant diseases prevalence. The mean annual costs were: for adalimumab 13,346.48 € and 12,120.09 €, etanercept 15,268.28 € and 14,420.46 €, infliximab 16,589.67€ and 13,889.49 €, and ustekinumab 18.370,50 € and 15.500,44 €. **CONCLUSIONS:** The current cost analysis clearly shows that the expenditure associated with the use of adalimumab both, at the initiation of therapy and maintenance, reflects the lowest price charged for a biological drug in patients with moderate to severe plaque psoriasis, in daily clinical practice in Spain.

PSS21

TREATMENT PATTERNS, COSTS AND QUALITY OF LIFE IN PATIENTS WITH PLAQUE PSORIASIS IN DENMARK

Ragnarson tennvall G[1], Hjortsberg C[1], Gniadecki R[2], Jemec GBE[3], Kragballe K[4], Miller IM[3]
[1]*IHE, The Swedish Institute for Health Economics, Lund, Sweden,* [2]*University of Copenhagen, Bispebjerg Hospital, Copenhagen, Denmark,* [3]*Roskilde Hospital, Roskilde, Denmark,* [4]*Aarhus University Hospital, Aarhus, Denmark*

OBJECTIVES: The aim of the study was to analyse and estimate health-related quality of life (HRQoL), costs of psoriasis during 12 months and disease severity among patients with psoriasis in Denmark who had received different types of treatment. **METHODS:** The study is based on 131 patients included from three dermatology clinics and data from two different sources; a patient survey and a retrospective chart review. Information about HRQoL (EQ-5D AND EQ-VAS), Dermatology Life Quality Index (DLQI), disease severity, resource utilisation in health care and productivity losses was collected from patient questionnaires. Patient characteristics and type of treatment were collected from patient records. **RESULTS:** During the study period, 16% of the patients used only emollients and/or topical corticosteroids and 31% used systemic treatment (not biological drugs). During part of or during the whole 12 months period 53% received biological treatment. Mean direct cost per patient related to in- and out-patient care was estimated to DKK10,682, and indirect cost was DKK9,668. Cost for drugs was DKK88,534 and cost for light treatment was DKK3,775 per patient. Indirect costs were DKK4,300 for patients with no or minor psoriasis problems and DKK22,000 for patients with moderate to very severe problems. Light treatment and hospitalisation costs made up the greatest part in patients receiving local topical treatment. These costs were also higher in the topical group than in all other treatment groups. The mean QoL values for all patients were: EQ-5D 0.76, EQ-VAS 74, and DLQI 5.0. The latter value corresponds to "small effect on patient's life". Fewer patients treated with biological drugs experienced problems with treatment than other treatment groups. **CONCLUSIONS:** Patients with more extensive psoriasis problems experienced lower QoL and a larger disease burden. Indirect costs increased with disease severity. Costs increased with the use of more potent drugs (biological and systemic drugs).

PSS22

A COST-EFFECTIVENESS ANALYSIS OF OFF-LABEL BIOLOGICS TO TREAT SARCOID POSTERIOR UVEITIS VERSUS STANDARD OF CARE: COMPARING INFLIXIMAB TO METHOTREXATE AND SYSTEMIC STEROIDS

Padula WV[1], Yilmaz T[2], Cordero-Coma M[3]

[1]University of Colorado Health Sciences Center, Denver, CO, USA, [2]State University of New York Stony Brook, Stony Brook, NY, USA, [3]Hospital de Leon, Leon, Castilla y Leon, Spain

OBJECTIVES: To evaluate whether infliximab, a modern off-label biologic, is cost-effective for treating sarcoid posterior uveitis compared to methotrexate and systemtic steroids. Sarcoid posterior uveitis is a progressive eye disease that can lead to blindness if untreated. Ophthalmologists have utilized infliximab, a TNF-alpha inhibitor, which reverses effects of uveitis. **METHODS:** A semi-Markov model followed patients' therapy from the onset of sarcoid posterior uveitis using the societal perspective. The lifetime model simulated health states that could lead to successful reversal of uveitis with standard or intensified treatment with systemic steroids, methotrexate, or infliximab. Probabilities, health utilities, and costs were included in the model based on findings from literature. Costs and effects were discounted at 3% ($US; 2010 values). We conducted univariate sensitivity analyses, threshold analyses, and a Bayesian multivariate probablistic sensitivity analysis using 10,000 Monte Carlo simulations. Results were interpretted from a predetermined willingness-to-pay of $50,000/QALY. **RESULTS:** In order of cost, base case results showed systemic steroids most affordable ($26,871; 14.58 QALYs), followed by methotrexate ($40,351; 15.92 QALYs), and then infliximab ($46,547; 15.04 QALYs). Methotrexate was cost-effective compared to steroids, with an incremental cost-effectiveness ratio of $10,053/QALY. Methotrexate dominated infliximab. Univariate sensitivity analyses suggested that the model was sensitive to the utility of a patient's successful recovery from uveitis (0.84 QALYs). If patients' health utility after successful recovery is below 0.750, then infliximab has a greater net benefit than methotrexate. The multivariate probabilistic sensitivity analysis showed that methotrexate dominated infliximab in 60% of the simulations. **CONCLUSIONS:** This cost-effectiveness analysis suggests that despite major advances in the use of biologics for treating sight-threatening sarcoid posterior uveitis, methotrexate remains a less expensive and more cost-effective strategy. Methotrexate should be adopted as the standard of care for treatment considering its incremental cost-effectiveness at a reasonable willingness-to-pay. Other therapeutic options, such as infliximab, may be considered for certain cases.

PSS23

PHARMACOECONOMIC ANALYSES OF PARTIALLY HYDROLYZED INFANT FORMULAS IN PREVENTION OF ATOPIC DERMATITIS: COMPARATIVE RESULTS FROM 5 EUROPEAN COUNTRIES

Iskedjian M[1], Berbari J[2], Navarro V[1], Farah B[2], Detzel P[3], Spieldenner J[3]
[1]PharmIdeas Europe SAS, Lyon, France, [2]PharmIdeas Research and Consulting, Ottawa, ON, Canada, [3]Nestlé Nutrition Institute, Vevey, Switzerland

OBJECTIVES: Pharmacoeconomic analyses (PEs) were performed in five European countries to determine costs, consequences and cost effectiveness of a partially hydrolysed 100% whey-based infant formula, manufactured by Nestlé S.A, Switzerland (PHF-W) in the prevention of atopic dermatitis (AD) in 'at risk' children when compared to standard cow's milk formula (SF) or extensively hydrolyzed formula (EHF). **METHODS:** The PEs were performed in France, Germany, Spain, Denmark and Switzerland, using decision-analytic models depicting AD treatment pathways, as well as resource utilisation and costs associated with the treatment of AD in healthy yet 'at risk' newborns who could not be exclusively breastfed. A time horizon of 12 months including 6 months of formula consumption was applied, with country-specific resource use and costs. In four settings, SF was the main comparator and the final outcome of the PEs was the incremental cost per avoided case (ICER) of AD when comparing subjects who used PHF-W versus SF. Given a lack in significant differences in efficacy between PHF-W and EHF, a cost-minimization approach was used in all settings to compare these formulas. Three perspectives were applied: the Ministry of Health (MOH), the family and society. **RESULTS:** The analyses of PHF-W vs. SF generated ICERs ranging from €801 to €1343 (MOH), from -€1796 to -€454 (family) and from -€995 to €719 (society). The costs of formula and time loss were the most important cost drivers. In the analyses of PHF-W versus EHF in prevention, PHF-W demonstrated savings ranging from €4-€120 million, or €1.3-€64 million for the MOH perspective. The robustness of the models and the direction of the results were confirmed by one-way and probabilistic sensitivity analyses. **CONCLUSIONS:** In five European countries, PHF-W appears to be the product best positioned in prevention at a reasonable cost when compared to SF and with important cost-savings versus EHF.

PSS24

COST-EFFECTIVENESS OF USTEKINUMAB VS ETANERCEPT FOR SEVERE PSORIASIS

Sura M[1], Avxentyeva M[2], Omelyanovsky V[2], Zorin N[2], Hailov P[2]
[1]Research center for clinical and economic evaluation and pharmacoeconomics, Moscow , Russia, [2]Research center for clinical and economic evaluation and pharmacoeconomics, Russian State Medical University, Moscow, Russia

OBJECTIVES: To evaluate cost-effectiveness of ustekinumab vs etanercept for severe psoriasis in Russia. **METHODS:** Cost-effectiveness analysis was performed. The data about efficacy and safety of biologic agents was analyzed. Cost-effectiveness ratio (CER) was calculated for ustekinumab and etanercept. Pharmaceutical costs were taken into account only. Achievement of PASI 75 was a criterion of efficacy, data about it was extracted from 12 weeks comparative clinical trial. **RESULTS:** The efficacy of ustekinumab was higher than etanercept in a direct comparative trial (67.5 and 56.8% of patients achieved PASI 75 by week 12 respectively). Both biologic agents were generally well tolerated in most patients. Ustekinumab was a bit less costly than etanercept: 470.00 and 496.62 thousands rub (16.92 and 17.88 thousands $) for 12-weeks treatment respectively. Therefore CER was more favorable for ustekinumab than for etanercept: 696.30 thousands rub (25.06 thousands $) and 874.33 thousands rub ($31.47 thousands $) per patient with PASI 75 achieved respectively. **CONCLUSIONS:** Ustekinumab is a dominanting alternative to etanercept for patients with severe psoriasis in Russia.

PSS25

THE COST-EFFECTIVENESS OF OZURDEX® (DEXAMETHASONE INTRAVITREAL IMPLANT IN APPLICATOR) COMPARED WITH OBSERVATION FOR THE TREATMENT OF MACULAR OEDEMA FOLLOWING CENTRAL AND BRANCH RETINAL VEIN OCCLUSION

Hayward E[1], Almond C[2], Trueman D[3], Yeh WS[4], Kowalski JW[5]
[1]Allergan EAME, Marlow, Buckinghamshire, UK, [2]BresMed Health Solutions, Sheffield, South Yorkshire, UK, [3]Abacus International, Bicester, Oxfordshire, UK, [4]Allergan, Irvine, CA, USA, [5]Allergan, Inc., Irvine, CA, USA

OBJECTIVES: Ozurdex (dexamethasone 700 μg intravitreal implant in applicator) was the first EMA licensed pharmacotherapy for macular oedema following central and branch retinal vein occlusion (CRVO, BRVO), a leading cause of vision loss. The objective of this analysis was to evaluate the cost-effectiveness of Ozurdex compared with a strategy of observation for the treatment of macular oedema (ME) following CRVO, and for BRVO patients with macular haemorrhage (BRVO-MH) or who have failed prior laser treatment (BRVO-PL). The analysis was performed from a UK NHS perspective. **METHODS:** A cost-utility model was developed to estimate the lifetime costs and effects of Ozurdex compared with observation in patients with CRVO, BRVO-MH and BRVO-PL based on the GENEVA 008 and GENEVA 009 studies. Patients in the model could move between six BCVA defined health states (best corrected visual acuity) based on the number of letters read correctly on the Early Treatment of Diabetic Retinopathy Study (ETDRS) chart. Cost data were obtained from literature and NHS reference costs. Utility values ranged between 0.599 and 0.862 and were derived from a preference-based scoring algorithm, the Visual Function Questionnaire Utility Index (VFQ-UI), valued by members of the general population using time-trade off (TTO). **RESULTS:** Ozurdex was shown to be cost-effective relative to observation with ICERs of £16,522, £17,741 and £6,361 for patients with CRVO, BRVO-MH and BRVO-PL respectively. One-way sensitivity analysis demonstrated that the proportion of patients affected in the baseline defined worse-seeing eye was a key driver of cost-effectiveness. Probabilistic sensitivity analysis demonstrated that at a threshold of £30,000, Ozurdex was a cost effective option in 85.2% of simulations for CRVO, 82.1% of simulations for BRVO-MH and 98.2% of simulations for BRVO-PL. **CONCLUSIONS:** Ozurdex is a cost-effective treatment option from a UK NHS perspective for macular oedema secondary to CRVO, BRVO-MH and BRVO-PL.

PSS26

THE USE OF A MIXED-TREATMENT COMPARISON TO ASSESS THE COST-EFFECTIVENESS OF OZURDEX® (DEXAMETHASONE INTRAVITREAL IMPLANT IN APPLICATOR) COMPARED WITH BEVACIZUMAB INTRAVITREAL INJECTIONS FOR PATIENTS WITH MACULAR OEDEMA FOLLOWING BRANCH RETINAL VEIN OCCLUSION

Almond C[1], Hayward E[2], Freemantle N[3], Brereton NJ[1]
[1]BresMed Health Solutions, Sheffield, South Yorkshire, UK, [2]Allergan UK, Marlow, Buckinghamshire, UK, [3]University College London, London, Hampstead, UK

OBJECTIVES: Ozurdex (dexamethasone 700 μg intravitreal implant in applicator) was the first licensed pharmacotherapy for macular oedema following branch retinal vein occlusion (BRVO) in the UK; however unlicenced use of Bevacizumab given by intravitreal injection was considered a potential comparator for economic evaluation. No head to head RCTs exist to compare outcomes; a mixed treatment comparison (MTC) was performed to synthesise available data. **METHODS:** A lifetime cost-utility model was produced with a treatment period of up to 3 years. Patients received an average of 9.96 bevacizumab or 2.24 Ozurdex treatments, 75% of which were costed based on a day case setting. Efficacy was measured in terms of letters gained on the Early Treatment of Diabetic Retinopathy Study (ETDRS) chart. This was estimated from an MTC where the network of evidence included comparisons of Ozurdex versus observation, observation versus grid laser and grid laser versus bevacizumab. QALYs were calculated from the letters gained using a coefficient obtained from regression analysis predicting the Visual Function Questionnaire Utility Index (VFQ-UI) score from BCVA. Differences in AE profiles were accounted for within the analysis. **RESULTS:** The day 180 results of the MTC indicated a difference (p=ns) in BCVA of 1.74 letters (95% CI -9.57 to 6.19) favouring bevacizumab; MTC Results at day 60 show this trend to be reversed. The analysis also demonstrated that an Ozurdex based regimen is less costly than a bevacizumab regimen making the ICER difficult to interpret. Therefore net monetary benefit (NMB) was calculated to demonstrate an NMB of Ozurdex vs. bevacizumab (based on day 180 results) of £2,228 at a willingness to pay per QALY of £20,000, robust to sensitivity analyses. **CONCLUSIONS:** The results of this analysis indicate that Ozurdex is a cost-effective treatment for macular oedema following BRVO when compared with bevacizumab, from a UK NHS perspective.

PSS27

WE TREAT EYES, NOT PEOPLE: THE SYSTEMATIC OVERESTIMATIONS OF UTILITY IN AGE-RELATED MACULAR DEGENERATION MODELS

Visser MS[1], Amarakoon S[2], Missotten T[2], Busschbach J[1]
[1]Erasmus University Medical Center, Rotterdam, The Netherlands, [2]Rotterdam Ophthalmic Institute, Rotterdam, Zuid-Holland, The Netherlands

OBJECTIVES: Cost-effectiveness models in age-related macular degeneration use the utilities based on the better-seeing eye, because this mainly influence quality of life. Most models use the utility as if we only treat better-seeing eyes, although in trials the majority of the treated eyes are the poorer-seeing eyes. This discrepancy results in overestimating the QALY. Therefore a correction should be applied. The objective of this study is to estimate the influence on the (incremental) cost-effec-

tiveness when correcting for the poorer-seeing eye. **METHODS:** An existing Markov model comparing three treatment frequencies of Bevacizumab (Avastin) is used, to investigate the effect of the correction of the poorer-seeing eye. We examined several scenarios of the poorer-seeing eye; no influence(0%), 10% and 20% influence of the utility of the better-seeing eye. In addition, it can be argued that treating the poorer-seeing eye has a preventive function, as it can become the future better-seeing eye. In the model a switch of the better-seeing eye is assumed after two and four years. **RESULTS:** By including the correction of the utility of the poorer-seeing eye the incremental cost-effectiveness ratio's (ICER) change from €5,260, €31,167 and €3,712, to respectively €10,375, €60,124 and €7,377 (20% influence). Lowering the influence from 20% to 0% has an effect of respectively, €13,706, €78,314 and €9,796. When inserting a switch at two and four years, the ICER reduces from €10,375, €60,124 and €7.377 to respectively €7,325, €53,649 and €4,848 at four years and almost half at 2 years. **CONCLUSIONS:** The results show that overestimating the QALY by excluding the poorer-seeing eye results in a lower incremental cost-effectiveness. Poorer-seeing eyes should be used when modeling eye-diseases. Whether the poorer-seeing eye contributes 20%, 10% or 0% has a small impact on the change in ICER's. The preventive function of treating the poorer-seeing eye should also be taken into account.

PSS28

ECONOMIC BURDEN OF ADVANCED MELANOMA: FINDINGS FROM A LARGE US HEALTH INSURANCE DATABASE

Oster G[1], Taneja C[1], Penrod JR[2], Yang AS[2], Edelsberg J[1]
[1]*Policy Analysis Inc. (PAI), Brookline, MA, USA,* [2]*Bristol-Myers Squibb, Plainsboro, NJ, USA*

OBJECTIVES: To assess the economic burden of unresectable or metastatic ("advanced") melanoma. **METHODS:** Using data from calendar years (CY) 2003-2008 from a large health insurance database and case-finding algorithms that we developed for use in such data, we identified all persons with Stage III unresectable or Stage IV melanoma at initial presentation, as well as those who presented with earlier-stage disease in prior years and progressed to advanced disease (i.e., recurrent cases). We tallied health care costs on an all-cause basis for all such persons alive for one or more day in CY2008. Health care costs were tallied by category of utilization (e.g., hospitalizations, outpatient visits, outpatient pharmacotherapy, etc.) as well as on an overall basis. Reimbursed amounts were used as a proxy for costs. **RESULTS:** We identified 1527 persons with advanced melanoma in CY2008 (Stage III unresectable, 267; Stage IV, 1260). Stage IV patients were more likely to be hospitalized during the year than those with Stage III disease (39% vs 26%, respectively; $p<0.01$). Mean (SD) total annual cost per patient was $42,848 ($66,279), and was higher for those with Stage IV versus Stage III unresectable disease ($45,786 vs $28,983; $p<0.01$). Outpatient services (including the cost of infused drugs) accounted for approximately 54% of total costs, while hospitalization and outpatient pharmacotherapy accounted for 37% and 9%, respectively. **CONCLUSIONS:** Our findings suggest that the economic burden of advanced melanoma is high, especially in patients with Stage IV disease.

PSS29

TREATMENT PATTERNS OF PSORIASIS PATIENTS AND TRENDS OVER TIME

Zhang F[1], Guerin A[2], Gauthier G[2], Day R[1], Khan Z[1]
[1]*Celgene Corporation, Summit, NJ, USA,* [2]*Analysis Group, Ltee., Montreal, QC, Canada*

OBJECTIVES: Several treatment options are available for psoriasis, an incurable dermatological condition, but there is limited information on actual treatment patterns. This retrospective study aimed to provide a snap shot of the use of psoriasis medications and recent trends over time in current clinical practice in psoriasis patients with co-morbid conditions. **METHODS:** Adult patients with ≥2 documented psoriasis diagnoses (ICD-9 codes: 696.1 were selected from a large US administrative claims database (2004-2008). The index date was defined as the latest date with a psoriasis diagnosis. Psoriasis treatments, including topical therapies, phototherapy, conventional systemic therapies, and biologics, were identified during the 6 months following the index date and described for the entire psoriasis population, a sub-group of obese patients (body mass index [BMI] ≥30), and stratified by index year to examine trends over time. **RESULTS:** A total of 106,128 psoriasis patients were selected. The mean age was 52±15 years and 52% were female. Overall, 62.3% of psoriasis patients were on topical therapies, 12.1% used biologics, 7.4% used other immunosuppressant agents, 5.6% used phototherapy and 27.2% were untreated. Over time, biologic use increased from 8.7% in 2004 to 21.0% in 2008, while the use of other treatments did not show this trend. In the sub-group of psoriasis patients with BMI information (N=1874; 646 obese and 1,228 non-obese), more obese patients were treated with biologics (20.0% vs. 15.0%) and other immunosuppressant agents (12.4% vs. 6.9%) than non-obese patients. **CONCLUSIONS:** The majority of psoriasis patients were treated with topical therapies. There has been an increase in the proportion of patients using biologics in the recent years. In addition, biologics and other immunosuppressant therapies were more likely to be used among obese patients.

Sensory Systems Disorders – Patient-Reported Outcomes & Preference-Based Studies

PSS30

ASSESSMENT OF UTILITY LOSS FROM DIABETIC MACULAR EDEMA BASED ON RESTORE TRIAL

Knudsen MS[1], Thomas S[2], Gallagher M[3], Mitchell P[4]
[1]*IMS Health, London, UK,* [2]*Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA,* [3]*Novartis Pharma AG, Basel, Switzerland,* [4]*University of Sydney, Westmead, Australia*

OBJECTIVES: Evidence is limited on the extent to which health state utility decrements differ between changes in the better-seeing and worse-seeing eyes following treatment. This study presents estimates of the utility levels as a function of the visual acuity in the treated eye stratified by the condition of the fellow (untreated) eye in patients treated for visual impairment caused by diabetic macular edema (DME). **METHODS:** Data from RESTORE clinical trial with (12 months follow up of ranibizumab treatment for DME) were analyzed. 8 health states were defined by BCVA in the treated eye. Mean utility was estimated using multivariate regression (repeated measures analysis). The regression was tested for confounders including disease severity. The influence of BCVA in the fellow eye on the health index was explored by separating treated eyes into cohorts according to visual acuity of the fellow eye: better, equal or worse. Results were compared with other published studies. **RESULTS:** The utility ranged from 0.86 (SE=0.014) with BCVA 76-100 letters (Snellen score) to 0.55 (SE=0.083) with BCVA 0-25 letters (unadjusted model). Disease severity had a non-significant effect on this range ($p>0.05$). BCVA of the worse seeing eye had a significant impact on the utility (utility decrement -0.11 from 76-100 letters to 36-45 letters), with better seeing eyes demonstrating a utility decrement -0.14 from 76-100 letters to 36-45 letters. Results were inconclusive for health states below 35 letters due to small numbers. **CONCLUSIONS:** This explorative analysis reveals that visual acuity of a worse seeing eye has a significant impact on utility and may be comparable to the impact on the better seeing eye. Importantly, these findings are supported by improvements in quality of life observed using the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) for DME patients treated with ranibizumab in the worse seeing eye in RESTORE.

PSS31

ASSOCIATION BETWEEN EQ-5D AND DERMATOLOGY LIFE QUALITY INDEX (DLQI) IN PATIENTS WITH CHRONIC HAND ECZEMA

Cortesi PA[1], Scalone L[1], De Pità O[2], Angelini G[3], Cristaudo A[4], Girolomoni G[5], Gola M[6], Ayala F[7], Cannavò SP[8], Satta R[9], Gallo R[10], Lisi P[11], Peserico A[12], Pigatto P[13], Mantovani LG[14], Belisari A[15], Giannetti A[16]
[1]*University of Milano - Bicocca, Monza, Italy,* [2]*Istituto Dermopatico dell'Immacolata (IDI)-IRCCS, Roma, Italy,* [3]*University of Bari, Bari, Italy,* [4]*Istituto Dermatologico San Gallicano IRCCS, Roma, Italy,* [5]*University of Verona, Verona, Italy,* [6]*University of Florence, Florence, Italy,* [7]*University Federico II of Naples, Napoli, Italy,* [8]*University of Messina, Messina, Italy,* [9]*University of Sassari, Sassari, Italy,* [10]*Di.S.E.M., University of Genoa, Genoa, Italy,* [11]*University of Perugia, Perugia, Italy,* [12]*University of Padua, Padua, Italy,* [13]*University of Milan, Milano, Italy,* [14]*Federico II University of Naples, Naples, Italy,* [15]*CHARTA Foundation, Milano, Italy,* [16]*University of Modena, Modena, Italy*

OBJECTIVES: HRQoL is often impaired in patients with skin diseases but it is often assessed with different instruments, generating data not directly comparable or not suitable to estimate utility. Assessing the association between HRQoL measures obtained with different instruments could be useful to obtain more complete data. The dermatology life quality index (DLQI) is a condition-specific questionnaire widely used to assess HRQoL in subjects with skin diseases. We aimed to estimate the association between EQ-5D VAS and utility score with the DLQI summary score (max 30 and min 0; higher score corresponds to more impaired quality of life) in patients with severe CHE and refractory to therapy with topical potent corticosteroids. **METHODS:** Within a naturalistic, multicentre cost-of-illness study; patients aged ≥18 years, consecutively accessing at the participating centres, completed the EQ-5D and DLQI questionnaires during the enrolment visit. Individual patient utility was estimated from EQ-5D responses using the standard UK scoring algorithm. A multivariable linear regression model was built to estimate the association between the EQ-5D VAS and utility score with the DLQI summary score, adjusted for age and gender. The bootstrap resampling was used to calculate standard errors and 95% confidence intervals. **RESULTS:** A total of 104 patients (mean age+SD=44.5+15.0, 39.4% male) were enrolled. DLQI mean+SD summary score was 11.3+6.3, EQ-5D VAS mean+SD=60.4+23.3 and EQ-5D utility mean+SD=0.50+0.31. EQ-5D VAS and utility showed a linear negative relationship with DLQI summary score. One point rise in DLQI was associated with a EQ-5D VAS decrease of 1.84 (SE=0.34; 95%CI=-2.52,-1.16; R2=0.261) and a utility index decrease of 0.025 (SE=0.005; 95%CI=-0.035,-0.014; R2=0.254) in utility. **CONCLUSIONS:** DLQI summary score is significantly associated with the EQ-5D VAS and utility index. Our results could be useful to derive EQ-5D information from DLQI data, to perform economic evaluations targeted to patients with severe CHE refractory to therapy with topical potent corticosteroids.

PSS32

IMPACT OF DRY EYE ON EVERYDAY LIFE (IDEEL) - SYMPTOM BOTHER: ESTIMATING CUT-OFF SCORES FOR DRY EYE SEVERITY GROUPS

Acaster S[1], Verboven Y[2], Begley C[3], Chalmers R[3], Abetz L[4], Thompson T[1]
[1]*Oxford Outcomes Ltd, an ICON Plc Company, Oxford, UK,* [2]*Alcon Research Ltd, Puurs, Belgium,* [3]*Indiana University, Bloomington, IN, USA,* [4]*Mapi Values Ltd, Bollington, Cheshire, UK*

OBJECTIVES: The aims of the study were to estimate score ranges associated with dry eye severity based on the Impact of Dry Eye on Everyday Life (IDEEL) Symptom Bother (SB) domain, and to evaluate the overall performance of the SB domain. **METHODS:** A total of 210 participants (130 dry eye patients, 32 Sjogren's patients and 48 controls) completed the IDEEL SB domain and reported their degree of dry eye severity on an ordinal response scale of none, mild, moderate or severe. Ordinal regression analysis using a proportional-odds model was used to provide SB cut-off score ranges associated with the highest probability of membership of each of the four individual response categories. ROC analysis was used to examine the specificity and sensitivity of the overall SB scale. **RESULTS:** Ordinal regression revealed SB to be a significant predictor of patient-reported dry eye severity ($\chi^2=225.59$, $p<0.001$). Examination of individual probabilities associated with each SB score revealed that the following score ranges were associated with the highest probability of membership of each dry eye category: None (0-16), Mild (17-38), Moderate (39-65), Severe (66+). ROC curve analysis revealed excellent performance of the SB

domain at differentiating adjacent dry eye categories across a range of probability cut-offs with the following Area Under the Curve (AUC) statistics resulting from 2000 stratified bootstrap replicates for each curve: None versus Mild (AUC=0.96, CI=0.90-0.98), Mild versus Moderate (AUC=0.74, CI=0.66-0.84) and Moderate versus. Severe (AUC=0.82, CI=0.74-0.90). **CONCLUSIONS:** The IDEEL SB domain provides a simple and effective basis for differentiating categories of patient-reported dry eye severity.

PSS33

ESTIMATION OF MEANINGFUL CHANGE ON THE SKINDEX-29 AND DERMATOLOGY LIFE QUALITY INDEX IN PATIENTS WITH CHRONIC HAND ECZEMA

Augustin M[1], Lloyd AJ[2], Purwins S[1], Diepgen TL[3]
[1]*University Clinics of Hamburg, Hamburg, Germany,* [2]*Oxford Outcomes, an ICON plc Company, Oxford , Oxon, UK,* [3]*University Heidelberg, Heidelberg, Germany*

OBJECTIVES: A key question when interpreting quality of life data is: which magnitude of change is clinically relevant? To document a minimal important difference (MID) for the Skindex-29 and Dermatology Life Quality Index (DLQI) in patients with chronic hand eczema. **METHODS:** Secondary psychometric analysis was undertaken on data from two cost-of-illness studies in Germany (N=310). Patients completed the Skindex-29 and DLQI. The Skindex-29 is summarised into domains measuring symptoms, emotions, and functioning, plus a total score. DLQI (10-items) is assessed as a total score. MID was assessed using statistical methods including standard error of measurement (SEM) and ½ standard deviation (½SD). Internal consistency was also estimated in order to support estimation of the SEM. Estimates were benchmarked against existing values. **RESULTS:** Internal consistency for Skindex dimensions (symptoms α=0.834; emotions α=0.910; function α=0.934) and DLQI (α=0.835) was confirmed. The MID estimated for DLQI was (SEM=2.04, ½SD = 2.53); and for Skindex-29 was symptoms (SEM=8.16, ½SD = 10.01); emotion (SEM=6.80, ½SD = 11.34); function (SEM=5.53, ½SD = 10.77) and total score (SEM=4.13, ½SD = 9.51). **CONCLUSIONS:** The study confirms good internal consistency properties of the Skindex-29 and DLQI in patients with chronic hand eczema and demonstrates the MID for this measure. The DLQI MID based on SEM method is close to a recent report in a Danish study of hand eczema patients using an anchor-based approach which established the DLQI MID at 2.0 (Hald et al., 2011). The DLQI MID for other skin diseases has previously been proposed to range from 2.3 to 5.7 in stable plaque psoriasis (Shikiar et al., 2006) and of 2.24 to 3.10 in chronic idiopathic urticaria (Shikiar et al., 2005) which is consistent with current estimates.

PSS34

QUALITATIVE GROUNDING FOR A NEW PATIENT ASSESSMENT MEASURE IN OPHTHALMOLOGY: THE FUNCTIONAL ASSESSMENT OF VISUAL TASKS (VISTAS)

Atkinson MJ[1], Tally S[1], Heichel CW[2], Kozak I[2]
[1]*University of California, San Diego (UCSD), San Diego, CA, USA,* [2]*Shiley Eye Center, University of California San Diego, La Jolla, CA, USA*

OBJECTIVES: Patients' ability to perform vision-dependent tasks is essential to daily function and quality of life. Visual function measures do not typically assess both corrected and uncorrected function and lack an intermediate visual range scale. To address these limitations, the current qualitative study identifies the preliminary content and item pool for a future measure (Functional Assessment of Visual Tasks - VISTAS). **METHODS:** Ophthalmology patients (n=72) with mild to severe myopia, hyperopia, presbyopia, astigmatism, cataracts and glaucoma participated in a variety of qualitative studies (life event journaling, interviews, on-line and face-to-face focus groups). The objective of these studies was to identify and thematically group meaningful visual tasks occurring in the near, intermediate and distance visual ranges. The journal entries and transcripts were thematically coded and organized into related domains of life function. **RESULTS:** Some task groupings were comprised of activities that occur predominantly within the distance visual range. These groupings included; mobility (ambulation), driving, leisure and sports, and social functioning. Some task groupings relied more heavily on the predominantly near and intermediate visual ranges. These groupings included; technology use and activities of daily living. Other task groupings were heterogeneous in terms of visual ranges required for their performance. **CONCLUSIONS:** Participants identified a wide variety of distance-specific visual tasks that impacted the quality of their lives. These included tasks related to their physical safety as well as to functioning at home and in the workplace. The thematic analysis provided a rich body of information with which to design items to assess important functional dimensions that are made more difficult by visual impairment. The measurement properties of this pool of candidate items were evaluated in clinical samples as a part of two larger psychometric validation studies.

PSS35

VALIDATION OF THE EIGHTEEN ITEM FUNCTIONAL ASSESSMENT OF VISUAL TASKS (VISTAS-18) USING A NEW LENS PRESCRIPTION METHODOLOGY

Atkinson MJ[1], Tally S[1], Kozak I[2], Heichel CW[2], Kulischak J[3]
[1]*University of California, San Diego (UCSD), San Diego, CA, USA,* [2]*University of California, San Diego (UCSD), La Jolla, CA, USA,* [3]*Shiley Eye Center, University of California San Diego, La Jolla, CA, USA*

OBJECTIVES: To psychometrically evaluate the VISTAS item pool and develop four new distance-specific visual function scales (VISTAS-18). **METHODS:** Study participants (n=139) were recruited from those attending an optometry clinic to change an existing eyeglass prescription. Sampling was balanced across myopic, hyperopic, presbyopic, and astigmatic conditions. Four VISTAS-18 Function Scales (Near, Intermediate, Extended-Intermediate and Distant Function) were identified and refined using PCA factor analysis with oblique rotation. Lens prescription data and visual acuity assessments in the near, intermediate and distant ranges were used to provide concurrent criterion-related validity to the new scales. **RESULTS:** Participants' mean age was 50.7 years (SD 15.0) and was roughly balanced by gender (f:m 4:3). Astigmatism (97/139), Presbyopia (92/139), Myopia (88/139), Hyperopia (43/139), and Cataracts (28/139) were the most common causes of poor vision. Factor analysis revealed three and four-factor solutions that explained over 80% of the variance in task difficulty. The VISTAS-18 Function Scales were internally consistent (Cronbach's Alpha = 0.89 - 0.96) with normally distributed uncorrected task difficulty scores and floor effects associated with corrected ratings. Moderate correlations were observed between the uncorrected VISTAS-18 Function Scales scores and both the logMAR visual acuity (r2 = 0.41 - 0.63) and temporary lens strength (r2 = 0.30 - 0.66). With one exception, the correlations between change in lens strength and change in VISTAS-18 Function Scale scores were all significant. **CONCLUSIONS:** This study provides initial structural and criterion-related validity for the 4 VISTAS-18 Function Scales. The VISTAS-18 Function Scales responded linearly across the range of both visual acuity and corrective lens strength in each distance range. Despite the small numbers of evaluable cases, three of the VISTAS scales were responsive to relatively minor adjustments in lens strength in the near, intermediate and distant visual ranges.

PSS36

DEMONSTRATING CONCEPTUAL EQUIVALENCE: TRANSLATION OF THE CU-Q2OL FROM ITALIAN INTO ENGLISH

Arnold BJ[1], Baiardini I[2], Parks-Vernizzi E[1], Zazzali JL[3]
[1]*FACITtrans, Elmhurst, IL, USA,* [2]*University of Genoa, Genoa, Italy,* [3]*Genentech, Inc., South San Francisco, CA, USA*

OBJECTIVES: Translation and linguistic validation of patient reported outcomes (PRO) measures is an essential component of research methodology in preparation for multinational research studies. The Chronic Urticaria Quality of Life questionnaire (CU-Q2oL) is a disease specific tool developed in Italian to assess chronic urticaria from the patient's viewpoint. The objective of this work wasto translate and linguistically validate the CU-Q2oL from Italian to English for use in the US. **METHODS:** The CU-Q2oL was translated into English according to industry standard methodology. After the translation was completed, five patients completed the translated questionnaire and participated in a cognitive debriefing interview. Interviews were conducted using a standardized guide to assess the relevance, understandability, and appropriateness of the translations. Qualitative analyses were performed to ensure equivalence and that the content validity of the CU-Q2oL was maintained for the English version. **RESULTS:** The study sample consisted of 5 patients diagnosed with chronic idiopathic urticaria (80% male). Mean age of the patients was 39 years. The sample consisted of English speaking patients in the US. All CU-Q2oL items were well understood and proved relevant to the patients in this sample. Of interest, terms such as, "hives", and "swelling of the eyes" were clearly understood as intended. **CONCLUSIONS:** The results indicate that the English version of the CU-Q2oL translation is conceptually equivalent to the Italian source version and easily understood by the target population in the United States. We consider the translation to be acceptable for PRO assessment in research and clinical practice. Future research could include testing of the questionnaire with patients in other English-speaking countries to confirm its acceptability beyond the US.

PSS37

THE CLINICAL AND ECONOMIC BURDEN OF ACUTE OTITIS MEDIA: A LARGE PROSPECTIVE OBSERVATIONAL COHORT STUDY IN EUROPE

Liese JG[1], Giaquinto C[2], Silfverdal SA[3], Carmona A[4], Larcombe J[5], Garcia-Sicilia J[6], Fuat A[7], Muñoz Hiraldo E[8], Arroba Basanta ML[9], Vollmar J[10], Holl K[11], Delgleize E[11], Knerer G[12], Pirçon JY[11], Rosenlund M[11]
[1]*University Children's Hospital, Würzburg, Germany,* [2]*University of Padova, Padova, Italy,* [3]*Umeå University, Umeå, Sweden,* [4]*Instituto Hispalense de Pediatria, Sevilla, Spain,* [5]*Harbinson House Surgery and University of Durham, Durham, UK,* [6]*Hospital Materno-Infantil Universitario La Paz, Madrid, Spain,* [7]*Carmel Medical Practice (Darlington) and University of Durham, Durham, UK,* [8]*Health Centre Dr Castroviejo, Madrid, Spain,* [9]*Universidad Autónoma de Madrid, Madrid, Spain,* [10]*GlaxoSmithKline & CO. K. G., Munich, Germany,* [11]*GlaxoSmithKline Biologicals, Wavre, Belgium,* [12]*GlaxoSmithKline Biologicals, Wavre , Belgium*

OBJECTIVES: Acute otitis media (AOM) is one of the commonest paediatric bacterial infections, often requiring general practitioner/paediatrician consultation and antibiotic prescription. AOM management guidelines differ between countries. We aimed to prospectively assess the incidence and economic burden of AOM across five European countries. **METHODS:** A large, prospective, observational cohort study was conducted to investigate AOM incidence in Europe, gathering information on clinical symptoms, treatment and quality-of-life. A total of 5882 healthy children aged <6 years were enrolled from 73 medical practices in Germany, Italy, Spain, Sweden and the UK. A patient reported outcome (PRO) questionnaire was distributed to parents to assess costs associated with medically diagnosed AOM. Assessment included direct medical costs (e.g. medication/physician consultations/hospitalisations), direct non-medical costs (e.g. transportation/baby-sitting), and indirect costs (e.g. absence from work/school). **RESULTS:** Of 1419 AOM episodes recorded in 1113/5882 children, 91.1% had a questionnaire available. Medication (any) was taken for 58.8% of episodes, but the proportion varied between countries (Spain: 14.8%; Germany: 33.2%; Italy: 93.8%; UK: 94.6%; Sweden: 95.7%). The child missed day-care/school in 48.9% of episodes (median hours missed: 18); the caregiver missed work in 17.1% of episodes (median hours missed: 16). Hospitalisation rates were similar across countries (≤1.0%). The mean total cost/episode ranged between €24.16 (Spain) and €306.09 (Sweden). Mean direct medical costs

ranged between €9.44 (UK) and €121.17 (Sweden); mean direct non-medical costs were ≤€2.85/episode. Indirect costs contributed significantly to the total cost/episode in Italy (81.4%; €91.14), UK (79.8%; €37.55), Germany (60.0%; €26.74) and Sweden (59.5%; €182.07), whereas indirect costs contributed only 14.7% (€3.54) in Spain, where the value associated with absence from work/school was low. **CONCLUSIONS:** AOM was associated with substantial economic burden in these European countries. The cost per episode and the contribution of direct/indirect costs varied between countries, potentially reflecting socio-economic differences and variation in AOM management.

PSS38

3-D STUDY - DESCRIPTION OF THE CARE OF THE DENTAL PAIN

Wierzba C[1], Auges M[2], Watt M[3], Taieb C[2]
[1]*Dentist, PARIS, France,* [2]*PFSA, Boulogne Billancourt, France,* [3]*PFOC, Castres, France*

OBJECTIVES: Highlight the action of two analgesics combining paracetamol and codeine (Klipal 600® and EfferalganDafalgan Codeine®), with a minimum of 50 mg of codeine at a time. **METHODS:** Multicentre, longitudinal, prospective, observational study, performed in metropolitan France from data collected by the dental surgeons that have accepted to participate in it. **RESULTS:** A total of 105 patients were included. Klipal 600® was prescribed for 76 of them versus 24 for the other group. 56.2% of the patients are women. The average age is 45.57 + 14.64. The measurement of the average pain intensity, evaluated each day over a 6 day period by a VAS, shows an insignificant difference at the inclusion between the 2 groups ($p = 0.23$). But, contrary to the Efferalgan/Dafalgan codeine® group, the score differential for the pain intensity is statistically significant between Day 1 and Day 2 with the Klipal 600® group and the improvement is significant up to the fourth day. The pain qualification was evaluated by the Saint Antoine pain questionnaire (abbreviated format) bearing on 16 sensory and emotional qualifiers specifying the description of the pain experienced. The difference is not significant between the 2 groups at the inclusion ($p = 0.09$), then it is observed that the pain qualification score is reduced beginning on the second day for the 2 groups. For the 2 groups, it is observed that the average number of tablets is in the order of 2.3 during the first 48 hours with a similar progressive decrease up to the sixth day. The prescription of one tablet at a time for the Klipal® is an advantage for the follow up of the treatment and its effectiveness. **CONCLUSIONS:** In reality, this study demonstrates a quicker improvement in pain in the Klipal® group, also associated with reduced consumption of the treatment and a better effectiveness.

PSS39

ASSESSMENT OF THE HEALTH STATUS USING THE 12-ITEM MEDICAL OUTCOMES STUDY SHORT FORM (SF-12) QUESTIONNAIRE (2578 DERMATOLOGICAL OUT-PATIENTS)

Tabolli S, Pagliarello C, Paradisi A, Spagnoli A, Sampogna F, Abeni D
IDI IRCCS, Rome, Italy

OBJECTIVES: To assess whether the SF-12 questionnaire could yield a valid description of the health status of a large number of dermatological out-patients. **METHODS:** The SF-12 and the 12-item General Health Questionnaire (GHQ-12) were utilized. Questionnaires were self-completed by the out-patients in the waiting rooms of a dermatological hospital. At the end of the visit the dermatologists recorded the diagnosis and the evaluation of the clinical severity. **RESULTS:** Data were complete for 2.578 patients. We observed a reduction in the Physical Component Summary score (PCS-12) with increasing age, while the Mental Component Summary score (MCS-12) was stable. PCS-12 and MCS-12 scores were worse in women. For the MCS-12 scores, the lowest mean values were seen in the group of patients with dermatitis, and were dramatically lower in almost all the diseases observed compared to the scores reported for non-dermatological conditions and to the normative values. 23% of patients were identified as GHQ-12 positive. GHQ-12 positives had lower PCS-12 and MCS-12 scores compared to GHQ-12 negatives (mean values, PCS: 48.3±4.8 vs. 44.5±6.5; MCS: 43.9±6.7 vs. 39.4±7.0, respectively). PCS-12 and the MCS-12 mean values were lower for GHQ-12 "cases" in all diseases, independently from the level of clinical severity of the disease. **CONCLUSIONS:** The impact of the dermatological diseases is dramatically high for the mental components of the health status; the mean values of MCS-12 were very low, and when compared to other relevant conditions only tumours and nervous system diseases showed lower values. The use of the generic SF-12 and GHQ-12 questionnaires allowed to have a clear picture of the health status of dermatological patients, to compare different diseases within the dermatological specialty, and to make comparisons between skin conditions and other non-dermatological diseases.

PSS40

THE EFFECT OF ACUTE OTITIS MEDIA IN CHILDREN ON PARENTS' QUALITY OF LIFE: DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE IMPLEMENTED IN A PROSPECTIVE OBSERVATIONAL COHORT STUDY IN EUROPE

Liese JG[1], Giaquinto C[2], Silfverdal SA[3], Carmona A[4], Larcombe J[5], Garcia-sicilia J[6], Fuat A[7], Muñoz Hiraldo E[8], Arroba basanta ML[9], Sloesen B[10], Vollmar J[11], Holl K[10], Pirçon JY[10], Rosenlund M[10]
[1]*University Children's Hospital, Würzburg, Germany,* [2]*University of Padova, Padova, Italy,* [3]*Umeå University, Umeå, Sweden,* [4]*Instituto Hispalense de Pediatria, Sevilla, Spain,* [5]*Harbinson House Surgery (Sedgefield) and University of Durham, Durham, UK,* [6]*Hospital Materno-Infantil Universitario La Paz, Madrid, Spain,* [7]*Carmel Medical Practice (Darlington) and University of Durham, Durham, UK,* [8]*Health Centre Dr Castroviejo, Madrid, Spain,* [9]*Universidad Autónoma de Madrid, Madrid, Spain,* [10]*GlaxoSmithKline Biologicals, Wavre, Belgium,* [11]*GlaxoSmithKline GmbH & Co. K.G., Munich, Germany*

OBJECTIVES: Acute otitis media (AOM) is one of the commonest paediatric bacterial infections and is often recurrent. AOM may impact upon parents' quality of life (QoL), but there are currently no validated tools devoted specifically to measuring this impact. **METHODS:** An AOM-specific questionnaire was developed, based on a published questionnaire measuring the effect of children's recurrent ear, nose and throat infections on parents' QoL. Fourteen AOM-related questions were grouped into three scores: emotional score (ES; eight items), daily disturbance score (DDS; six items) and total score (TS; 14 items). A fifteenth generic question assessed overall quality of life (global score; GS). Responses were measured using a five-point Likert scale; higher scores indicate greater impact on QoL. Validation of the questionnaire followed a standard procedure for QoL tools, with multitrait analyses and internal consistency reliability using Cronbach's alpha. The tool was applied in a large, prospective, observational cohort study including 5882 healthy children aged <6 years enrolled from 73 medical practices in Germany, Italy, Spain, Sweden and the UK, 1113 of whom experienced a total of 1419 AOM episodes during follow-up. **RESULTS:** The questionnaire was completed for 1063 episodes (75%). The item convergent and discriminant validity criteria were met successfully. The homogeneity and satisfactory consistency of the GS showed correlations between 0.4 and 0.6 for 12 items. The internal consistency reliability of the questionnaire was assessed as "good" or "excellent". All scores had a mean around 30/100 (ES: 30.49 [SD: 20.30]; DDS: 29.35 [SD: 21.99]; TS: 30.00 [SD: 19.37]; GS: 30.02 [SD: 26.24]) and increased significantly with AOM severity, assessed by parents using a faces scale tool (AOM-FS). **CONCLUSIONS:** An AOM-specific parental QoL questionnaire was successfully developed and validated, demonstrating good performance across five European countries. Correlation was observed between AOM severity and QoL scores.

PSS41

IMPACT ON QUALITY OF PATIENTS WITH ACTIVE AND INACTIVE PSORIASIS IN SPAIN

Dauden E[1], Herrera E[2], Puig L[3], Sánchez-Carazo JL[4], Toribio J[5], Caloto MT[6], Nocea G[6]
[1]*Hospital Universitario La Princesa, Madrid, Spain,* [2]*Hospital Universitario Virgen de la Victoria, Malaga, Spain,* [3]*Hospital de la Santa Creu i Sant Pau, Barcelona, Spain,* [4]*Hospital General Universitario de Valencia, Valencia, Spain,* [5]*CHU Santiago; Hospital Gil Casares, Santiago de Compostela, Galicia, Spain,* [6]*MSD Spain, Madrid, Spain*

OBJECTIVES: Estimate the impact of psoriasis on quality of life of patients according to clinical features of the disease. **METHODS:** Patients ≥18 years with a diagnosis of plaque psoriasis. Variables: demographic and clinical data, health status perceived by the patient and quality of life (QoL) questionnaires specific for psoriasis: PDI (15 items with 4 response options, and overall result from 0=minimal impact to 45=maximum impact) and PSO-LIFE (20 items, with a timeframe of 7 days, are answered on a 5-point Likert scale (from "Always" to "Never") and the overall result ranging from 0= maximum impact to 100=minimal impact). **RESULTS:** A total of 304 patients were included (182 with active-psoriasis and 122 with inactive-psoriasis), mean age 44 (SD=15) years and 56% men. The mean time from psoriasis diagnosis was 18 years (SD=12), the mean weight 76 (SD=16.5) kg, the PASI index was 17 (SD=7.4) for active-psoriasis and 5.6 (SD=5.3) for inactive-psoriasis; 47% of active-psoriasis and 7.5% of inactive-psoriasis patients reported their overall health status as being "rather", "quite" or "very" poor. Two questionnaires show a poorer QoL in patients with active-psoriasis compared with those with inactive-psoriasis: PDI of 8.3 (SD=8.1) against 3.6 (SD=5.5), and PSO-LIFE 57.4 (SD=20.4) versus 76.4 (SD=20.6) respectively. There is a correlation between PASI and PSO-LIFE score ($r=-0.43$;$p<0.01$) and patients with visible affected areas such as head or upper limbs showed greater impact in QoL (63;SD=22) compared with trunk and lower limbs (74.8,SD=24) or patients not affected at the time of inclusion in the study (78.5;SD=21.6). After adjusting by age, education and duration of the last psoriasis episode, there are significant differences in PSO-LIFE scores between patients with active and inactive psoriasis ($p<0.01$). **CONCLUSIONS:** The quality of life in patients with psoriasis is affected especially in patients with active psoriasis and in patients with localized lesions in visible areas.

PSS42

EVALUATION OF THE IMPACT OF WRITING EXERCISES AND EDUCATIONAL INTERVENTIONS ON QUALITY OF LIFE IN PATIENTS WITH PSORIASIS

Tabolli S[1], Pagliarello C[1], Sampogna F[1], Di Pietro C[1], Abeni D[1], Centro Studi GISED I[2]
[1]*IDI IRCCS, Rome, Italy,* [2]*Centro Studi GISED, BERGAMO, Italy*

OBJECTIVES: To test the efficacy an "emotional writing" exercises to improve quality of life of patients with psoriasis undergoing systemic treatments. **METHODS:** This study was designed as a controlled randomized intervention. Seven Clinical centers in Italy were involved. The intervention group (n = 100) wrote about the most stressful event in their life for three sessions of 20 minutes each. The Control group (n = 100) received only the educational materials that were also given to the intervention group. The recruitment time was twelve months, and the follow-up time was also 12 months. The SF-12, GHQ-12, Skindex_29, and PASI scores were evaluated at baseline and after 1, 6, and 12 months. Data were analyzed using Generalized Estimating Equations model. **RESULTS:** Ninety-seven patients were allocated to the Writing group and 105 to the Control group. forty-two patients of the first group and 49 of the control group reached the 12-mont follow-up visit. Data were consistent with the expected improvement after the start of treatment as observed at the different follow-up times: the severity of psoriasis decreased, the impact of psoriasis on quality of life decreased, and the health status improved both for the physical and mental components.The proportion of patients reaching PASI-50 (i.e., a reduction of 50% in the PASI score) observed at different follow-up times was similar in the two study groups and was not associated with any of the examined demographic variables. No advantage was observed for the intervention group also in terms of QoL and general health status. **CONCLUSIONS:** The longitudinal analysis did not prove relevant differences between the group receiving ed-

ucational materials and doing the writing exercise compared to the group receiving only educational materials.

PSS43

A SYSTEMATIC REVIEW OF OBSERVATIONAL STUDIES OF PATIENTS WITH OCULAR HYPERTENSION OR GLAUCOMA RECEIVING LONG TERM TOPICAL EYE THERAPIES

Christova L[1], Cottrell S[1], Mudge M[1], Tilden D[1], Harvey C[2]
[1]*THEMA Consulting Pty Ltd, Pyrmont, NSW, Australia,* [2]*Merck Sharp & Dohme (Australia) Pty Limited, North Ryde, NSW, Australia*

OBJECTIVES: To systematically evaluate evidence for the detrimental impact of long-term therapy with preservative containing topical antiglaucoma treatments (P) in patients/subjects with glaucoma or ocular hypertension (OH) **METHODS:** Systematic review and qualitative synthesis of observational studies comparing the use of P and preservative-free (PF) treatments in patients/subjects with glaucoma or OH. **RESULTS:** Eleven studies met review inclusion criteria. Studies differed considerably in terms of design (cross sectional, case control, before-after), treatments recieved (nature and number of anti-glaucoma agents received, different nature and/or concentration of preservative) and duration of follow-up. Reported outcomes variously included subjective ocular symptoms, clinical measures of lacrymal function, sub-clinical markers of ocular surface change or inflammation and vision related quality of life (QoL). There were no reports of generic measures of QoL or long-term sequelae, e.g. requirement/ success of glaucoma-related surgery. The disparity of the studies meant that data were not amenable to statistical pooling. However, qualitatively, the studies provide a body of evidence which may support an association between the long-term use of P and an increase in subjective symptoms and clinical and sub clinical signs that are suggestive of damage to the ocular surface. The most common apparent side effect reported is dry-eye which directly affects vision related QoL. The expression of symptoms and signs of toxicity appear to be dose dependant and reversible when exposure to preservative is reduced or discontinued. However, the studies cannot exclude other contributory factors that may be inherent in topical therapy per se, e.g., the toxicity of the active agent itself and/or cumulative physical effects of administration. **CONCLUSIONS:** The findings suggest that the preservatives included in some topical antiglaucoma treatments may at least contribute to observed changes to the ocular surface, impairment of lachrymal function and more subjective symptoms experienced by patients.

PSS44

USING STRUCTURAL EQUATION MODELING TO INVESTIGATE THE ASSOCIATION OF TREATMENT SATISFACTION WITH DISEASE SEVERITY AND HEALTH RELATED QUALITY OF LIFE

Umar N[1], Schaarschmidt ML[1], Schmieder A[1], Peitsch WK[1], Terris D[2]
[1]*Heidelberg University, Mannheim, Baden-Württember, Germany,* [2]*University of Georgia, Athens, GA, USA*

OBJECTIVES: The assessment of patients' treatment satisfaction in psoriasis treatment has been undermined by the lack of consensus regarding its conceptualization as a measure of treatment success. Our objective is to use structural equation modeling to test a conceptual model of association between treatment satisfaction, disease severity and health related quality of life (HRQoL). **METHODS:** Participants completed the Treatment Satisfaction Questionnaire for Medication (TSQM) and the Dermatology Quality of Life Index (DLQI) at the initial study visit (t1) at 3-month (t2) and at 6-month (t3) follow-up visits. The Psoriasis Area and Severity Index (PASI) was similarly assessed at t1, t2 and t3. We used structural equation modeling to simultaneously investigate the association of TSQM with DLQI and PASI. **RESULTS:** In separate models, ΔTSQM was significantly associated with ΔPASI (β = -0.21, P = 0.01), and ΔDLQI (β = -0.66, P < 0.001), while ΔPASI was significantly associated with ΔDLQI (β =0.18, P = 0.041). In the simultaneous model, that included ΔPASI, ΔDLQI and ΔTSQM, the significant association between PASI and DLQI diminished (β= 0.04, P = 0.56). This pattern suggested that ΔTSQM mediate the association between ΔPASI and ΔDLQI. **CONCLUSIONS:** Treatment satisfaction mediates the relationship between disease severity and HRQoL in patients with moderate-to-severe psoriasis. Using treatment satisfaction as a measure of therapeutic success may be important in both clinical trials and in routine management of psoriasis. Understanding this association may also assist physicians to identify factors they can modify to improve treatment satisfaction and adherence thus, the efficiency of psoriasis treatment.

PSS45

TREATMENT PATTERNS, TREATMENT SATISFACTION, DISEASE SEVERITY AND QUALITY OF LIFE IN PATIENTS WITH PSORIASIS IN DENMARK, FINLAND, AND SWEDEN

Ragnarson tennvall G[1], Hjortsberg C[1], Bjarnason A[2], Gniadecki R[3], Heikkilä H[4], Jemec GBE[5], Kragballe K[6], Miller IM[5], Svensson A[7]
[1]*IHE, The Swedish Institute for Health Economics, Lund, Sweden,* [2]*Sahlgrenska University Hospital, Gothenburg, Sweden,* [3]*University of Copenhagen, Bispebjerg Hospital, Copenhagen, Denmark,* [4]*University Hospital of Helsinki, Helsinki, Finland,* [5]*Roskilde Hospital, Roskilde, Denmark,* [6]*Aarhus University Hospital, Aarhus, Denmark,* [7]*Skåne University Hospital, Malmö, Sweden*

OBJECTIVES: The aim of the study was to investigate health related quality of life (HRQoL), disease severity and treatment satisfaction in patients with psoriasis from three Nordic countries and to analyse how these measures vary across different treatment groups. **METHODS:** The study is based on data from patient surveys and retrospective chart reviews of psoriasis patients in Denmark, Finland, and Sweden. Information about HRQoL (EQ-5D and EQ-VAS), Dermatology Life Quality Index (DLQI), disease severity, and treatment satisfaction was collected from patient questionnaires. Patient characteristics and type of treatment were collected from patient records. Patients were categorised according to the most advanced psoriasis drug treatment received during the last 12 months: emollients, topical steroids, systemic but not biological drugs, or biological drugs. **RESULTS:** Six centres included 404 patients, 64% were men and the mean age was 51 years. The majority of the patients (76%) had plaque psoriasis. During the last 12 months, 13% had used only emollients, 33% topical corticosteroids, 28% systemic drugs, and 26% were treated with biological drugs during part of or during the whole period. Mean HRQoL according to EQ-5D was 0.75, EQ-VAS 73 and DLQI 6.2. Patients who had not been treated with biological drugs rated their present condition and disease as severe or very severe more frequently than those who were treated with biological drugs during part of or during the whole period. At the time of the survey 70% in the group treated with biologic drugs indicated that the disease had no or small effect on their life and they experienced a higher degree of treatment satisfaction than patients in the other groups. **CONCLUSIONS:** Biological treatment is associated with fewer psoriasis related problems and better treatment satisfaction. Patients treated with only emollients had the lowest treatment satisfaction.

PSS46

AVAILABILITY OF RESOURCES FOR PATIENTS WITH WET AGE-RELATED MACULAR DEGENERATION: OPTIMAL STUDY

Balañá M[1], Lahoz R[1], Casaroli-marano RP[2], Roura M[1]
[1]*Novartis Farmacéutica, S.A., Barcelona, Spain,* [2]*Institut Clínic d'Oftalmologia, Hospital Clínic de Barcelona, Barcelona, Spain*

OBJECTIVES: The aim of this study was to assess the availability of resources for patients with wet age-related macular degeneration (wAMD) in current clinical practice. **METHODS:** Observational, cross-sectional and multicenter study. Eligible subjects were ≥18 years old, with primary/secondary active subfoveal AMD-related choroidal neovascularization (CNV) diagnosed 12-18 months prior to inclusion study. Demographics and resources management (medical visits, treatment time, number/type of specialists, working tools) data were analyzed. **RESULTS:** 266 patients were included (39 centers involved).The median age (Q1-Q3) was 77.0 (71.0-82.0) years, 55.6% were women. Investigators visited weekly 20.0 (10.0-50.0) patients with wAMD, 10.0 (10.0-25.0) new patients. At present, 100.0 (45.0-250.0) were under treatment provided mainly in operating rooms (61.5%). Centers only have accessible 1.0 (1.0-2.0) operating rooms being available for treatment 2.0 (2.0-5.0) days per week. In most cases (74.4%) operating rooms were located in different floors/buildings from ophthalmology services. Waiting time until visit starts was 40.0 (30.0-60.0) minutes and duration of treatment administration was 20.0 (15.0-50.0) minutes. Time between visit request until medical visit was 20.0 (15.0- 30.0) days, and from diagnosis to treatment 7.0 (5.0-10.0) days. Staff working in ophthalmology departments was mainly: retinologist [3.0 (2.0-5.0) per center], ophthalmologists [2.5 (1.1-5.0)], fellows [2.2 (1.0-3.0)], nurses [1.5 (1.0-3.0)], optometrists [1.5 (1.0-3.0)] and administrative staff [1.0 (1.0-2.0)]. Clinicians considered insufficient staff resources for explorations (84.6%) and treatment (46.2%). 30.8% and 20.5% of investigators reflected lack of diagnostic tools such as optical coherence tomography and fluorescein angiography, respectively. **CONCLUSIONS:** The results of this study show that more resources for diagnosis and treatment of wAMD disease are required. These data presented, together with the current policy of reducing the budget in the Spanish Health System invites reflection on the possible recession that may suffer the diagnosis and treatment of wAMD and globally our health system and its implications.

ISPOR 14TH ANNUAL EUROPEAN CONGRESS FINANCIAL DISCLOSURE INFORMATION FOR RESEARCH PRESETNATIONS

The International Society for Pharmacoeconomics and Outcomes Research asked all abstract contributors to disclose financial support for their research.
The following financial support was declared:

Reference Code	Financial Support
AD1	None
AD2	Janssen-Cilag SpA, Milano, Italy
AD3	None
AD4	Mediguard, Rockville, MD, USA SA
CN1	Bristol-Myers Squibb, Wallingford, CT, USA
CN2	University of Twente, Enschede, The Netherlands; Sawtooth Software, Sequim, WA, USA
CN3	Pfizer Global Health Partnership, New York, NY, USA; EORTC Charitable Trust, Bruxelles, Belgium; King Baudouin Foundation, Bruxelles, Belgium; Belgian Cancer Foundation, Bruxelles, Belgium
CN4	Briston-Myers Squibb, Princeton, NJ, USA
DA1	None
DA2	ZonMw, Den Haag, The Netherlands
DA3	None
DA4	None
HG1	None
HG2	None
HG3	Health Research Board, Dublin, Ireland
HG4	None
HT1	None
HT2	None
HT3	Quintiles, Hoofddorp, The Netherlands
HT4	None
MA1	Allergan, Irvine, CA, USA
MA2	Janssen, High Wycombe, UK
MA3	None
MA4	None
MO1	National Institute for Health Research, London, UK
MO2	BMS, Brussels, Belgium
MO3	National Institute for Health Research, London, UK
MO4	ZONMw, The Hague, The Netherlands
MT1	BMS, Plainsboro, NJ, USA
MT2	None
MT3	HTA Consulting, Cracow, Poland
MT4	None
NI1	NETSCC, Southampton, UK
NI2	Medtronic, Tolochenaz, Switzerland
NI3	None
NI4	Eli Lilly, Indianapolis, IN, USA
PCN1	Pfizer Oncology, New York, NY, USA
PCN2	Bristol-Myers Squibb Canada, Montreal, QC, Canada
PCN3	None
PCN4	Eisai Inc., Woodcliff Lake, NJ, USA
PCN5	Eisai Inc., Woodcliff Lake, NJ, USA
PCN6	Eisai Inc., Woodcliff Lake, NJ, USA
PCN7	Amgen, Brussels, Belgium
PCN8	None
PCN9	Amgen, Inc., Thousand Oaks, CA, USA
PCN10	Amgen, Inc., Thousand Oaks, CA, USA
PCN11	None
PCN12	BMS Spain, Madrid, Spain
PCN13	iOMEDICO AG, Freiburg, Germany
PCN14	None
PCN15	None
PCN16	Novartis Pharmaceuticals Corporation, Florham Park, NJ, USA
PCN17	Institute of Health Carlos III and Spanish Ministry of Health, Madrid, Spain
PCN18	None
PCN19	Sanofi Pasteur MSD, Maidenhead, UK
PCN20	Bristol-Myers Squibb , Lawrenceville, NJ, USA
PCN21	Bristol-Myers Squibb, Lawrenceville, NJ, USA
PCN22	None
PCN23	Janssen-Cilag Limited, High Wycombe, UK
PCN24	None
PCN25	Fondo de Investigación Sanitaria, Madrid, Spain
PCN26	Takeda Global Research & Development Centre (Europe) Ltd., London, UK
PCN27	None
PCN28	Evidencias, Campinas, Brazil
PCN29	Evidencias, Campinas, Brazil
PCN30	Abbott Laboratories, Abbott Park, IL, USA
PCN31	Novartis Biociências SA, Sao Paulo, Brazil
PCN32	Croatian Society for Pharmacoeconomics and Health Economics, Zagreb, Croatia
PCN33	Amgen, Zug, Switzerland
PCN34	Amgen, Zug, Switzerland
PCN35	Evidencias, Campinas, Brazil
PCN36	Canadian Institute for Health Research, Ottawa, ON, Canada
PCN37	ROCHE SAS, Neuilly Sur Seine, France
PCN38	Genesis Pharma, Athens, Greece
PCN39	Abbott Laboratories, Abbott Park, IL, USA
PCN40	Amgen, Inc., Thousand Oaks, CA, USA
PCN41	GlaxoSmithKline, Marly le Roi, France
PCN42	None
PCN43	MSD, Moscow, Russia
PCN44	Sanofi Pasteur MSD, Maidenhead, UK
PCN45	BMS, Rueil Malmaison, France
PCN46	None
PCN47	None
PCN48	Novartis Biociências SA, São Paulo, Brazil
PCN49	None
PCN50	Pfizer Oncology, New York, NY, USA
PCN51	Abbott, Abbott Park, IL, USA
PCN52	Bristol-Myers Squibb, Brussels, Belgium
PCN53	Sanofi Pasteur MSD, Lyon, France
PCN54	Janssen, Issy-les-Moulineaux, France
PCN55	Genomic Health, Geneva, Switzerland
PCN56	Genentech Inc., South San Francisco, CA, USA
PCN57	None
PCN58	Janssen Cilag Farmaceutica, Sao Paulo, Brazil
PCN59	None
PCN60	GlaxoSmithKline, Moscow, Russia
PCN61	AstraZeneca, Macclesfield, UK
PCN62	GlaxoSmithKline Biologicals, Wavre, Belgium
PCN63	Pfizer Portugal, Porto Salvo, Portugal
PCN64	NETSCC, London, UK
PCN65	Novartis Pharmaceuticals Corporation, Florham Park, NJ, USA
PCN66	Roche, São Paulo, Brazil
PCN67	Roche, São Paulo, Brazil
PCN68	Institut Paoli-Calmettes, Marseille, France
PCN69	Roche Farma S.A., Madrid, Spain
PCN70	Merck KGaA-Merck Serono, Darmstadt, Germany
PCN71	Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT, USA
PCN72	GlaxoSmithKline, Madrid, Spain
PCN73	Novartis Pharmaceuticals, East Hanover, NJ, USA
PCN74	None
PCN75	Merck & Co., Inc., Whitehouse Station, NJ, USA
PCN76	CONnective Tissue Cancers NETwork to integrate European Experience in Adult and Children -project no. LSHC-CT-2005-018806, BRUXELLES, Belgium; Clara, Lyon, France
PCN77	Amgen, Neuilly-sur-Seine, France
PCN78	ZonMw, Den Haag, The Netherlands
PCN79	Roche, Paris, France
PCN80	None
PCN81	None
PCN82	Roche Hellas, Athens, Greece
PCN83	None
PCN84	None
PCN85	None
PCN86	Roche Polska Sp. z o.o., Warsaw, Poland
PCN87	MerckSerono UK, Feltham, UK
PCN88	Amgen, Neuilly-sur-Seine, France
PCN89	Merck & Co., Inc., Whitehouse Station, NJ, USA
PCN90	None
PCN91	None
PCN92	Celgene, Lisboa, Portugal
PCN93	The Netherlands Organization for Health Research and Development, Den Hague, The Netherlands
PCN94	None
PCN95	Merck & Co, Whitehouse Station, NJ, USA
PCN96	None
PCN97	None
PCN98	Robert Koch Institute, Berlin, Germany
PCN99	Bristol-Myers Squibb, Paço de Arcos, Portugal
PCN100	Ferring International, Saint-Prex, Switzerland
PCN101	Janssen-Cilag, High Wycombe, UK
PCN102	Astellas Pharma Europe, Staines, UK
PCN103	Roche Products Limited, Welwyn Garden City, UK
PCN104	Roche, Bucharest, Romania
PCN105	Amgen-Hellas, Athens, Greece

Reference Code	Financial Support
PCN106	Dutch Health Care Insurance Board (CVZ), Diemen, The Netherlands
PCN107	None
PCN108	Pfizer China, Beijing, China
PCN109	None
PCN110	Astra Zeneka, Athens, Greece
PCN111	None
PCN112	Ontario Cancer Research Network, Toronto, ON, Canada
PCN113	Janssen Korea, Seoul, South Korea
PCN114	Baxter Healthcare SA, Zurich, Switzerland
PCN115	Amgen (Europe) GmbH, Zug, Switzerland
PCN116	Amgen (Europe) GmbH, Zug, Switzerland
PCN117	Amgen (Europe) GmbH, Zug, Switzerland
PCN118	None
PCN119	F. Hoffmann-La Roche AG, Basel, Switzerland
PCN120	GlaxoSmithKline, Collegeville, PA, USA
PCN121	Pfizer, New York, NY, USA
PCN122	Universiti Teknologi MARA (UiTM), Pulau Pinang, Malaysia
PCN123	Sanofi Pasteur MSD, Lyon, France
PCN124	Medical Research Council, London, UK
PCN125	Novartis Pharmaceuticals Corporation, Florham Park, NJ, USA
PCN126	Pfizer Korea, Seoul, South Korea
PCN127	National University of Singapore, Singapore, Singapore
PCN128	Sanofi-aventis, Bridgewater, NJ, USA
PCN129	None
PCN130	Astellas Pharma, Leiderdorp, The Netherlands
PCN131	Instituto de Salud Carlos III, Madrid, Spain; AGAUR, Barcelona, Spain
PCN132	None
PCN133	Kyung Hee University, Seoul, South Korea
PCN134	Boehringer Ingelheim GmbH, Ingelheim, Germany
PCN135	GlaxoSmithKline, Marly le Roi, France
PCN136	Universiti Teknologi MARA (UiTM), Pulau Pinang, Malaysia
PCN137	GlaxoSmithKline, Espoo, Finland; The Finnish Cancer Organisations, Helsinki, Finland
PCN138	Roche Farma S.A., Madrid, Spain
PCN139	None
PCN140	None
PCN141	Celgene Corporation, Summit, NJ, USA
PCN142	None
PCN143	None
PCN144	None
PCN145	National Medical Research Council, Singapore, Singapore
PCN146	None
PCN147	None
PCN148	Bristol-Myers Squibb, Uxbridge, UK
PCN149	Pfizer, Sandwich, UK
PCN150	Genentech Inc., S San Francisco, CA, USA
PCN151	Bayer Schering Pharma AG, Berlin, Germany
PCN152	National Cancer Institute, NIH, Bethesda, MD, USA
PCN153	None
PCN154	None
PCN155	Pfizer Ltd., Tadworth, UK
PCN156	Eli Lilly, Indianapolis, IN, USA
PCN157	Celgene Corporation, Cambridge, MA, USA
PCN158	National Human Genome Research Institute, NIH, Bethesda, MD, USA
PCN159	None
PCN160	Health Research Board (HRB), Dublin, Ireland
PCN161	Bristol-Myers Squibb, Princeton, NJ, USA
PCN163	None
PCN164	None
PCN165	Sanofi Pasteur MSD, Lyon, France
PCN166	Pfizer Pharmaceuticals Korea Limited, Seoul, South Korea
PCN167	Pfizer, Inc, Seoul, South Korea
PCN168	None
PCN169	Groupement pour l'Elaboration et la Réalisation de Statistique, Boulogne, France
PCN170	None
PCN171	None
PCN173	None
PCN174	None
PCN175	Institut national d'excellence en sante et en services sociaux (INESSS), Quebec, QC, Canada
PCN176	None
PCN177	None
PCN178	None
PCN179	None
PCN180	None
PCN181	None
PCN182	National Cancer Center, Tokyo, Japan
PCN183	ZonMw, Den Haag, The Netherlands
PCN184	None
PCN185	Pfizer Inc, New York, NY, USA
PCN186	None
PCN187	Amgen, Inc., Thousand Oaks, CA, USA
PCN188	Merck Serono, Darmstadt, Germany; Amgen, Munich, Germany
PCN189	Bristol-Myers Squibb Ltd., Uxbridge, UK
PCN190	Institut national d'excellence en santé et en services sociaux (INESSS), Quebec, QC, Canada; Fonds de la recherche en santé du Québec, Quebec, QC, Canada
PCN191	Roche Korea, Seoul, South Korea
PCN192	None
PCN193	National Institute for Health Research, London, UK
PCN194	None
PCN195	None
PCN196	None
PCN197	ZONMW, Den Haag, The Netherlands
PCN198	None
PCN199	AstraZeneca, Wilmington, DE, USA
PCN200	Pfizer Oncology, New York, NY, USA
PCN201	Qatar University, Doha, Qatar
PCV1	Bristol-Myers Squibb S.r.l., Rome, Italy
PCV2	None
PCV3	None
PCV4	Sanofi, Warsaw, Poland
PCV5	None
PCV6	Eli Lilly and Company, Indianapolis, IN, USA; Kowa Pharmaceuticals America, Inc., Montgomery, AL, USA
PCV7	Pfizer, Madrid, Spain
PCV8	Otsuka America Pharmaceutical, Inc., Rockville, MD, USA
PCV9	Daiichi Sankyo, Inc., Tokyo, Japan; Eli Lilly and Company, Indianapolis, IN, USA
PCV10	Abbott Labs, Abbott Park, IL, USA
PCV11	Daiichi Sankyo, Inc., Tokyo, Japan; Eli Lilly and Company, Indianapolis, IN, USA
PCV12	Pfizer Ltd., Surrey, UK
PCV13	AstraZeneca, Wilmington, DE, USA
PCV14	sanofi, Sydney, Australia
PCV15	None
PCV16	None
PCV17	Actelion, Moscow, Russia
PCV18	The Medicines Company, Abingdon, UK
PCV19	None
PCV20	None
PCV21	None
PCV22	None
PCV23	AstraZeneca UK Ltd., Luton, UK
PCV24	None
PCV25	MSD Ltd., Hertford Road, Hoddesdon, Hertfordshire, UK
PCV26	None
PCV27	None
PCV28	None
PCV29	Amgen Inc., Thousand Oaks, CA, USA
PCV30	Amgen Inc., Thousand Oaks, CA, USA
PCV31	None
PCV32	AstraZenca, Wilmington, DE, USA
PCV34	Daiichi Sankyo, Inc., Parsippany, NJ, USA
PCV35	None
PCV36	GlaxoSmithKline, London, UK
PCV37	Novonordisk, Malmö, Sweden
PCV38	AstraZeneca, Wilmington, DE, USA
PCV39	Pfizer, Berlin, Germany; Bristol-Myers Squibb, Muenchen, Germany
PCV40	MSD, Madrid, Spain
PCV41	GE Healthcare, Chalfont St Giles, UK
PCV42	Daiichi-Sankyo Europe GmbH, Munich, Germany
PCV43	None
PCV44	Roche Diagnostics, Vienna, Austria
PCV45	Astrazeneca, Madrid, Spain
PCV46	None
PCV47	None
PCV48	None
PCV49	None
PCV50	Sanofi-Aventis, Montreal, QC, Canada
PCV51	AstraZeneca, Zug, Switzerland
PCV52	Sanofi-aventis, Guildford, UK
PCV53	Medtronic, Madrid, Spain
PCV54	None
PCV55	None
PCV56	SANOFI-AVENTIS, Athens, Greece
PCV57	Böhringer Ingelheim, Vienna, Austria
PCV58	Institute for Health Economics and Policy, Tokyo, Japan
PCV59	Merck & Co, Inc, Whitehouse Station, NJ, USA
PCV60	Boehringer ingelheim Pty Limited, North Ryde, Australia
PCV61	Boehringer Ingelheim, Barcelona, Spain

Reference Code	Financial Support
PCV62	Pfizer, Madrid, Spain
PCV63	Boehringer Ingelheim, Madrid, Spain
PCV64	None
PCV65	None
PCV66	Eli Lilly and Company, Indianapolis, IN, USA; Kowa Pharmaceuticals America, Inc., Montgomery, AL, USA
PCV67	National Insitute for Food and Nutrition Science, Budapest, Hungary
PCV68	Medco Health Solutions, Franklin Lakes, NJ, USA
PCV69	Sanofi-Aventis, Gouda, The Netherlands
PCV70	AstraZeneca GmbH, Wedel, Germany
PCV71	None
PCV72	AstraZeneca Pharma Poland, Warsaw, Poland
PCV73	NIHR Health Technology Assessment Programme, Southampton, UK
PCV74	National Institute of Health Research, London, UK
PCV75	None
PCV76	SANOFI-AVENTIS, Athens, Greece
PCV77	Boehringer Ingelheim Hellas, Athens, Greece
PCV78	SANOFI-AVENTIS, Athens, Greece
PCV79	Astra Zeneka, Athens, Greece
PCV80	None
PCV81	AstraZeneca Canada, Toronto, ON, Canada
PCV82	Novartis Pharma AG, Basel, Switzerland
PCV83	AstraZeneca, Athens, Greece
PCV84	Takeda, Vienna, Austria
PCV85	None
PCV86	AstraZeneca, Wilmington, DE, USA
PCV87	Astra Zeneca, Zoetermeer, The Netherlands
PCV88	AstraZeneca, Wilmington, DE, USA
PCV89	Astrazeneca, Madrid, Spain
PCV90	Transition Patient Services, Shrewsbury, NJ, USA
PCV91	Instituto de Salud Carlos III, Madrid, Spain
PCV92	Grupo Menarini, Barcelona, Spain
PCV93	None
PCV94	sanofi australia pty Ltd., Sydney, Australia
PCV95	SINOPEC, Port Harcourt, Nigeria
PCV96	None
PCV97	New Zealand Ministry of Health, Wellington, New Zealand
PCV98	None
PCV99	None
PCV100	AstraZeneca UK, Luton, UK
PCV101	IRSC, Montreal, QC, Canada
PCV102	Novartis, Emmaus, PA, USA
PCV103	Ministry of Higher Education, Malaysia, Malaysia, Malaysia
PCV104	Daiichi Sankyo Europe GmbH, Munich, Germany
PCV105	Pfizer, New York, NY, USA
PCV106	None
PCV107	None
PCV108	sanofi, Sydney, Australia
PCV109	Silpakorn University Research and Development Institute, Nakhon Pathom, Thailand
PCV110	Boehringer Ingelheim, Ingelheim, Germany
PCV111	Merck, Sharp & Dohme, Whitehouse Station, NJ, USA
PCV112	Daiichi Sankyo Europe GmbH, Munich, Germany
PCV113	Daiichi Sankyo Europe GmbH, Munich, Germany
PCV114	NIHR Heallth Technology Assessment Programme, Southampton, UK
PCV115	None
PCV116	Kantar Health, Princeton, NJ, USA
PCV117	Daiichi Sankyo Europe, Munich, Germany
PCV118	Shire , Boulogne Billancourt, France
PCV119	Novartis Farmacéutica, S.A., Barcelona, Spain
PCV120	Medtronic, Madrid, Spain
PCV121	Novartis Pharma AG, Basel, Switzerland
PCV122	Servier, Lyon, France
PCV123	None
PCV124	The Social Insurance Institution, Helsinki, Finland
PCV125	Sanofi-Aventis, Guildford, UK
PCV126	HTA Consulting, Krakow, Poland; Sequence HC Partners, Warszawa, Poland
PCV127	Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA
PCV128	Bayer, Newbury, UK
PCV129	Servier Poland, Warsaw, Poland
PCV131	None
PCV132	Boehringer Ingelheim, Ingelheim am Rhein, Germany
PCV133	None
PCV134	Eli Lilly and Company, Indianapolis, IN, USA; Kowa Pharmaceuticals America, Inc., Montgomery, AL, USA
PCV135	Eli Lilly and Company, Indianapolis, IN, USA; Kowa Pharmaceuticals America, Inc., Montgomery, AL, USA
PCV136	Eli Lilly and Company, Indianapolis, IN, USA; Kowa Pharmaceuticals America, Inc., Montgomery, AL, USA
PCV137	None
PCV138	None
PCV139	Boehringer Ingelheim, Sao Paulo, Brazil
PCV140	Ministry of Health & Welfare, Seoul, South Korea
PCV141	Eli-Lilly and Co Greece, Athens, Greece
PCV142	None
PCV144	Bayer Schering Pharma AG, Wuppertal, Germany
PCV145	None
PCV146	None
PCV147	None
PCV148	None
PC1	Lundbeck SAS, Issy-les-Moulineaux, France
PC2	None
PC3	Health Research Board, Dublin, Ireland; Irish Cancer Society, Dublin, Ireland
PC4	Instituto de Salud Carlos III, ISCIII GR09/0026, Madrid, Spain
PDB1	None
PDB2	None
PDB3	sanofi-aventis, Montréal, QC, Canada
PDB4	Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA
PDB5	Sanofi-Aventis, Berlin, Germany
PDB6	Eli Lilly and Company, Indianapolis, IN, USA
PDB7	Sanofi-Aventis, Laval, QC, Canada
PDB8	Lilly and Co. Ltd., Indianapolis, IN, USA; Amylin Pharmaceuticals Inc, San Diego, CA, USA
PDB9	Bristol-Meyers Squibb, Princeton, NJ, USA
PDB10	Amylin Pharmaceuticals, Inc., San Diego, CA, USA; Eli Lilly and Company, Indianapolis, IN, USA
PDB11	Amylin Pharmaceuticals, Inc., San Diego, CA, USA
PDB12	sanofi-aventis, Bridgewater, NJ, USA
PDB13	sanofi-aventis, Laval, QC, Canada
PDB14	NovoNordisk, Vandtårnsvej, Søborg, Denmark
PDB15	NA, Serbia and Montenegro
PDB16	NOVARTIS, Rueil-Malmaison, France
PDB17	None
PDB18	PFSA, Boulogne, France
PDB19	Novo Nordisk Pharma Sp. z o.o., Warsaw, Poland
PDB20	None
PDB21	Eli Lilly and Company, Indianapolis, IN, USA
PDB22	Eli Lilly and Company, Indianapolis, IN, USA
PDB23	None
PDB24	Novo Nordisk Farmaceutici Spa, Rome, Italy
PDB25	sanofi-aventis U.S., Inc, A SANOFI Company, Bridgewater, NJ, USA
PDB26	Eli Lilly and Company, London, UK
PDB27	Eli Lilly and Company, London, UK
PDB28	Eli Lilly and Company, Indianapolis, IN, USA
PDB29	Novo Nordisk, Sofia, Bulgaria
PDB30	None
PDB31	Croatian Society for Pharmacoeconomics and Health Economics, Zagreb, Croatia
PDB32	Novo Nordisk Sp. z o.o., Warsaw, Poland
PDB33	None
PDB34	None
PDB35	Lilly UK, Surrry, UK
PDB36	Boehringer Ingelheim Ltd., Berkshire, Bracknell, UK
PDB37	IPSEN, PARIS, France
PDB38	Novartis, Vienna, Austria
PDB39	Bristol-Myers Squibb Ltd., Uxbridge, UK
PDB40	Novo Nordisk Pharma Sp. z o.o., Warsaw, Poland
PDB41	Janssen-Cilag S.A., Madrid, Spain
PDB42	Merck Serono, Athens, Greece
PDB43	Janssen-Cilag S.A., Madrid, Spain
PDB44	Takeda, London, UK
PDB45	Novo Nordisk, Lda., Lisbon, Portugal
PDB46	None
PDB47	AstraZeneca, Molndal, Sweden
PDB48	Novo Nordisk, Copenhagen, Denmark
PDB49	Eli Lilly and Company, Indianapolis, IN, USA
PDB50	Novartis, Florham Park, NJ, USA
PDB51	Novo Nordisk, Princeton, NJ, USA
PDB52	None
PDB53	None
PDB54	Novartis, Basel, SD, Switzerland
PDB55	None
PDB56	AMGEN, Barcelona, Spain
PDB57	None
PDB58	Merck and Company, Inc., Whitehouse Station, NJ, USA
PDB59	Novo Nordisk, Virum, Denmark
PDB60	None
PDB61	None
PDB62	AstraZeneca, Molndal, Sweden
PDB63	Boehringer Ingelheim France, Paris, France
PDB64	Novartis Farmacéutica S.A., Barcelona, Spain
PDB65	None

Reference Code	Financial Support
PDB66	Novo Nordisk, Princeton, NJ, USA
PDB67	None
PDB68	The Israel National Institute for Healt Policy Research, Tel Hashomer, Israel
PDB69	None
PDB70	Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA
PDB71	None
PDB72	None
PDB73	None
PDB74	None
PDB75	None
PDB76	None
PDB77	None
PDB78	Merck Sharp & Dohme Corp., Whitehouse Station, NJ, USA
PDB79	Eli Lilly and Company, Indianapolis, IN, USA
PDB80	None
PDB81	None
PDB82	Novartis Hungary, Budapest, Hungary
PDB83	None
PGI1	Bristol-Myers Squibb, Princeton, NJ, USA
PGI2	None
PGI3	Bristol-Myers Squibb, Rueil-Malmaison, France
PGI4	AstraZeneca Turkey, Istanbul, Turkey
PGI5	Almirall S.A., Barcelona, Spain
PGI6	UK National Health Service Research & Development Programme Health Technology Assessment Programme, Southampton, UK
PGI7	None
PGI8	None
PGI9	None
PGI10	National Research Foundation (NRF), Pretoria, South Africa
PGI11	None
PGI12	None
PGI13	None
PGI14	Janssen-Cilag, Beerse, Belgium
PGI15	Janssen-Cilag, Tilburg, The Netherlands
PGI16	EPAC ONLUS, Rome, Italy
PGI17	Evidencias, Campinas, Brazil
PGI18	Roche Farmacêutica Química, Lda., Amadora, Portugal
PGI19	None
PGI20	Fresenius Kabi, Moscow, Russia
PGI21	Health and Labour Sciences Research Grants of Ministry of Health, Labor, and Welfare, Tokyo, Japan
PGI22	Shimane University Hospital, Izumo, Japan
PGI23	Shire, Wayne, PA, USA
PGI24	AstraZeneca R&D, Mölndal, Sweden
PGI25	Bristol Myers-Squibb, Princeton, NJ, USA
PGI26	Novartis Farmacéutica, S.A., Barcelona, Spain
PGI27	Kantar Health, New York, NY, USA
PGI28	Shire Development, Inc., Wayne, PA, USA
PGI29	None
PGI30	EPAC, Rome, Italy
PGI31	Shire Development, Inc., Wayne, PA, USA
PGI32	Norgine, Uxbridge, UK
PGI33	German Federal Ministry for Education and Research, Berlin, Germany
PHP1	None
PHP2	None
PHP3	None
PHP4	Ministry of Public Health, Brussels, Belgium
PHP5	None
PHP6	None
PHP7	None
PHP8	Double Helix Consulting, London, UK
PHP9	None
PHP10	Novo Nordisk Pharma S.A., Madrid, Spain
PHP11	Eucomed, Brussels, Belgium
PHP12	None
PHP13	None
PHP14	None
PHP15	None
PHP16	None
PHP17	None
PHP19	London School of Economics, London, UK
PHP20	None
PHP21	LSE, London, UK
PHP22	European Commission, Executive Agency for Health and Consumers (EAHC), Luxembourg, Luxembourg; Austrian Federal Ministry of Health, Vienna, Austria
PHP23	Quintiles, Hawthorne, NY, USA
PHP24	None
PHP25	The National Institute for Health Policy, Ramat Gan, Israel
PHP26	None
PHP27	None
PHP28	None
PHP29	GIRP, Brussels, Belgium
PHP30	European Commission (Directorate-General for Enterprise and Industry), Belgium, Belgium
PHP31	Sanofi-aventis, Paris, France
PHP32	Bridgehead International, London, UK
PHP33	None
PHP34	None
PHP35	None
PHP36	Seventh Framework Programme of the European Community, Brussels, Belgium
PHP37	Glaxosmithkline, Tres Cantos, Spain
PHP38	None
PHP39	Pfizer Korea, Inc., Seoul, South Korea
PHP40	None
PHP41	None
PHP42	None
PHP43	None
PHP44	None
PHP45	None
PHP46	RIZIV, Brussels, Belgium
PHP47	None
PHP48	CARPC, Zagreb, Croatia
PHP49	None
PHP50	None
PHP51	None
PHP52	None
PHP53	Bristol Myers Squibb, Warszawa, Poland
PHP54	None
PHP55	Schering Plough, Welwyn Garden City, UK
PHP56	None
PHP57	None
PHP58	The University of Sheffield, Sheffield, UK
PHP59	Express Scripts, Inc., St. Louis, MO, USA
PHP60	Apoteket AB, Stockholm, Sweden
PHP61	Valencian Community Government. Health Department, Valencia, Spain; Universitat Politècnica de València, Valencia, Spain
PHP62	None
PHP63	None
PHP64	Health Department of the City of Zurich, Zurich, Switzerland
PHP65	National Association of Pharmacies (ANF), Lisbon, Portugal
PHP66	Fonds de la recherche en santé du Québec, Montréal, QC, Canada; Pfizer, Montréal, QC, Canada; sanofi-aventis, Laval, QC, Canada
PHP67	None
PHP68	None
PHP69	None
PHP70	None
PHP71	None
PHP72	International Health Policy Program, Nonthaburi, Thailand
PHP73	None
PHP74	None
PHP75	GSK France, Marly Le Roi, France
PHP76	None
PHP77	None
PHP78	GlaxoSmithKline GmbH&Co. KG, Munich, Germany
PHP79	None
PHP80	None
PHP81	None
PHP82	None
PHP83	Abbott Nutrition International, Maidenhead, UK
PHP84	Ministry of Science and Higher Education of the Republic of Poland, Warsaw, Poland
PHP85	Finnish Medicines Agency, Kuopio, Finland
PHP86	None
PHP87	The Commonwealth Fund, New York City, NY, USA
PHP88	None
PHP89	None
PHP90	None
PHP91	Ministry of Health, Wealth and Labour, Tokyo, Japan
PHP92	None
PHP93	None
PHP94	None
PHP95	None
PHP96	None
PHP97	Ministry of Health, Brussels, Belgium
PHP98	None
PHP99	Sanofi, Paris, France
PHP100	None
PHP101	None
PHP102	None
PHP103	None

Reference Code	Financial Support
PHP104	Pharmerit International, Rotterdam, The Netherlands
PHP105	Top Institute Pharma, Leiden, The Netherlands
PHP106	Dutch Health Care Insurance Board (CVZ), Diemen, The Netherlands
PHP107	Hellenic Association of Pharmaceutical Companies (SFEE), Athens, Greece
PHP108	Pharma.be, Brussels, Belgium
PHP109	None
PHP110	None
PHP111	None
PHP112	None
PHP113	None
PHP114	None
PHP115	None
PHP116	RTI Health Solutions, Research Triangle Park, NC, USA; Eli Lilly and Company, Indianapolis, IN, USA
PHP117	Medical Research Council, London, UK
PHP118	None
PHP119	None
PHP120	None
PHP121	None
PHP122	None
PHP123	Costello Medical Consulting, Cambridge, UK
PHP124	None
PHP125	None
PHP126	None
PHP127	None
PHP128	Roche, São Paulo, Brazil
PHP129	None
PHP130	None
PHP131	Double Helix Consulting, London, UK
PHP132	Johnson&Johnson Medical, Norderstedt, Germany
PHP133	None
PHP134	None
PHP135	None
PHP136	The Ministry of Science and Technological Development, Beograd, Serbia and Montenegro
PHP137	None
PHP138	None
PHP139	None
PHP140	None
PHP141	None
PHP142	None
PHP143	None
PHP144	None
PHP145	Costello Medical Consulting, Cambridge, UK
PHP146	General Electric Co., Fairfield, CT, USA; Eli Lilly & Co, Indianapolis, IN, USA; Novartis AG, Basel, Switzerland; F. Hoffmann-La Roche Ltd., Basel, Switzerland; Johnson and Johnson Services, Inc., New Brunswick, NJ, USA; Glaxo- SmithKline plc, Middlesex, UK; Sanofi-aventis, Paris, France; Pfizer Inc., New York, NY, USA; Amgen Inc., Thousand Oaks, CA, USA; Genentech Inc., South San Francisco, CA, USA; Merck & Co, Inc., Whitehouse Station, NJ, USA; Bayer HealthCare Pharmaceuticals Inc, Wayne, NJ, USA; Janssen AI, South San Francisco, CA, USA; Allergan, Irvine, CA, USA
PHP147	None
PHP148	IHS, Denver, CO, USA
PHP149	None
PHP150	None
PHP151	LSE Health, London, UK; European Commission, Brussels, Belgium
PHP152	Costello Medical Consulting, Cambridge, UK
PHP153	None
PHP154	Tehran University of Medical Sciences, Tehran, Iran
PHP155	None
PHP156	None
PHP157	None
PHP158	None
PHP159	ONCOTYROL - Center for Personalized Cancer Medicine GmbH, Innsbruck, Austria; Austrian Federal Ministry for Science and Research, Vienna, Austria
PHP160	European Medicines Agency, London, UK
PHP161	Lilly, Moscow, Russia
PHP162	None
PHP163	None
PHP164	None
PHP165	None
PHP166	Double Helix Consulting, London, UK
PHP167	None
PHP168	None
PHP169	None
PIH1	Teva Pharmaceuticals, Kansas City, MO, USA
PIH2	Abbott Laboratories Limited, Saint-Laurent, QC, Canada
PIH3	Abbott Laboratories Limited, Saint-Laurent, QC, Canada
PIH4	Abbott Laboratories Limited, saint-Laurent, QC, Canada
PIH5	Abbott Laboratories Limited, Saint-Laurent, QC, Canada

Reference Code	Financial Support
PIH6	None
PIH7	None
PIH8	None
PIH9	None
PIH10	None
PIH12	PFSA, Boulogne, France
PIH13	GlaxoSmithKline Biologicals, Wavre, Belgium
PIH14	None
PIH15	None
PIH16	None
PIH17	Bayer Schering Pharma, Berlin, Germany
PIH18	Sanofi Pasteur MSD, Maidenhead, UK
PIH19	GlaxoSmithKline Biologics, Wavre, Belgium
PIH20	World Endometriosis Research Foundation, London, UK
PIH21	GlaxoSmithKline Biologicals, Wavre, Belgium
PIH22	Pfizer, Beijing, China; Pfizer, New York, NY, USA
PIH23	Shire Pharmaceuticals, Wayne, PA, USA
PIH24	Bayer, São Paulo, Brazil
PIH25	Instituto de Salud Carlos III, Madrid, Spain
PIH26	Bayer Korea Ltd., Seoul, South Korea
PIH27	GlaxoSmithKline, Mississauga, ON, Canada
PIH28	GlaxoSmithKline, Buenos Aires, Argentina
PIH29	German Research Foundation (DFG), Berlin, Germany; federal Ministry for Education and Research (BMBF), Berlin, Germany
PIH30	Bayer, Bratislava, Slovak Republic
PIH31	Merck Sharp & Dohme, Sydney, Australia
PIH32	Registrat Mapi, Lyon, France
PIH33	None
PIH35	None
PIH36	Thai Health Promotion Foundation, Bangkok, Thailand
PIH37	None
PIH38	None
PIH39	Pfizer Ltd., Tadworth, UK
PIH40	Shire HGT, Cambridge, MA, USA
PIH41	None
PIH42	PFSA, Boulogne, France
PIH43	Fondo de Investigación Sanitaria, Madrid, Spain
PIH44	QualityMetric Incorporated, Lincoln, RI, USA
PIH45	Sanofi Pasteur MSD, Maidenhead, UK
PIH46	None
PIH47	None
PIH48	Bayer Schering Pharma, Berlin, Germany
PIH49	PFSA, Boulogne, France
PIH50	None
PIH51	Federal Ministry of Education and Research, Berlin, Germany
PIH52	None
PIH53	Eli Lilly, Indianapolis, IN, USA
PIH54	None
PIH55	Shiraz University of Medical Sciences, Shiraz, Iran
PIH56	None
PIH57	Service Public Fédéral Santé Publique, Brussels, Belgium
PIH59	None
PIH60	None
PIH61	None
PIH62	None
PIH63	Pfizer, New York, NY, USA
PIH64	Ethicon, Germany, Germany
PIH65	GlaxoSmithKline Biologicals, Wavre, Belgium
PIH66	None
PIH67	Pfizer, New York, NY, USA
PIH68	Bayer Schering Pharm, Berlin, Germany
PIN1	None
PIN2	Gilead Sciences, Warsaw, Poland
PIN3	Bristol-Myers Squibb, rueil-Malmaison, France
PIN4	Pfizer Inc, New York, NY, USA
PIN5	Novartis Pharmaceuticals Australia, North Ryde, Australia
PIN6	Bristol Myers Squibb, Istanbul, Turkey
PIN7	Janssen Pharmaceutica NV, Beerse, Belgium
PIN8	Bristol Myers Squibb, Istanbul, Turkey
PIN9	None
PIN10	Pfizer Inc, New York, NY, USA
PIN11	Bristol Myers Squibb, Princeton, NJ, USA
PIN12	Pfizer, Collegeville, PA, USA
PIN13	None
PIN14	Novartis Pharma, Basel, Switzerland
PIN15	None
PIN16	None
PIN17	Sanofi Pasteur MSD, Lyon, France
PIN18	Gilead, Warszawa, Poland
PIN19	Roche, Moscow, Russia
PIN20	Pfizer SLU, Madrid, Spain

Reference Code	Financial Support
PIN21	Bayer HealthCare Pharma, Moscow, Russia
PIN22	None
PIN23	Abbott SpA, Campoverde di Aprilia, Italy
PIN24	None
PIN26	Abbott Laboratories, Abbott Park, IL, USA
PIN27	None
PIN28	None
PIN29	Pfizer Pharmaceutics Inc., São Paulo, Brazil
PIN30	Pfizer Inc, New York, NY, USA
PIN31	Pfizer Inc., New York, NY, USA
PIN32	Bayer HealthCare Pharmaceuticals, Wayne, NJ, USA; Bayer Schering Pharma, Berlin, Germany
PIN33	None
PIN34	The Netherlands Vaccine Institute (NVI), Bilthoven, The Netherlands
PIN35	sanofi-pasteur MSD, Maidenhead, UK
PIN36	Ethicon, JNJ, Somerville, NJ, USA
PIN37	Janssen AB, Sollentuna, Sweden
PIN38	Deutsche Leberstiftung, Hannover, Germany
PIN39	None
PIN40	Pfizer Pharmaceutics Inc., São Paulo, Brazil
PIN41	None
PIN42	National Health and Medical Research Council (NHMRC) Australian-based Public Health Training Fellowship (630724), Canberra, Australia
PIN43	Abbott Srl, Campoverde di Aprilia (LT), Italy
PIN44	Sanofi Pasteur MSD, Lyon, France
PIN46	Pfizer, Kuala Lumpur, Malaysia
PIN47	None
PIN48	None
PIN49	Pfizer Inc., New York, NY, USA
PIN50	Merck & Co, Whitehouse Station, NJ, USA
PIN51	Pfizer, San Jose, Costa Rica
PIN52	Pfizer Inc., New York, NY, USA
PIN53	Roche Polska Sp. z o.o., Warsaw, Poland
PIN54	Pfizer Canada, Inc., Kirdland, QC, Canada
PIN55	None
PIN56	Roche Farma, Madrid, Spain
PIN57	Pfizer Inc., New York, NY, USA
PIN58	Pfizer, São Paulo, Brazil
PIN59	p, San Jose, Costa Rica
PIN60	None
PIN61	Janssen-cilag, Sao Paulo, Brazil
PIN62	Roche Farma, Madrid, Spain
PIN63	Pfizer, San Jose, Costa Rica
PIN64	Pfizer, San Jose, Costa Rica
PIN65	GlaxoSmithKline GmbH, Munich, Germany
PIN66	Janssen Cilag Farmaceutica, São Paulo, Brazil
PIN67	None
PIN68	Merck & Co., Inc, Moscow, Russia
PIN69	Sanofi Pasteur MSD, Lyon, France
PIN70	Sanofi Pasteur, Lyons, France
PIN71	Bayer HealthCare Pharma, Moscow, Russia
PIN72	Dutch Higher Education, Den Haag, The Netherlands
PIN73	Bristol-Myers Squibb, Rueil-Malmaison, France
PIN74	Sanofi Pasteur MSD, Lyon, France
PIN75	Sanofi Pasteur, Lyon, France
PIN76	Pfizer Pharmaceutics Inc., São Paulo, Brazil
PIN77	Astellas Pharma Europe Ltd., Staines, UK
PIN78	None
PIN79	Gilead, Warszawa, Poland
PIN80	AstraZeneca, Wedel, Germany
PIN81	Shanghai Roche, Shanghai, China
PIN82	Bristol-Myers Squibb, Mu, Germany
PIN83	Roche Polska Sp. z o.o., Warsaw, Poland
PIN84	Abbott SpA, Campoverde di Aprilia, Italy
PIN85	None
PIN86	Fundació IMIM, Barcelona, Spain
PIN87	Janssen Cilag Farmaceutica, Sao Paulo, Brazil
PIN88	None
PIN89	Bristol-Myers Squibb, Paris, France
PIN90	Janssen Cilag, Neuss, Germany
PIN91	None
PIN92	Roche, Madrid, Spain
PIN93	None
PIN94	None
PIN95	Instituto de Salud Carlos III, ISCIII GR09/0026, Madrid, Spain
PIN96	Institute for Health Management, National Institutes of Health, Ministry of Health, Kuala Lumpur, Malaysia
PIN97	None
PIN98	BMS, Princeton, NJ, USA
PIN99	None
PIN100	None
PIN101	None
PIN102	None
PIN103	Abbott Italia Srl, Campoverde di Aprilia, Italy
PIN104	None
PIN105	None
PIN106	None
PIN107	Novartis Canada, Montreal, QC, Canada
PIN108	Janssen-Cilag GmbH, 41470 Neuss, Germany
PIN109	2GlaxoSmithKline Biologicals, Wavre, Belgium
PIN110	CRUCELL, Berne, Switzerland
PIN111	None
PIN112	Pfizer SLU, Madrid, Spain
PIN113	ANRS, Paris, France; Health Secretariat of the State of São Paulo, São Paulo, Brazil; DRCD, Paris, France
PMD1	alcon france, Rueil-Malmaison, France
PMD2	National Institute for Health Research (NIHR) Health Technology Appraisal programme, Southampton, UK
PMD3	National Institute for Health Research (NIHR) Health Technology Programme, Southampton, UK
PMD4	None
PMD5	National Institute for Health Research (NIHR) Health Technology Programme, Southamptom, UK
PMD6	Medtronic International, Tolochenaz, Switzerland
PMD7	Roche Diagnostics, Mannheim, Germany
PMD8	None
PMD9	Bayer, São Paulo, Brazil
PMD10	St. Jude Medical, St. Paul, MN, USA
PMD11	Medtronic, Madrid, Spain
PMD12	Johnson&Johnson Medical, Madrid, Spain
PMD13	Cordis Corporation, Bridgewater, NJ, USA
PMD14	Cordis Corporation, Bridgewater, NJ, USA
PMD15	Biotronik SE & Co KG, Berlin, Germany
PMD16	Novartis, Basel, Switzerland
PMD17	None
PMD18	Medtronic International, Tolochenaz, Switzerland
PMD19	None
PMD20	Medtronic, France, France
PMD21	MEDTRONIC ITALIA, Milan, Italy
PMD22	Johnson & Johnson, Madrid, Spain
PMD23	The Netherlands Organisation for Health Research and Development, The Hague, The Netherlands
PMD24	3M Skin & Wound Care Division, Neuss, Germany
PMD25	Edwards Lifesciences, Milano, Italy
PMD27	Medtronic, Madrid, Spain
PMD28	Netherlands Leprosy Relief Agency, Jos, Nigeria
PMD29	Bayer, São Paulo, Brazil
PMD30	Medtronic International Trading Sarl, Tolochenaz, Switzerland
PMD31	Bayer, Barcelona, Spain
PMD32	None
PMD33	None
PMD34	MITACS, Hamilton, ON, Canada
PMD35	Johnson & Johnson Medical, Madrid, Spain
PMD36	alcon france, Rueil-malmaison, France
PMD37	alcon france, Rueil-malmaison, France
PMD38	Critical Diagnostics, San Diego, CA, USA
PMD39	None
PMD40	St. Jude Medical, St. Paul, MN, USA
PMD41	None
PMD42	Ministry of Higher Education, Kuala Lumpur, Malaysia
PMD43	Therakos, Madrid, Spain
PMD44	Ministry of Higher Education, Kuala Lumpur, Malaysia
PMD45	Medtronic International Sarl, Tolochenaz, Switzerland
PMD46	Apex Pharma Kft., Budapest, Hungary
PMD48	HeartWare Inc., Framingham, MA, USA
PMD49	NIHR, HTA programme, London, UK
PMD50	None
PMD51	Bayer HealthCare Pharmaceuticals, Berlin, Germany
PMD52	Biotronik SE & Co KG, Berlin, Germany
PMD53	Medtronic France SAS, Boulogne Billancourt, France
PMD54	AstraTech, Mölndal, Sweden
PMD55	AstraTech, Mölndal, Sweden
PMD56	Baxter Healthcare, Westlake Village, CA, USA
PMD57	GE HealthCare, Chalfont St Giles, UK
PMD58	German Federal Ministry of Education and Research, Berlin, Germany
PMD59	Medtronic, Tolochenaz, Switzerland
PMD60	GlaxoSmithKline, Research Triangle Park, NC, USA
PMD61	Taipei City Hospital, Taipei, Taiwan; Buddhist Tzu Chi General Hospital, Taipei Branch, New Taipei, Taiwan
PMD62	Astellas, Deerfield, IL, USA
PMD63	Bayer Korea, Seoul, South Korea
PMD64	None

Reference Code	Financial Support
PMD65	None
PMD66	Biotronik SE & Co KG, Berlin, Germany
PMD67	Edwards Lifesciences, Newbury, UK
PMD68	Abbott Vascular, Santa Clara, CA, USA
PMD69	AstraTech, Mölndal, Sweden
PMD70	None
PMD71	Biotronik SE & Co KG, Berlin, Germany
PMD72	None
PMD73	National Institutes of Health, Bethesda, NM, USA
PMD74	Baxter Healthcare Corporation, Braine l'Alleud, Belgium
PMD75	Roche Diagnostics, Bratislava, Slovak Republic
PMD76	Quintiles, Hoofddorp, The Netherlands
PMD77	None
PMD78	ZonMW, Den Haag, The Netherlands
PMD79	Center for Translational Molecular Medicine (CTMM), Eindhoven, Netherlands; Netherlands Heart Foundation, The Hague, The Netherlands
PMD80	ETHICON, Livingston, UK
PMD81	Center for Translational Molecular Medicine, Eindhoven, The Netherlands
PMD82	Medtronic, Milan, Italy
PMD83	The National Institute for Health Research Health Technology Assessment, Southampton, UK
PMD84	None
PMD85	Pfizer Inc., New York, NY, USA
PMD86	None
PMH1	None
PMH2	University of the Basque Country, UPV/EHU, Leioa, Spain
PMH3	Eli Lilly and Company, Indianapolis, IN, USA
PMH4	Eli Lilly and Company, Indianapolis, IL, USA
PMH5	Eli Lilly and Company, Indianapolis, IN, USA
PMH6	Janssen, Neuss, Germany
PMH7	Lundbeck SAS, Issy les Moulineaux, France
PMH8	None
PMH9	National Research Foundation (NRF), Pretoria, South Africa
PMH10	Florida Agency for Health Care Administration, Tallahassee, FL, USA
PMH11	University of Utah Interdisciplinary Seed Grant, Salt Lake City, UT, USA
PMH12	Eli Lilly and Company, Indianapolis, IN, USA
PMH13	Eli Lilly and Company, Indianapolis, IN, USA
PMH14	TEVA Innovative España, Madrid, Spain
PMH15	Bayer HealthCare Pharmaceuticals, Berlin, Germany
PMH16	Reckitt Benckiser Pharmaceuticals, Madrid, Spain
PMH17	AstraZeneca, Warsaw, Poland
PMH18	AstraZeneca, Warsaw, Poland
PMH19	Janssen Pharmaceuticals, Birkerød, Denmark
PMH20	None
PMH21	Washington State Division of Alcohol and Substance Abuse, Olympia, WA, USA
PMH22	None
PMH23	None
PMH24	None
PMH25	None
PMH26	Génome Québec, Montreal, QC, Canada; Génome Canada, Montreal, QC, Canada
PMH27	Reckitt Benckiser, Slough, UK
PMH29	AstraZeneca, Istanbul, Turkey
PMH31	Eli Lilly (HTA ACE-J Group), Indianapolis, IN, USA
PMH32	None
PMH33	Janssen, Madrid, Spain
PMH34	Sanofi, Warszawa, Poland
PMH35	Janssen Pharmaceutica, Beerse, Belgium
PMH36	Bayer Vital GmbH, Leverkusen, Germany
PMH37	Lundbeck SAS, Issy-les-Moulineaux, France
PMH38	Reckitt Benckiser Healthcare (Italy) SpA – Drug Business Unit., Milan, Italy
PMH39	ZonMW , Den Haag, The Netherlands
PMH40	Servier Laboratories (Aust) Pty Ltd., Hawthorn, Australia
PMH42	Janssen Korea, Seoul, South Korea
PMH43	Takeda Pharmaceutical Company, Deerfield, IL, USA
PMH44	Advanced Pain Centers, S.C., Hoffman Estates, IL, USA
PMH45	None
PMH46	Janssen-Cilag B.V., Tilburg, The Netherlands
PMH47	Novartis Farmacéutica, S.A., Barcelona, Spain
PMH48	AstraZeneca, Madrid, Spain
PMH49	Astrazeneca, Wilmington, DE, USA
PMH50	Reckitt Benckiser Pharmaeuticals, Richmond, VA, USA
PMH51	None
PMH52	None
PMH53	Instituto Salud Carlos III. FIPSE 3035/99, FIS 00/1017, Madrid, Spain; DIUE Generalitat de Catalunya. 2009 SGR 718, Barcelona, Spain
PMH54	None
PMH55	Takeda Pharmaceutical Company, Deerfield, IL, USA
PMH56	Roche, Basel, Switzerland
PMH57	Takeda Pharmaceutical Company, Deerfield, IL, USA
PMH58	Pfizer, Madrid, Spain
PMH59	Eli Lilly and Company, Indianapolis, IN, USA
PMH60	Lundbeck, Issy-les-Moulineaux, France
PMH61	Shire Pharmaceuticals, Inc, Wayne, PA, USA
PMH62	Takeda Pharmaceutical Company, Deerfield, IL, USA
PMH63	None
PMH64	NHRI, Jhunan, Taiwan
PMH65	AstraZeneca, Södertälje, Sweden
PMH66	None
PMH67	IMS Health Sweden AB, Stockholm, Sweden
PMH68	AstraZeneca, Södertälje, Sweden
PMH69	"Prends soin de toi" Program, Montréal, QC, Canada
PMH70	Glaxosmithkline, Paris, France
PMH71	AstraZeneca Pharmaceuticals, L.P, Wilmington, DE, USA
PMH72	AstraZeneca Pharmaceuticals, LP, Wilmington, DE, USA
PMH73	vdek Baden-Wuerttemberg, Stuttgart, Germany; KV BaWue, Stuttgart/Karlsruhe, Germany
PMH74	Universitat Politècnica de València, Valencia, Spain
PMH75	Reckitt Benckiser Pharmaeuticals, Richmond, VA, USA
PMH76	Lundbeck A/S, Copenhagen, Denmark
PMH77	Manipal University, Manipal, India; Association of Community Pharmacists of India, Manipal, India
PMH78	Manipal University, Manipal, India; ACPI, Manipal, India
PMH79	National Institute of Mental Health, Bethesda, MD, USA
PMH80	Lundbeck SAS, Issy-les-Moulineaux, France
PMH81	Lundbeck, Hamburg, Germany
PMH82	None
PMH83	None
PMH84	Pfizer, Madrid, Spain
PMS1	None
PMS2	AHW, Edmonton, AB, Canada
PMS3	Eli Lilly and Company, Indianapolis, IN, USA
PMS4	Auxilium, Malvern, PA, USA
PMS5	None
PMS6	Roche, Woerden, The Netherlands
PMS7	None
PMS8	Eli Lilly and Company, Indianapolis, IN, USA
PMS9	DePuy Mitek, Inc., Raynham, MA, USA
PMS10	None
PMS11	Pfizer, Rome, Italy
PMS12	BristolMeyerSquibb Italia, Rome, Italy
PMS13	Pfizer, Moscow, Russia
PMS14	Immunex Corporation, a wholly owned subsidiary of Amgen Inc., and by Wyeth, which was acquired by Pfizer Inc. in October 2009, Thousand Oaks, CA, USA
PMS15	Immunex Corporation, a wholly owned subsidiary of Amgen Inc., and by Wyeth, which was acquired by Pfizer Inc. in October 2009, Thousand Oaks, CA, USA
PMS16	Janssen-Cilag, Neuss, Germany
PMS17	None
PMS18	None
PMS19	Amgen Hellas, Marousi, Greece
PMS20	None
PMS21	Ministry of Health and Welfare, Seoul, South Korea
PMS22	Amgen Canada Inc., Mississauga, ON, Canada
PMS23	Ministry of Health, Labor and Welfare, Tokyo, Japan
PMS24	Abbott Labs, Istanbul, Turkey
PMS25	None
PMS26	Pfizer, New York, NY, USA
PMS27	Amgen CEE HO, Vienna, Austria
PMS28	Amgen CEE HO, Vienna, Austria
PMS29	Bristol-Myers Squibb, Rueil Malmaison, France
PMS30	Roche Farmacêutica Química, Lda., Amadora, Portugal
PMS31	Bristol Myers Squibb Pharmaceuticals, London, UK
PMS32	Pfizer Brazil, Sao Paulo, Brazil
PMS33	None
PMS34	UCB Mexico, Mexico, Mexico
PMS35	Amgen Hellas, Athens, Greece
PMS36	Pfizer Brazil, Sao Paulo, Brazil
PMS37	HFA Healthcare, Birmingham, UK
PMS38	MedImmune LCC, Gaithersburg, MD, USA
PMS39	None
PMS40	Pfizer Brazil, Sao Paulo, Brazil
PMS41	MSD Australia, Sydney, Australia
PMS42	None
PMS43	Pfizer Portugal, Lisbon, Portugal
PMS44	Amgen, Cambridge, UK
PMS45	UCB, Bruxelles, Belgium
PMS46	UCB, Madrid, Spain
PMS47	Merck, Whitehouse Station, NJ, USA
PMS48	Amgen, Barcelona, Spain

Reference Code	Financial Support
PMS49	Roche, Woerden, The Netherlands
PMS50	None
PMS51	None
PMS52	None
PMS53	None
PMS54	None
PMS55	None
PMS56	Centre for Public Affairs Studies Foundation, Budapest, Hungary; Roche Hungary, Budapest, Hungary; TÁMOP 4.2.1/B-09/1/KMR-2010-0005, Budapest, Hungary
PMS57	Eli Lilly and Company, Indianapolis, IN, USA
PMS58	Eli Lilly and Company, Indianapolis, IN, USA
PMS59	Merck & Co., Inc., Whitehouse Station, NJ, USA
PMS60	Eli Lilly and Company, Indianapolis, IN, USA
PMS61	UCB, Brussels, Belgium
PMS62	Celgene Corporation, Warren, NJ, USA
PMS63	USB, Monheim, Germany
PMS64	Pfizer, Tadworth, UK
PMS65	Graduate School of Chulalongkorn University, Bangkok, Thailand
PMS66	Eli Lilly and Company, Indianapolis, IN, USA
PMS67	None
PMS68	Abbott Greece, Athens, Greece
PMS69	None
PMS70	Eli Lilly and Company, Indianapolis, IN, USA
PMS71	None
PMS72	Eli Lilly and Company, Indianapolis, IN, USA
PMS73	Pfizer, Moscow, Russia
PMS74	None
PMS75	Merck, Sharp & Dohme, Paço de Arcos (Oeiras), Portugal
PMS76	DePuy Mitek, Inc., Raynham, MA, USA
PMS77	Washington State Department of Labor and Industries, Olympia, WA, USA
PMS78	Medtronic Inc, Tolochenaz, Switzerland
PMS79	Bristol Myers Squibb Pharmaceuticals, London, UK
PND1	Biogen Idec, Wellesley, MA, USA
PND2	Teva Neuroscience Inc, Hersham, PA, USA
PND3	TEVA Pharma SLU, Madrid, Spain
PND4	None
PND5	None
PND6	None
PND7	NOVARTIS PHARMA AG, Basel, Switzerland
PND8	PFSA, Boulogne, France
PND9	TEVA Innovative España, Madrid, Spain
PND10	Biogen Idec, Weston, MA, USA
PND11	TEVA Pharma, Madrid, Spain
PND12	GlaxoSmithKline, Research Triangle Park, NC, USA; Human Genome Services, Rockville, MD, USA
PND13	GlaxoSmithKline, Marly le Roi, France
PND14	Instituto de Salud Carlos III, Madrid, Spain
PND15	Allergan Singapore, Singapore, Singapore
PND16	Novartis Slovakia, Bratislava, Slovak Republic
PND17	Novartis Pharmaceuticals, Basel, Switzerland
PND18	GlaxoSmithKline, Research Triangle Park, NC, USA
PND19	None
PND20	None
PND21	None
PND22	None
PND23	None
PND24	None
PND25	Laboratoire GlaxoSmithKline, Marly le Roi, France
PND26	Teva Pharmaceuticals, Kansas City, MO, USA
PND27	IPSEN, Paris, France
PND28	TEVA PHARMA, MADRID, Spain
PND29	None
PND30	Almirall, Barcelona, Spain
PND31	Shire Australia Pty Limited, North Ryde, Sydney, Australia
PND32	GSK, Warszawa, Poland
PND33	Novartis Pharma B.V, Arnhem, The Netherlands
PND34	UCB, Brussels, Belgium
PND35	Novartis, Vilvoorde, Belgium
PND36	sanofi-aventis, Bridgewater, NJ, USA
PND37	Teva Pharmaceuticals, Kansas City, MO, USA
PND38	Neurosearch, Copenhagen, Denmark
PND39	Shire Australia Pty Ltd., North Ryde, Sydney, Australia
PND40	Merck & Co., Inc, West Point, PA, USA
PND41	None
PND42	Sanofi-aventis, Bridgewater, NJ, USA
PND43	Astellas Pharma Global Development, Leiderdorp, The Netherlands
PND44	Shire, Cambridge, MA, USA
PND45	PatientsLikeMe, Inc., Cambridge, MA, USA; Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA
PND46	Neurosearch, Copenhagen, Denmark
PND47	Neurosearch, Copenhagen, Denmark
PND48	PFSA, Boulogne, France
PND49	None
PND50	University of Georgia, College of Pharmacy, Department of Clinical and Administrative Pharmacy, Athens, GA, USA
PND51	Allergan, Irvine, CA, USA
PND52	Merck Serono, Geneva, Switzerland
PND53	Biogen Idec, Weston, MA, USA
PND54	Medtronic International Trading Sarl, Tolochenaz, Switzerland
PND55	None
PND56	None
PND57	Bayer HealthCare Pharmaceuticals, Wayne, NJ, USA
PND58	Shire HGT, Basingstoke, UK
PND59	None
PND60	Teva Pharmaceuticals, Kansas City, MO, USA
PND61	Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA
PND62	None
PND63	GlaxoSmithKline GmbH & Co. KG, Munich, Germany
PND64	Bayer HealthCare, Wayne, NJ, USA
PND65	None
PND66	CAPES, Ribeirao Preto, Brazil
PND67	None
PND68	EAHC, Luxembourg, Luxembourg
PRM1	None
PRM2	Novartis Pharmaceuticals, Barcelona, Spain
PRM3	None
PRM4	None
PRM5	None
PRM6	None
PRM7	None
PRM8	Chulalongkorn University, Bangkok, Thailand
PRM9	Costello Medical Consulting, Cambridge, UK
PRM10	None
PRM11	Symmetron limited, Elstree, UK
PRM12	None
PRM13	None
PRM14	TI Pharma, Leiden, The Netherlands; Utrecht University, Utrecht, The Netherlands; University Medical Center Utrecht, Utrecht, The Netherlands; GSK, Zeist, The Netherlands; University Medical Center Groningen, Groningen, The Netherlands; Groningen University, Groningen, The Netherlands; Sanofi-Aventis, Gouda, The Netherlands
PRM15	None
PRM16	None
PRM17	Departament de Salut de la Generalitat de Catalunys, Barcelona, Spain; AGAUR (2009 SGR 1095), Barcelona, Spain
PRM18	None
PRM19	Double Helix Consulting, London, UK
PRM20	None
PRM21	None
PRM22	None
PRM23	UK NHS Health Technology Assessment (HTA) Programme, Southampton, UK
PRM24	None
PRM25	Sanofi-aventis, Paris, France
PRM26	the university of Sheffield, Sheffield, UK
PRM27	None
PRM28	HTA Consulting, Krakow, Poland
PRM29	None
PRM30	PatientsLikeMe, Cambridge, MA, USA
PRM31	None
PRM32	ZonMW, The Hague, The Netherlands
PRM33	Instituto de Salud Carlos III, Madrid, Spain
PRM34	None
PRM35	None
PRM36	None
PRM37	None
PRM38	University of Sheffield, Sheffield, UK
PRM39	None
PRM40	None
PRM41	University of Sheffield, Sheffield, UK
PRM42	None
PRM43	Almac Clinical Technologies, Souderton, PA, USA
PRM44	None
PRM45	None
PRM46	None
PRM47	None
PRM48	None
PRM49	None
PRM50	None
PRM51	HealthCore, Inc., Wilmington, DE, USA
PRM52	Beca Chile, Santiago, Chile

Reference Code	Financial Support
PRM53	None
PRM54	Thomson Reuters, Washington, DC, USA
PRM55	None
PRM56	None
PRM57	None
PRM58	None
PRM59	None
PRM60	Bristol-Myers Squibb, Lawrenceville, NJ, USA
PRM61	None
PRM62	National Institute for Health Research, London, UK
PRM63	GlaxoSmithKline Biologicals, Wavre, Belgium
PRM64	None
PRM65	None
PRM66	None
PRM67	None
PRM68	Hospital Quiron Bizkaia, Bilbao, Spain
PRM69	None
PRS1	Pfizer Pharmaceutics Inc., São Paulo, Brazil
PRS2	Adheris, Inc., Burlington, MA, USA
PRS3	Talecris Biotherapeutics, Frankfurt, Germany
PRS4	Instituto de Salud Carlos III, Madrid, Spain
PRS5	Roche Polska Sp. z o.o., Warsaw, Poland
PRS6	Boehringer Ingelheim GmbH, Ingelheim, Germany
PRS7	Pfizer Brazil, Sao Paulo, Brazil
PRS8	Vertex Pharmaceuticals Incorporated, Cambridge, MA, USA
PRS9	Stallergenes GmbH, Kamp-Lintfort, Germany
PRS10	ALK-Abello, Hørsholm, Denmark
PRS11	Stallergenes, Kamp-Lintfort, Germany
PRS12	Chiesi España SA, Barcelona, Spain
PRS13	Allergopharma, Reinbek, Germany
PRS14	novartis, Sao Paulo, Brazil
PRS15	Novartis, Sao Paulo, Brazil
PRS16	Nycomed Pharma, Madrid, Spain
PRS17	Basilea Pharmaceutica Ltd., Basel, Switzerland
PRS18	Vertex Pharmaceuticals Incorporated, Cambridge, MA, USA
PRS19	Oblikue Consulting, Barcelona, Spain
PRS20	AstraZeneca AB, Södertälje, Sweden
PRS21	Pfizer SLU, Madrid, Spain
PRS22	None
PRS23	Vertex Pharmaceuticals Incorporated, Cambridge, MA, USA
PRS24	Pfizer SLU, Madrid, Spain
PRS25	GlaxoSmithKline, Uxbridge, UK
PRS26	None
PRS27	Cegedim Strategic Data Medical Research Ltd., London, UK
PRS28	Novartis, East Hanover, NJ, USA
PRS29	None
PRS30	Novartis Pharmaceuticals Australia, North Ryde, Australia
PRS31	Novartis, Sao Paulo, Brazil
PRS32	Novartis Pharma BV, Arnhem, The Netherlands
PRS33	Pfizer Hellas, Athens, Greece
PRS34	Nycomed Pharma S.A., Madrid, Spain
PRS35	Novartis, Athens, Greece
PRS36	Chiesi Farmaceutici, Parma, Italy
PRS37	GlaxoSmithKline, Moscow, Russia
PRS38	Nycomed, Stockholm, Sweden
PRS39	Nycomed Pharma AG, Dübendorf, Switzerland
PRS40	GSK, Warszawa, Poland
PRS41	Stallergenes GmbH, Kamp-Lintfort, Germany
PRS42	None
PRS43	None
PRS44	None
PRS45	MSD Ltd., Hoddesdon, UK
PRS46	Organisation Pneumologique pour la Recherche et l'Amélioration des Soins (OPRAS), Paris, France
PRS47	GlaxoSmithKline, Moscow, Russia
PRS48	Pfizer, San Jose, Costa Rica
PRS49	None
PRS50	Novartis Pharma B.V., Arnhem, The Netherlands
PRS51	Forest Research Institute, Jersey City, NJ, USA
PRS52	ZonMW, The Hague, The Netherlands
PRS53	Novartis Pharmaceuticals UK Limited, Camberley, UK
PRS54	GlaxoSmithKline, Uxbridge, UK
PRS55	Novartis Pharmaceuticals UK Limited, Camberley, UK
PRS56	Boehringer Ingelheim GmbH, Ingelheim am Rhein, Germany
PRS57	GlaxoSmithKline Slovakia, Bratislava, Slovak Republic
PRS58	None
PRS59	Novartis Pharmaceuticlas, Barcelona, Spain
PRS60	Novartis Pharmaceuticals, Barcelona, Spain
PRS61	None
PRS62	None
PRS63	None
PRS64	None
PRS65	Novartis Pharmaceuticals UK Limited, Frimley, UK
PRS66	None
PRS67	Bayer Schering Pharma, Diegem, Belgium
PRS68	Johnson and Johnson Medical Asia-Pacific, Singapore, Singapore
PRS69	None
PRS70	Pfizer UK Ltd., Tadworth, Surrey, UK
PRS71	Pfizer Global Pharmaceuticals, New York, NY, USA
PRS72	GlaxoSmithKline, Verona, Italy
PRS73	Nestlé Nutrition Institute, Vevey, Switzerland
PRS74	None
PRS75	None
PRS76	GlaxoSmithKline, London, UK
PRS77	Novartis, Horsham, UK
PR1	Novo Nordisk, Søborg, Denmark
PR2	None
PR3	None
PR4	Commonwealth Fund, New York, NY, USA
PSS1	alcon france, rueil-malmaison, France
PSS2	Novartis Pharmaceuticals Canada Inc, Dorval, QC, Canada
PSS3	Novartis Pharmaceuticals Canada Inc, Dorval, QC, Canada
PSS4	ALCON, Puurs, Belgium
PSS5	ALCON, Puurs, Belgium
PSS6	Bayer Korea, Seoul, South Korea
PSS7	Novartis Pharma A.G., Basel, Switzerland
PSS8	Bristol-Myers Squibb, Uxbridge, UK
PSS9	Novartis Pharma B.V., Arnhem, The Netherlands
PSS10	ALCON, Puurs, Belgium
PSS11	None
PSS12	Novartis Pharmaceuticals Canada Inc, Dorval, QC, Canada
PSS13	Celgene Corporation, Summit, NJ, USA
PSS14	Basilea Pharmaceutica International Ltd., Basel, Switzerland
PSS15	None
PSS16	Novartis, Vienna, Austria
PSS17	Novartis Hungary, Budapest, Hungary
PSS18	Allergan Pharmaceuticals Ireland, Westport, Ireland
PSS19	ALCON, Puurs, Belgium
PSS20	Abbott Laboratories, Madrid, Spain
PSS21	Janssen-Cilag A/S, Birkeröd, Denmark
PSS22	None
PSS23	Nestlé Nutrition Institute, Vevey, Switzerland
PSS24	Janssen, Moscov, Russia
PSS25	Allergan EAME, Marlow, UK
PSS26	Allergan EAME, Marlow, UK
PSS27	Eye Hospital, Rotterdam, The Netherlands
PSS28	Bristol-Myers Squibb, Plainsboro, NJ, USA
PSS29	Celgene Corporation, Summit, NJ, USA
PSS30	Novartis AG, Basel, Switzerland
PSS31	Basilea Pharmaceutica Ltd., Basel, Switzerland
PSS32	Alcon Research Ltd., Basel, Switzerland
PSS33	Basilea, Basel, Switzerland
PSS34	Alcon Laboratories, Fort Worth, TX, USA
PSS35	Alcon Laboratories, Fort Worth, TX, USA
PSS36	Genentech, Inc, South San Francisco, CA, USA
PSS37	GSK, Wavre, Belgium
PSS38	PFSA, Boulogne, France
PSS39	None
PSS40	GSK Biologicals, Wavre, Belgium
PSS41	MSD, Madrid, Spain
PSS42	Italian Drug Agency (AIFA), Rome, Italy
PSS43	Merck Sharp & Dohme (Australia) Pty Limited, North Ryde, Sydney, Australia
PSS44	None
PSS45	Janssen-Cilag, Stockholm, Sweden
PSS46	Novartis Farmacéutica, S.A., Barcelona, Spain
PSU1	None
PSU2	Novartis Pharmaceutical Corporation, East Hanover, NJ, USA
PSU3	Novartis Pharmaceutical Corporation, East Hanover, NJ, USA
PSU4	Novartis Pharmaceutical Corporation, East Hanover, NJ, USA
PSU5	None
PSU6	alcon france, Rueil-malmaison, France
PSU7	None
PSU8	Alcon research Ltd., Puurs, Belgium
PSU9	Amgen, Inc., Thousand Oaks, CA, USA
PSU10	Philips Healthcare, Hamburg, Germany
PSU11	Baxter, Maurepas, France
PSU12	Abbott Laboratories, Abbott Park, IL, USA
PSU13	Pfizer S.L.U, Madrid, Spain
PSU14	Teva Pharmaceuticals, Kansas City, MO, USA
PSU15	Bristol-Myers Squibb, Rueil-Malmaison, France
PSU16	Instituto de Salud Carlos III, Madrid, Spain
PSU17	None

Reference Code	Financial Support
PSU18	National Health Service, Madrid, Spain
PSU19	None
PSU20	AATM, Barcelona, Spain; FIS, Madrid, Spain
PSU21	None
PSU22	Alcon Laboratories, Fort Worth, TX, USA
PSU23	None
PSU24	None
PSU25	Instituto de Salud Carlos III, Madrid, Spain
PSU26	None
PSU27	None
PSU28	None
PSY1	Janssen Global Services LLC, Beerse, Belgium
PSY2	Abbott Canada, St-Laurent, QC, Canada
PSY3	Johnson&Johnson Medical, Madrid, Spain
PSY4	Merck & Co, Whitehouse Station, NJ, USA
PSY5	Gruenenthal GmbH, Aachen, Germany
PSY6	Amgen, Thousand Oaks, CA, USA
PSY7	None
PSY8	Astellas Pharma, Madrid, Spain
PSY9	None
PSY10	Ipsen Pharma, Barcelona, Spain
PSY11	None
PSY12	Eli Lilly and Company, Indianapolis, IN, USA
PSY13	Eli Lilly and Company, Indianapolis, IN, USA
PSY14	Eli Lilly and Company, Indianapolis, IN, USA
PSY15	None
PSY16	Novo Nordisk A/S, Soborg, Denmark
PSY17	GlaxoSmithKline, Stockley Park, UK
PSY18	Pfizer Pharmaceutics Inc., São Paulo, Brazil
PSY19	Amgen Europe, Zug, Switzerland
PSY20	Glaxo Smith Kline, Paris, France
PSY21	Eli Lilly and Company, Indianapolis, IN, USA
PSY23	Pfizer, Madrid, Spain
PSY24	Pfizer, Madrid, Spain
PSY25	None
PSY26	None
PSY27	Amgen (Europe) GmbH, Zug, Switzerland
PSY28	Baxter Healthcare, Harlow, UK
PSY29	Astellas, Vienna, Austria
PSY30	None
PSY31	Grünenthal GmbH, Aachen, Germany
PSY32	Grünenthal GmbH, Aachen, Germany
PSY33	GlaxoSmithKline, Moscow, Russia
PSY34	Vifor Ltd., Zurich, Switzerland
PSY35	Genesis Pharma SA, Athens, Greece
PSY36	National Institute for Health Research, Southampton, UK
PSY37	Ethicon, Paris, France
PSY38	GlaxoSmithKline, Research Triangle Park, NC, USA
PSY39	None
PSY40	Grünenthal GmbH, Aachen, Germany
PSY41	Canadian Haemophilia Society, Toronto, ON, Canada
PSY42	Pfizer Deutschland DmbH, Berlin, AL, Germany
PSY43	Novo Nordisk A/S, Søborg, Denmark
PSY44	Eli Lilly and Company, Indianapolis, IN, USA
PSY45	UCB, Brussels, Belgium
PSY46	ZonMw, Den Haag, The Netherlands
PSY47	Baxter, Deerfield, IL, USA
PSY48	None
PSY49	PFSA, Castres, France
PSY50	PFSA, Castres, France
PSY51	None
PSY52	None
PSY53	Medco Health Solutions, Inc, Franklin Lakes, NJ, USA
PSY54	None
PSY55	Dutch Society for Hematology, Amsterdam, The Netherlands
PSY56	None
PSY57	CSD Medical Research, London, UK
PSY58	Pfizer, Madrid, Spain
PUK1	Astellas Pharma Europe Ltd., Staines, UK
PUK2	Takeda Global Research & Development Centre (Europe) Ltd., London, UK
PUK3	None
PUK4	Bristol Myer Squibb, Princeton, NJ, USA
PUK5	Bristol-Myers Squibb EU, Paris, France
PUK6	PFSA, Boulogne, France
PUK7	None
PUK8	Mitsubishi Tanabe Pharma America (MTPA), Inc., Warren, NJ, USA
PUK9	None
PUK10	Astellas Pharma Europe Ltd., Staines, UK
PUK11	Gambro Hospal GmbH, Gröbenzell, Germany
PUK12	Eli Lilly and Company, Indianapolis, IN, USA
PUK13	None
PUK14	None
PUK15	Amgen Europe, Zug, Switzerland
PUK16	Pfizer, Madrid, Spain
RS1	Association of British Pharmaceutical Industry, London, UK
RS2	Costello Medical Consulting Ltd., Cambridge, UK
RS3	Bristol-Myers Squibb, Braine L'Alleud, Belgium
RS4	Costello Medical Consulting, Cambridge, UK
UT1	None
UT2	None
UT3	Medical Research Council, London, UK
UT4	Grünenthal GmbH, Aachen, Germany
VI1	ZonMw, DenHaag, The Netherlands
VI2	None
VI3	Roche Oy, Espoo, Finland
VI4	None

ISPOR 14TH ANNUAL EUROPEAN CONGRESS RESEARCH ABSTRACTS AUTHOR INDEX

C

D

E

F

M

VALUE IN HEALTH 14 (2011) A535-A570

Available online at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.elsevier.com/locate/jval

ABSTRACTS

ISPOR 3RD LATIN AMERICA CONFERENCE RESEARCH ABSTRACTS

PODIUM SESSION I: CARDIOVASCULAR DISORDERS OUTCOMES RESEARCH

CV1

A COST-UTILITY ANALYSIS OF PROPHYLACTIC THERAPY FOR VENOUS THROMBOEMBOLISM WITH DABIGATRAN ETEXILATE OR ENOXAPARIN

Burbano-Levy X[1], Herrán S[1], Sánchez G[1], Mieth K[2], Alfonso-Cristancho R[3]
[1]*RANDOM Foundation, Bogotá, Colombia,* [2]*Fundación Santa Fe de Bogotá - Banco de Huesos y Tejidos de la Fundación Cosme y Damián, Bogotá, Colombia,* [3]*University of Washington, Seattle, WA, USA*

OBJECTIVES: To conduct a cost-utility evaluation of dabigatran etexilate compared with enoxaparin for the prevention of venous thromboembolism (VTE) after total knee replacement (TKR) and total hip replacement (THR) in Colombia. **METHODS:** An acute phase model, using decision analysis, and a long-term simulation Markov model were developed to compare the clinical outcomes, utilities, and direct medical costs of dabigatran 220 mg once daily and subcutaneous enoxaparin 40 mg once daily for VTE prophylaxis after TKR or THR. Time frame for the acute inpatient-phase was 14 days for TKR and 30 days for THR; adjustments for adverse events and average length of hospital stay were performed. The long-term simulation was performed using 6-months cycle transitions to eight health states for both TKR and THR. Transition probabilities for VTE and bleeding events were derived from Phase III studies comparing the two treatments. The probabilities of long-term events were estimated using data from published longitudinal studies. The payer perspective for a lifetime horizon was used. Sensitivity analyses were performed to assess the model robustness. The annual discount rate was set at 3.0%. **RESULTS:** During the acute phase, for TKR, patients with dabigatran had lower direct medical costs than enoxaparin (US$1.005,83 vs. US$1.392,25), with 0.1 difference in QALYs (0.9 vs.0.8 respectively). For THR, cost of dabigatran were US$868.73, and US$1,007.55 for enoxaparin; no differences in QALYs were calculated. In the long-term follow-up, for both procedures, the costs associated with dabigatran were US$115,433, compared to US$122,695 for enoxaparin, with differences in QALYs of 7.4 for dabigatran and 6.7 for enoxaparin. Life-term analyses reported a dominance of dabigatran over enoxaparin. Results were robust across sensitivity analyses. **CONCLUSIONS:** In Colombia, thromboprophylaxis with dabigatran was cost-saving compared with enoxaparin in patients undergoing major joint replacement.

CV2

COST-EFFECTIVENESS OF PRASUGREL VERSUS CLOPIDOGREL IN PATIENTS WITH ACUTE CORONARY SYNDROMES UNDERGOING PERCUTANEOUS CORONARY INTERVENTION IN THE PRIVATE SECTOR IN MÉXICO

Mondragon R[1], Arrieta-Maturino E[2], Vargas-Valencia JJ[3], Ramírez-Gámez J[2], Martínez-Fonseca J[2], Guzman-Sotelo M[2]
[1]*Hospital Central-Sur de Alta Especialidad PEMEX, México D.F., México,* [2]*Eli Lilly and Company, México D.F., México,* [3]*Econopharma Consulting S. A. de C. V., México D.F., México*

OBJECTIVES: To evaluate the cost-effectiveness of prasugrel versus clopidogrel in patients with acute coronary syndromes (ACS) undergoing percutaneous coronary intervention (PCI) from the private healthcare payer perspective in Mexico. **METHODS:** The alternatives were prasugrel (loading dose 60 mg, maintenance dose 10 mg daily) versus clopidogrel (loading dose 300 mg, maintenance dose 75 mg daily). A Markov model was developed. Only direct medical care costs were considered for one year. The efficacy measure was a composite of the death from cardiovascular causes, nonfatal myocardial infarction or nonfatal stroke, and stent thrombosis reported in the trial directly comparing prasugrel and clopidogrel (TRITON TIMI-38). Three types of populations were evaluated separately; overall, patients with diabetes mellitus and the subset of diabetics treated with insulin. Care costs were derived from medical records, and the costs of drugs were assumed to be the same. Costs and the model were validated by experts. **RESULTS:** According to the model, patients treated with prasugrel had fewer events in the three types of populations evaluated over a 12 month time horizon. The number of events; death from cardiovascular causes, nonfatal myocardial infarction-stroke and stent thrombosis avoided by 10,000 patients were distributed as follows: overall population, 15, 239 and 132, diabetics, 51, 667 and 175, diabetics on insulin, 87, 1041 and 496. The average cost per patient (2010 Mexican pesos) treated with prasugrel was lower compared with clopidogrel, for the overall population (MXN$106,549 vs. MXN$108,991), diabetics (MXN$114,832 vs. MXN$130,872) and diabetics treated with insulin (MXN$121,089 vs. MXN$157,502) **CONCLUSIONS:** Results from the present analysis suggest that the use of prasugrel (instead of clopidogrel) in patients with ACS undergoing PCI, represents a more effective strategy at a lower cost (dominant strategy), a cost-saving alternative for institutions of private healthcare in Mexico.

CV3

ANÁLISIS DE COSTO EFECTIVIDAD EN EL CIERRE DE LA COMUNICACIÓN INTERATRIAL OSTIUM SECUNDUM: TÉCNICA PERCUTÁNEA VERSUS QUIRÚRGICA

Flores A[1], Contreras I[2], Alva E[3]
[1]*CMN 20 de Noviembre ISSSTE, México D.F., México,* [2]*Instituto Mexicano del Seguro Social, México D.F., México,* [3]*CMN SXXI, México D.F., México*

OBJETIVOS: La comunicación interatrial (CIA) es la segunda cardiopatía congénita en la infancia y la tercera en el adulto. Realizamos un análisis costo-efectividad del cierre de la CIA con Técnica Percutánea (TP) con oclusor Amplatzer septal occluter ASOÒ vs Técnica Quirúrgica (TQ), desde la perspectiva del proveedor de servicios de salud. **METODOLOGÍAS:** Mediante una cohorte prospectiva de pacientes con CIA atendidos en un hospital de tercer nivel del Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (ISSSTE), se identificaron y compararon los costos y efectividades del cierre con TP y con TQ, en ocho meses de seguimiento. La medida de efectividad fue el éxito clínico en el cierre sin complicaciones mayores al final del seguimiento (ECSCM). Se estimó el costo promedio por paciente y rango intercuartílico, mediante la identificación y cuantificación de los recursos utilizados durante el seguimiento. Los costos unitarios se obtuvieron de las bases de datos de la institución. Los costos se expresaron en pesos mexicanos del 2010. Se definió un valor de $p < 0.05$ como estadísticamente significativo y se utilizaron las pruebas de U de Mann Whitney y Chi cuadrada. **RESULTADOS:** Entre enero de 2008 y Diciembre de 2009 se estudiaron 89 pacientes con CIA; Un total de 51 fueron tratados con TQ y 38 con TP, la ECSCM con TQ fue 69% vs. 94% con TP ($p<0.05$). El costo promedio por paciente en el grupo de TQ fue: $137,495.16 ($108,418.10-$146,661.60) vs. $99,850.96 ($99,746.50-$102,008.90) con TP ($p<0.05$). El costo por paciente con ECSCM con TQ fue $225,395.34 vs. $109,509.72 con TP. El costo-efectividad incremental del tratamiento con TP vs TQ es de -$124,719.00. **CONCLUSIONES:** El cierre de la CIA, en una institución de seguridad social mexicana mediante TP es costo-ahorradora al compararse con la TQ, información que debe ser considerada por los tomadores de decisiones.

CV4

COST-EFFECTIVENESS OF IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR IN PATIENTS WITH RISK FACTORS FOR SUDDEN DEATH IN ARGENTINA

Alcaraz A[1], Gonzalez Zuelgaray J[2], Augustovski F[1]
[1]*Institute for Clinical Effectiveness and Health Policy, Buenos Aires, Argentina,* [2]*PRONETAC, Buenos Aires, Argentina*

OBJECTIVES: To evaluate the cost-effectiveness and cost-utility of the implantable cardioverter–defibrillator (ICD) among patients who are at risk for sudden death in Argentina, from three insurance categories: public health, social security and private. **METHODS:** We developed a Markov model to evaluate the survival, quality of life and cost of the prophylactic implantation of an ICD, as compared with pharmacological therapy, among three different target populations defined using clinical trials selected through a systematic review. We measured effectiveness, resource use and cost parameters. A healthcare system perspective was adopted and a 3% discount rate was used. **RESULTS:** The use of an ICD was more costly but more effective than control therapy. The cohort with the greatest benefits was represented by the MADIT I study showing an incremental cost effectiveness rate (ICER) of $8,539 (dollar 2009) for public, $9,371 for social security and $10,083 for private sector. ICERs for MADIT II population were $17,379, $18,574 and $19,799, respectively. The secondary prevention cohort showed the worst results with ICERs of $21,016, $22,520 and $24,012. The analysis was robust to different deterministic and probabilistic sensitivity analyses, except for the cost of ICD and for battery life. **CONCLUSIONS:** The results varied considerably depending on the cohort and discretely according to the health system. ICD could be cost-effective in Argentina, mainly in the MADIT I patients.

PODIUM SESSION I: HEALTH CARE EXPENDITURE OR REIMBURSEMENT STUDIES

EX2

HEALTH CARE RESOURCE USE AMONG PATIENTS WITH BIPOLAR DISORDER FROM BRAZIL AND VENEZUELA: SUBGROUP ANALYSIS OF DATA FROM A LARGE MULTINATIONAL LONGITUDINAL STUDY (WAVE-BD STUDY)

Vieta E[1], Baptista T[2], Bifano M[3], Kerr-Corrêa F[4], Grohs G[5], de Oliveira I[6], Vielma X[7], Montes C[8], Beluche S[8]
[1]*Bipolar Disorders Programme University of Barcelona, Hospital Clínic, IDIBAPS, CIBERSAM, Barcelona, Spain,* [2]*Instituto Autónomo Universidad de Los Andes, Departmento de Fisiología, Facultad de Medicina Universidad de Los Andes, Mérida, Venezuela,* [3]*Humana Docencia, Instituto*

de Medicina Integral, Caracas, Venezuela, [4]Universidade Estadual Paulista (UNESP), Botucatu, Brazil, [5]Instituto de Psiquiatria de Santa Catarina, Florianópolis, Brazil, [6]Sanatório São Paulo, Salvador, Brazil, [7]Hospital General Dr. Miguel Pérez Carreño, Caracas, Venezuela, [8]Medical Department, AstraZeneca Pharmaceuticals, Caracas, Venezuela

OBJECTIVES: WAVE-bd (International ambispective study of the clinical management and burden of bipolar disorder [BD]) is ongoing to provide the healthcare community with updated and representative longitudinal data on this disease. As part of this study, healthcare utilization was assessed in a cohort of Brazilian and Venezuelan BD patients. **METHODS:** Multinational, multicenter, non-interventional, longitudinal study of patients diagnosed with BD with ≥1 mood event in the preceding 12 months (retrospective data collection from index mood event to enrollment, followed by a minimum of 9 months' prospective follow-up). Site and patient selection provided a representative sample of patients from both countries, including private settings and hospitals. Data from Brazil and Venezuela for the overall BD population (inclusive of BD type I and II) are presented. **RESULTS:** In total, 397 patients were recruited from public hospitals and university hospitals in Brazil [n=146 (88.0%) and n=20 (12.0%), respectively; N=166] and from private practice and public and university hospitals in Venezuela [n=76 (32.9) and n=155 (67.1), respectively; N=231]. Planned visits to the psychiatrist were the most frequently used resource (7.77 ± 7.02 [mean ± SD] visits/patient-year) and there were also 0.48 ± 1.35 spontaneous visits to this specialist. The mean number of visits to the psychologist was 0.99 ± 5.13 per patient-year. Hospitalization rates since diagnosis and the index study event were 0.33 ± 0.54 and 0.18 ± 0.54 per patient-year, respectively. Visits to group therapy sessions, general practitioners and the emergency room since the index study event were 0.13 ± 1.82, 0.56 ± 0.71 and 0.15 ± 0.75 per patient-year, respectively. There were 140 ± 460 suicide attempts per 1000 patient-years since diagnosis. **CONCLUSIONS:** Management of patients with BD representative of everyday clinical practice involved considerable use of resources in two Latin American countries. Study funded by AstraZeneca; Clinical Trials Registry: NCT01062607.

EX3

INCREMENTAL COST OF IMPLEMENTING A CARE PROGRAM FOR PEOPLE WITH TYPE 2 DIABETES IN ARGENTINA

Gonzalez L, Caporale JE, Elgart JF, Gagliardino JJ
CENEXA - Centro de Endocrinología Experimental y Aplicada (UNLP-CONICET La Plata, Centro Colaborador OPS/OMS), La Plata, Buenos Aires, Argentina

OBJECTIVES: To estimate the incremental cost of implementing a care program for people with type 2 diabetes in Argentina. **METHODS:** ALAD guidelines were used to identify resources necessary to implement a diabetes care program in two Argentinean provinces with opposite socioeconomic characteristics (Cordoba and Misiones). Microcosting techniques were employed to estimate this cost from a public payer perspective, and considering a province without such diabetes program. Probabilistic sensitivity analysis following Monte Carlo simulation was used to determine the number of visits and practices, probability of insulin treatment, combined drug therapy for hypertension, dislipidemia, annual number of test strips for self-monitoring blood glucose (SMBG) and unit cost. **RESULTS:** The SMBG represent in both provinces ~50% of the annual incremental cost per patient followed by that of the treatment of hypertension, dyslipidemia and diabetes. The lowest corresponded to human resources (<5%). The annual individual incremental expenditure was 32% higher in Córdoba due to the pharmacological treatment of diabetes (> 90%). Best statistical distribution comparison for incremental costs in Córdoba and Misiones indicates that: a) Misiones has a 32% average incremental cost lower than Córdoba; and b) the dispersion around the adjusted mean is greater for Cordoba than for Misiones. The main determinants of incremental costs variation associated to proposed treatment in Córdoba and Misiones were: a) probability of insulin treatment; b) unitary cost of SMBG strips; c) number of HbA1c determinations; and d) number of strips and lancets needed. The impact of each of these variables would be different in each province. **CONCLUSIONS:** These data: a) provide the first objective evaluation of the cost of a diabetes program in Argentina, from a public payer perspective, and b) identify critical issues to consider when planning the implementation of such a program in places with limited resources.

EX4

EFECTIVIDAD DE LOS INDICADORES DE CALIDAD DE LA PRESCRIPCIÓN REGIONALES EN EL SNS ESPAÑOL

Garrido E[1], Sabater FJ[2], Hurtado P[1], Espinós B[1], Guarga L[1], García Losa M[2], Vieta A[1], Badia X[1]
[1]*IMS Health HEOR, Barcelona, Spain,* [2]*IMS Health HEOR, Madrid, Spain*

OBJECTIVOS: En el Sistema Nacional de Salud (SNS) español, las estatinas son uno de los grupos terapéuticos de mayor gasto farmacéutico. Las 17 regiones españolas gestionan su presupuesto sanitario mediante la implementación de diferentes políticas farmacéuticas. Las regiones consideran a simvastatina la estatina de elección y por ello algunas regiones fomentan su prescripción a través de los indicadores de calidad de la prescripción (ICP). El objetivo de este estudio fue analizar el efecto de la existencia de ICP de estatinas en la potenciación de la prescripción de simvastatina respecto al resto de principios activos del grupo. **METODOLOGÍAS:** Para identificar los ICP se ha realizado una búsqueda en los sitios web de los servicios de salud de las regiones. Con las bases de datos de IMS Health, se han analizado las cuotas de mercado de simvastatina vs el resto de estatinas por región (unidades vendidas de enero a septiembre de 2010). Se ha analizado la correlación bivariada no paramétricas entre la existencia de ICP de estatinas vs la cuota de mercado de simvastatina. **RESULTADOS:** 6 regiones tenían ICP en funcionamiento. Las cuotas de mercado de simvastatina oscilaron entre el 24,3% (Valencia) y el 51,1% (Andalucía). La cuota de mercado de simvastatina se correlacionó positivamente de manera estadísticamente significativa con la existencia de ICP de estatinas en las regiones (r=0,660, p=0,014). La R2 reveló que la existencia de ICP de estatinas explicaba un 41% de la variabilidad en la cuota de mercado de simvastatina entre regiones. **CONCLUSIONES:** Parece ser que la existencia de un ICP de estatinas se traduce en una relación significativa con las ventas de simvastatina y, en concreto, con un aumento en la cuota de mercado de simvastatina frente al resto de estatinas en las regiones. Los ICP se pueden considerar como una política efectiva en el SNS Español.

PODIUM SESSION I: EXAMINING THE QALY

QA1

MEASURING THE BENEFITS OF HEALTH CARE: DALYS AND QALYS – DOES THE CHOICE OF MEASURE MATTER? A CASE STUDY

Colantonio L[1], Augustovski F[1], Galante J[1], Bardach A[1], Caporale J[1], Zarate V[2], Chuang LH[3], Kind P[2]
[1]*IECS - Instituto de Efectividad Clinica y Sanitaria, Buenos Aires, Argentina,* [2]*University of York, York, UK,* [3]*York Trials Unit, York, UK*

OBJECTIVES: Health benefit measurement is key in economic evaluations. Two main generic paradigms have been proposed, quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs). We explored, using two previously published models, the differences in the estimation of benefits through QALY or DALY, and whether these differences could lead to different conclusions and decision making. **METHODS:** Two previously published preventive models, developed in Excel and delivering outputs in QALYs, were adapted to estimate DALYs: a Human Papilloma Virus (HPV) – a Markov model to compare screening to vaccination in 12 year old girls - and a pneumococcal vaccination model (PNEUMO)- a deterministic model which considers the occurrence of pneumococcal diseases in a calendar year, across all age cohorts. We selected Argentina, Chile and the UK as country examples as models were used in these countries and EQ-5D social value weights wereavailable to provide as model inputs for local QALYs weights. A primary study with descriptive vignettes was done (n=73) to obtain descriptive EQ-5D data for all health states included in both models. Several alternative scenario analyses were carried-out. **RESULTS:** In HPV, QALYs gains were generally larger than DALYs avoided, which leads to more favorable decisions using the former. Differences were larger in UK and smaller in Argentina. The incorporation of discounting and age weighting increased differences in all countries, where incremental DALYs avoided represented the 75%, 68% and 43% of the QALYs gained in Argentina, Chile and UK respectively. Differences directly influenced decision making using usual thresholds. In PNEUMO differences using QALYs or DALYs were less consistent and sometimes in opposite directions. Chile showed the largest gains using both metrics. **CONCLUSIONS:** This exploratory analysis shows that using different benefit metrics in these case studies could influence final results and decisions informed by cost-effectiveness thresholds.

QA2

ANALISIS DE COSTO-UTILIDAD DE RITUXIMAB POSTERIOR AL FALLO POR ANTI-TNF EN ARTRITIS REUMATOIDE PARA COLOMBIA

Romero M[1], Latorre M[2], Alvarado C[2], Karpf E[1], Alvis N[3]
[1]*Fundación Salutia, Bogotá, Colombia,* [2]*Productos Roche Colombia, Bogotá, Colombia,* [3]*Universidad de Cartagena, Cartagena de Indias, Bolívar, Colombia*

OBJECTIVOS: Evaluar la costo-utilidad de Rituximab en pacientes con artritis reumatoide (AR) que fallaron al tratamiento con un anti-TNF-α. **METODOLOGÍAS:** Se elaboró un modelo Markov para comparar Rituximab frente a anti-TNF (Adalimumab, Infliximab y Etanercept) posterior al fallo por efectividad de otro anti-TNF. La perspectiva fue del tercero pagador y el horizonte temporal de cinco años. Se aplicó descuento del 3% a costos y desenlaces (Años de Vida Ajustados por Calidad –QALY). Los costos de atención fueron tomados a precios del 2011. Las probabilidades de transición se extrajeron de estudios clínicos según variaciones en el nivel de enfermedad de acuerdo al Disease Activity Score (DAS-28). Las utilidades fueron obtenidas de un estudio realizado en 300 pacientes colombianos, mediante la aplicación del cuestionario Health Assesment Questionnaire (HAQ) y según el nivel de DAS-28. Se realizó un análisis de sensibilidad tipo Montecarlo. **RESULTADOS:** En un horizonte temporal de cinco años, el costo del brazo con Rituximab fue de USD$2,305,891 frente a USD$2,046,357 con anti-TNF y una utilidad de 213.54 y 99.33 QALY respectivamente. La razón costo utilidad incremental (ICUR) fue de USD$2,009.27 USD/QALY's. Cuando los análisis se hicieron en un horizonte de tres años Rituximab mostró dominancia. Los resultados fueron robustos frente al análisis de sensibilidad. **CONCLUSIONES:** Rituximab, desde la perspectiva del tercer pagador, es costo-útil frente a otros anti-TNF's para el tratamiento de segunda línea de Artritis Reumatoide, ante falla en primera línea de los anti-TNF en Colombia.

QA3

COSTO-EFECTIVIDAD DE DABIGATRAN VERSUS WARFARINA EN EL MANEJO DE LA FIBRILACION AURICULAR EN COLOMBIA

Alfonso-Cristancho R[1], Herran S[2], Caicedo M[2], Gomez E[3]
[1]*University of Washington, Seattle, WA, USA,* [2]*RANDOM Foundation, Bogotá, DC, Colombia,* [3]*Clinica Shaio, Bogotá, Colombia*

OBJECTIVOS: Estimar la costo-efectividad de dabigatran o warfarina en fibrilación auricular (FA) no complicada en Colombia. **METODOLOGÍAS:** Se creó un modelo de Markov integrando las complicaciones asociadas a FA, permitiendo la transición a ocho diferentes estados de salud, incluida la muerte. La utilización de recursos para el manejo de la enfermedad fue derivada de las guías de la Sociedad de Cardiología de Colombia y validada por expertos clínicos para ajustar a la práctica usual. Los costos médicos directos fueron derivados de diferentes fuentes (públicas y privadas). Las utilidades fueron calculadas a partir de la literatura. La perspectiva del

análisis fue la del pagador con un horizonte temporal de 20 años. Los valores máximos y mínimos de efectividad y del uso de recursos fueron incluidos en los análisis de sensibilidad. Los resultados fueron descontados a una tasa del 3% anual. **RESULTADOS:** Al cabo de 20 años de seguimiento, los costos médicos directos promedio (descontados) ascendieron a US$69,972 para warfarina y US$80,173 para dabigatran; los años de vida estimados por el modelo fueron mayores para dabigatran (9.5 vs. 9.2), al igual que los QALYs (8.6 vs. 8.2). La razón de costo-efectividad incremental calculada fue de US$25,122 por QALY adicional ganado con dabigatran comparado con warfarina. El mayor impacto de los costos y uso de recursos asociados a la enfermedad se debió a los eventos y complicaciones. El 77.1% de los costos asociados a la enfermedad fueron consecuencia de los eventos y complicaciones en el grupo de warfarina mientras que con dabigatran fue del 62.9%. **CONCLUSIONES:** En Colombia, el uso de dabigatran para el manejo de FA no complicada comparado con warfarina resulta en un incremento de años de vida y QALYs, a expensas de un aumento de los costos del tratamiento pero con una reducción de eventos y costos de las complicaciones.

QA4

COST-UTILITY OF SACRAL NEUROMODULATION VERSUS AUGMENTATION CYSTOPLASTY FOR TREATMENT OF REFRACTORY URGE INCONTINENCE IN MÉXICO

Oliva-Oropeza P[1], Quiroz Angulo ME[2], Marco Antonio AC[3]
[1]*Institute of Social and Security Services for State Workers, México D.F., México,* [2]*Medtronic México, México D.F., México,* [3]*V&M Servicios de Consultoria S.C., México D.F., México*

OBJECTIVES: The purpose of this study was to conduct a cost-utility analysis comparing sacral neuromodulation and augmentation cystoplasty for the management of refractory urge urinary incontinence in Mexico. **METHODS:** Using a health care provider perspective, a state transition model was developed to compare costs (2011 Mexican pesos) and effectiveness (quality adjusted life-years, QALYs) of sacral nerve stimulation and augmentation cystoplasty. Evaluated in a Mexican hypothetical cohort, the primary outcome was the incremental cost-utility ratio (ICUR) which was defined as (sacral nerve stimulation cost – augmentation cystoplasty cost) / (sacral nerve stimulation QALYs – augmentation cystoplasty QALYs). The clinical data were obtained from major clinical trials. Costs were obtained from Diagnosis Related Groups database of the Mexican Social Security Institute. The sensitivity analysis was performed to assess the impact of varying efficacy, costs and adverse event rates over the range of reported values. **RESULTS:** In the base case scenario, sacral nerve stimulation was more effective (3.54 vs 1.64 QALYs) and more expensive ($191,825 vs. $107,912) than augmentation cystoplasty at 5-years. The incremental cost-utility ratio was $44,164 per additional QALY. Assuming a cost-effectiveness threshold of three times GDP per capita established by the World Health Organization, the sacral nerve stimulation is considered cost effective. In the sensitivity analyses, time horizon and cost of medical device were the most important determinants of variability in costs and clinical benefits. The ICUR remained cost-effective. Discount rate of 5% was applied. **CONCLUSIONS:** The use of sacral neuromodulation for refractory UUI treatment in Mexico will generate considerable quality of life improvements and it is economically cost-effective when compared with augmentation cystoplasty. Future cost-effectiveness studies should be made when botulinum toxin A injections become available in the country for the management of refractory UUI and when additional long-term efficacy and complications data become accessible.

PODIUM SESSION I:
HEALTH POLICY TREATMENT PATTERNS

TP1

PREVALENCE OF LIPID ABNORMALITIES BEFORE AND AFTER INTRODUCTION OF LIPID MODIFYING THERAPY AMONG MEXICAN PATIENTS

Aguilar-Salinas CA[1], Rivera MDR[2], Perez J[2], Limon F[3], Diggle A[3], Ambegaonkar BM[4]
[1]*Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubiran, México City, DF, México,* [2]*OMEESTADISTICOS, S.C., México D.F., México,* [3]*MSD México, México D.F., México,* [4]*Merck and Co., Inc., Whitehouse Station, NJ, USA*

OBJECTIVES: This study longitudinally examined the prevalence of lipid abnormalities and utilization of lipid-modifying therapies (LMT) to determine treatment gap in Mexican patients from regular clinical practice. **METHODS:** Using standardized chart from The Instituto Nacional de Ciencias Medicas y Nutricion, we identified patients ≥18 years of age, who initiated LMT between July 2001 and September 2007, continued treatment for 1 year, and had a complete lipid panel (LDL-C, HDL-C and triglycerides) one-year pre and post therapy. Patients with history of coronary heart disease (CHD), diabetes and 10-year CHD risk>20% were classified as high CV risk. Threshold levels for LDL-C, HDL-C and triglycerides were specified as per NCEP ATPIII Guidelines. **RESULTS:** Among 332 patients, at baseline, 2% had complete lipid control while 74%, 44% and 82% experienced elevated LDL-C, low HDL-C and elevated triglycerides respectively. Elevated LDL-C coupled with low HDL-C and/or elevated triglycerides was prevalent among 61%. LMT was introduced after one year with about 30% patients utilizing statin monotherapy and statins in combination with fibrates while about one-third used fibrate monotherapy. Post therapy, 71%, 47% and 77% continued to experience elevated LDL-C, low HDL-C and elevated triglycerides respectively while elevated LDL-C coupled with low HDL-C and/or elevated triglycerides persisted among 58%. A subset of high risk patients (n=104) had similar results with no meaningful improvement in lipid abnormalities pre and post therapy. **CONCLUSIONS:** In this longitudinal study of Mexican patients, there were no meaningful improvements in proportion of patients with controlled LDL, HDL-C, TG or multiple lipid abnormalities after initiation of LMT. Prevalence of lipid abnormality pre and post treatment did not change notably despite relatively high proportion of patients (over 60%) using fibrate therapy, either alone or in combination with statins. Economic and social issues are most likely contributing to poor goal attainment rates.

TP2

PATRONES DE TRATAMIENTO DE LA LEUCEMIA MIELOIDE CRÓNICA (LMC) EN PACIENTES RESISTENTES O INTOLERANTES A IMATINIB EN INSTITUCIONES DE SALUD PÚBLICA EN MÉXICO

Hernández-Rivera G[1], Aguayo-González Á[2], Cantu-Rodríguez OG[3], Cervera E[4], Gomez-Almaguer D[3], Gutiérrez-Aguirre CH[3], Lopez-Hernández M[5], Martínez-Baños D[6], Oropeza P[7], Rico E[8], Juarez-Garcia A[1], Vargas-Valencia J[9]
[1]*Bristol-Myers Squibb, México D.F., México,* [2]*Instituto Nacional de Ciencias Médicas y Nutrición Salvador, México D.F., México,* [3]*Hospital Universitario Dr. José Eleuterio González, Monterrey, México,* [4]*Instituto Nacional de Cancerología, México D.F., México,* [5]*Centro Médico Nacional 20 de Noviembre ISSSTE, México City, DF, México,* [6]*Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, México D.F., México,* [7]*Hospital General de Zona 8 IMSS, México D.F., México,* [8]*Hospital General Regional 110 IMSS, Guadalajara, México,* [9]*Econopharma Consulting, México D.F., México*

OBJECTIVOS: Identificar los patrones de tratamiento de la LMC en pacientes resistentes o intolerantes a Imatinib en instituciones de salud pública en México. **METODOLOGÍAS:** Se realizó una revisión retrospectiva de expedientes clínicos en seis hospitales públicos en México. Se incluyeron 242 pacientes adultos con LMC, en tratamiento con Imatinib durante al menos 12 meses. Se definieron operacionalmente resistencia e intolerancia a imatinib, dada la naturaleza retrospectiva del estudio, como un aumento o una disminución (incluida la suspensión) de la dosis de imatinib, respectivamente. **RESULTADOS:** Se observa una razón hombres-mujeres de 1:1.22, edad promedio de 49.4 años, el 94.24% de los casos se encuentran en fase-crónica al momento del diagnóstico; fase-acelerada 5.35%; y 0.41% en fase-blástica. El aspirado de médula ósea, la biopsia y el PCR para BCR/ABL, son empleados como pruebas diagnósticas en el 32%, 2% y 66% de los pacientes respectivamente. El 63.3% inician con 400mg de imatinib, el 19.7% de 500-600mg, el 2% con 800mg, y el 14.9%<400mg, con una duración media de 32.1 meses. El 57% reportan resistencia, el 15.7% intolerancia, y el 13% reportan resistencia e intolerancia. El monitoreo incluye análisis citogenético en el 82% de los casos, hibridación in situ en el 88% de los casos, PCR 24.8%, análisis de mutaciones en el 9.1% de los casos. **CONCLUSIONES:** Los patrones de tratamiento de la LMC son consistentes con las recomendaciones de las guías clínicas, con incrementos en la dosis de Imatinib o cambio a un inhibidor de tirocincinasa de segunda generación, en el caso de una respuesta no adecuada. Sin embargo, las pruebas de diagnóstico y monitoreo no se realizan en el total de pacientes o se realizan con frecuencias menores a las recomendadas en las guías internacionales. La posible explicación a esto es la falta de acceso a las pruebas de monitoreo en el sistema de salud.

TP3

PATRONES DE TRATAMIENTO Y COSTOS DE ATENCION EN PACIENTES CON ARTRITIS REUMATOIDE, DESDE LA PERSPECTIVA DEL PROVEEDOR DE SERVICIOS DE SALUD EN MÉXICO

Contreras I[1], Juarez-Garcia A[2], Martinez-Rivera G[2], Vallejos Parás A[3], Ojeda Méndez J[3], Villasis-Keever A[2], Rangel S[2]
[1]*Instituto Mexicano del Seguro Social, México D.F., México,* [2]*Bristol-Myers Squibb, México D.F., México,* [3]*Universidad Nacional Autónoma de México, México D.F., México*

OBJECTIVOS: La Artritis Reumatoide (AR) es una condición crónica, sistémica, rápidamente progresiva, con perdida de la funcionalidad y disminución en calidad de vida de quien la padece, con alto impacto económico a la sociedad. El objetivo de este análisis fue identificar los esquemas de tratamiento para pacientes con AR y estimar el costo de atención, desde la perspectiva del proveedor de servicios de salud. **METODOLOGÍAS:** Estudio observacional, transversal y retrospectivo en 233 expedientes clínicos de pacientes con diagnóstico de AR, tratados durante 1 año, en el Instituto Mexicano del Seguro Social. Los esquemas de tratamiento se clasificaron en: Anti-inflamatorios no esteroideos(AINEs); Fármacos Modificadores de la Enfermedad (FARME); y terapia biológica. Se estimó el costo promedio por paciente y el rango intercuartilíco en cada grupo de tratamiento. Se identificaron el tipo y cantidad de medicamentos, consultas y paraclínicos registrados en archivos clínicos. Los costos unitarios se obtuvieron de bases de datos institucionales. El costo fue descrito en pesos mexicanos del año 2010. Se consideró valor de $p < 0.05$ como estadísticamente significativo, mediante prueba de Kruskal-Wallis. **RESULTADOS:** El 90.1% de los pacientes fueron mujeres, el promedio de edad fue 50.9 años ± 15.1, el tiempo promedio de evolución de la enfermedad fue 9.5 años ± 8.9, el promedio de articulaciones dolorosas fueron 2.55 ± 1.16. La frecuencia de los esquemas de tratamiento: AINEs 2%, FARME 34%, AINEs y FARME 54%, FARME y Biológicos 6%, AINEs/FARME/Biológicos 3%. Costos del tratamiento: AINEs $10,374.62 ($8,100.58-$11,250.26), FARME $12,615.82 ($8,624.20 - $14,176.42) AINEs y FARME $13,243.99 ($8,726.04 - $14,678.25); FARME y Biológicos $170,028.85 ($146,148.91 - $176,805.53), AINEs/FARME/Biológicos $194,472.09 ($161,478.45 - $202,562.02) (p<0.000). **CONCLUSIONES:** El esquema de tratamiento AINEs/FARME fue el más utilizado. Sin embargo, el uso de biológicos comienza a ser una alternativa factible y muy probablemente necesaria para la atención de AR en el sistema de salud público.

PODIUM SESSION I:
VACCINE OUTCOMES RESEARCH

VA1

EVALUACION RÁPIDA DEL IMPACTO DE LA INTRODUCCION DE LA VACUNA CONTRA EL ROTAVIRUS EN COLOMBIA

Rico Mendoza FA[1], Porras A[1], Alvis N[2], De La Hoz F[1], Cediel N[1], Del Rio F[2]
[1]*Universidad Nacional de Colombia, Bogotá, Colombia,* [2]*Universidad de Cartagena, Cartagena de Indias, Bolívar, Colombia*

OBJECTIVOS: El presente estudio evaluó las coberturas de vacunación antirotavírica en la cohorte de población colombiana menor de 2 años de edad que ha sido vacunada desde el año 2008 y además, estimó la incidencia acumulada de hospitalización por diarrea y la efectividad de la vacuna contra la enfermedad diarreica severa. **METODOLOGÍAS:** Se realizó una encuesta poblacional en hogares con niños mayores de dos meses y menores de 24 meses en 5 ciudades de Colombia (Cali, Bogotá, Barranquilla, Cartagena y Riohacha). Los 3500 niños se seleccionaron aleatoriamente, usando un muestreo por conglomerados bietápico, de las zonas más vulnerables de las ciudades seleccionadas. **RESULTADOS:** Se encontró una cobertura de vacunación del 87.3% contra rotavirus. El 43,2% (1453) con un (IC95%: 36,8 – 66,7) niños menores de 24 meses reportaron haber tenido al menos 1 episodio de EDA desde el nacimiento. Se encontró una incidencia acumulada de hospitalización de 4,5% en los niños con dos dosis de vacuna a diferencia de los niños sin vacuna que tuvieron 11,3% (OR 0,37; IC 95% 0,24-0,57). Se encontró que una o dos dosis de vacuna contra rotavirus son protectoras para hospitalización y esta diferencia es estadísticamente significativa (OR: 0,31 IC95%: 0,16 – 0,57). **CONCLUSIONES:** La efectividad de la vacuna (con el esquema completo) para enfermedad severa (hospitalización) se mantiene en niveles muy similares a los obtenidos en los estudios clínicos experimentales. Esto confirma la validez de los estudios pre introducción que pese a la limitación de la información epidemiológica que usaron, aparentemente mostraban la carga de enfermedad real. Una o dos dosis de vacuna contra rotavirus protegen contra hospitalización por EDA. Dado que este estudio se realizó en poblaciones de alta morbilidad y mortalidad por diarrea y se encontró una protección adecuada de la vacuna podríamos inferir que otras poblaciones de menor riesgo también se están viendo beneficiadas.

VA2
COST EFFECTIVENESS ANALYSIS OF VACCINATION PROGRAMS WITH 10-VALENT (PCV10) AND 13-VALENT (PCV13) PNEUMOCOCCAL VACCINES IN BOGOTÁ, COLOMBIA

Torres C[1], Jaramillo J[2], Coronell W[3], Gutierrez MV[4], Caceres HA[4]
[1]*Universidad del Bosque, Bogotá, Colombia,* [2]*Hospital Universitario del Valle, Universidad del Valle - Centro IMBANACO, Cali, Colombia,* [3]*Universidad de Cartagena, Hospital Bocagrande, Cartagena, Colombia,* [4]*Pfizer S.A., Bogotá, Colombia*

OBJECTIVES: Pneumococcus was responsible for more than 50% of the preventable deaths in infants under 5 years of age according to the Pan American Health Organization before the introduction of conjugate vaccines. The objective of this analysis is to evaluate the cost effectiveness of vaccinating the Bogota, Colombia population younger than 2 years of age with 13- valent vaccine (PCV 13) in comparison to the 10-valent or PHiD-CV vaccine (PCV 10) both in same schedule. **METHODS:** In order to estimate the costs and the impact of the pneumococcal disease, a Markov model simulating vaccination and outcomes of 10 annual birth cohorts was adapted to the Colombian conditions from the Health System perspective. The probabilities and the costs were extracted from a literature review and tariff manuals applicable for Colombia for January 2011, with costs presented in US$. The results in health are expressed as number of cases of diseases and deaths prevented, as well as in terms of life years saved (LYs). Probabilistic sensitivity analyses were done. **RESULTS:** Over a 10 year period, vaccinating with PCV13 prevents 1,680 cases of invasive pneumococcal disease, 9,842 hospitalized pneumonia, 805 non complicated pneumonia, 16,011 cases of acute Otitis media and 473 deaths, saving 11,414 LY's compared to PCV10. The total costs including vaccination costs and medical costs are US$ 7,828,204 less for PCV13 compared to PCV10 (US$ 215,750,926 vs. US$ 223,579,130). The model shows robustness in the sensibility analysis. **CONCLUSIONS:** The analysis suggests that vaccinating infants with PCV13 in Bogotá, Colombia is a cost-saving alternative in comparison with PHiD-CV. The results in economic and disease burden are substantial and they support the decision making in favor of PCV13 for its high impact in public health.

VA3
A COST-EFFECTIVENESS ANALYSIS OF A 10-VALENT PNEUMOCOCCAL CONJUGATE VACCINE IN CHILDREN IN SIX LATIN AMERICAN COUNTRIES

García Martí S[1], Colantonio L[1], Bardach A[1], Lopez A[1], Caporale J[1], Augustovski F[1], Pichon Riviere A[1], Knerer G[2], Gomez JA[3]
[1]*Institute for Clinical Effectiveness and Health Policy, Buenos Aires, Argentina,* [2]*GlaxoSmithKline Biologicals, Wavre, Belgium,* [3]*GlaxoSmithKline, Victoria, Buenos Aires, Argentina*

BACKGROUND: A recently developed 10-valent pneumococcal non-typable *H influenzae* protein D-conjugate vaccine (PHiD-CV) is expected to afford protection against more than two thirds of isolates causing IPD in children in Latin America, and also against acute otitis media caused by both Spn and NTHi. **OBJECTIVES:** to assess the cost-effectiveness of PHiD-CV in comparison to non-vaccination in children under 10 years of age in Argentina, Brazil, Chile, Colombia, Mexico and Peru. **METHODS:** We used a static, deterministic, compartmental simulation model. The dosing regimen considered included three vaccine doses (at 2 months, 4 months and 6 months) and a booster dose (at 13 months) (3 + 1 schedule). Model outcomes included number of cases prevented, deaths averted, quality-adjusted life- years (QALYs) gained and costs avoided. **RESULTS:** The largest effect in case prevention was observed in pneumococcal meningitis (range 26% for Peru up to 47% for Colombia), neurologic sequelae after meningitis (range between 37% for Peru and 65% for Brazil) and bacteremia (range 42% for Argentina up to 49% for Colombia). The model showed a significant proportion of deaths averted annually (range between 17% for Peru and 33% for Brazil). Overall, the health benefits achieved with PHiD-CV vaccination resulted in a gain of QALYs (range 14% for Peru up to 26% for Brazil). Compared to non-vaccination cost-effectiveness analysis demonstrated significant health benefits in favor of 10-valent pneumococcal vaccination implementation, with ICER values between -230 (Chile) and 7,088 (Brazil), $US dollars 2010 per QALY gained. In Chile, negative ICER value reflected net cost savings. Indirect costs affected results more than herd immunity. **CONCLUSIONS:** The incorporation of the 10-valent pneumococcal conjugate vaccine into routine infant immunization programs in Latin American countries could be a valid a strategy to optimize use of available resources improving both health and quality of life for populations in the region.

VA4
COSTO-EFECTIVIDAD DE LA VACUNA CONTRA EL VPH SUBTIPOS 16 Y 18 EN MÉXICO

Muciño-Ortega E[1], Valencia-Mendoza A[1], Flores-Leonard Y[2], Bertozzi Kenefick SM[1]
[1]*Instituto Nacional de Salud Pública, Cuernavaca, México,* [2]*Instituto Mexicano del Seguro Social, Cuernavaca, México*

OBJECTIVOS: El cáncer cérvico-uterino (CaCU) permanece como una causa importante de mortalidad en México. El objetivo de esta investigación fue estimar el costo-efectividad de la vacunación contra virus del papiloma humano (VPH) 16 y 18 en niñas adolescentes desde la perspectiva de un proveedor público de servicios de salud en México. **METODOLOGÍAS:** Se construyó un modelo de Markov de la progresión de la infección por subtipos oncogénicos de VPH en mujeres a lo largo de su vida (desde los 12 años), un brazo considera que son vacunadas con tres dosis de la vacuna bivalente contra VPH, mientras que el otro no. Las mujeres son susceptibles de someterse al programa de detección oportuna (PDDO) de CaCU en ambos brazos del modelo. Se consideran los costos de vacunación, PDDO, tratamiento de lesiones precancerosas y CaCU. Los resultados (descontados al 3%) fueron expresados como costo incremental por año de vida ganado (respecto de sólo PDDO). Los parámetros de la infección, epidemiológicos, efectividad de las intervenciones y los costos provienen de revisión de literatura. Se realizó validación cruzada del modelo. Los resultados fueron obtenidos con simulaciones Montecarlo y se derivó la curva de aceptabilidad. **RESULTADOS:** El costo asociado al PDDO fue de MX$2,159.7 por mujer, menor en MX$1,885.4 al costo del PDDO+vacunación. La efectividad del PDDO correspondió a 28.605 años de vida, mientras que la de PDDO+vacunación fue de 28.630 años de vida. La razón de costo efectividad incremental fue de MX$134,205.79/año de vida ganado. La vacunación reduciría en 47% la morbi-mortalidad por CaCU. La curva de aceptabilidad muestra que PDDO+vacunación presenta la mayor probabilidad de ser costo-efectivo a partir de una disponibilidad a pagar de MX$84,000. **CONCLUSIONES:** La vacunación contra VPH 16 y 18, aunada al PDDO de CaCU constituye una alternativa potencialmente costo-efectiva para disminuir la morbi-mortalidad por CaCU en México.

PODIUM SESSION II:
CANCER OUTCOMES RESEARCH

CN1
COST-EFFECTIVENESS OF TRASTUZUMAB IN THE ADJUVANT TREATMENT OF EARLY BREAST CANCER IN SIX LATIN AMERICAN COUNTRIES

Pichon-Riviere A[1], Augustovski F[1], Garay OU[1], Buendia J[2], Rodríguez A[3], Vallejos C[4], Huayanay L[5], Oliveira C[6]
[1]*Institute for Clinical Effectiveness and Health Policy, Buenos Aires, Argentina,* [2]*Universidad de Buenos Aires, Ciudad Autonoma de Buenos Aires, Argentina,* [3]*Fondo Nacional de Recursos, Montevideo, Uruguay,* [4]*Universidad de La Frontera, Temuco, Chile,* [5]*Universidad Peruana Cayetano Heredia, Lima, Peru,* [6]*ANVISA, Brasilia, Brazil*

OBJECTIVES: To evaluate the cost-effectiveness of adjuvant trastuzumab in six Latin American (LA) countries (Argentina, Bolivia, Brazil, Chile, Perú and Uruguay) in early HER2-positive breast cancer. **METHODS:** A Markov model was designed to evaluate life years, quality adjusted life years (QALYs) and costs from a health sector perspective. A systematic search on effectiveness, local epidemiology and costs was undertaken to populate the model. Two face to face meetings of countries teams were held to agree on model structure, required parameters, and a costing template to use a common methodology. Two main transition probability scenarios for the no-trastuzumab cohort were built and calibrated, one using trial data (TD) and one using local/Globocan data (LD) in order to better fit local cancer prognosis. The base case scenario was with 55-year-old women, and used a 5% discount rate. Currency used was 2010 US dollars ($). **RESULTS:** Trastuzumab benefits ranged from 0.9 to 1.1 QALY in the TD scenario, and between 1.5 to 2.6 QALY in the LD scenario. Incremental discounted costs of the trastuzumab strategy ranged from $39,000 to $68,000 in the TD scenario, and $40,000 to $66,000 in the LD scenario. Incremental cost-effectiveness ratios ranged from 39,000 to 60,000 $/QALY in the TD scenario, and between 21,000 and 40,000 $/QALY in the LD scenario. **CONCLUSIONS:** Using the usually cited 3GDP threshold, these study results suggest that adjuvant trastuzumab for early breast cancer may not be cost-effective in most situations in the participant LA countries. Since trastuzumab was shown to be cost-effective in many studies conducted in developed countries, our results highlight the urgent need to evaluate many of the other new "biologic" treatments for cancer and other diseases, as many of them are currently used in LA but have shown, in other settings, much more unfavourable cost-effectiveness profiles than trastuzumab.

CN2
CANCER DE PULMON Y TABACO, ANALISIS DEL COSTO DE ATENCION MEDICA

Quintana Carrillo R[1], Arrieta Rodríguez O[2], Zinser Sierra J[2], Correa Acevedo M[2], Mohar Betancurt A[2], Reynales Shigematsu L[3]
[1]*Instituto Nacional de Salud Pública, México D.F., México,* [2]*Instituto Nacional de Cancerología, México D.F., México,* [3]*Instituto Nacional de Salud Pública, Cuernavaca, México*

OBJECTIVOS: Estimar los costos directos de atención médica del Cáncer de Pulmón (CP) atribuibles al consumo de tabaco, en el Instituto Nacional de Cancerología (INCAN). **METODOLOGÍAS:** Durante el 2009 se estimaron los costos directos de 290 pacientes con diagnóstico nuevo de CP en el Instituto. El análisis de costos se hizo desde la perspectiva del proveedor de servicios, empleando la metodología *Cost of*

Illness (COI), basada en la prevalencia, así como la creación de un panel de expertos multidisciplinario que clasificó la atención médica, tomando en cuenta la gravedad de la enfermedad (CP I – CP IV): Ambulatoria, Hospitalización, Quirófano, Unidad de Cuidados Intensivos, Quimioterapia, Radioterapia y Cuidados Paliativos. Finalmente empleamos la fracción atribuible por tabaco para estimar los costos por tabaquismo. Los costos están expresados en pesos mexicanos ($) y en dólares americanos (USD) del 2009. **RESULTADOS:** El costo promedio anual por paciente asociado al consumo de tabaco fue de $1,105,250.9 (84,590.5 USD), independientemente de la gravedad de la enfermedad. Los niveles de severidad III y IV del CP fueron los más costosos para el INCAN, con un costo promedio anual por paciente de $862,398.9 (66,003.8 USD) y $1,174,011.5 (89,853.1 USD). El costo total anual del CP por tabaquismo en el INCAN fue de $245,735,016.9 (18,807,354.8 USD), donde el CP IV explicó el 96 % de este costo anual. **CONCLUSIONES:** Los resultados obtenidos confirman los altos costos del CP atribuido al tabaquismo y presentan evidencia científica para apoyar las políticas de salud orientadas al control del consumo de tabaco. El CP al ser una enfermedad evitable, los recursos económicos destinados al tratamiento de la enfermedad podrían asignarse en otras áreas de interés dentro del Instituto.

CN3
COST EFFECTIVENESS OF LIPOSOMAL DOXORUBICIN VERSUS PACLITAXEL FOR THE TREATMENT OF AIDS-KS

Raimundo K[1], Asche C[2]
[1]*University of Utah College of Pharmacy, Salt Lake City, UT, USA,* [2]*Center for Health Outcomes Research, University of Illinois College of Medicine and University of Utah College of Pharmacy, Salt Lake City, UT, USA*

OBJECTIVES: AIDS-Kaposi's Sarcoma (KS) is a cancer that occurs among patients infected with HIV/AIDS. To treat AIDS-KS, the FDA approved the chemotherapy treatments: liposomal anthracyclines (doxorubicin and daunorubicin) and paclitaxel. At present, there is no economic study evaluating the cost-effectiveness of liposomal anthracyclines versus paclitaxel. This study aims to compare liposomal doxorubicin to paclitaxel through a cost minimization analysis (CMA) followed by a cost effectiveness analysis (CEA). **METHODS:** Available cost-studies have indicated that liposomal doxorubicin is more cost effective than liposomal daunorubicin thus removed from this analysis. For the CMA and CEA, total costs were calculated based on the Average Wholesale Price (AWP) of 2010 minus 20%, for a more realistic approach of acquisition cost. All costs associated with adverse events were estimated based on a Cancer Institute in US dollars as of 2010. Clinical outcomes were derived from the package insert and one phase III trial comparing the two drugs. **RESULTS:** The CMA showed that the total treatment with liposomal doxorubicin costs $14,819 compared to $15,135 for paclitaxel. After accounting for response rate of 57% for paclitaxel and 46% for liposomal doxorubicin, the results showed that paclitaxel costs $ 26,553 per response while liposomal doxorubicin costs $ 32,215.One-way sensitivity analysis showed that our results hold true in a wide range of cost values and the total cost of cycles have the biggest impact in our analysis. Our model was highly sensitive to the response rate due to the small difference in total treatment cost. **CONCLUSIONS:** In our scenario, paclitaxel is more cost-effective than liposomal doxorubicin. After accounting for all the factors that contribute to cost, and response rate, paclitaxel is more expensive and more cost-effective than liposomal doxorubicin. Future research includes the use of other sources of acquisition cost and a different scenario to validate or refute our results.

CN4
EVALUACION DE COSTOS DEL TRATAMIENTO DE PRIMERA LINEA PARA CANCER COLORRECTAL METASTASICO (MCRC) CON ESQUEMAS BASADOS EN: FOLFIRI, FOLFOX O XELOX MAS BEVACIZUMAB, EN CINCO INSTITUCIONES MEXICANAS

Ruiz G Calderillo
Instituto Nacional de Cancerología, México D.F., México

OBJECTIVOS: Realizar una evaluación de costos del tratamiento de primera línea para el Cáncer Colorrectal Metastásico (CCRm) con esquemas basados en: FOLFIRI, FOLFOX o XELOX más Bevacizumab, en cinco instituciones mexicanas. **METODOLOGÍAS:** Se desarrolló un análisis de costos del tratamiento del CCRm, basado en los costos de los servicios de atención médica hospitalaria, incluyendo los insumos utilizados para el proceso mismo de atención terapéutica. Se utilizó la metodología de costeo con base en actividades, que se basa en el microcosteo de procesos. Se revisaron 35 expedientes clínicos de pacientes con diagnóstico de CCRm tratados con quimioterapia de combinación: FOLFOX (oxaliplatino 170 mg/m^2, fluorouracilo 1 g/m^2 y ácido folínico 190 mg/m^2), FOLFIRI (irinotecan 200 mg/m^2, fluorouracilo 2,780 mg/m^2 y ácido polínico 190 mg/m^2) o XELOX (capecitabina y oxaliplatino 170 mg/m^2), con bevacizumab 400 mg/kg. De la revisión de expedientes se obtuvo información acerca de los procedimientos efectuados para el diagnóstico y el tratamiento oncológico. Posteriormente se realizó una comparación entre costos y efectividad expresada como costo por meses libres de progresión ganados. Se utilizó como punto de referencia los resultados obtenidos con el uso FOLFIRI Y FOLFOX en este grupo de pacientes (práctica habitual en las instituciones de salud evaluadas). **RESULTADOS:** El total de gastos esperados por diagnóstico asciende a 21,960; 10,110 por Biopsia y 11,850 por estudios. El tratamiento basado en FOLFIRI+Bevacizumab tiene un costo de 29,216 (19,283–34,988) y el basado en FOLFOX+Bevacizumab 22,262 (12,859–29,822). Adicional a la Quimioterapia se incluyen los gatos por esquema de seguimiento en cada ciclo, estos ascienden a 8249. El costo esperado total de la enfermedad (diagnostico, tratamiento y seguimiento) asciende a 59,425. **CONCLUSIONES:** Este análisis nos permite conocer el costo de atención del CCRm con la adición de un medicamento biológico que incrementa su efectividad.

PODIUM SESSION II: HEALTH SERVICES RESEARCH

HS1
INTERCHANGEABILITY BETWEEN PNEUMOCOCCAL CONJUGATE VACCINES AND SCHEMES

Ciapponi A, García Martí S, Rey-Ares L, Glujovsky D, Bardach A, Valanzasca P, Lee A, Cafferata ML
Institute for Clinical Effectiveness and Health Policy, Buenos Aires, Argentina

BACKGROUND: Streptococcus pneumoniae (pneumococcus) is a leading cause of serious illness among children worldwide. Pneumococcal conjugate vaccines that include 7, 9, 10, 11, 13, and 15 serotypes have been developed. **OBJECTIVES:** Assess the comparative efficacy, cost-effectiveness, immunogenicity and safety of interchangeability among Pneumococcal Conjugate Vaccines and Schemes. **METHODS:** A systematic search was conducted in December 2010 on the main electronic literature and regional databases, generic and academic Internet search and metasearch engines, Cochrane Central Register of Controlled Trials. Databases containing regional proceedings or congresses, annals and doctoral theses were also searched. No language or temporal restriction was imposed. We included all randomized controlled trials, economic evaluations, systematic reviews and meta-analysis evaluating antibody response, cost-effectiveness and clinical effectiveness of the interchangeability among Pneumococcal conjugated vaccines. Pairs of reviewers independently selected and assessed the quality of the studies and discrepancies were solved by consensus of the whole team. **RESULTS:** A total of 21 out of 159 studies were included. There is currently no direct data available on the interchangeability among PCV for primary series. Some studies demonstrated non-inferiority immunogenicity between PHiD-CV and PCV7. The tolerability profile of PHiD-CV was similar to that of PCV7, when both vaccines were coadministered with other routine pediatric vaccines. Regarding cost effectiveness profiles PhiD-CV and PCV13 were consistently more costeffective than PCV7 at a constant price. When PHiD-CV and PCV13 were compared against each other the results varied according to price, indirect effects and indirect costs. **CONCLUSIONS:** In general, PHiD-CV gains more QALYs due to the prevention of more frequent yet less severe events such as otitis media; and PCV13 prevents less frequent events but more costly as invasive diseases (meningitis or bacteremia). Although we found no direct evidence, the two scientific recommendations identified in the search advise that PCV13 and PHiD-CV could be interchanged with PCV7.

HS2
ANALISIS DE COSTOS DEL PROGRAMA AMPLIADO DE INMUNIZACIONES EN COLOMBIA 2009

Romero M[1], Arango C[1], Chavez D[1], Otero J[1], Alvis N[2]
[1]*Fundación Salutia, Bogotá, Colombia,* [2]*Universidad de Cartagena, Cartagena de Indias, Bolívar, Colombia*

OBJECTIVOS: Establecer costos de aplicación de los biológicos contenidos en el Programa Ampliado de Inmunizaciones (PAI) en Colombia, que sirvan en evaluaciones económicas posteriores. **METODOLOGÍAS:** Se combinaron dos tipos de estudio: microcosteo tipo bottom up de centros vacunadores en municipios, desde la perspectiva del tercer pagador, y una revisión presupuestal de las asignaciones y gastos del PAI año 2009 en las direcciones territoriales de salud. Para lograr representatividad nacional se seleccionaron 62 municipios según nivel de pobreza distribuidos en 5 regiones, elegidos mediante un muertreo probabilístico, estratificado, polietápico. Se recolectó información por tipo de bilógico y por los diferentes elementos del costo. Se realizó análisis de datos con medidas de tendencia central. Los datos fueron recolectados en pesos colombianos (COP) y convertidos a dólares americanos (USD) del 2009. **RESULTADOS:** Los costos de aplicación de vacunas presentan diferencias por tipo de biológico y región. Los mayores costos por dosis aplicada son neumococo (30.21USD) y (30.07USD) polio inyectable (VIP), frente a los más bajos: (3.53USD) polio oral (VOP) y toxoide tetánico (3.81USD). A nivel regional los costos más altos corresponden a los de Orinoquia y Amazonia que son las de mas difícil acceso. Por categoría de municipios mostró que los biológicos son más costosos en los de mayor pobreza. El recurso humano tiene un peso porcentual del 35.92% del total y del 58% si se excluye el costo de los biológicos. La perdida de biológico significó 6.55% frente al costo, con variaciones según el biológico. **CONCLUSIONES:** La mediana del costo total por aplicación de una dosis incluida en el PAI sería de 6.32USD. Si se excluyen los costos de desperdicio y el costo del biológico, la mediana de aplicación sería de 3.92USD. Estos costos están influenciados por el nivel de productividad de los centros y es similar al notificado por estudios internacionales.

HS3
THE ECONOMIC BURDEN OF ROAD TRAFFIC INJURIES ON HEALTH SYSTEM AND SOCIETY IN BELIZE

Heredia Pi IB[1], Pérez Núñez R[1], Hijar Medina M[1], Jones S[2], Silveira Rodrigues EM[3]
[1]*National Institute of Public Health, Cuernavaca, México,* [2]*Pan American Health Organization/ World Health Organization, Trinidad and Tobago,* [3]*Pan American Health Organization/World Health Organization, Washington, DC, USA*

OBJECTIVES: To estimate the economic cost of road traffic injuries in Belize. **METHODS:** A cross-sectional study was conducted using secondary cost data and assuming the health system and social perspectives. Two major databases were analyzed: the mortality database, containing all deaths during 2001-2007, and the national hospital discharge database, containing all discharges during 2007. Additionally, a third database containing all emergency ambulance services provided by BERT to persons involved in RTI in the Belize District during 2007 was analyzed.

A descriptive analysis was performed for all databases. Central tendency and dispersion measures were calculated for the continuous variable (mean, median, standard deviation, maximum and minimum value) as well as frequencies and percentages for the categorical variables. Costing was done in 2007 Belize Dollars after adjusting by inflation using the Belize National Consumer Price Index. Costs were also discounted at an annual rate of 3% and 5%. Multi-way sensitivity analysis was carried out in order to incorporate uncertainty in the estimations. **RESULTS:** A total of 63 (or 61 if adjusted) people died as a consequence of RTI during 2007 (a mortality rate of 20.72 deaths per 100,000 inhabitants), 338 were hospitalized and a total of 565 slightly injured was estimated. A total of 2,501 Years of Potential Life were Lost in Belize due to premature death. All this translated in a total economic cost of BZ$31,966,045 due to RTI during 2007. This figure represents 1.26% of Belizean GDP during 2007. The great majority of the cost is for fatal injuries, specifically on indirect cost attributed to premature death. Direct cost was estimated at BZ$491,549, of which 2.09% was spent on fatalities, 61.61% on severely injured and 36.30% on slightly injured. **CONCLUSIONS:** The economic cost estimations make clear the need to prevent RTI utilizing a strategic and multisectoral approach that focuses on addressing the main problems identified.

HS4

IMPACTO ECONOMICO EN LA ATENCION MEDICA DE ENFERMEDADES ASOCIADAS AL TABAQUISMO EN UNA POBLACION MEXICANA

Pérez Zincer F[1], Quintana Carrillo R[2], Barrios Nanni R[1], Chagoya Bello J[1], Ramos Reyna E[1], Reynales Shigematsu L[3]
[1]*Hospital Central Militar, México D.F.,México,* [2]*Instituto Nacional de Salud Pública, México D.F., México,* [3]*Instituto Nacional de Salud Pública, Cuernavaca, México*

OBJECTIVOS: Estimar la carga económica que representan las enfermedades vinculadas al consumo de tabaco en el Hospital Central Militar (HCM), a través del costo directo de atención médica (CDAM). **METODOLOGÍAS:** La estimación del CDAM atribuible al consumo de tabaco fue realizada en pacientes con diagnóstico de primera vez de las enfermedades: CP (20), IAM (123), EPOC (160) y EVC (288), en 2009. El análisis de costos fue realizado desde la perspectiva del proveedor de servicios, aplicando la metodología *Cost of Illness* (COI), basada en la prevalencia así como la creación de un panel de expertos multidisciplinario, que clasificó la atención médica: Ambulatoria, Urgencias, Hospitalización, Quirófano, Unidad de Cuidados Intensivos, Quimioterapia y Radioterapia. Finalmente utilizamos la fracción atribuible por tabaco para estimar los costos. Los costos fueron reportados en pesos mexicanos ($) y en dólares (USD) del 2009. **RESULTADOS:** Durante el 2009, el costo promedio anual por paciente sin importar la gravedad de la enfermedad fue de $213,723.6 (16,357.4 USD) para el IAM, $130,901.8 (10,018.6 USD) para el ECV, $85,272.6 (6,526.3 USD) para el EPOC y $767,709.5 (58,756.7 USD) para el CP; respectivamente. Para el mismo año, el costo total anual asociado al tabaquismo fue de $21,159,968.2 (1,619,480.3 USD) para el IAM, $20,000,245.3 (1,530,720.8 USD) para el ECV, $15,652,522.9 (1,197,967.4 USD) para el EPOC y $35,203,438.6 (2,694,298.2 USD) para el CP; respectivamente. El CP resultó más costoso para el HCM. **CONCLUSIONES:** Los resultados obtenidos dimensionan el enorme costo económico del problema de la atención de las enfermedades asociadas al tabaquismo en el HCM y proveen información sólida para apoyar las políticas de salud para el control del tabaco. Ya que las enfermedades asociadas al tabaquismo son prevenibles, los recursos económicos destinados al tratamiento de dichas enfermedades podrían dirigirse a otros programas prioritarios del HCM.

PODIUM SESSION II: INFECTION OUTCOMES RESEARCH

IN1

EVALUACION DE COSTO-EFECTIVIDAD CON EL USO DE LINEZOLID PARA EL TRATAMIENTO DE INFECCIONES COMPLICADAS DE PIEL Y TEJIDOS BLANDOS

Vargas-Valencia JJ[1], Sotelo-Guzmán M[1], Díaz-Ponce H[2], Galindo-Suárez RM[2], Muciño-Ortega E[2], Mould-Quevedo J[3]
[1]*Econopharma Consulting S.A. de C.V., México D.F., México,* [2]*Pfizer S.A. de C.V., México D.F., México,* [3]*Pfizer, New York, NY, USA*

OBJECTIVOS: Las infecciones complicadas de piel y tejidos blandos (ICPTB) son causa común de hospitalización, situación que representa un reto clínico y económico para los prestadores de servicios de salud. El objetivo de esta investigación fue estimar el costo-efectividad de linezolid en el tratamiento de ICPTB vs vancomicina y teicoplanina, desde la perspectiva del Instituto Mexicano del Seguro Social (IMSS). **METODOLOGÍAS:** Se construyó un árbol de decisiones que evaluó la tasa de éxito microbiológico, los días de estancia hospitalaria (en piso y unidad de cuidado intensivos, UCI) y los costos directos del tratamiento con linezolid inyectable, seguido por linezolid oral (600mg dos veces/día), vancomicina inyectable (1,000mg dos veces/día) y teicoplanina inyectable (400mg el primer día, días subsecuentes: 200mg) en pacientes con ICPTB en un horizonte de 38 días. La respuesta microbiológica se extrajó de literatura. La relación de insumos (estudios de laboratorio, consultas y medicamentos) y procedimientos médicos, así como el manejo hospitalario se extrajó de la literatura y se complementó con opinión de expertos. Los costos corresponden al IMSS para el año 2010. Se realizó análisis de sensibilidad probabilístico. **RESULTADOS:** La tasa de éxito microbiológico con linezolid fue 93.1%, superior a la de vancomicina (88.2%, $p=0.025$) y teicoplanina (44.1%, $p<0.0001$). Los días de estancia en UCI fueron 13.03, 17.53 y 21.82 con linezolid, vancomicina y teicoplanina, respectivamente. El costo esperado por evento para linezolid ($609,987) fue menor en comparación con el de vancomicina ($725,130) y teicoplanina ($930,172). El tratamiento con linezolid se asocia a una menor estancia en UCI y a una baja en el costo del tratamiento debido al pasar de la administración intravenosa a la oral. Las curvas de aceptabilidad muestran que linezolid es una alternativa dominante. **CONCLUSIONES:** Linezolid constituye una alternativa dominante sobre vancomicina y teicoplanina en el tratamiento de ICPTB en el contexto del IMSS.

IN2

CHRONIC HEPATITIS C TREATMENT FOR GENOTYPE 2 OR 3: COST-EFFECTIVENESS ANALYSIS OF PEG AS FIRST LINE TREATMENT WITH THE BRAZILIAN PROTOCOL

Blatt CR[1], Storb BH[1], Mühlberger N[2], Wurm J[2], Farias MR[1], Siebert U[2]
[1]*Universidade Federal de Santa Catarina / UNISUL /UMIT, Florianopolis, Santa Catarina, Brazil,* [2]*UMIT - University for Health Sciences, Medical Informatics and Technology / ONCOTYROL, Hall i. T., Tirol, Austria*

OBJECTIVES: The Brazilian protocol recommends that the first line treatment for patients with chronic hepatitis C (CHC) and genotype 2 or 3 is interferon alfa (IFN) plus ribavirin for 24 weeks. For those that do not respond to this treatment the use of peginterferon alfa (PEG) plus ribavirin for 48 weeks is recommended. Our objective was to compare the cost and effectiveness of first line treatment of genotype 2 or 3 with peginterferon with the current Brazilian protocol. **METHODS:** Target Population: CHC patients with genotype 2 or 3 in Brazil. Interventions: PEG-SEC: interferon alfa (IFN) plus ribavirin (RBV) for 24 weeks for patients with genotype 2/3; for nonresponders subsequently peginterferon (PEG) plus RBV for 48 weeks; PEG-FIRST: PEG+RBV for 48 weeks for all patients. Study Type: Cost-effectiveness analysis. Data Sources: Effectiveness data from a meta-analysis conducted with Brazilian studies. Treatment cost for antiviral drugs, secondary drugs, diagnostic tests, outpatient visits to physicians and other professionals, hospitalizations, nurse and pharmaceutical care from a micro-costing study converted to 2010 USD. Perspective: Health care system. Outcome Measure: Sustained Viral Response (SVR), direct costs and incremental cost effectiveness ratio (ICER). **RESULTS:** With a SVR rate of 76.6% and costs of USD 6,943, PEG-SEC was more effective and less costly than PEG-FIRST (SVR: 73.2%, costs: USD 11,297). Sensitivity analyses: For PEG-SEC to remain dominant, the proportion of patients undergoing second line treatment with PEG+RBV must be >88%. If only 0.5% of patients undergo second line treatment with PEG+RBV, the ICER of PEG-FIRST is USD 71,529 per additional SVR. **CONCLUSIONS:** In the Brazilian context, IFN for genotype 2 or 3 as first line, and PEG+RBV for those who fail to achieve SVR is more effective and less costly than PEG+RBV as first line treatment.

IN3

DENGUE MÁS QUE UN PROBLEMA DE SALUD PÚBLICA: ESTIMACIÓN DE LOS COSTOS DIRECTOS DE LA EPIDEMIA DEL AÑO 2010 EN COLOMBIA

Bello SL[1], Díaz E[2], Malagon JN[2], Romero M[2], Salazar V[2]
[1]*Instituto Nacional de Salud de Colombia, Bogotá, DC, Colombia,* [2]*Fundación Salutia, Bogotá, DC, Colombia*

OBJECTIVOS: Determinar los costos directos en atención de pacientes con Dengue en Colombia durante la epidemia 2010. **METODOLOGÍAS:** La población a riesgo fue calculada basada en los datos de morbilidad y mortalidad e indicadores de salud nacionales entre 1999 y 2009 publicados por el Ministerio de la Protección social. El consolidado de datos de casos de dengue y dengue grave (clasificación revisada de dengue OMS 2009) del Sistema de Vigilancia Epidemiológica Nacional reportados del 01 de enero al 31 de Diciembre de 2010 sirvieron para establecer la historia natural de la enfermedad, con lo que se construyó un árbol de decisiones que representa los desenlaces de los pacientes con dengue. Se consideraron entre los costos directos: atención médica ambulatoria, urgencias, hospitalización y asistencia en las unidades de cuidado intensivo. Los costos individuales fueron estimados de las tarifas nacionales estandarizadas. **RESULTADOS:** Durante 2010 hubo 157,152 casos de Dengue, 94% (n=147,670) fueron de dengue y 6% (n=9482) Dengue Grave. La tasa de letalidad fue de 2.28. Los costos directos ascendieron a US$81.8 millones, de los cuales US$5.4 millones correspondieron a la atención en los servicios ambulatorios y de urgencias. US$76 millones correspondieron a gastos de hospitalización y UCI. El costo promedio por paciente fue de US$520.48. Hubo un incremento del 12.14% en los costos durante la epidemia de un comparado con un período previo no epidémico. **CONCLUSIONES:** El dengue representa una patología de alto impacto económico en Colombia. No existen estudios previos. Comparado con otros países, el costo de la atención de dengue es mayor. Es necesario realizar estudios de costo efectividad de las intervenciones de control regular y otras intervenciones del control vectorial en períodos inter epidémicos para disminuir los costos directos en una futura epidemia. Estos resultados podrían apoyar la evaluación de los costos de una vacuna contra dengue en el país.

IN4

MORBIDITY AND MORTALITY OF COMMUNITY ACQUIRED PNEUMONIA IN ADULTS IN SIX COUNTRIES IN LATIN AMERICA

Rosado-Buzzo A[1], Garcia-Mollinedo L[1], Camacho-Cordero L[1], Roberts CS[2], Mould-Quevedo JF[2], Trejo-Martinez A[1], Luna-Casas G[1]
[1]*Links & Links S.A, de C.V., México D.F., México,* [2]*Pfizer Inc, New York, NY, USA*

OBJECTIVES: To estimate the morbidity and mortality of community acquired pneumonia (CAP) in adults over 50 years of age in Argentina, Brazil, Chile, Colombia, Mexico, and Venezuela. **METHODS:** Local data sources were used to estimate the number of cases of hospitalized and outpatient pneumonia cases and deaths in the year 2009. Pneumonia cases were queried in adults ?50 years of age using ICD-9 codes. CAP episodes were estimated from pneumonia proportionally by age based on prior publications that compared ICD-9 coded hospitalizations to confirmed CAP by chart review. Incidence rates were calculated as cases per 100,000 population. Case-fatality rates (CFR%) associated with CAP requiring inpatient care were based on hospital mortality rates reported for each country. **RESULTS:** Cases of CAP hospitalization (incidence per 100,000 person years) in adults ?50 were: Argentina=21,619 (218.5); Brazil=123,033 (333.9); Chile=16,544 (401.4); Colombia=14,699

(178.1); Mexico=44,807 (224.7); Venezuela=17,205 (348.5). The number of hospital deaths (CFR%) were: Argentina=2,772 (13%); Brazil=25,725 (21%); Chile=1,671 (10%); Colombia=1,622 (11%); Mexico=7,249 (16%); Venezuela=6,040 (35%). Cases of outpatient CAP (incidence) were: Argentina=19,243 (194.5); Brazil=94,448 (256.5); Chile=12,010 (291.4); Colombia=10,039 (121.6); Mexico=30,635 (153.6); Venezuela=14,339 (290.4). The percent of episodes treated as outpatient was 53% (range 45%-61%) among those aged 50-64 and 25% (range 4%-25%) among those ?75. Across countries, 51% of hospitalizations (range 42%-63%) and 69% of deaths (range 65%-72%) were in adults ?75 years. **CONCLUSIONS:** CAP is a common cause of hospitalization and mortality in adults in Latin America. Incidence increases substantially with increasing age, as does the likelihood of hospitalization.

PODIUM SESSION II: PATIENT-REPORTED OUTCOMES STUDIES

PR1

RESPONSIVENESS OF THE COPD ASSESSMENT TEST (CAT) QUESTIONNAIRE DURING EXACERBATIONS OF COPD

Agusti A[1], Soler JJ[2], Molina J[3], Muñoz MJ[4], Garcia-Losa M[5], Roset M[6], Jones PW[7], Badia X[6]
[1]*Hospital Clínic IDIBAPS, Barcelona & CIBER Enfermedades Respiratorias (Spain), Barcelona, Spain,* [2]*Hospital de Requena, Requena (Valencia), Spain,* [3]*Centro de Salud Francia, Madrid, Spain,* [4]*GlaxoSmithKline SA, Tres Cantos (Madrid), Spain,* [5]*IMS Health, Madrid, Spain,* [6]*IMS Health, Barcelona, Spain,* [7]*St George's, University of London, London, UK*

OBJECTIVES: To assess the measurement properties and response to change of the Spanish version of the CAT questionnaire during exacerbations of COPD (ECOPD). **METHODS:** Observational, prospective study in 49 centers in Spain. Patients hospitalized because of ECOPD (n=224) completed the CAT, the St. George's Respiratory Questionnaire-adapted for COPD (SGRQ-C) and the London Chest Activities of Daily Living (LCADL) questionnaire during the first 48 hours of admission and 4±1 weeks after hospital discharge. Another group of clinically stable COPD patients (n=153) also completed the same questionnaires on two occasions, at recruitment and 4±1 weeks later. **RESULTS:** Internal consistency (Cronbach's alpha) was 0.86. Test re-test reliability (Intraclass Correlation Coefficient) was 0.83. CAT scores correlated with both the SGRQ ($r=0.82$; $p<0.01$) and the LCADL ($r=0.63$; $p<0.01$). Change in CAT during ECOPD correlated well with change in SGRQ ($r=0.63$, $p<0.01$).The CAT discriminated between stable and ECOPD patients (15.8 vs 22.4, $p<0.01$), as well as between patients with different levels of airflow limitation and dyspnea (MRC scale). The effect size in CAT scores for ECOPD patients reporting their health state as "much better" after discharge was 0.90; for "quite a lot better" 0.63, and for "slightly better" 0.59. **CONCLUSIONS:** The Spanish version of CAT is sensitive to change during ECOPD and has similar properties to those of the original English version. Funded by GlaxoSmithKline.

PR2

THE BEAUTY OF MAPPING: NEED THE MEAN HEALTH-RELATED QUALITY OF LIFE SCORE FOR A GROUP OF HIP PATIENTS AND DON'T HAVE EQ-5D? JUST USE THE OXFORD HIP SCORE!

Pinedo Villanueva RA[1], Turner D[1], Judge A[2], Raftery JP[1], Arden NK[2]
[1]*University of Southampton, Southampton, Hampshire, UK,* [2]*University of Oxford, Oxford, Oxfordshire, UK*

OBJECTIVES: To assess different mapping methods for the estimation of a group's mean EQ-5D score based on responses to the Oxford Hip Score (OHS) questionnaire. **METHODS:** Four models were considered: a) linear regression using total OHS as a continuous regressor; b) linear regression employing responses to the twelve OHS questions as categorical predictors, c) two-part approach combining logistic and linear regression; and d) response mapping. The models were internally validated on the estimation dataset, which included OHS and EQ-5D scores for THR, both before and six months after procedure for 1759 operations. An external validation was also performed. **RESULTS:** All models estimated the mean EQ-5D score within 0.005 of a utility, OLS continuous being the most accurate (overestimation of 0.0005 at external validation) and OLS categorical the more consistent (a maximum estimation error of 0.03 at calibration by deciles). Age, gender and deprivation did not improve the models. More accurate estimations at the individual level were achieved for higher scores of observed OHS and EQ-5D. **CONCLUSIONS:** Based on these results, when EQ-5D scores are not available, answers to the OHS questionnaire can be used to estimate a group's mean EQ-5D with a high degree of accuracy. The application of the response mapping approach allows for the mapping of OHS onto EQ-5D to be undertaken in any country where a value set is available to produce the single index EQ-5D summary score.

PR3

PRIMARY HEALTH CARE EVALUATION IN CHILE: PATIENTS' PERSPECTIVE

Leisewitz T[1], Nogueira L[2], Peñaloza B[1], Bastías G[1], Villarroel L[1]
[1]*Pontificia Universidad Católica de Chile, Santiago, RM, Chile,* [2]*Harvard University, Boston, MA, USA*

BACKGROUND: Chile's health indicators are good compared with other Latin American countries with similar gross national product. Nonetheless, disparities in health care services are not absent in Chile. **OBJECTIVES:** The aim of this study was to evaluate satisfaction with primary health care and health-related Quality of Life (hrQoL) between patients in urban and rural areas of Chile. **METHODS:** A national-representative sample of 1544 patients was surveyed at 38 primary care centers. The "Encuesta de expectativas, percepcion y satisfaccion usuaria con modelo de salud familiar" (survey of patient expectations, perception and satisfaction with the family health model) and the EQ-5D questionnaire were administered to assess patient satisfaction level, and self-evaluated health, respectively. Using the Chilean social value for reported health states, a mathematic equation was used to compute the average hrQoL. **RESULTS:** Patient satisfaction was 5.28 ± 0.30 (scale 1 to 7). There was a statistically significant difference between urban and rural areas (5.45 ± 1.06 and 5.10 ± 1.28 points, respectively). The mean hrQoL for the entire population was 0.77 ± 0.00 (scale 0 to 1), with a statistical significant difference between rural and urban areas (0.78 ± 0.24 and 0.75 ± 0.25, respectively). Using stepwise multivariate regression we were able to explain 25.4% ($R^2=0.254$) of the variability in patient satisfaction. Length of consultation with the health care professional (Beta = 0.215, p value <0.001), patient education level (Beta = -0.115, p value = 0.006), and year in which the center was founded (Beta = 0.089, p value = 0.025) were identified as explanatory variables. **CONCLUSIONS:** Despite evaluating better-perceived quality of health services, urban patients rated lower their self-assessed health. These results should motivate policy makers in looking for innovative ways to diminish the gap in quality between urban and rural areas.

PR4

CALIDAD DE VIDA Y VICTIMIZACION EN ADOLESCENTES ESTUDIANTES DE MÉXICO

Hidalgo CA[1], Jiménez G[1]
[1]*Universidad de Guadalajara, Jalisco, México*

OBJECTIVOS: Analizar la calidad de vida (CV) de adolescentes estudiantes de secundaria de Jalisco México acorde a la percepción de ser víctima de alguna agresión, intimidación o maltrato. **METODOLOGÍAS:** Estudio transversal analítico llevado a cabo en 2010 con 570 adolescentes estudiantes de nueve secundarias de Jalisco, México (11-17 años, media 13.3, 47.2% mujeres, 20% trabajaban, 1er grado 31%, 2do. 23.1%, 3ro. 44.3%), contestaron un instrumento en línea que incluyó el módulo perceptual del Quality of Life Instrument-research (YQOL-R) en español, 4 ítems sobre violencia del Youth Risk Behavior Survey 2007 y un ítem del modulo contextual del YQOL-R. Estadísticas: t de student, analizado con SPSS 17. Ética: consentimiento informado, voluntario, privado y confidencial. **RESULTADOS:** Un total de 17.1% no fueron a la escuela los pasados 30 días, por sentirse que podrían estar inseguros en la escuela o en el camino para llegar a ella, a 12.4% los trató de lastimar alguien con un arma en la escuela en los pasados 12 meses, 22.1% maltratados en la escuela, 22.6% maltratados electrónicamente (maltratados o intimidados por email, chat, mensajes, páginas web) y 26.6% durante las últimas 4 semanas los hicieron sentirse rechazado/a por su apariencia, personas de su edad. La CV fue significativamente menor para los que no fueron a la escuela por sentirse inseguros ($p<0.001$), en quienes trataron de lastimar con un arma en la escuela ($p=0.37$), quienes fueron maltratados en la escuela ($p<0.001$), quienes fueron maltratados electrónicamente ($p=0.047$) y quienes se sintieron rechazados por su apariencia ($p<0.001$). **CONCLUSIONES:** En estudiantes de secundaria ser víctima de maltrato y agresión está asociado con menor CV total. Es fundamental la elaboración de programas de intervención en este nivel que garanticen escuelas más seguras en su interior y alrededores para mejorar la CV de los adolescentes.

PODIUM SESSION II: RESEARCH ON METHODS

RM1

COMPARING THE USE OF DYNAMIC AND STATIC INFECTIOUS DISEASE MODELS IN LATIN AMERICA WITH NORTH AMERICA, EUROPE, ASIA AND OTHER REGIONS.

Vargas-Palacios A[1], Stevenson M[1], Dueñas A[2], Wailloo A[1]
[1]*The University of Sheffield, Sheffield, South Yorkshire, UK,* [2]*IÉSEG School of Management - Lille-Paris, Paris, France*

OBJECTIVES: To establish whether there are differences in the type of methodology (static or dynamic) used to assess the cost-effectiveness of vaccination programmes between Latin America and other regions of the world. **METHODS:** A systematic review from 1950 to 2010 of the cost-effectiveness of vaccine interventions was performed. Modelling methodologies were categorised as static where the number infected was not related to the number infectious, and where herd immunity (an immunity that occurs when the vaccinated proportion of the population provides protection to unprotected individuals) was not incorporated. Models were categorised as dynamic otherwise. Static models were sub-classified into Decision trees (DT) and static Markov models (sMM); dynamic models were sub-classified into dynamic Markov models (dMM), System dynamics including Susceptible, Exposed, Immune and Recovered models (SD), Discrete event simulation (DES) and Agent-based models (ABM). **RESULTS:** A total of 310 relevant studies were found. 251 (81%) adopted a static approach (131 sMM and 120 DT) whilst 59 (19%) used a dynamic approach (52 SD, 3 DES, 3 ABM and 1 dMM). The majority of papers were set in Europe (120, 39%) and North America (97, 31%), with 26 (8%) in Latin America, 37 (12%) in Asia and 30 (10%) in other regions. The proportion of models that were dynamic within Latin America (23%) compared favourably with North America (15%), Europe (26%), Asia (8%) and the remaining regions (15%). However, two of the six dynamic studies undertaken in Latin America used modellers based in Europe or North America. **CONCLUSIONS:** Despite the limitations associated with static models these are more prevalent than dynamic methodologies when modelling the cost-effectiveness of vaccine interventions. This conclusion was applicable to all regions, with the results for Latin America comparable with other regions. This systematic review suggests that worldwide education of researchers in the advantages of dynamic methodologies is needed.

RM2

APLICACION DE MODELOS DE REGRESION CON STATA PARA EL ESTUDIO DEL CONSUMO DE RECURSOS EN UNIDADES DE CUIDADOS INTENSIVOS NEONATALES

Reyes-Lopez A

Hospital Infantil de México Federico Gómez, México D.F., México

OBJECTIVOS: Mostrar la importancia de utilizar técnicas de regresión diseñadas expresamente para modelar variables de conteo, así como describir las herramientas disponibles en el programa estadístico Stata para esta clase de modelos. **METODOLOGÍAS:** Los datos utilizados provienen de una muestra de 335 niños con peso bajo al nacimiento atendidos en un hospital pediátrico de tercer nivel de la Ciudad de México, de los cuales se obtuvieron distintas variables sobre consumo de recursos, así como variables demográficas y clínicas que se emplearon como regresores. Primero se realizó la prueba de sobredispersión para comprobar el cumplimiento del supuesto básico de la regresión poisson. Posteriormente se compararon gráficamente las probabilidades estimadas con cuatro diferentes modelos de regresión y se realizaron las pruebas de la razón de verosimilitud y de Vuong para determinar el modelo con el que se obtiene el mejor ajuste, utilizando para ello también los criterios de información de Akaike y bayesiano. Una vez elegido el modelo más apropiado para cada variable de resultado, se estimaron nuevamente los coeficientes de regresión y se obtuvo el cambio porcentual en el valor esperado de la variable de conteo con el comando 'listcoef' de Stata, que facilita a los usuarios la interpretación de los efectos. **RESULTADOS:** El modelo de regresión binomial negativa resultó el más apropiado para predecir los días de estancia hospitalaria, número de pruebas de laboratorio y gabinete, y los días con antibioticoterapia. El modelo de regresión binomial negativa con exceso de ceros fue el de mejor ajuste para los días con nutrición parenteral, días con oxigenoterapia, número de transfusiones, días con administración de aminas y días con ventilador. La variable que se ajustó a un modelo de poisson fue el número de interconsultas. **CONCLUSIONES:** Los modelos de regresión lineal aplicados a datos de conteo pueden producir estimaciones ineficientes, inconsistentes y sesgadas.

RM3

A COMPARISON BETWEEN MARKOV CHAINS AND SYSTEM DYNAMICS MODELING FOR THE ESTIMATION OF METABOLIC SYNDROME COSTS IN A PUBLIC HEALTH CARE DELIVERY ORGANIZATION IN MÉXICO

Olmedo-Bustillo C, Oliva-Oropeza P, Rivas-Oropeza I, Aranzeta-Ojeda F
Institute of Social and Security Services for State Workers, México D.F., México

OBJECTIVES: The objective of this study was to compare life-time costs for a population obtained through Markov chain (MC) and system dynamics (SD) methodologies. While both methodologies are based on the concepts of state and transition, the meanings of each differ. The importance of this study lies in the fact that in some cases information is available for one type of model or the other, and the possibility of using either tool for modeling a situation is of pragmatic interest. **METHODS:** Models of increasing degrees of complexity were developed. At each level of complexity, a MC model and a SD model were developed and the differences in results obtained were compared. SD models were simulated with Vensim software and MC models with TreeAge Pro software. Data were drawn from an institutional survey and from literature. An important issue in this comparison is that Markov models are based on transition probabilities while system dynamic models rely on material flows. Also, simulation techniques differ in that Montecarlo methods move a patient trough the model until it exits before including another patient, while SD models treat all patients in the cohort simultaneously. Thus, transformations for the set of mathematical expressions in each modeling methodology may lead to similar numerical results while not being conceptually equivalent. **RESULTS:** The simplest models led to equivalent aggregate numerical results. In these cases, the probability of leaving state S_n (MC) is numerically equivalent to inverse residence time (SD). More complex models required adapting the structure of one to be equivalent to the other. **CONCLUSIONS:** Applications of each methodology overlap at a certain aggregation level. When a long period is studied and not much detail is required in each state, SD seems an appropriate tool. When more precision is needed for individual patients, MC analysis seems a better choice.

RM4

FACTORES PREDICTORES DE OBSTRUCCIONES CORONARIAS SIGNIFICATIVAS EN PACIENTES ADULTOS CON CINEANGIOCORONARIOGRAFÍAS REALIZADAS EN URUGUAY, FINANCIADAS POR EL FONDO NACIONAL DE RECURSOS

Morales M, Perna A, Fernández G, Lombide I
Fondo Nacional de Recursos, Montevideo, Uruguay

OBJECTIVOS: La realización de una cineangiocoronariografía (CACG) es el gold standard para definir la anatomía coronaria. El porcentaje de lesiones coronarias no significativas depende de la definición de "lesión significativa" variando según la magnitud de obstrucción definida, siendo del 9 al 25 % cuando consideramos lesiones menores al 50 %. Existen factores predictores como sexo masculino, edad avanzada, diabetes, dislipemia y presentar un test de isquemia no invasivo positivo. El Fondo Nacional de Recursos (FNR), financia, según normativas de cobertura institucionales, prestaciones médicas altamente especializadas en Uruguay, entre ellas las CACG de las cuales reúne un registro único nacional; procedimientos costosos y no exentos de complicaciones. Objetivos:1) conocer el porcentaje de CACG con lesiones coronarias significativas (mayores al 50 %) realizados entre 1/12/2009 y 31/05/2010; 2) Identificar el tratamiento elegido luego de la realización de la CACG; 3) describir en el proceso de decisión factores predictores que permitan identificar pacientes con alto riesgo de tener lesiones coronarias significativas. **METODOLOGÍAS:** Estudio retrospectivo de una cohorte histórica de pacientes consecutivos mayores de 18 años, con CACG realizada en el período establecido financiada por el FNR. De 2586 CACG realizadas se excluyeron las solicitadas por enfermedad cardíaca no coronaria. **RESULTADOS:** Incluidas 2.326 CACG, 67,2% sexo masculino con media de edad 62,4 años (56 -75 años P25-P75). El total de CACG realizadas con lesiones mayores al 50 % fueron 1.999 (85,9 %). En 541 (22,4 %) se optó por tratamiento médico. Las variables retenidas en el modelo de regresión logística fueron: edad > 50 años, sexo masculino, prestador privado, antecedentes de cardiopatía isquémica, diabetes, infarto trasmural y tener un estudio funcional por imágenes realizado. El modelo mostró buena discriminación (curva ROC 0.76). **CONCLUSIONES:** Este conocimiento podrá ser utilizado para futuras decisiones sobre el financiamiento de los casos con mayor riesgo de lesión coronaria significativa.

POSTER SESSION I

Cancer – Cost Studies

PCN1

SELECTING A MIX OF PREVENTION STRATEGIES AGAINST CERVICAL CANCER FOR MAXIMUM EFFICIENCY WITH AN OPTIMISATION PROGRAM

Demarteau N[1], Gomez JA[2], Lorenzato F[3], Standaert B[1]
[1]*GlaxoSmithKline Biologicals, Wavre, Belgium,* [2]*GlaxoSmithKline, Middlesex, UK,* [3]*GlaxoSmithKline, Rio de Janeiro, Brazil*

BACKGROUND: Screening and vaccination against human papillomavirus (HPV) can help protect against the development of cervical cancer (CC). Neither alone can provide 100% protection against CC. Selecting the most efficient combination of screening and vaccination to prevent CC is therefore an important question to address. **OBJECTIVES:** To identify the mix of CC prevention strategies (screening and/or vaccination against HPV) that minimize CC burden within a fixed budget in Brazil. **METHODS:** The optimal mix of strategies for CC prevention was determined using an optimisation program. The evaluation uses two models. One is a Markov cohort model, adapted to the Brazilian setting, used as the evaluation model. It estimates the costs and outcomes of 52 different prevention strategies combining screening and vaccination. The other is an optimisation model in which the results of each prevention strategy of the previous model are entered as input data. The latter model determines the combination of prevention options to minimize CC under budget, screening and vaccination coverage constraints. The base-case constraints were current budget, screening of 50% women aged 18 to 65 every 3 years, and a maximum 80% vaccination coverage. Sensitivity analyses were conducted on the optimization constraints. **RESULTS:** The base-case optimal prevention strategy would be to have 30% vaccinated only at age 12, 50% both vaccinated and screened with a screening interval extended to 5 years and 20% without any prevention strategy. This would result in a 54% CC reduction from pre-vaccination levels with no budget increase. A sharp reduction in CC is seen when the vaccine coverage exceeds the maximum screening coverage, or when screening coverage exceeds the maximum vaccine coverage, while maintaining the budget. **CONCLUSIONS:** Our models predicted that implementation of vaccination combined with adjusting the screening interval would optimize CC prevention budget allocation to minimize the CC burden in Brazil.

PCN2

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF AN IMMEDIATE CARE CENTER AT THE NATIONAL CANCER INSTITUTE, MEXICO

Nieves U[1], Guajardo J[1], Cerezo O[1], Plancarte R[1], Apodaca A[1], Torres J[1], Rodriguez F[2]
[1]*National Cancer Institute, México, Tlalpan, México,* [2]*Universidad Nacional Autónoma de México, México, Coyoacan, México*

OBJECTIVES: To assess cost and clinical consequences (day of hospital stay avoided), together with a budget impact analysis and assess frequency of symptoms. **METHODS:** Evaluation of Immediate Care Center records during September 2009. Data collected were: chief complaint, primary disease (oncologic), semiology, requested studies, percentage of hospitalized patients, days of hospital stay. We compared days of hospitalization related to the main symptoms cause of consultation in 2009 versus 2005 getting hospitalization days and costs avoided through a full economic study type analysis cost-effectiveness, retrospective, analytical, longitudinal with a design before and after comparing the effectiveness and efficiency of the implementation of a multidisciplinary service (medical oncologist, surgical oncologist, algologist, internist). **RESULTS:** A total of 583 records were analyzed. Breast cancer was the most common diagnosis (28%), pain as main symptom present (52%) and as a reason for consultation (31.82%). In semiology the most frequent causes of hospitalization in 2009 (with immediate care center) were: somatic pain, dyspnea and fever, these symptoms were compared with patients who require hospitalization for the same reason in September of 2005 (without immediate care center) noting a reduction of 9.08, 3.28 and 3.12 respectively on "days of hospital stay avoided." The percentage of patients hospitalized for 2005 were 25.55% of 493 versus 10.46% of 583 patients during September of 2009. The stratified ICER for somatic pain was $ - 1615 MXN, - $1513 MXN for dyspnea, and - $1169 MXN for fever. We estimated an average monthly savings of $ 659,072.00 MXN pesos. **CONCLUSIONS:** The implementation of an immediate care service for cancer patient management through a comprehensive and multidisciplinary approach results in a highly cost – effectiveness measure in the resolution of symptoms, using timely and appropriate diagnostic and therapeutic tools with consequent decrease in hospitalization rates, reflecting"days of hospital stay avoided" adding an estimated annual budget impact of $ 7, 908, 860.00 MXN pesos.

PCN3

ESTIMACION DE LA CARGA DE LOS TUMORES NEUROENDOCRINOS EN COLOMBIA

Ruiz A[1], Alfonso-Cristancho R[2], Mejia A[1], Gonzalez D[3], Maestre K[4], Herran S[1]
[1]*RANDOM Foundation, Bogotá, Colombia,* [2]*University of Washington, Seattle, WA, USA,* [3]*Fundación Santa Fe de Bogotá, Bogotá, Colombia,* [4]*Novartis Pharma AG, Bogotá, Colombia*

OBJECTIVOS: Estimar el impacto en morbi-mortalidad, uso de recursos y costos asociados a los tumores Neuroendocrinos (TNE) de intestino medio en fase avan-

zada en Colombia. **METODOLOGÍAS:** Mediante un modelo de Markov se estimaron desenlaces clínicos y uso de recursos asociados al manejo de TNE. El modelo consta de 3 estadios: enfermedad estable, enfermedad progresiva y muerte. Las probabilidades de transición entre estadios fueron calculadas a partir de la literatura. Las variables de costos y su frecuencia de uso fueron validadas con expertos clinicos. Los costos de los recursos asociados a la enfermedad se extrajeron de instituciones públicas y privadas en Colombia. El horizonte temporal fue de 10 años con una tasa de descuento del 3% anual. **RESULTADOS:** El modelo nos permitió estimar que en grupo de pacientes con TNE, la progresión de la enfermedad estaría presente en un 69,3% de los pacientes y un 24,2% adicional, fallecería al cabo de diez años de seguimiento. En promedio, cada paciente acumularía 3,4 años libres de progresión. Los costos médicos directos asociados al manejo de la enfermedad estable es de aproximadamente US$3,738, mientras el costo anual asciende a US$51,333 para la enfermedad progresiva. Después de diez años, el costo promedio acumulado por paciente alcanzaría US$254,690. Según los estimados de incidencia, en Colombia, se presentarían 176 nuevos casos por año, y según la distribución de los pacientes y el nivel de progresión, los costos médicos directos asociados a esta patología podrían superar US$ 1,400,000 al año. **CONCLUSIONES:** El impacto financiero de los TNE en el sistema de salud en Colombia es sustancial. Alternativas de tratamiento que extiendan el tiempo libre de progresión de la enfermedad y reduzcan la mortalidad pueden tener un efecto favorable para el sistema de salud colombiano.

PCN4

COSTO-EFECTIVIDAD DE OCTREOTIDE COMPARADO CON TERAPIA DE SOPORTE USUAL PARA EL TRATAMIENTO DE TUMORES NEUROENDOCRINOS EN COLOMBIA

Ruiz A[1], Alfonso-Cristancho R[2], Mejia A[1], Gonzalez D[3], Maestre K[4], Herran S[1]
[1]*RANDOM Foundation, Bogotá, Colombia,* [2]*University of Washington, Seattle, WA, USA,* [3]*Fundación Santa Fe de Bogotá, Bogotá, Colombia,* [4]*Novartis Pharma AG, Bogotá, Colombia*

OBJECTIVOS: Estimar la costo-efectividad de octreotide LAR comparada con terapia de soporte usual (TS) para el tratamiento de tumores neuroendocrinos (TNE) avanzados de intestino medio en Colombia desde la perspectiva del pagador. **METODOLOGÍAS:** En un modelo de Markov se simuló una cohorte de pacientes con TNE asignándolos a tratamiento con TS o TS más octreotide. El modelo, que comprende 3 estados de salud (enfermedad estable, enfermedad progresiva y muerte), permite la estimación de desenlaces clínicos, uso de recursos y costos asociados al manejo de la enfermedad. Las probabilidades de transición fueron calculadas a partir de la literatura. Los costos médicos directos de los recursos asociados a la enfermedad se obtuvieron de instituciones públicas y privadas en Colombia, y fueron validados por expertos clínicos. El horizonte temporal fue de 10 años, aplicando una tasa de descuento del 3% anual a los costos y la efectividad. **RESULTADOS:** Después de 10 años de seguimiento, 69.3% de los pacientes con TNE habían progresado y 24.2% habían muerto con TS comparado con 57.5% de progresión y 12.4% de mortalidad con octreotide. En promedio, los pacientes con TS alcanzaron 3.2 años libres de progresión (LP) versus 5.2 LP con octretide. Los costos médicos directos de TS en enfermedad estable alcanzaron US$ 3,738, comparado con U$ 51,333 para enfermedad progresiva. Para el grupo con octreotide, los costos alcanzaron US$ 20,739 y US$ 58,505, respectivamente. La razón incremental de costo-efectividad por año de vida ganado libre de progresión con octreotide es de US$ 16,062 (US$ 8,217-US$ 26,107). Los análisis de sensibilidad para los costos y la efectividad demostraron la robustez del modelo. **CONCLUSIONES:** En Colombia, la adición de octreotide a TS para el manejo de TNE de intestino medio parece ser una alternativa costo-efectiva, aumentando el tiempo libre de progresión y disminuyendo la mortalidad.

PCN5

EFECTIVIDAD CLÍNICA Y COSTO-EFECTIVIDAD DEL TRATAMIENTO DE SEGUNDA LÍNEA PARA CARCINOMA METASTÁSICO DE CÉLULAS RENALES

Romero M, Díaz E, Malagon J
Fundación Salutia, Bogotá, Colombia

OBJECTIVOS: Revisar la literatura existente para determinar cuál es la mejor alternativa desde efectividad y costos para el tratamiento de segunda línea para Carcinoma Renal Metastásico (CCRm) en Colombia. **METODOLOGÍAS:** Se realizó una revisión de la literatura científica publicada entre enero de 2000 y diciembre de 2010 en las bases de datos de Pubmed, EBSCO, BEST PRACTICE, LILACS, Cochrane y Google Scholar, usando combinaciones de términos MESH. La calidad de los artículos seleccionados fue evaluada usando los criterios Bobenrieth Astete por dos investigadores independientes. Los costos de atención fueron estimados tomando los costos unitarios de tratamiento establecidos de una media de precio de mercado a precios de 2010 y a las dosis de manejo promedio identificadas en la revisión de literatura. Al momento del estudio solo se encuentran disponibles en Colombia Bevacizumab, Everolimus, Sorafenib y Sunitinib para tratamiento de CCRm. **RESULTADOS:** Se seleccionaron 83 artículos entre guías de Práctica Clínica, meta análisis, revisiones sistemáticas y estudios primarios. En segunda línea de tratamiento, ante el fallo con antiangiogenicos y/o citoquinas, que son la primera opción para primera línea, Everolimus mejora supervivencia libre de progresión comparado contra placebo (4,9 meses vs. 1,9 meses). En el caso de fallo en la terapia inicial con IL2, la terapia de elección son inhibidores de la tiroxina quinasa. Sin embargo, esto corresponde menos del 5% de los casos. No se encontró evidencia suficiente para soportar el uso de la terapia secuencial en CCRm. Los costos de tratamiento promedio mensual con Everolimus fueron de US$ 660, menor que la mayoría de tratamientos utilizados en primera línea. **CONCLUSIONES:** De la información disponible, Everolimus es la mejor alternativa terapéutica para segunda línea con mayor evidencia de efectividad y costos favorables para el sistema de salud colombiano.

PCN6

EVALUACION ECONOMICA DEL DASATINIB EN EL TRATAMIENTO DE LA LEUCEMIA MIELOIDE CRONICA EN PACIENTES RESISTENTES AL IMATINIB EN CHILE

Orozco JJ[1], Valencia JE[2], Aiello E[3], Caputo M[4]
[1]*Universidad CES, Medellin, Colombia,* [2]*Bristol-Myers Squibb, Bogotá, Colombia,* [3]*Bristol-Myers Squibb, Buenos Aires, Argentina,* [4]*Bristol-Myers Squibb, Santiago de Chile, Chile*

OBJECTIVOS: Dentro del tratamiento de la Leucemia Mieloide Crónica (LMC) en Chile y con base en un modelo económico realizado previamente por el York Health Economics Consortium, se compararon los costos y la relación de costo-efectividad de 100 mg/día y 140 mg/día de dasatinib, de 800 mg/día de nilotinib y el uso de dosis mayores de imatinib (800 mg/día), para cada fase de la enfermedad (crónica, acelerada y blástica), en pacientes con resistencia o intolerancia a la dosis habitual de imatinib. **METODOLOGÍAS:** Se utilizó un modelo de Markov, con una cohorte hipotética de 10.000 pacientes con LMC en sus tres fases, durante toda la vida y con una tasa de descuento del 3,5% para los costos y beneficios. Los resultados incluyeron los costos de cada alternativa de tratamiento con dasatinib, nilotinib o imatinib y los QALYs ganados. Los costos se expresan en Pesos Chilenos del año 2010. **RESULTADOS:** En fase crónica dasatinib 100 mg/día produjo una mayor cantidad de QALYs con 6,65 y la menor relación de costo-efectividad en las tres fases. En relación con los otros tratamientos con 31.658.391, 42.056.630 y 70.436.294 CLP por QALY ganado. **CONCLUSIONES:** Dasatinib 100 mg/día mostró mejores relaciones de costo-efectividad que nilotinib 800 mg/día y que imatinib 800 mg/día para el tratamiento de pacientes con resistencia o intolerancia a la dosis habitual de imatinib en la fase crónica. Dasatinib 140 mg/día, mostró tener mejor relación de costo efectividad que el imatinib 800 mg/día y que nilotinib 800 mg/día en fase acelerada, y que imatinib 800 mg/día en fase blástica. Aunque hubo un aumento de los costos en general, especialmente debido al dasatinib 140 mg/ día, este hecho se explica por el aumento en años de vida ganados y, en consecuencia, el mayor uso de medicamentos y recursos médicos.

PCN7

IMPACTO PRESUPUESTARIO DEL TRATAMIENTO EN PRIMERA LÍNEA PARA CÁNCER COLORRECTAL METASTÁSICO BASADO EN XELOX + ANTI-VEGF O XELOX + ANTI-EGFR

Gomez E, Torrecillas L, Cervantes L
Centro Médico Nacional 20 de Noviembre ISSSTE, México, D.F., México

OBJECTIVOS: Realizar una evaluación de impacto presupuestario del tratamiento en primera línea del cáncer colorrectal metastático (CCRm) tratado con XELOX+anti-VEGF (Capecitabina+ Oxaliplatino+ anti-VEGF) o XELOX+anti-EGFR (Capecitabina+ Oxaliplatino +Anti-EGFR) en el Centro Médico Nacional (CMN) 20 de Noviembre del ISSSTE en la Ciudad de México. **METODOLOGÍAS:** Se realizó un análisis de impacto presupuestario de los pacientes con CCRm en el que se incluyeron los costos directos (quimioterapia, biológico y premedicación) de cada tratamiento. Se tomó en cuenta un escenario de 6 ciclos, con un intervalo de 21 días para cada uno. Los costos de los insumos se tomaron de las tarifas estimadas del CMN ISSSTE 20 de Noviembre, utilizándose la metodología de microcosteo de procesos. Los resultados de efectividad se adecuaron a la presencia o ausencia de la mutación del gen KRAS. **RESULTADOS:** El costo por tratamiento de XELOX+anti-VEGF fue de 283,963 MXP vs. 480,244 MXP para XELOX+anti-EGFR. Un análisis de sensibilidad comprobó que el costo del biológico representa aproximadamente 80% del costo del tratamiento. Adicional a esto, la efectividad de XELOX+anti-VEGF es superior que a la de XELOX+anti-EGFR para los casos de KRAS silvestre y KRAS mutado. **CONCLUSIONES:** XELOX+anti-VEGF es un tratamiento más barato y más efectivo que XELOX+anti-EGFR (+196,281). Por cada paciente tratado con XELOX+anti-EGFR se pueden tratar 1.6 pacientes con XELOX+anti-VEGF y tener mas probabilidad de éxito clínico dada la mayor eficacia sin importar si el gen KRAS es silvestre o mutado. El enorme diferencial de costo (+98%) con respecto a XELOX+anti-EGFR proviene del alto costo del biológico de la aplicación semanal (3 por ciclo) y la dosis de impregnación que el anti-EGFR requiere.

PCN8

COST-EFFECTIVENESS ANALYSIS OF AN OPIOID IN COMBINATION WITH GABAPENTIN VERSUS MONOTHERAPY FOR THE TREATMENT OF NEUROPATHIC PAIN

Galindo L[1], Guajardo J[1], Plancarte R[1], Cerezo O[2], Najera E[3], Gonzalez I[1]
[1]*National Cancer Institute, México, Tlalpan, México,* [2]*Oncology National Institute, México D.F., México,* [3]*Universidad Nacional Autónoma de México, México, Coyoacan, México*

OBJECTIVES: This study aimed to compare the cost-effectiveness of gabapentin combined with an opioid versus gabapentin monotherapy for the management of neuropathic cancer pain. **METHODS:** Randomized controlled trial aimed to compare monotherapy versus combined therapy to control neuropathic pain, in a subset of cancer/HIV-AIDS/Chemotherapy/PHN/DN patients. Patients were randomized to one of the following treatment protocols: 1) gabapentin and opioid combination (GO group), and 2) Gabapentin monotherapy (GG group) both groups are titrated according to pain response. Changes in pain intensity, DN-4, patient satisfaction and analgesic drug consumption were evaluated at 0, 7, 30, 60 and 90 days. Side effects were also recorded. We carried out an interim analysis in order to keep recruit patients for the entire protocol. **RESULTS:** Fifty-four patients diagnosed with neuropathic pain were included. Forty-nine patients completed the study. These data suggest that GO treatment provides better relief of neuropathic pain in cancer patients compared with monotherapy. Besides, the GO treatment is a very-high cost-effectiveness alternative, cause in countries like Mexico the threshold falls below 1 GDP per capita. **CONCLUSIONS:** Our preliminary clinical observation shows that the addition of gabapentin to an opioid analgesic (tramadol + gabapentin) is safe with fewer side effects and demonstrate greater effectiveness

at lower cost compared with gabapentin as monotherapy. Resulting in greater satisfaction and better adherence to treatment.

PCN9

ECONOMIC EVALUATION OF PANITUMUMAB VS CETUXIMAB IN PATIENTS WITH COLORECTAL CARCINOMA (CRCM) WITH NON-MUTATED (WILD-TYPE) KRAS AFTER FAILURE OF CHEMOTHERAPY REGIMENS IN MEXICO

Arocho R[1], Rivera Hurtado R[2]
[1]*Amgen, Inc., Barcelona, Spain,* [2]*Amgen México, México D.F., México*

OBJECTIVES: Panitumumab, a fully human monoclonal antibody directed against epidermal growth factor receptor (EGFR), is indicated as a monotherapy for the treatment of patients with EGFR-expressing CRCm and non-mutated KRAS status. The aim of this study was to conduct an economic evaluation of panitumumab vs cetuximab in Mexican patients with CRCm. **METHODS:** A cost minimization analysis (CMA) was performed from a Public Healthcare System perspective considering a 20-week timeframe. The analysis compared the treatment costs of CRCm patients with panitumumab and cetuximab. Only direct medical costs were considered. Drug cost for cetuximab was calculated according to Mexican Public Healthcare Sector acquisition price list for 2010. Panitumumab price for the Mexican Public Healthcare Sector was provided by Amgen Mexico ($94.36 MXP/mg). Recommended doses and frequency were based on each product label and the number of cycles was based on data from clinical trials. Anthropometric values were obtained from published data in Mexican Public Healthcare Sector oncology (CRCm) patients. The cost of administration was calculated from an official Mexican Public Healthcare Sector price list for 2010. A probabilistic sensitivity analysis was performed considering two scenarios: per vial of drug (assuming wastage of unused medication) and per mg of drug (assuming no wastage). **RESULTS:** Panitumumab resulted in an overall monthly cost savings of 20% (per vial scenario) and 12.4% (per mg sceanrio) compared with cetuximab. When the analysis was restricted to the acquisition drug costs, monthly savings of panitumumab compared with cetuximab were estimated to be 19.1% and 11.2% in per vial and per mg scenarios, respectively. Regarding the sensitivity analysis, 100% of iterations resulted cost-saving in both scenarios (per vials and per mg). **CONCLUSIONS:** According to these results, panitumumab represents a cost-saving strategy vs cetuximab for the treatment of patients with CRCm in the Mexican setting.

PCN10

ANALISIS DE MINIMIZACION DE COSTOS ENTRE EL USO DE IOPROMIDE MEDIANTE UN SISTEMA DE APLICACION EN CASCADA (SIAC) FRENTE AL USO DE OTROS MEDIOS DE CONTRASTE CONVENCIONALES EN RADIOLOGIA INVASIVA EN COLOMBIA

Romero M[1], Karpf E[1], Oyuela M[2]
[1]*Fundación Salutia, Bogotá, Colombia,* [2]*Bayer Colombia, Bogotá, Colombia*

OBJECTIVOS: Realizar una evaluación económica del uso de Iopromide mediante un sistema de aplicación en cascada (SIAC), frente a los demás medios de contraste para radiología invasiva disponibles en Colombia e incluidos dentro del plan de beneficios colombiano (POS). **METODOLOGÍAS:** Se realizó un análisis de minimización de costos comparando SIAC frente al uso de otros medios de contraste convencionales en radiología invasiva desde la perspectiva del hospital. La efectividad y seguridad del uso de Iopromide es similar a la de los ya incluidos en el POS según reportes de estudios clínicos. Los costos y frecuencias de uso fueron obtenidos de tres hospitales en Colombia durante el primer trimestre del 2011. Se tomaron los costos promedios obtenidos de las diferentes observaciones. No se incluyeron costos por eventos adversos, por cuanto son similares en las diferentes opciones. **RESULTADOS:** El costo de utilizar SIAC en un paciente promedio de 70 Kg fue de USD 35.57 frente a USD 39.44 cuando se utilizó otros medios de contraste convencional. Lo que representa un ahorro de USD 3.90 por paciente. La diferencia fundamental se debió a menor desperdicio de medio de contraste y menor tiempo requerido. El análisis de sensibilidad no muestra cambios en los resultados. El análisis de impacto presupuestario muestra el importante ahorro que significaría para el país la conversión tecnológica pasando de utilizar los medios actuales a la nueva tecnología que utiliza el sistema de aplicación SIAC para un peso promedio de adultos en Colombia de 70 kg. **CONCLUSIONES:** El uso de Iopromide mediante la aplicación de SIAC sería mejor que utilizar otros medios de contraste por cuanto es menos costoso y utilizado de manera adecuada tendrían igual efectividad a los otros medios de contraste comparados y de esta manera incentiva la productividad al interior de las unidades de radiología.

Cardiovascular Disorders – Cost Studies

PCV1

COSTS, LENGTH OF STAY AND ALL-CAUSE MORTALITY IN RUPTURED VERSUS UNRUPTURED CEREBRAL ANEURYSM AMONG INPATIENTS IN THE UNITED STATES

Wallace KL, Hashemi L, Minshall ME
Covidien, Mansfield, MA, USA

OBJECTIVES: Cerebral aneurysms are pathological dilatations of the cerebrovasculature that are prone to rupture. Risk of aneurysm rupture is determined by size, location and patient co-morbidities, and five-year cumulative rupture rates have been reported to be as high as 50% in giant aneurysms [1]. The current study was undertaken to assess the differences in overall hospital discharge costs, length of stay (LOS) and all-cause mortality rates between inpatients with ruptured versus. unruptured cerebral aneurysms. **METHODS:** All inpatient discharges were selected from the Premier Perspective™ Database that had a primary diagnosis code for a ruptured or unruptured aneurysm, AND a primary procedure code for treatment of the aneurysm between 1/1/2008 and 6/30/2010 (index hospitalization). Costs, LOS and mortality were compared between ruptured and unruptured aneurysm groups. To minimize differences in baseline characteristics between groups, propensity adjustment was performed for age, gender and severity of illness (based on the Patient Refined Diagnosis Related Groups). **RESULTS:** A total of 2977 ruptured and 3836 unruptured aneurysm discharges met the inclusion criteria for the study. After 1:1 propensity matching, 1163 patients in each group were included in the analysis for outcome comparisons. Mean total cost per discharge was significantly higher in the ruptured group ($51,118, s.d. $33,790) than the unruptured group ($33,585, s.d. $32,255). Mean LOS was also significantly higher in the ruptured group (13.6 days, s.d. 12.7) versus. the unruptured group (6.5 days, s.d. 11.2). The all-cause mortality rate was significantly higher in ruptured (7.7%) versus. unruptured (1.8%) cerebral aneurysms. **CONCLUSIONS:** Preventing rupture in patients with cerebral aneurysms would likely decrease burden to the health care system, and also improve survival rates for patients. 1International Study of Unruptured Intracranial Aneurysms Investigators. Unruptured Intracranial Aneurysms: Natural History, Clinical Outcome, and Risks of Surgical and Endovascular Treatment. ([1] Lancet; 2003; 362:103-10)

PCV2

ESTIMATED COST OF ACUTE CORONARY SYNDROME FOR 2011: CASE OF MEXICO

Ramirez MA[1], Sanchez A[1], Piha T[2], Polanco AC[1], Hernandez R[3], De los Rios M[4]
[1]*AstraZeneca, México D.F., México,* [2]*AstraZeneca, Cotia, São Paulo, SP, Brazil,* [3]*AstraZeneca, Miami, FL, USA,* [4]*Centro para el Des. de la Medicina y de Asistencia Medica Esp., Culiacan, Sinaloa, México*

OBJECTIVES: To estimate the costs of acute coronary syndrome in Mexico and its impact on the Mexican healthcare system, considering direct and indirect cost under the public and private perspectives to support further HTA incorporation. **METHODS:** In this study we adopted the societal perspective, including the public and private perspectives. Direct costs were retrieved from national databases and only hospitalization period was considered. For indirect costs the Human Capital Approach method was used with two major costs included in the analysis: loss of productivity among patients that died of a MI or unstable angina event and the loss of productivity of the period between the main event (MI or angina) and the return to work (recovery time). For the study we assumed the age from 25 to 64 years old as active labor age (65 is the age of retirement in Mexico), a recovery time of 3.4 months and the average income of the population to estimate the loss of productivity for each working month lost. **RESULTS:** The estimated direct costs associated to Acute Coronary Syndrome for 2011 under the public perspective is US$153,629,253 and for private it is US$179,725,285. The estimated indirect cost for 2011 is US$918,239,181. So, the total estimated costs for ACS in Mexico for 2011 is US$1,251,593,719. **CONCLUSIONS:** Due the high impact of ACS costs for the Mexican healthcare system (U$1,251,593,719), projected for the year of 2011, it is very relevant to evaluate measures that can reduce such events beyond those already in use.

PCV3

ESTIMATED COST OF ACUTE CORONARY SYNDROME FOR 2011: CASE OF BRAZIL

Piha T[1], Ramirez MA[2], Sanchez A[2], Mariz VO[1], Neves JE[3], Teich V[4], Araujo DV[4]
[1]*AstraZeneca, Cotia, São Paulo, SP, Brazil,* [2]*AstraZeneca, Ciudad del México, México D.F., México,* [3]*AstraZeneca, Miami, FL, USA,* [4]*MedInsight Evidências, São Paulo, SP, Brazil*

OBJECTIVES: To estimate the costs of acute coronary syndrome in Brazil and its impact on the Brazilian healthcare system, considering direct and indirect cost under the public and private perspectives to support further HTA incorporation. **METHODS:** In this study we adopted the societal perspective, including the public (SUS) and supplementary (SHS) healthcare system perspectives. Direct costs were retrieved from national databases [1] and only hospitalization period was considered. For indirect costs the Human Capital Approach method was used with two major costs included in the analysis: loss of productivity among patients that died of a MI or unstable angina event and the loss of productivity of the period between the main event (MI or angina) and the return to work (recovery time). For the study we assumed the age from 25 to 64 years old as active labor age (65 is the age of retirement in Brazil), a recovery time of 3.4 months and the average income of the population to estimate the loss of productivity for each working month lost. **RESULTS:** The estimated direct costs associated to Acute Coronary Syndrome for 2011 under the SUS perspective is US$ 314,080,370 and for SHS it is US$ 309,781,809. The estimated indirect cost for 2011 is US$ 1,703,908,984. So, the total estimated costs for ACS in Brazil for 2011 is US$ 2,327,771,163. **CONCLUSIONS:** Due the high impact of ACS costs for the Brazilian healthcare system (U$ 2,327,771,163.11), projected for the year of 2011, it is very relevant to evaluate measures that can reduce such events beyond those already in use.

PCV4

ANALISIS COSTO EFECTIVIDAD EN EL LARGO PLAZO DE LOS STENTS LIBERADORES DE FARMACO VS STENTS CONVENCIONALES EN PACIENTES CON CARDIOPATIA ISQUEMICA EN EL IMSS

Gonzalez-Diaz BE[1], Salinas Escudero G[2], Granados-Garcia V[1], Contreras Hernández I[1], Calderón Abbo M[1]
[1]*Instituto Mexicano del Seguro Social, México D.F., México,* [2]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México D.F., México*

OBJECTIVOS: Estimar la razón costo-efectividad (RCE) del uso de los stents liberadores de fármaco (DES, drug eluting stent) comparado contra los stents desnudos (BMS, bare metal stent) en una cohorte de pacientes con enfermedad coronaria en el Instituto Mexicano del Seguro Social (IMSS). **METODOLOGÍAS:** Análisis de costo-efectividad en una cohorte de pacientes isquémicos con indicación de ICP (Inter-

vención Coronaria Percutánea). La medida de efectividad fue la tasa de éxitos clínicos sin eventos adversos cardiovasculares mayores a 3 años. El costo y la efectividad los tratamientos se obtuvo del seguimiento clínico de la cohorte de n=230 pacientes en el Hospital de Cardiología del IMSS seguidos por 3 años. Se utilizó la técnica de micro-costeo, los costos provienen de bases de costos institucionales (2010). Los resultados están expresados en dólares americanos (USD) del 2010 (tipo de cambio MX$12.63: $1 USD). Se empleó una tasa de descuento del 5%. Además del modelo determinístico, se realizó un análisis de sensibilidad probabilístico y se estimó la curva de aceptabilidad. **RESULTADOS:** El 59.3% de los pacientes de la cohorte utilizó BMS y el 40.87% DES. El grupo con DES mostró los mayores costos promedio por paciente USD$16,635 comparado con BMS USD$13,432. Las efectividades DES encontradas fueron de 88% y las de BMS 74%. La RCE fue de USD$15,263 en el caso de DES y de USD$22,480 con BMS. El DES se ubicó como la alternativa costo-efectiva y dominante frente al empleo del BMS. La curva de aceptabilidad muestra que el tratamiento de DES se ubicó como la alternativa costo-efectiva independientemente de la Disponibilidad a Pagar por parte de la institución. **CONCLUSIONES:** Los resultados del análisis realizado sugieren que DES es una alternativa de tratamiento intervencionista de revascularización con mejores resultados en salud, y que también representa una alternativa costo ahorradora respecto a BMS.

PCV5

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF RIVAROXABAN IN THE PREVENTION OF THROMBOEMBOLIC EVENTS IN PATIENTS PERFORMING HIP AND KNEE ARTHROPLASTY IN COMPARISON WITH NO TREATMENT UNDER THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM PERSPECTIVE

Schiola A[1], Silva AP[2], Santoni NB[2], Paladini L[3], Teich V[3], Pepe C[3], Rocha MM[3]
[1]*Bayer de México, S.A. de C.V., México D.F., México,* [2]*Bayer Brasil, São Paulo, SP, Brazil,* [3]*MedInsight Evidências, São Paulo, SP, Brazil*

OBJECTIVES: To develop a cost-effectiveness and a budget impact analysis of Rivaroxaban in the prevention of thromboembolic events in patients performing hip and knee arthroplasty in comparison with no treatment under the Brazilian private health care system perspective. **METHODS:** A decision tree analysis was developed for the first 90 days, considering the occurrence of Deep Venous Thrombosis, Pulmonary Embolism and thromboembolic events, followed by a Markov model, for Post Thrombotic Syndrome and Thrombotic Pulmonary Hypertension. The time horizon of the analysis was 5 year. The cycle duration was 1 year and the corresponding epidemiological and efficacy data were obtained from a critical appraisal of the scientific literature. Unit costs for drugs, procedures, materials and daily hospital were obtained from Kairos Magazine (Maximum price consumers 18%ICMS), Hierarchical Brazilian Classification of Medical Procedures (CBHPM 5th edition), Simpro Magazine Maximum price consumers 18% ICMS) and search UNIDAS 2008, respectively. A budget impact analysis was developed considering an increase of 10% per year in market share of Rivaroxaban. **RESULTS:** Total costs associated with Rivaroxaban and no treatment, considering the indication for knee arthroplasty, were BRL363 (US$214) and BRL1,040 (US$612), respectively. And considering the indication for hip arthroplasty, were BRL332 (US$195) and BRL462 (US$272), respectively. Rivaroxaban reduces the number of all thromboembolic events in 0.0793 and 0.0246, for knee and hip arthroplasty, respectively. Rivaroxaban treatment is more effective and cheaper than no treatment in both indications (dominant). The high cost associated with no treatment patient is due to the high number of events in this group. The budget impact analysis estimated an economy of BRL206,165 (US$121,274) and BRL104,351 (US$61,383) for knee and hip indication, respectively, in 5 years. **CONCLUSIONS:** By this pharmacoeconomic analysis, the treatment with Rivaroxaban, shown to reduce treatment costs and events compared with no treatment.

PCV6

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF RIVAROXABAN IN THE PREVENTION OF THROMBOEMBOLIC EVENTS IN PATIENTS PERFORMING HIP AND KNEE ARTHROPLASTY IN COMPARISON WITH ENOXAPARIN UNDER THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM PERSPECTIVE

Schiola A[1], Silva AP[2], Santoni NB[2], Paladini L[3], Teich V[3], Pepe C[3], Rocha MM[3]
[1]*Bayer de México, S.A. de C.V., México D.F., México,* [2]*Bayer Brasil, São Paulo, SP, Brazil,* [3]*MedInsight Evidências, São Paulo, SP, Brazil*

OBJECTIVES: To develop a cost-effectiveness and a budget impact analysis of Rivaroxaban in the prevention of thromboembolic events in patients performing hip and knee arthroplasty in comparison with Enoxaparin under the Brazilian private health care system perspective. **METHODS:** A decision tree analysis was developed for the first 90 days, considering the occurrence of Deep Venous Thrombosis, Pulmonary Embolism and thromboembolic events, followed by a Markov model, for Post Thrombotic Syndrome and Thrombotic Pulmonary Hypertension. The time horizon of the analysis was 5 year. The cycle duration was 1 year and corresponding epidemiological and efficacy data were obtained from a critical appraisal of the scientific literature. The outcomes were expressed as the incremental number of all thromboembolic events. The analysis considered only direct medical costs. Unit costs for drugs, procedures, materials and daily hospital were obtained from Kairos Magazine (Maximum price consumers 18% ICMS), Hierarchical Brazilian Classification of Medical Procedures (CBHPM 5thedition), Simpro Magazine (Maximum price consumers 18%ICMS) and UNIDAS 2008, respectively. A budget impact analysis was developed considering an increase of 10% per year in market share of Rivaroxaban. **RESULTS:** Total costs associated with Rivaroxaban and Enoxaparin, considering the indication for knee arthroplasty, were BRL363 (US$214) and BRL632 (US$372), respectively. Rivaroxaban reduces the number of all thromboembolic events in 0.0167. Rivaroxaban treatment is more effective and cheaper than Enoxaparin treatment (dominant). Total costs associated with Rivaroxaban and Enoxaparin, considering the indication for hip arthroplasty, were BRL332 (US$195) and BRL468 (US$275), respectively. The number of all thromboembolic events was the same. Rivaroxaban treatment is cheaper with same efficacy. The budget impact analysis estimated an economy of BRL98,810 (US$58,124) and BRL184,630 (US$108,606) for knee and hip indication, respectively, in 5 years. **CONCLUSIONS:** By this pharmacoeconomic analysis, the treatment with Rivaroxaban, shown to reduce treatment costs and events compared with Enoxaparin.

PCV7

COST-EFFECTIVENESS OF PRASUGREL VERSUS CLOPIDOGREL IN PATIENTS WITH ACUTE CORONARY SYNDROMES UNDERGOING PERCUTANEOUS CORONARY INTERVENTION IN THE PUBLIC HEALTH CARE SYSTEM IN MEXICO

Mondragon R[1], Arrieta-Maturino E[2], Vargas-Valencia JJ[3], Martínez-Fonseca J[3], Guzman-Sotelo M[3], Galindo-Suarez RM[2], Ramírez-Gámez J[2]
[1]*Hospital Central-Sur de Alta Especialidad PEMEX, México D.F., México,* [2]*Eli Lilly and Company, México D.F., México,* [3]*Econopharma Consulting S.A. de C.V., México D.F., México,* [4]*Pfizer, Inc., México City, México*

OBJECTIVES: To evaluate the cost-effectiveness of prasugrel versus clopidogrel in patients with acute coronary syndromes (ACS) undergoing percutaneous coronary intervention (PCI) from the public healthcare payer perspective in Mexico. **METHODS:** The alternatives were prasugrel (loading dose 60 mg, maintenance dose 10 mg daily) versus clopidogrel (loading dose 300 mg, maintenance dose 75 mg daily). A Markov model was developed. Only direct medical care costs were considered for one year. The efficacy measure was a composite of the death from cardiovascular causes, nonfatal myocardial infarction or nonfatal stroke and stent thrombosis reported in the trial directly comparing prasugrel and clopidogrel (TRITON TIMI-38). Three types of populations were evaluated separately; overall, patients with diabetes mellitus, and the subset of diabetics treated with insulin. Care costs were derived from medical records, and the costs of drugs were assumed to be the same. Costs and the model were validated by experts. **RESULTS:** According to the model prasugrel had fewer events in the three types of populations evaluated over a 12 month time horizon. The number of events; death from cardiovascular causes, nonfatal myocardial infarction-stroke and stent thrombosis avoided by 10,000 patients were distributed as follows: overall population, 31, 650 and 147, diabetics, 92, 1363 and 203, diabetics on insulin, 174, 2531 and 499. The average cost per patient (2010 Mexican pesos) treated with prasugrel was lower compared with clopidogrel, for the overall population (MXN$ 69,972 vs. MXN$ 82,991), diabetics (MXN$79,971 vs. MXN$ 105,756) and diabetics treated with insulin (MXN$ 85,750 vs. MXN$ 137,144). **CONCLUSIONS:** Results from the present analysis suggest that the use of prasugrel (instead of clopidogrel) in patients with ACS undergoing PCI represents a more effective strategy at a lower cost (dominant strategy), a cost-saving alternative for institutions of public healthcare in Mexico.

PCV8

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF RIVAROXABAN IN THE PREVENTION OF THROMBOEMBOLIC EVENTS IN PATIENTS PERFORMING HIP AND KNEE ARTHROPLASTY IN COMPARISON WITH DABIGATRAN UNDER THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM PERSPECTIVE

Schiola A[1], Silva AP[2], Santoni NB[2], Paladini L[3], Teich V[3], Pepe C[3], Rocha MM[3]
[1]*Bayer de México, S.A. de C.V., México D.F., México,* [2]*Bayer Brasil, São Paulo, SP, Brazil,* [3]*MedInsight Evidências, São Paulo, SP, Brazil*

OBJECTIVES: To develop a cost-effectiveness and a budget impact analysis of Rivaroxaban in the prevention of thromboembolic events in patients performing hip and knee arthroplasty in comparison with Dabigatran under the Brazilian private health care system perspective. **METHODS:** A decision tree analysis was developed for the first 90 days, considering the occurrence of Deep Venous Thrombosis, Pulmonary Embolism and thromboembolic events, followed by a Markov model, for Post Thrombotic Syndrome and Thrombotic Pulmonary Hypertension. The time horizon of the analysis was 5 year. The cycle duration was 1 year and corresponding epidemiological and efficacy data were obtained from a critical appraisal of the scientific literature. The outcomes were expressed as the incremental number of all thromboembolic events. The analysis considered only direct medical costs. Unit costs for drugs, procedures, materials and daily hospital were obtained from Kairos Magazine (Maximum price consumers 18%ICMS), Hierarchical Brazilian Classification of Medical Procedures (CBHPM 5thedition), Simpro Magazine (Maximum price consumers 18%ICMS) and UNIDAS 2008, respectively. A budget impact analysis was developed considering an increase of 10% per year in market share of Rivaroxaban. **RESULTS:** Total costs associated with Rivaroxaban and Dabigatran, considering the indication for knee arthroplasty, were BRL363 (US$214) and BRL371 (US$218), respectively. The number of all thromboembolic events was the same. Rivaroxaban treatment is cheaper with same efficacy. Total costs associated with Rivaroxaban and Dabigatran, considering the indication for hip arthroplasty, were BRL332 (US$195) and BRL485 (US$285), respectively. Rivaroxaban reduces the number of all thromboembolic events in 0.0140. Rivaroxaban treatment is more effective and cheaper than Dabigatran treatment (dominant). The budget impact analysis estimated an economy of BRL3,894 (US$2,291) and BRL150,642 (US$88,613) for knee and hip indication, respectively, in 5 years. **CONCLUSIONS:** By this pharmacoeconomic analysis, the treatment with Rivaroxaban, shown to reduce treatment costs and events compared with Dabigatran.

PCV9

COSTO–EFECTIVIDAD DE LOS ÁCIDOS GRASOS OMEGA 3 COMO COADYUVANTE DE LA SIMVASTATINA EN EL TRATAMIENTO DE LA HIPERTRIGLICERIDEMIA

Rendon D, Ordoñez J, Orozco JJ

Universidad CES, Medellin, Colombia

OBJECTIVOS: Evaluar la relación costo-efectividad del omega-3 como coadyuvante de segunda línea en los pacientes con hipertrigliceridemia, que vienen utilizando simvastatina versus simvastatina sola. **METODOLOGÍAS:** Para la búsqueda de las eficacias se realizó una búsqueda sistemática de la literatura de acuerdo a unos criterios establecidos previamente. Los costos monetarios fueron evaluados de acuerdo al mercado interno farmacéutico. Se tomó el valor de la mediana y se utilizaron los valores extremos para el análisis de sensibilidad. **RESULTADOS:** El tratamiento con simvastatina 40 mg + 4 gr/día de ácidos grasos del aceite de pescado Omega 3 tuvó una mejor relación de costo-efectividad en comapración con el tratamiento tradicional de solo simvastatina 40 mg/día, en pacientes con hipertrigliceridemia. Las efectividades fueron determinadas como el porcentaje de disminución de los niveles de triglicéridos respecto de los valores iniciales. El estudio seleccionado en la revisión sistemática determinó la efectividad del primer tratamiento en un 29.5% frente a un 6.3% del segundo. La relación de costo-efectividad a las 8 semanas, fue de 7,971 pesos por unidad porcentual de disminución los triglicéridos para el tratamiento con Omega-3, versus 17,938 pesos para la simvastatina sola. El análisis incremental mostró un costo de 5264 pesos por unidad porcentual adicional de disminución de los triglicéridos por encima de la opción de simvastatina sola. **CONCLUSIONES:** El tratamiento con simvastatina 40 mg mas 4 gr/dia de ácidos grasos del aceite de pescado Omega 3, tiene una mejor relación de costo- efectividad que el tratamiento tradicional de simvastatina 40 mg sola, tanto cuando se consideró un horizonte de 8 semanas como para las 52 semanas. Esto es importante para el diseño de nuevos programas de promoción y prevención en el marco del sistema general de seguridad social en Colombia.

PCV10

UN ESTUDIO DE MINIMIZACION DE COSTOS PARA EVALUAR EL TRATAMIENTO CON METOPROLOL EN PACIENTES CON HIPERTENSION ARTERIAL EN MÉXICO

Lopez JA[1], Briones B[2]
[1]*Sandoz México, México D.F., México,* [2]*Novartis Farmaceutica, México D.F., México*

OBJECTIVOS: El objetivo de este análisis es comprobar la relación costo-efectividad de dos alternativas de metoprolol, un beta-bloqueador de liberación prolongada con amplia experiencia clínica en su uso para el manejo de la hipertensión arterial, para el manejo de pacientes hipertensos en México. **METODOLOGÍAS:** Este es un estudio de minimización de costos desde la perspectiva institucional del Instituto de Seguridad Social del Estado de México y Municipios (ISSEMYM). Se evaluaron dos alternativas de metoprolol para el manejo de hipertensión arterial: el metoprolol genérico actualmente disponible en el cuadro básico de medicamentos institucional (metoprolol genérico actual), y el metoprolol genérico de marca Lopresor R® (metoprolol genérico de marca). La medición de eficacia se igualó a una constante, debido a que los estudios de bioequivalencia, avalados por la autoridad sanitaria, corroboran que el metoprolol genérico de marca es bioequivalente al metoprolol genérico actual. Los costos fueron obtenidos de la institución; están expresados en Pesos Mexicanos y son vigentes para el 2011. El horizonte temporal fue de 12 meses, por lo cual no se utilizó tasa de descuento. Una vez obtenido el resultado, se procedió a un análisis de impacto presupuestal para la institución. **RESULTADOS:** El análisis reveló un costo anual de $2,190.00 para metoprolol genérico de marca, en comparación con un costo anual de $2,754.11 para metoprolol genérico actual, dando como resultado un decremento en el costo anual de $564.11 por cada paciente tratado. El análisis de impacto presupuestal reveló que cada 1000 pacientes tratados con el metoprolol genérico de marca, en contraposición al metoprolol genérico actual, representan un ahorro anual para la institución de $564,107.50. **CONCLUSIONES:** La sustitución de metoprolol genérico actual por metoprolol genérico de marca representa, para la institución, un ahorro anual potencial de $564.11 por cada paciente tratado, y un ahorro anual potencial de $564,107.5 por cada 1000 pacientes tratados.

Diabetes/Endocrine Disorders – Clinical Outcomes Studies

PDB2

CALIDAD DE PRESCRIPCION DE HIPOGLUCEMIANTES ORALES EN UNA UNIDAD MEDICA FAMILIAR: CENTRO, TABASCO, MÉXICO, 2009

Zavala-González MA[1], Posada-Arévalo SE[2], Barrera-Olán L[3], López-Mandujano C[3], Mirón-Carrera MT[3], Santiago-Naranjo P[3]
[1]*Asociación Latinoamericana de Profesores de Medicina Familiar, A.C., Cárdenas, Tabasco, México,* [2]*Universidad Nacional Autónoma de México, Villahermosa, Tabasco, México,* [3]*Instituto Mexicano del Seguro Social, Delegación Tabasco, Villahermosa, Tabasco, México*

OBJECTIVOS: Determinar la calidad de la prescripción de hipoglucemiantes orales en pacientes con Diabetes Mellitus No Insulinodependiente (DMNID) derechohabientes usuarios de la Unidad de Medicina Familiar (UMF) No. 43 del Instituto Mexicano del Seguro Social (IMSS), en Villahermosa, Centro, Tabasco, México, durante el año 2009. **METODOLOGÍAS:** Diseño: observacional, retrospectivo, transversal, descriptivo. Universo: 2678 expedientes de pacientes con DMNID atendidos en la UMF No. 43 del IMSS, en Villahermosa, Centro, Tabasco, México, durante el año 2009. Muestra: probabilística simple, 254 expedientes (N=2,678, p=0.76, q=0.24, d=0.05, Z=1.96). Muestreo: aleatorizado, técnica de números aleatorios. Criterios de selección: expedientes clínicos completos. Variables: edad, sexo, obesidad, tiempo de evolución de la Diabetes Mellitus, esquema terapéutico, calidad de la prescripción y error de prescripción. Fuentes de información: expedientes completos. Procedimientos: se sistematizó la información de los esquemas terapéuticos de hipoglucemiantes orales prescritos a los pacientes, y se compararon contra las guías de prescripción, considerando adecuadas las prescripciones realizadas de acuerdo a las guías. Análisis: estadística descriptiva. Software: STATS™ 2.0, Epi Info™ 3.3.2. **RESULTADOS:** Un total de 254 expedientes clínicos: excluidos 34.3%, incluidos 65.7%. Expedientes clínicos estudiados: 167. Media de hipoglucemiantes orales prescritos 2±1, intervalo 1-3, moda 2. Esquema terapéutico más frecuentes: Glibenclamida y Metformina 58.1%. Calidad de la prescripción: 81% inadecuada, 19% adecuada. Error de prescripción más frecuente: intervalo inadecuado 61%. **CONCLUSIONES:** La calidad de la prescripción de hipoglucemiantes orales observada en esta serie es predominantemente inadecuada, en proporción mayor a la media estatal (23.7%). Se requiere educación continua y medidas gerenciales para corregir el problema.

PDB3

PREVALENCE OF SEVERE OSTEOPOROSIS IN DAILY CONSULTATION OF RHEUMATOLOGY AND ENDOCRINOLOGY SERVICES, COSTS AND QUALITY OF LIFE OF FRAGILITY FRACTURES IN MEXICO

Carlos F[1], Clark P[2], Chico G[2], Ramírez E[3], Franco F[3], Jasqui-Romano S[4]
[1]*R A C Salud Consultores, S.A. de C.V., México D.F., México,* [2]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México, DF, México,* [3]*Instituto Nacional de Rehabilitación, Secretaría de Salud, México D.F., México,* [4]*Eli Lilly and Company, México D.F., México*

OBJECTIVES: Osteoporosis (OP) and its fragility fractures (FF) impose a large burden on health system and the impact is growing due to population ageing. Severe or established OP defines a T-score < -2.5 in presence of a fragility fracture. We aimed to estimate the prevalence of severe OP in daily consultation of rheumatology and endocrinology services in hospitals of IMSS and ISSSTE and to assess the costs and quality of life (QoL) associated with FF in Mexico. **METHODS:** A prospective study was performed in 11 specialty (6 rheumatology and 5 endocrinology) services from 9 hospitals of IMSS and ISSSTE through March 1 to April 27, 2010. Data of adults attending to outpatient consultation was collected in a clinical report form. The analysis was done following a frequentist statistical approach. We also conducted a systematic review of published and non-published data of direct medical costs (acute attention, physical therapy and outpatient visits) and QoL related with major FF in Mexico. Expert opinion was used when local information was not available. All costs were updated to December 2010 and figures are expressed in Mexican pesos. **RESULTS:** During the period of study, 84 out of the 3527 medical consultations were given to patients diagnosed with severe OP, comprising a 2.4% of the total consultations in these services. Prevalence of severe OP was slightly higher in rheumatology (2.6%) than in endocrinology (2.2%) services. First-year total cost per patient with hip, vertebral, forearm and humerus FF were estimated at $82631, $53332, $39006 and $41942, respectively. FF significantly reduced QoL, with hip and vertebral fractures affecting the most. **CONCLUSIONS:** This study shows that severe OP is common in rheumatology and endocrinology services. Since a prior fracture increases the risk of future fractures, patients with severe OP entail a high economic burden to the health system.

Diabetes/Endocrine Disorders – Cost Studies

PDB4

GASTOS COM MEDICAMENTOS E CARACTERÍSTICAS DE INDIVÍDUOS COM HIPERTENSÃO E DIABETES MELLITUS, EM MUNICÍPIOS DA REDE FARMÁCIA DE MINAS - MINAS GERAIS, BRASIL

Pereira VOM, Cherchiglia ML, Acurcio FA
Universidade Federal de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil

OBJETIVOS: Descrever características sociais, demográficas, além dos gastos mensais com medicamentos por indivíduos com hipertensão arterial e/ou *diabetes mellitus*, em municípios selecionados da Rede Farmácia de Minas. **MÉTODOS:** A estratégia geral de delineamento foi a de um estudo epidemiológico seccional (inquérito) sobre a utilização de medicamentos, realizado por meio de seleção aleatória em 32 dos 67 municípios participantes do Programa Farmácia de Minas. Esse programa, implementado no estado de Minas Gerais, visa garantir o acesso a medicamentos por meio da estruturação da rede pública estadual de assistência farmacêutica. A população alvo foi constituída por pacientes hipertensos e/ou diabéticos, residentes nos referidos municípios. Foram entrevistados 4815 indivíduos, no período de 18 de janeiro a 22 de fevereiro de 2010. Os gastos mensais com medicamentos foram expressos em unidade monetária brasileira, Real (R$), e também foram descritos em proporções do salário mínimo vigente no período de realização das entrevistas. **RESULTADOS:** Observou-se que os indivíduos entrevistados possuíam em média 61,2 anos (mediana=62). Dentre eles, a maior parte (68,7%) era do sexo feminino e 64,6% possuíam primeiro grau incompleto ou nunca haviam estudado. Cerca de 41% dos entrevistados apresentaram algum gasto para a aquisição de medicamentos nos 30 dias anteriores à realização das entrevistas. O gasto médio mensal foi de R$ 103,80, e o mediano, de R$60,00. Esses valores de gastos com medicamentos equivalem, respectivamente, a 20% e a 12% do valor do salário mínimo vigente à época da realização das entrevistas. Os gastos também foram caracterizados pela concentração. Os dez indivíduos com os maiores gastos foram responsáveis por 8,8% dos gastos totais. **CONCLUSÕES:** Os resultados deste trabalho poderão ser úteis para direcionar o planejamento de novas análises, sobre o perfil de utilização de medicamentos por indivíduos com hipertensão e/ou *diabetes mellitus*, em municípios da Rede Farmácia de Minas.

PDB5

USE OF A DISCRETE EVENT SIMULATION MODEL TO ESTIMATE CLINICAL AND ECONOMIC OUTCOMES OF VARIOUS SELF-MONITORING OF BLOOD GLUCOSE REGIMES PLUS CONVENTIONAL PHARMACOLOGIC TREATMENT ON TYPE-2 DIABETIC PATIENTS IN MEXICO

Zanela OO[1], Cabra HA[1], Muñoz DF[2]
[1]*Johnson & Johnson Medical, México D.F., México,* [2]*Instituto Tecnológico Autónomo de México, México D.F., México*

OBJECTIVES: Estimate the effects on glycosylated hemoglobin (HbA_{1c}) and the accumulated cost of treatment of the use and provision of various self-monitoring of blood glucose (SMBG) regimes plus conventional pharmacologic treatment on type-2 diabetic (T2D) patients from the Mexican public health system perspective. **METHODS:** The individual experience of a T2D patient was simulated using a discrete event simulation (Arena™). Patients were created with unique, randomly assigned baseline characteristics, cloned three times and sent to each of the considered SMBG regimes (0, 1, 2 and 3 times daily). T2D- and complication-related pharmacologic treatment & resource utilization, and treatment algorithms and goals were based on published clinical guidelines. Treatment therapies included lifestyle modifications alone, oral antidiabetics (OADs) and insulin use. HbA1c was the main driver of disease progression, determining initial state, clinical evolution and drug/insulin dosages. Complication and acute event development for each SMBG regime was assessed through published local relative risk studies. Considered OADs and insulin types were assumed equally effective. Clinical and cost data were obtained from published literature. Mortality was assessed by disease duration. Simulation was run with 250,000 patients for 10 years using a 4.5% annual discount rate. Average per-patient costs are shown in inflation-adjusted 2011 MXP. **RESULTS:** More intensive SMBG regimes resulted in lower final average HbA1c levels; 1, 2 and 3 times daily SMBG regimes resulted in lesser costs than no SMBG after years 3, 3 and 4, respectively. Year-10 accumulated costs for the former were $598,189, $590,616 and $589,008, and $614,162 for no SMBG. Savings are due to fewer complications and slower disease progression under any SMBG regime. **CONCLUSIONS:** As more intensive SMBG regimes result in lower HbA_{1c} levels and treatment costs, glycemic control should be an objective of every T2D integral treatment strategy, potentially reducing the social and economic burden imposed by the disease.

PDB6

EDUCATIONAL INTERVENTIONS IN PATIENTS WITH TYPE-2 DIABETES IMPROVE CLINICAL AND METABOLIC OUTCOMES AND OPTIMIZE THE USE OF TREATMENT RESOURCES IN ARGENTINA: THE PRODIACOR STUDY

Caporale JE[1], Elgart JF[1], Gonzalez L[1], Rucci E[1], Lapertosa S[2], Villagra M[2], Gagliardino JJ[1]
[1]*CENEXA - Centro de Endocrinología Experimental y Aplicada (UNLP-CONICET La Plata, Centro Colaborador OPS/OMS), La Plata, Buenos Aires, Argentina,* [2]*Hospital, Corrientes, Corrientes, Argentina*

OBJECTIVES: To evaluate the efficacy of educational interventions in the PRODIACOR study and estimate pharmacological treatment costs. **METHODS:** PRODIACOR is a 3-year prospective and randomized controlled trial, aimed at improving the quality of care of people with type 2 diabetes, preventing complications and optimizing resource use. It includes 4 groups (control, educated patients, educated physicians and educated patients and physicians) with 9 physicians and 117 patients each. Clinical and metabolic changes were recorded in *ad-hoc* forms (annual and semiannual). Costs and utilization rates were obtained from the administrative dataset of the coverage institutions involved. We verified differences in means and proportions using ANOVA and Chi2. **RESULTS:** After the 3-year follow up we recorded significant improvements ($p<0.001$) in all groups in systolic blood pressure (142±17 vs. 134±15 mmHg), HbA1c (7.8±1.5 vs. 7.1±0.8%) and total cholesterol (4.7±0.9 vs. 4.4±0.7 mmol/L). All these changes were significantly larger in the intervention groups. The percentage of patients at target for all these parameters was significantly larger ($p<0.01$) in these groups. In the educated groups, we also recorded a significant increment in combined against oral monotheraphy (42 vs. 30%) and insulin use (15 vs. 9%). Drug consumption and strips for blood glucose represented 64 and 83% of the total care cost at baseline and 3-year follow up, respectively. This cost increased (113%) in the control group while it significantly decreased (11 to 20%) in the intervention groups, particularly in the patient/physician educated group. The cost to decrease HbA1c by 1% or SBP by 10 mmHg in the patient/physician educated group was lower than in the control group ($161 vs. $547, $16 vs. $77, respectively). **CONCLUSIONS:** Educational interventions implemented at primary care level improved the clinical and metabolic outcomes of people with Type 2 diabetes and optimized the use of resources.

PDB7

COST-EFFECTIVENESS OF SAXAGLIPTIN TREATMENT IN THREE LATIN AMERICAN COUNTRIES

Elgart JF[1], Caporale JE[1], Aiello EC[2], Waschbusch M[2], Jotimliansky L[2], Gagliardino JJ[1]
[1]*CENEXA - Centro de Endocrinología Experimental y Aplicada (UNLP-CONICET La Plata, Centro Colaborador OPS/OMS), La Plata, Buenos Aires, Argentina,* [2]*Bristol-Myers Squibb, Buenos Aires, Argentina*

OBJECTIVES: To evaluate the economic consequences of saxagliptin (SAXA) *versus* sulfonylurea (SU) administration in combination with metformin (MET) after failure of MET monotherapy treatment, in patients with type 2 diabetes (T2DM). **METHODS:** A discrete event simulation model (Cardiff Long term cost-utility model) based on UKPDS 68 with a fixed time increase was used to simulate disease progression and to obtain an estimate of the treatment's economic and health consequences in patients with T2DM from Argentina, Chile and Peru. The clinical efficacy parameters for SAXA were obtained from the literature; drug acquisition costs, adverse effects (AEs) and microvascular and macrovascular complications were obtained from local studies. Costs were expressed in US dollars (2009), with an annual 3.5% discount. The time horizon was 20 years. **RESULTS:** In all countries, the number of non-fatal events was lower in the SAXA+MET group than in the SULF+MET group. The model also predicted a lower number of fatal macrovascular and microvascular events for the SAXA+MET-treated group. In Argentina and Perú, the total cost of the SAXA+MET cohort was higher than that of the SULF+MET cohort (14% and 3%, respectively), while in Chile the total cost of the SAXA+MET cohort was 3% lower than that of the SULF+MET. Treatment with SAXA+MET resulted in a higher number of QALYs (Argentina: 9,392 vs. 9,172; Chile: 9,794 vs. 9,594; Peru: 9,796 vs. 9,597) and LYGs (Argentina: 20,898 vs. 20,797; Chile: 23,068 vs. 23,019; Peru: 23,079 vs. 23,028) as compared with SULF+MET. The additional cost per QALY was U$S6,691, U$S2,446 and -U$S2,243 for Argentina, Peru and Chile, respectively. **CONCLUSIONS:** Considering the GDP *per capita* in Argentina and Peru, the addition of SAXA instead of SU to MET therapy would result in acceptable cost-effectiveness ratios in T2DM patients, being this combination cost-saving (dominant cost-effectiveness ratio) in Chile.

PDB8

COST-EFFECTIVENESS STUDY OF ORAL HYPOGLYCEMIC AGENTS IN OUTPATIENTS DIAGNOSED WITH TYPE-2 DIABETES ATTENDING A PRIMARY CARE PUBLIC CLINIC IN MEXICO CITY

Diaz de León-Castañeda C, Altagracia-Martínez M, Kravzov-Jinich J, Cárdenas-Elizalde R, Martínez-Núñez JM
Universidad Autónoma Metropolitana - Xochimilco, México D.F., México

OBJECTIVES: To assess the cost-effectiveness (CE) ratios of oral hypoglycemic agents (OHA's) most used (acarbose, metformin and glyburide) on the initial pharmacologic therapy of outpatients diagnosed with type 2 diabetes in a primary care public clinic in Mexico City. **METHODS:** We conducted a cost-effectiveness study based on a Markov model during a time horizon of one year and from the perspective of the Mexican society. The model designed included two health states ($HbA_{1c} \leq 7\%$ and $HbA_{1c} > 7\%$) and 6 months for the evaluation of monotherapy with OHA's and 6 months for the addition of a second OHA in case of failure of the first (metformin - glyburide dual therapy) were considered. We assessed the total monthly costs of the treatments with the OHA's through a structured questionnaire applied to 27 outpatients recently diagnosed with type 2 diabetes in treatment in a primary care public clinic in Mexico City during 2009. The efficacies (treatments success probabilities if $HbA_{1c} \leq 7\%$ was reached) as well adverse events frequencies were assessed through a systematic review of published randomized clinical trials and meta-analysis of selected studies based on structured inclusion criteria. We used a commercial computational program to perform the cost-effectiveness analysis for a hypothetical cohort of 10,000 patients through a Monte Carlo simulation and an univariate sensibility analysis was performed. **RESULTS:** The CE ratios found were glyburide US$ 272.63/QALY, metformin US$ 246.48/QUALY and acarbose US$ 409.86/QALY. Acarbose and metformin showed high frequency of gastrointestinal adverse events (78% and 54% respectively), and glyburide showed mainly hypoglycemia (31%). The sensitivity analysis did not show changes for the most CE therapy when the success probabilities or the treatment costs were modified. **CONCLUSIONS:** Initial monotherapy with glyburide offers the best cost-effectiveness ratio.

PDB9

ANALISIS DE COSTO–EFECTIVIDAD DEL USO DE DETEMIR EN DIABETES TIPO 2 FRENTE AL RIESGO DE PRESENTAR EVENTOS CARDIOVASCULARES Y MUERTE

Romero M[1], Chavez D[1], Karpf E[1], Alvis N[2]
[1]*Fundación Salutia, Bogotá, Colombia,* [2]*Universidad de Cartagena, Cartagena de Indias, Bolívar, Colombia*

OBJECTIVOS: Analizar la relación costo-efectividad del uso de Detemir frente a otras insulinas (Glargine e insulina NPH) para tratamiento de diabetes tipo 2 en Colombia. **METODOLOGÍAS:** Mediante un modelo probabilístico de Markov se realizó un análisis de costo-efectividad, desde la perspectiva del tercero pagador, en un horizonte temporal de 5 años en una cohorte de 10,000 personas con edad media de 45 años. Como desenlaces se evaluaron eventos cardiovasculares y muertes evitadas, relacionadas con eventos de hipoglicemia severa y Años de Vida Salvados (AVS). Se utilizaron los IC de las probabilidades de los desenlaces evaluados obtenidas de la revisión de estudios clínicos. Los costos se extrajeron de bases de datos de prestadores de servicios de salud en Colombia, a precios 2010. Se utilizó una tasa de descuento del 3% para costos y resultados. Se realizó un análisis de sensibilidad tipo montecarlo con 1000 iteraciones para probar la solidez de los resultados. **RESULTADOS:** En un horizonte temporal de 5 años el Detemir presentó un menor número de eventos de hipoglicemia severa (730) frente a Glargine y NPH (1910 y 2140) respectivamente, a su vez menor número de eventos macrovasculares (1052) y microvasculares (1019) frente a Glargine (1115, 1040) y NPH (1130 y 1042). Detemir evitó 112 y 131 muertes frente a Glargine y NPH equivalentes a 3935 y 3363 AVS respectivamente. Luego del descuento el ICER por AVS con Detemir frente a Glargine fue de 1043 USD y frente a NPH 8795.5 USD. En el análisis de sensibilidad Detemir se mantiene costo-efectivo en el 100% de los casos por debajo del umbral de costo efectividad frente a los comparadores, tomando como umbral lo propuesto por la OMS. **CONCLUSIONES:** Detemir, desde la perspectiva del tercer pagador, es costo-efectivo frente a Glargine y NPH para tratamiento de diabetes tipo 2 en Colombia.

PDB10

ECONOMIC EVALUATION OF DULOXETINE AS FIRST-LINE TREATMENT FOR PAINFUL DIABETIC PERIPHERAL NEUROPATHY IN MEXICO

Carlos F[1], Ramírez-Gámez J[2], Dueñas-Tentori H[2], Ramos E[1]
[1]*R A C Salud Consultores, S.A. de C.V., México D.F., México,* [2]*Eli Lilly and Company, México D.F., México*

OBJECTIVES: To perform an economic evaluation of duloxetine, pregabalin and (either branded or generic) gabapentin for managing pain in patients with painful diabetic peripheral neuropathy (PDPN) in Mexico. **METHODS:** The analysis was conducted using a three-month decision model, which compares duloxetine 60mg once daily (DUL), pregabalin 150mg twice daily (PGB) and gabapentin 600mg three-times daily (GBP) for patients with PDPN and moderate-to-severe pain, under the perspective of the Mexican public health care system. We performed a systemic

review and calculated placebo-adjusted risk ratios for achieving good pain relief (GPR), any adverse event (AE) and withdrawal owing to intolerable AE. Direct medical costs included drug acquisition and additional visits due to lack of efficacy (poor pain relief) or intolerable AE. Unit costs were taken from local sources. Adherence rates (based in number of daily doses needed) were used to estimate the expected drug costs. All costs are expressed in 2010 USD (1USD:12.50MXN Pesos). Utility values drawn from published literature were applied to health states. Proportion of patients with GPR and quality-adjusted life years (QALY) were assessed. **RESULTS:** Branded-GBP was dominated by all the other options. PGB was more costly and less effective than DUL. Compared with branded-GBP and PGB, DUL led to savings of $80,080 and $85,920 (per 1000 patients) USD. The incremental cost per QALY gained with DUL used instead of generic-GBP was $8,194. This amount is slightly lower than the estimated gross domestic product per capita in Mexico for 2010. During a second-order Monte Carlo simulation, DUL had the highest probability of being cost-effective (61%), followed by generic-GBP (25%) and PGB (14%). **CONCLUSIONS:** This study suggests that DUL provides overall savings and better health outcomes compared with branded-GBP and PGB. Administering DUL rather than generic-GBP is a highly cost-effective intervention to manage PDPN in Mexico.

PDB11

ECONOMIC EVALUATION OF TERIPATIDE IN THE MANAGEMENT OF WOMEN WITH POSTMENOPAUSAL OSTEOPOROSIS AND HIGH RISK OF FRAGILITY FRACTURES IN MEXICO

Carlos F[1], Clark P[2], Jasqui-Romano S[3]
[1]*R A C Salud Consultores, S.A. de C.V., México D.F., México,* [2]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México D.F., México,* [3]*Eli Lilly and Company, México D.F., México*

OBJECTIVES: Fragility fractures (FF) are associated with increased mortality, deterioration in health-related quality of life and high costs. Teriparatide stimulates bone remodeling. The aim of this study was to assess the cost and health effects of teriparatide in women with postmenopausal osteoporosis (PMOP) and high risk of FF from the perspective of public healthcare system in Mexico. **METHODS:** Target population was women aged 70 years, with PMOP, T-score −4.0 and three clinical risk factors, with a recent vertebral fracture not candidates to receive bisphosphonates. Competing alternatives were: (1) daily subcutaneous injection of teriparatide 20mcg for 18 months and (2) no therapy. A Markov microsimulation model was developed with a 30 years time horizon divided into 6-month cycles and is composed by 5 health states: hip, vertebral, forearm and humerus fracture and death. The incidence of FF was obtained from the FRAX® algorithms for Mexican women. Efficacy data was gathered from placebo-controlled clinical trials of teriparatide. We analyzed acquisition costs of teriparatide and medical care costs due to FF. Frequency and location of fractures avoided and quality adjusted life years (QALYs) were estimated. All costs are expressed in 2010 USD (1USD:12.50MXN Pesos) **RESULTS:** Teriparatide avoided 324 FF per a thousand patients (hip: 43; vertebral: 164; humerus: 35; forearm: 82). The number needed to treat (NNT) to prevent one FF was 3.09. Teriparatide was slightly more expensive ($20,052 vs. $22,209 USD) but more effective, with net gains of 87 QALYs per a thousand patients. The cost per additional QALY gained with teriparatide was $24,925 (below the upper limit of 3 times the gross domestic product per capita in Mexico). Teriparatide was found to be cost-effective therapy in 80% of the simulations performed in the probabilistic sensitivity analysis. **CONCLUSIONS:** Teriparatide is a cost-effective intervention in women with PMOP and high risk of FF.

Gastrointestinal Disorders – Cost Studies

PGI1

RESOURCE UTILIZATION AND COST OF MANAGEMENT OF COMPLEX PERIANAL FISTULA IN CROHN'S DISEASE IN SPAIN

Badia X[1], Lara N[1], Garcia-Losa M[2], Zanotti C[3], Orofino J[3]
[1]*IMS Health, Barcelona, Spain,* [2]*IMS Health, Madrid, Spain,* [3]*Cellerix, SA, Tres Cantos, Spain*

OBJECTIVES: To assess health care resources use and costs associated with management of complex perianal fistula in Crohn's disease (CPCD) in Spain. **METHODS:** Multicenter, retrospective and observational study conducted by 13 gastroenterologists from 11 hospitals in the Autonomous Community of Madrid, Spain. Direct healthcare resources consumption (pharmacological treatments, laboratory/diagnostic tests, visits to specialists, emergency department visits and hospitalizations/surgical procedures) were recorded for 97 adult patients with CPCD active at some time between January 1, 2005 and study data collection (4.2±1.5 years). **RESULTS:** 527 treatments were recorded: 73.1% pharmacological (32.3% antibiotics, 20.5% immunomodulators, 20.3% biological therapies) and 26.9% surgical. Mean per patient-year global cost was €7821.4. Percentage cost per treatment type and [mean per patient-year cost] breakdown was 78.7% [€5773.5] pharmacological cost, 11.12% [€1027.4] hospitalizations/surgical procedures, 6.5% [€640] specialists visits, 3.4 [€350] laboratory/diagnostic tests, and 0.2%, [€30.4] emergency department visits. Mean per patient-year cost per pharmacological treatment type was: €12.5 antibiotics, €1050.6 immunomodulators, and €4710.4 biological therapies. **CONCLUSIONS:** Pharmacological treatments are the main cost driver of CPCD management in Spain, being biological therapies the main component. Study funded by Cellerix, S.A. (Spain).

PGI2

COST-EFFECTIVENESS ANALYSIS OF THE USE OF ADALIMUMAB FOR THE TREATMENT OF CROHN'S DISEASE (CD) IN MEXICO

Mayen-Herrera E, Pozos JC, Yang M, Cortina D
Abbott Laboratories de México, México, D.F. México

OBJECTIVES: To estimate the cost-effectiveness of adalimumab CD treatment versus standard care and infliximab for patients with severe active CD. **METHODS:** The model combines clinical, utility, and cost data. Four disease states (remission; moderate; severe; very severe) based on the Crohn's Disease Activity Index range are used as measures of patient disease status. For the adalimumab arm, a cohort for the proposed adalimumab regimen using actual observations from the EOW arm in a randomized controlled clinical trial (CHARM) is used. For the standard care arm, the model simulates patient disease states based on randomized controlled trial data (CLASSIC I and CHARM) and calculates the probability of individuals being in each disease state. The base-case model analyzes lifetime patient clinical status. Hospitalization costs are estimated from the hospitalization unit cost and a regression model based on CHARM trial data. Disease state specific non-hospitalization, non-anti TNF costs are summarized over time for each patient to include other direct medical costs. For the adalimumab vs. infliximab model, the adalimumab regimen is compared to infliximab 5mg/kg maintenance therapy. The percentage of patients in remission over time is used as the measure of clinical efficacy. Indirect costs are estimated based on hospitalization stays and post-hospitalization recovery times. Costs are reported in Mexican Peso. **RESULTS:** Compared to standard care, adalimumab is dominant for patients with severe CD (cost difference -$16,825, gain in QALYs 0.1045). Adalimumab is dominant, with lower costs and higher efficacy compared with infliximab when treating patients with severe disease based on a societal perspective. Cost difference (adalimumab–infliximab) were -$19,784, and including infliximab "overdosing", the costs accounted for -$42,356. Sensitivity analyses confirm the results obtained in the cost-effectiveness analysis. **CONCLUSIONS:** Adalimumab maintenance therapy is dominant over standard care. The adalimumab regimen is cost-saving over infliximab 5mg/kg maintenance therapy.

PGI3

ADAPTACIÓN DE UN ANÁLISIS DE COSTO-EFECTIVIDAD DEL ENTECAVIR VS INTERFERÓN PEGILADO ALFA A VENEZUELA

Orozco JJ[1], Valencia JE[2], Aiello E[3], Baquero E[4]
[1]*Universidad CES, Medellin, Colombia,* [2]*Bristol-Myers Squibb, Bogotá, Colombia,* [3]*Bristol-Myers Squibb, Buenos Aires, Argentina,* [4]*Bristol-Myers Squibb, Caracas, Venezuela*

OBJECTIVOS: Mediante la adaptación a la realidad de Venezuela de un modelo realizado por Spackman y Veenstra y previo análisis de transferibilidad, se realizó un análisis de costo-efectividad del uso de 0.5 mg/día de entecavir versus interferón pegilado en la supresión de la replicación viral y la calidad de vida relacionada con la salud en términos de QALYs en pacientes con Hepatitis B Crónica. **METODOLOGÍAS:** Para la construcción de la cohorte hipotética, Spackman y Veenstra asumieron los datos de las eficacias así como las características de los pacientes reportadas en estudios clínicos recientes. Para el análisis de transferibilidad se siguieron los criterios de transferibilidad de la Task Force on Good Research Practices on Transferability of Economic Data de la ISPOR. En la adaptación del modelo se asumieron las probabilidades de cambio entre estados reportadas en el estudio original. Los costos médicos directos y de los medicamentos fueron tomados directamente del entorno local. Adicionalmente se tomaron las tablas de expectativa de vida del observatorio de salud global de la Organización Mundial de la Salud para Venezuela actualizadas al año 2008. Los resultados incluyeron los costos de cada alternativa de tratamiento tanto con entecavir como con interferón pegilado, así como los años de vida ajustados a calidad ganados. **RESULTADOS:** El entecavir 0.5 mg/día produjo 18,25 QALYs y una relación de costo efectividad media de 5.257 BsF por QALY, en comparación con el interferón pegilado (marketshare) que produjo 18,12 QALYs y una relación de costo efectividad media de 7.055 BsF por QALY. **CONCLUSIONES:** El entecavir a dosis de 0.5 mg/día mostró índices más bajos de costo-efectividad media con respecto al interferón pegilado en la supresión viral en pacientes con infección por el virus de la hepatitis B. En Venezuela, al igual que muchos países latinoamericanos, no están establecidos umbrales de costo efectividad.

Gastrointestinal Disorders – Patient-Reported Outcomes & Preference-Based Studies

PGI4

HEALTH-RELATED QUALITY OF LIFE IMPROVEMENTS IN PATIENTS WITH ACTIVE CROHN'S DISEASE FOLLOWING TREATMENT WITH CERTOLIZUMAB PEGOL IN THE MUSIC STUDY (NCT00297648)

Hébuterne X[1], †Lémann M[2], Coteur G[3], Ernault E[3], Colombel JF[4]
[1]*Centre Hospitalier Universitaire de Nice, Nice, France,* [2]*Hôpital Saint-Louis, Paris, France,* [3]*UCB, Braine l'Alleud, Belgium,* [4]*Centre Hospitalier Universitaire (CHU) de Lille, Lille, France*

OBJECTIVES: MUSIC, an open-label, 1-year study of certolizumab pegol (CZP), evaluated the efficacy of CZP in improving pathological changes in the intestinal mucosa of patients with active moderate-to-severe Crohn's disease (CD). The purpose of this posthoc study was to examine the relationship between CZP-mediated endoscopic improvement and changes in HRQoL in patients with CD. **METHODS:** Patients with active CD (CD Activity Index score >225 to <450) were treated with open-label CZP, 400 mg subcutaneously every 2 weeks for 3 doses (induction) then 400 mg every 4 weeks for up to 54 weeks (maintenance). Patients completed the Inflammatory Bowel Disease Questionnaire (IBDQ) at baseline, Week 10, and Week 54 to assess HRQoL. An exploratory analysis of the correlation between IBDQ remission (total score ≥170 points) and endoscopic remission (measured by a CD Endoscopic Index of Severity score of <6 points) was performed. **RESULTS:** Of 89 patients entering the study, 78 patients at Week 10 and 50 patients at Week 54 completed the IBDQ. At baseline, mean IBDQ total score was 120.2. At Week 10, mean change in IBDQ total score was 43.8 and the IBDQ remission rate was 43.8%. At Week 54, mean change in IBDQ total score was 44.1 and the IBDQ remission rate

was 29.2%. In patients with endoscopic remission at Week 10, the IBDQ remission rate was 69.7% compared with 33.3% in patients not reaching endoscopic remission. Similar results were observed at Week 54. **CONCLUSIONS:** Treatment with CZP at the recommended dose resulted in substantial improvement in HRQoL at 10 and 54 weeks of therapy, measured by the IBDQ. Higher rates of IBDQ remission were associated with endoscopic remission compared with nonremission, warranting further evaluation of CZP therapy on HRQoL in CD. †Dr Lémann died on August 26, 2010. We mourn the loss of our esteemed colleague.

Health Care Use & Policy Studies – Consumer Role in Health Care

PHP1

KENYA'S VILLAGE AGING INSENSITIVITY TO AGING POLICIES

Nyabade G
Go Fishnet Youth Project, Kisumu, Nyanza, Kenya

OBJECTIVES: Since independence in Kenya in 1963, there has been great challenges on policy making with regards to the village elderly and ageing. Inspite of our current advocacies, sensitization and awareness programmes being carried out by local non governmental humanitarian bodies and faith based entities, Kenyan elderly and ageing men and women lack government concern, services and new policies on especially the ageing village vulnerable ill-health policy and services in their life insurance The aim and purpose of my paper is to highlight worthy approaches and to identify areas of need as a priority in overcoming the impasse in Kenyan policy on ageing and health. **METHODS:** We conducted a village research on a door to door basis on policy and health development through Questionare as part of a research project on dimensions and actions of health in old age in rural communities in western Kenya and its policy implications. **RESULTS:** Five very sensitive areas of evidence of lack of awareness and government lack of action to the aged and ageing groups were highlighted. And required to (1) sensitize and give strength to the case on why action on old age-related health should be pursued, and (2) what action be taken to bring to light the uncertainties of the aged and ageing groups in Kenyas most forgotten rural insensitive communities. **CONCLUSIONS:** A continued formal research system on the five areas is essential to promote awareness of policies on aged and ageing groups in the insensitive villages and advocacy towards their ignorance and plight on matters related to their life insurance, policy making and advancement towards scientific debate on ageing and their health in the global community.

Health Care Use & Policy Studies – Disease Management

PHP2

DESCRIBING TRENDS AND DETERMINANTS OF NON-OPIOID ANALGESIC (NOA) PRESCRIBING IN CHRONIC NON-CANCER PAIN PATIENTS IN THE UNITED STATES OUTPATIENT SETTINGS

Rasu R[1], Fikru B[1], Vouthy KK[1], Rianon N[2], Agbor Bawa W[1], Knell M[1]
[1]*University of Missouri-Kansas City, Kansas City, MO, USA,* [2]*University of Texas Health Science Center-Houston, Houston, TX, USA*

OBJECTIVES: Cost of prescriptions is a large portion of the nation's health care expenditure. In 2007, the Kaiser Family Foundation estimated total prescription costs to be $202 billion, demonstrating a large burden to the US economy. This study evaluates determinates of non-opioid analgesic (NOA) prescribing patterns in the USA from the National Ambulatory Medical Care Survey (NAMCS) from 2002-2007. **METHODS:** NOA prescribing trends were determined using drug codes from NAMCS data. The data was collected on patients greater than 18 years, with ICD-9-CM codes for chronic-non-cancer pain as reasons for office visits. The study used cross-sectional analysis. A logistic model reported determinants of NOA in the study population. **RESULTS:** A total of 22,967 analgesic prescriptions were prescribed from 2002-2007 for men (37%) and women (63%) 18 years or older. Men were 1.46 times more likely ($p<0.05$) to receive NOA than Women. Medicare and Medicaid patients were 42% ($p<0.01$) and 44% ($p<0.01$) more likely to receive NOA than patients with other insurance types. Patients seen by primary care physicians (PCPs) were 56% ($p<0.05$) more likely to receive NOA than by non-PCPs. Low back pain (LBP) patients were 60% more likely to get NOA prescribed than patients with non-LBP. Geographical location was a statistically insignificant factor relating to the likelihood of a being prescribed NOAs. Socio-economic, education, lifestyle, diet, age group, ethnicity, and mental health status were also found to be insignificant. **CONCLUSIONS:** Men, patients with Medicare, Medicaid, and LBP were more likely to receive prescriptions for NOA. Physicians managing patients at risk of receiving NOA, reported in our results, may benefit from seeking evidence based policy for maximizing pain control in a cost-effective way.

PHP3

A REVIEW OF BREAST CANCER (BC) CARE AND OUTCOMES IN LATIN AMERICA & CARIBBEAN (LAC)

Justo N[1], Wilking N[2], Jönsson B[3]
[1]*i3 Innovus, Stockholm, Sweden,* [2]*Karolinska Institutet, Stockholm, Sweden,* [3]*Stockholm School of Economics, Stockholm, Sweden*

OBJECTIVES: Provide an overview of the burden of BC and of BC care and outcomes in LAC. **METHODS:** Review of literature (PubMed, LILACS, SCIELO), public databases (Globocan 2002 & 2008, CEPALSTAT, DIRAC, PAHO, WHOSYS, etc) and conference presentations (ASCO, ISPOR). Latin-American experts and patient organizations were surveyed. **RESULTS:** A total of 114,900 women present with and 37,000 die of BC annually in LAC. BC exhibits the highest incidence and mortality of all cancers, is steadily increasing and is expected to double by 2030. Age is the principal risk factor. High incidence in Argentina and Uruguay (ASR 74-91/100,000) and younger age at diagnosis and death (mean 57y) in Peru, Mexico, Colombia and Brazil translate into a heavy burden. LAC's low 5-year survival (~70-75%) is partly because ~30-40% patients are diagnosed in metastatic phases III and IV. However, BC mortality-to-incidence ratios (MIR) improvements are noticeable when comparing MIR2002 vs. MIR2008. Best MIRs are registered in Argentina, Uruguay and Chile. Costa Rica shows the most progress; Brazil, Mexico and Panama have not improved significantly. Suboptimal prevention policies; vast inequalities in access to diagnosis and treatment, a fragmented organisation and management of BC care, and poor uptake of evidence-based best practices were observed. Universal healthcare coverage is not the rule in LAC and, even in those countries where access to BC health services is guaranteed by law; resources are insufficient. Availability of BC-specialized surgeons, waiting times, node clearance policy and access to breast reconstruction vary greatly across countries and between public and private settings. Radiotherapy equipment is insufficient (except Uruguay, Chile, Venezuela). All modern systemic therapies are available but some not widely diffused for cost considerations. Palliative care is developing but, despite great efforts, many problems persist. **CONCLUSIONS:** Women go undiagnosed, uncared for or treated with suboptimal therapies; which results in high morbidity and associated societal costs.

Health Care Use & Policy Studies – Drug/Device/Diagnostic Use & Policy

PHP4

SIGNIFICANT DECREASE IN THE HUNGARIAN HEALTH INSURANCE PHARMACEUTICAL BUDGET BETWEEN 2006-2009

Boncz I[1], Donka-Verebes É[2], Oberfrank F[3]
[1]*University of Pécs, Pécs, Hungary,* [2]*Integra Consulting zRt., Budapest, Hungary,* [3]*Institute of Experimental Medicine (IEM)., Budapest, Hungary*

OBJECTIVES: At the end of 2006, there was an important reform in the Hungarian pharmaceutical market, including serious changes in the health insurance reimbursement of medicines. The aim of our study is to analyze the changes in the Hungarian health insurance pharmaceutical budget between 2006-2009. **METHODS:** Data were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. We analyzed the changes of the pharmaceutical budget between 2006-2009. Results are given in Hungarian Forint (HUF), US dollars (USD) and Euro (EUR). The annual average currency exchange rates were applied according to the data of the Central Bank of Hungary. **RESULTS:** In the first year, the Hungarian pharmaceutical budget decreased from 388.7 billion HUF (2006) to 323.6 billion HUF (2007) by 65.1 billion HUF (16.7 %). This decrease was a bit moderate both in Euro (0.18 billion EUR, 12.4 %) and in USD dollar (0.1 billion USD, 4.7 %) due to the stronger Hungarian currency. For 2009, the pharmaceutical budget slightly increased compared to 2007 up to 343.2 billion HUF which resulted in a decrease from 2006 to 2009 by 45.5 billion HUF (11.7 %). The decrease between 2006-2009 was more significant both in Euro (0.25 billion EUR, 16.8 %) and in USD dollar (0.15 billion USD, 8.1 %) due to the weakened Hungarian currency. **CONCLUSIONS:** Due to the reform of the whole Hungarian pharmaceutical market, the Hungarian health insurance pharmaceutical budget significantly decreased between 2006-2009. This decrease was moderate in EUR or USD between 2006-2007, however between 2006-2009 it became higher as the Hungarian currency weakened compared to EUR or USD during the world economic crisis.

PHP5

MODELO TEORICO DE UN CONSUMIDOR: SELECCION ENTRE UN BIOSIMILAR Y UN BIOTECNOLOGICO DE PATENTE BASADO EN PREFERENCIAS

Lechuga D
ITAM, México, D.F., México

OBJECTIVOS: Realizar un análisis teórico de las preferencias del paciente derivado de la elección entre dos bienes: un medicamento biotecnológico de patente y un medicamento biosimilar. **METODOLOGÍAS:** Suponemos que son bienes sustitutos perfectos, pues el paciente no puede consumir los dos bienes al mismo tiempo, debe elegir entre uno u otro. Definimos la función de utilidad del paciente como $U(BT,BS)=aBT+bBS$. Donde, BT es el Biotecnológico de patente, BS Biosimilar, a es la seguridad y eficacia del medicamento BT y b seguridad y eficacia del medicamento BS. Entre más seguro y eficaz sea el medicamento el paciente lo prefiere más. Entre mayor sea U su estado de salud es mejor. Suponemos que BT tiene estudios clínicos confiables que demuestran su seguridad y eficacia y que BS no presenta estudios clínicos y no se sabe su seguridad y eficacia real, por lo tanto BT es preferido, es decir $a>b$. El paciente posee una restricción presupuestal determinada por la ecuación $y=P_{BT}BT+P_{BS}BS$. Derivado de las inversiones en estudios clínicos suponemos que $P_{BT}>P_{BS}$. La tasa marginal de sustitución está determinada por la pendiente -a/b, es decir que el paciente sacrificará una unidad de BT por b/a unidades del bien BS. Dada la restricción presupuestal, la pendiente y tasa de sustitución objetivo es $-P_{BT}/P_{BS}$. **RESULTADOS:** De acuerdo a las preferencias del consumidor, su consumo óptimo se determinan de acuerdo a lo siguiente, si $P_{BT}/P_{BS}<a/b$ solo consumirá BT, si $P_{BT}/P_{BS}>a/b$ entonces el paciente solo consumirá BS, y si $P_{BT}/P_{BS}=a/b$ el paciente está indiferente entre consumir BT o BS. **CONCLUSIONES:** Podemos concluir que las preferencias del paciente son sensibles al precio y a la seguridad y eficacia del medicamento. Entre más seguro y eficaz sea BT el paciente lo prefiere y estará dispuesto a pagar más.

PHP6

CUADRO BÁSICO Y CATÁLOGO DE MEDICAMENTOS DEL SECTOR SALUD: ES ACTUALMENTE UN REFERENTE PARA LAS INSTITUCIONES PÚBLICAS Y/O CUMPLE CON LOS OBJETIVOS DE SU CREACIÓN

Rivera-Peña G[1], Vargas-Palacios A[2], Barraza-Llorens M[3], Gutierrez-Delgado C[1]

[1]Economic Analysis Unit, México, D.F., México, [2]The University of Sheffield, Sheffield, Sheffield, UK, [3]Instituto Mexicano del Seguro Social, México, D.F., México

OBJECTIVOS: Analizar las actualizaciones hechas al cuadro Básico y Catálogo de Medicamentos (CBM) del Sector Salud en el periodo 2006-2010. Analizar el grado de apego al CBM en las compras de medicamentos realizadas por diferentes instituciones del sector público de salud en el periodo 2006-2009. **METODOLOGÍAS:** Se identificaron en el Diario Oficial de la Federación las actualizaciones (inclusiones, modificaciones y exclusiones) realizadas al CBM en el periodo de 2006-2010. Se analizó información de compra pública de medicamentos para el periodo 2006-2009. Para el procesamiento de la información se construyó una base de datos con la información en el programa estadístico Stata. **RESULTADOS:** En el periodo 2006-2010 se han realizado 24 actualizaciones al CBM. En total se realizaron 359 cambios de los cuales el 39% corresponden a inclusiones, 53% actualizaciones y un 8% a exclusiones. El 78% de los cambios fueron realizados al Cuadro Básico de Insumos para el primer nivel de atención y el 22% restante al Catálogo de Insumos para el segundo y tercer nivel. Se identificó que aproximadamente sólo se compró el 80% del total de medicamentos listados en el CBM además de que se identificaron medicamentos cuyas presentaciones y/o sustancias activas no se encuentran listados en el CBM. **CONCLUSIONES:** La creación del CBM siguió tres objetivos fundamentales: promover la presentación uniforme para los medicamentos que adquiera el sector público; servir como instrumento de orientación para una prescripción adecuada así como evitar la dispersión de criterios institucionales; y servir como guía para la adquisición correcta de medicamentos. Los resultados encontrados dan evidencia de que estos objetivos no se están cumpliendo por lo que es necesario reordenar y analizar el contenido y uso que se da al CBM en las instituciones del sector público.

PHP7

IMPACT OF GLOBAL HEALTH CARE REFORMS ON PRICING, ACCESS AND HEALTH ECONOMICS AND OUTCOMES STRATEGY

Aggarwal S
PAREXEL Consulting, Bethesda, MD, USA

OBJECTIVES: During 2009-2010 major health care reforms were proposed and implemented in a number of nations, for example, Affordable Care Act in the US, AMNOG in Germany, HSPT in France, KVG in Switzerland and NHS proposed reform in the UK. These reforms have major implications on pricing, market access and HEOR strategy for drug and device products. **METHODS:** To understand the implications of these trends, we analyzed 2009-2010 reform bills and proposed changes worldwide. Additionally, we interviewed public and private payers, key opinion leaders and payer-influencers to understand implications of these reforms on drug and device manufacturers. **RESULTS:** The global healthcare landscape is expected to undergo significant change during 2011-2015. In the US, government will play increased role as a single payer, especially with–Medicare, Medicaid and CHIP programs– which will cover 114 million Americans, at a cost of $784 billion. In Germany, AMNOG bill marked the end of free drug pricing and would lead to increased insurance premiums (now 15.5% of wages). In the UK, NHS has proposed to replace PCTs with 500-1000 GP-led consortia and use value-based pricing for expensive drugs and devices. Overall, payers view that in the future, health economic assessments would play critical role in pricing, coverage and reimbursement of branded products. **CONCLUSIONS:** This analysis shows that global healthcare landscape is expected to undergo significant change during 2011-2015. Discussions with payers, KOLs and payer-influencers highlights increased importance of HEOR data in the future.

PHP8

MEASURING ADHERENCE TO DRUG TREATMENT IN MEXICAN PATIENTS: A SYSTEMATIC REVIEW

Uc-Coyoc R, Pérez-Reynaud AG, Coello-Reyes LA, Rodriguez-Díaz Ponce MA
Instituto Mexicano del Seguro Social, México, D.F., México

OBJECTIVES: Measuring the level of adherence to drugs is relevant to assess the clinical benefits of prescribed treatments. Adherence can be defined as the extent to which a patient intake of medicines coincides with the medical prescription. The purpose of this study is to review the degree of adherence to drugs among Mexican patients as part of the overall medical therapy. **METHODS:** A systematic review was performed to retrieve information on quantity measures of drug adherence to medical treatments in Mexico. Key words such as "treatment and patient adherence," "drug compliance" and "drug utilization" were searched in Pub Med, Medline, Embase, Medic Latina, and the Cochrane Library of Systematic Reviews from 1998 to 2010. **RESULTS:** Few published studies in Mexico quantify the extent of adherence to drugs among Mexican patients. Most of these studies measured drug adherence in three chronic diseases: diabetes, HIV/AIDS, and rheumatoid arthritis. These were carried out at the regional level with patients from public health institutions. The main methods used were pill-count, questionnaires, and interviews with patients. Adherence to diabetes medication reported frequencies in the range of 17.2%- 54.2%, while in antiretroviral treatment for HIV/AIDS, the range was from 42% to 85.3%. One study reported adherence to disease-modifying antirheumatic drugs in stable patients with early rheumatoid arthritis of 50.5%, with an increased risk of non-adherence as the drug treatment scales-up. **CONCLUSIONS:** The range of frequencies for drug adherence among diabetic and HIV/AIDS patients varies widely. This can be attributed to the different methods used to measure adherence and the lack of a standardized measuring technique. Adherence results are derived from regional studies; therefore, further research is needed in order to obtain estimates with national representation. This is important for the design of drug policies aimed at enhancing drug adherence to maximize the health benefits from treatments.

PHP9

PREDITORES DA QUANTIDADE DE MEDICAMENTOS TOMADOS EM PESSOAS COM DOENÇA CRÓNICA

Pais-ribeiro J[1], Silva I[2], Meneses R[2], Pedro L[3], Cardoso H[1], Abreu M[1], Melo V[1], Martins A[1], Vilhena E[1], Mendonça D[1], Martins-da-Silva A[1]
[1]*Porto University, Porto, Portugal,* [2]*Fernando Pessoa University, Porto, Portugal,* [3]*Polytechnic Institute, Lisboa, Portugal*

OBJETIVOS: O objetivo do presente estudo é identificar os principais preditores da quantidade de medicamentos tomados por indivíduos com doenças crónicas, de entre diferentes variáveis demográficas, de doença, personalidade, qualidade de vida e psicossomáticos. **MÉTODOS:** Participantes são 603 indivíduos, com 41,19 anos de idade média, escolaridades média de 9,87 anos, 72,5% mulheres, portadores de uma das seguintes doenças crónicas: epilepsia, diabetes tipo 1 e 2, cancro, miastenia gravis, esclerose múltipla, obesidade mórbida, com diagnóstico há mais de três anos. As variáveis avaliadas foram, o número de medicamentos que o indivíduo toma como variável dependente, e como variáveis independentes, variáveis psicossociais, tais como, personalidade (neuroticismo e extroversão), afecto positivo e negativo, componentes mental e físico do SF-36, sintomas psicossomáticos (dimensões, sistema nervoso, muscular e digestivo), variáveis demográficas (idade e escolaridade), e variáveis de doença (numero de anos de diagnóstico, número de internamentos no último ano, percepção da gravidade da doença). Recorreu-se à regressão linear hierárquica que incluía o número de medicamentos tomados como variável dependente e como variáveis independentes, no primeiro passo as variáveis demográficas, no segundo passo, as variáveis de doença, e no terceiro as variáveis psicossociais. **RESULTADOS:** A solução explica 20,6% da variância da variável dependente. Cada bloco acrescenta valores estatisticamente significativos à solução. Os resultados sugerem que um quinto da variância na quantidade de medicamentos tomados é explicada pelas variáveis psicossociais em que, no modelo final, as variáveis demográficas e de doença são excluídas da solução. Das variáveis independentes, os principais preditores são, o neuroticismo (t=5,62) os componentes físico e mental do SF-36, (t=5,45, e t=5,03) e o sistema nervoso da variável psicossomática (t=5,45) todos com um nível de significância $p<0,0001$. **CONCLUSÕES:** Um programa de intervenção que melhore a qualidade de vida é passível de contribuir para a redução na tomada de medicação não essencial.

PHP10

MEDICATION USE EVALUATION OF EXPENSIVE AND BROAD-SPECTRUM ANTIBIOTICS IN SONGKHLA HOSPITAL

Thoedratanaphong OS, Preechavechakul P
Songkhla Hospital, Songkhla, Thailand

OBJECTIVES: To evaluate expensive and broad-spectrum antimicrobials usage in Songkhla hospital. **METHODS:** A prospective, chart review was performed on all inpatients initiated with Levofloxacin, Meropenem, Imipenem/ Cilastatin, Piperacillin/ Tazobactam and Cefoperazone/ Sulbactam from March to December 2010. Pharmacist interventions were made when medication use evaluation (MUE) criterias were not met and/or drug related problems (DRPs) were detected. **RESULTS:** Overall, 347 patients received 412 courses with these antibiotics. Percentage of empiric therapy was 80 % and specific therapy was 20 %. Pneumonia and sepsis/ septic shock were leading indications of these antibiotic uses. Cefoperazone/Sulbactam was the most frequently used. The appropriate use of Levofloxacin, Meropenem, Imipenem/Cilastatin, Piperacilin/Tazobactam and Cefoperazone/ Sulbactam was 46%, 40%, 46% 70% and 53% respectively. No indication and incorrect drug dosage especially in patients with renal impairment were the most common misuse of these antibiotics. Acceptance of interventions from physician was 86% (25/29). The cost of inappropriate use of these antibiotics was 28,789 USD. **CONCLUSIONS:** MUE program should be continuously performed for effective use of antibacterial drug, safety and most benefit.

PHP11

THE USE OF METHYLPHENIDATE IN A GROUP OF PATIENTS WITH ATTENTION DEFICIT AND HYPERACTIVITY DISORDER

Gomez-galicia DL[1], Rodriguez-fragoso L[1], Lopez aymes G[1], Sánchez-Alemán M[2], Reyes-esparza JA[1]
[1]*Universidad Autonoma del Estado de Morelos, Cuernavaca, Morelos, México,* [2]*Instituto Nacional de Salud Pública, Cuernavaca, Morelos, México*

OBJECTIVES: to describe the use of stimulants in a group of Mexican children with ADHD in order to know some pharmacoepidemiological data **METHODS:** An observational and descriptive study in pediatrics patients based on a survey in a one year period (June 2009 to June 2010) was done. Survey was answered by children parents who signed an informed consent. Patients with diagnosis of ADHD and/or received stimulant treatment with and without co-morbidity were considering. **RESULTS:** Of 124 surveys, 85 were selected according to inclusion criteria. 61.2% of patients received pharmacologic treatment; the drug most use among them was the stimulant methylphenidate (94%). The mean age of stimulant users was 7.94 years (4-13 years), 81.2% were male, 76.5% were in a primary school and 94% had a non-pharmacologic treatment. The average daily dose was 13.95mg. Immediate release was the most prescribed form in three different commercial presentations, and 8% received the long term release. Children with seven years old were who received more methylphenidate prescription. The age and having a comorbidity increased the probability ($p<0.005$) for receiving methylphenidate treatment. The most frequent side effect reported was loss of appetite. **CONCLUSIONS:** Methylphenidate in an immediate action form was the most prescribed stimulant drug in seven years old children with ADHD in the population studied. High percentage of children received methylphenidate treatment.

Health Care Use & POLICY STUDIES – Equity and Access

PHP12
THE RATIO OF PUBLIC REIMBURSEMENT AND PATIENTS' CO-PAYMENT IN THE FINANCING OF SPA SERVICES IN HUNGARY

Turcsanyi K[1], Domján P[1], Boncz I[2]
[1]*University of Pécs, Zalaegerszeg, Hungary*, [2]*University of Pécs, Pécs, Hungary*

OBJECTIVES: Hungary has long and strong traditions in providing spa services. The reimbursement of spa services includes both public health insurance scheme and patient co-payment. The aim of our study is to explore the ratio of public reimbursement and patients' co-payment in financing of spa services in Hungary. **METHODS:** Data were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary covering the year 2007. We calculated within the total spa spending the annual health insurance reimbursement and the patients' co-payment at county and regional level. Hunmgary is devided into 7 regions and 20 counties. **RESULTS:** On nationwide level, the average ratio of patients' co-payment was 28.0 %, while the remaining 72.0 % was reimbursed by the National Health Insurance Fund Administration (OEP). At regional level, the ratio of patients' co-payment varied between 22.7 % (in the Northern-Great Plane region) and 35.4 % (in the Western-Transdanubian region). At county level, we found the lowest ratio of patients' co-payment in county Csongrád (19.8 %), Hajdú-Bihar (21.3 %) and Békés (23.1 %), while the highest ratio of patients' co-payment was observed in county Zala (53.4 %), Veszprém (46.6 %) and Somogy (33.3 %). **CONCLUSIONS:** In financing of spa services in Hungary, patient co-payment has a significant role: 28.0 % of total expenditures. There are important inequalities in the ratio of patient co-payment at both regional and county level.

PHP13
GEOGRAPHICAL INEQUALITIES OF HOME CARE (NURSING) IN HUNGARY

Cs. Horváth Z[1], Molics B[1], Ágoston I[1], Sebestyén A[2], Boncz I[1]
[1]*University of Pécs, Pécs, Hungary*, [2]*South-Trasdanubian Regional Health Insurance Fund Administration, Pécs, Hungary*

OBJECTIVES: Home care (nursing) was introduced into the Hungarian basic health insurance package in 1996. The aim of our study is to analyze the geographical inequalities in home care (nursing) in Hungary. **METHODS:** Data were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. The utilization of home care (nursing) services was measured by the number of patients and the number of visits. The geographical inequalities were calculated for county level. Both indicator was calculated to 10.000 population. **RESULTS:** The average number of patients in the Hungarian home care system was 50 / 10.000 population. We found the highest utilization in the following counties: Zala (65), Baranya (65), Jász-Nagykun-Szolnok (64), Vas (59), Csongrád (54), Borsod-Abaúj-Zemplén (54) and Gyõr-Moson-Sopron counties. The lowest utilization rate was measured in Komárom-Esztergom (43), Fejér (43), Nõgrád (38) and Szabolcs-Szatmár-Bereg (26) counties (all are for 10.000 population). The average number of home care visits was 1188 visits/10.000 population at national level. The number of home visits was the highest in Fejér (1342), Komárom-Esztergom (1333), Jász-Nagykun-Szolnok (1327), Nõgrád (1310), Gyõr-Moson-Sopron (1285) counties. The lowest home visit rate was measured in Budapest (1162), Somogy (1142) and Szabolcs-Szatmár-Bereg (614) counties (all are for 10.000 population). **CONCLUSIONS:** We found significant inequalities in the utilization of home care (nursing) in Hungary measured both by the number of patients and the number of visits per 10.000 population.

PHP15
IMPLICATIONS OF LATIN AMERICAN PHARMACEUTICAL PRICING REFORM FOR THE UK NHS

Shankland BDT, Kirpekar S
Double Helix Consulting, London, UK

OBJECTIVES: Mexico and Brazil have well-developed pharmaceutical pricing systems, with an increasing trend towards use of Health Technology Assessment in access decisions. However, there are significant differences in the prices of innovative medicines in the two countries. The object of the study is to clarify to what extent local decision making criteria can account for these discrepancies and therefore which evaluation mechanisms may have international relevance. **METHODS:** Secondary research was carried out to identify prices in Brazil and Mexico for 5 patented oncology medicines. A rating scale was then devised with the following decision domains for pricing and reimbursement: international referencing; cost-plus analysis; economic evaluation and budget impact; innovation; unmet needs; therapeutic referencing; negotiated agreements; demand side controls; and societal benefit. In primary research 4 senior stakeholders in Brazil and Mexico were asked to rate the importance of these domains in access decisions, and provide a rationale. **RESULTS:** Decision criteria in Mexico and Brazil reflect the historical origins of their respective health systems, but recent developments reflect a centralising trend in decision-making in both countries. This suggests that economic evaluation will increasingly determine access in both countries but pricing criteria will remain different, notably due to the greater role of price negotiation in Mexico. **CONCLUSIONS:** The mix of empirical and context-based decision criteria in Brazil and Mexico represent valuable alternative models for other countries, such as the UK National Health Service (NHS), which is currently contemplating a move towards "value-based pricing" for pharmaceuticals. In particular, Mexican and Brazilian evaluation mechanisms may inform future considerations of therapeutic innovation in the UK.

PHP16
WAITING TIME AND ITS IMPLICATIONS ON THE UTILIZATION OF ANTENATAL SERVICES IN A FREE SERVICE PROVISION SETTING IN THE ASANTE AKIM NORTH MUNICIPAL, GHANA

Agyei-Baffour P, Nakua E, Agyemang P, Owusu-Dabo E
Kwame Nkrumah University of Science and Technology (KNUST), Kumasi, Ashanti, Ghana

OBJECTIVES: The study sought to estimate the waiting time and assess its implications on the utilization of antenatal services in the Asante Akim North Municipal, Ghana. **METHODS:** The study was a cross sectional descriptive type using both qualitative and quantitative methods. In all 200 pregnant women presenting at the Konongo Odumasi Government Hospital and the Agogo Presbyterian Hospital were randomly selected for the study. Structured questionnaires were used to obtain data from respondents. Key informant and household heads interviews were also conducted and used to augment the information obtained. Descriptive and inferential statistics were used in the data analysis; statistical differences were set at 0.05 or less and at 95% confidence interval. **RESULTS:** Of the 200 respondents 35.5% (71) made four visits and 64.5% (129) made one or more visits. Pregnant mothers had to forego GH¢ 31(US$ 22.14) and GH¢ 15(US$10.17) as their incomes whenever they attended ANC. Significant differences existed between national health insurance policy holders and antennal clinic (ANC) visits ($p=0.022$), trimester of pregnancy and ANC visits ($p<0.001$), and place of residence (indicating distance to health facility and ANC visits ($p=0.017$). **CONCLUSIONS:** Long waiting is associated with high opportunity cost and are likely to reduce utilisation of ANC services in a free services provision setting. Further studies on feasibility of creating of separate pharmacy, laboratory and records units for antenatal clinic users and effects of waiting time on service utilization may be helpful to improve utilization of ANC services and reduction in pregnancy related maternal mortality.

Health Care Use & Policy Studies – Formulary Development

PHP17
MEXICO'S NATIONAL AND INSTITUTIONAL ESSENTIAL MEDICINE LISTS

Rivas R
CENETEC, México, D.F., México

BACKGROUND: Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. To be selected, medicines must be available through health systems, in suitable amounts and dosage forms. The Essential Medicines List can help countries rationalize the purchasing and distribution of medicines, thereby reducing costs to the health system. Most countries have national lists and some have provincial, state or institutional lists as well. Mexican Health System has 2 main institutions who provide healthcare services to population: IMSS and ISSSTE; each of them have an institutional list and also there is a National essential medicine list. **OBJECTIVES:** To compare the National essential medicine list with the institutional lists of IMSS and ISSSTE. **METHODS:** The National essential medicine list (2009 version) and the latest web versions available for the essential list of each institution where analyzed to compare by product key and by generic name for each of the 23 therapeutic groups excluding the groups referring to vaccines, nutrimental components and electrolytic solutions. **RESULTS:** There were a wide difference between the national essential list and the institutional list especially in the group for treating endocrinology, oncology and infectius conditions. Also there were big differences for more than 50% of the therapeutic groups examined between the institutions. **CONCLUSIONS:** There remains, significant opportunity for improvement of the national and institutional essential medicines list because don't seem to be uniform criteria to selection.

Health Care Use & Policy Studies – Health Care Costs & Management

PHP18
IMPACTO DE LA PARTICIPACION DEL FARMACEUTICO COMO PARTE DEL EQUIPO DE SALUD EN EL PRIMER NIVEL DE ATENCION SOBRE LOS COSTOS

Mino-Leon D[1], Contreras-Hernandez I[2], Anaya P[3], Reyes A[4]
[1]*Instituto de Geriatría, México, D.F., México*, [2]*Instituto Mexicano del Seguro Social, México, D.F., México*, [3]*GlaxoSmithKline México, México, D.F., México*, [4]*Universidad de la Sierra Sur, Oaxaca, Miahuatlán de Po, México*

OBJECTIVOS: Analizar el ahorro en costos por la intervención del farmacéutico sobre errores de prescripción, desde la perspectiva del proveedor de servicios de salud. **METODOLOGÍAS:** Análisis de costo-efectividad, tipo árbol de decisiones. Se estimaron costos y efectividades de incluir en las decisiones médicas un farmacéutico y corregir prescripciones de antihipertensivos e hipoglucemiantes combinados con analgésicos e hipolipemiantes. La medida de efectividad fue la probabilidad de otorgar prescripciones farmacológicas sin eventos adversos graves (EAG), con horizonte temporal de 30 días. La probabilidad de corrección por la intervención del farmacéutico se obtuvo a través de un ensayo clínico (EC) y la probabilidad de la ocurrencia de EAG (hemorragia gastrointestinal, rabdoimiolisis, enfermedad vascular cerebral y fractura de cadera) como consecuencia de la no corrección se obtuvo de la literatura publicada. Se estimaron los costos de la atención médica con y sin farmacéutico del EC y los costos esperados de los EAG de publicaciones de costos nacionales. Los costos son expresados en pesos mexicanos del 2010. **RESULTADOS:** Costo promedio por paciente esperado sin la intervención del farmacéutico durante el horizonte temporal fue de $12,481.60 y el costo promedio por paciente con la intervención fue de $9,127.97, lo que significó disminución en el costo por paciente de 27%. El número de prescripciones que evitaron interacciones riesgosas fue superior con la presencia del farmacéutico y la posibilidad de que un paciente no presentara alguno de los desenlaces evaluados por efecto de la inter-

vención de manera oportuna aumentó en 11%. El costo por paciente sin EAG de manera habitual fue de $16,981.77 mientras que con la intervención del farmacéutico fue de $11,158.89. La razón costo efectividad incremental demostró que por cada paciente adicional sin EAG el sistema de salud ahorra $40,405.18. **CONCLUSIONES:** La inclusión del farmacéutico en el equipo de atención fue costo-ahorradora.

PHP19

INCREASED MARKET SHARE OF PRIVATE, FOR-PROFIT HEALTH CARE PROVIDERS FROM THE HUNGARIAN HEALTH INSURANCE BUDGET BETWEEN 2006-2009

Boncz I[1], Endrei D[1], Molics B[1], Ágoston I[1], Turcsanyi K[2], Domján P[2], Betlehem J[1], Oláh A[1], Sebestyén A[3]
[1]*University of Pécs, Pécs, Hungary,* [2]*University of Pécs, Zalaegerszeg, Hungary,* [3]*South-Trasdanubian Regional Health Insurance Fund Administration, Pécs, Hungary*

OBJECTIVES: The potential role of private health care providers and privatization has been under heavy discussion in many countries. In the Hungarian health care, there was a clearly supporting health policy regarding the increasing role of private health care providers. The aim of the study is to analyze the market share of for-profit private sector from the public health insurance expenditures on medical services. **METHODS:** Data were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary, covering the period 2006-2009. The analysis includes the medical provisions (primary care, health visitors, dental care, out- and inpatient care, home care, kidney dialysis, CT-MRI). We calculated the health insurance reimbursement according to the following categories of health care providers' ownership status: local authorities, central government, for-profit companies and non-profit providers. **RESULTS:** In 2006 only 15.8% (112.8 billion Hungarian Forint, HUF) of total expenditure for medical services went to for-profit private providers, 53.9% to local authorities, 24.7% to central government and 5.6% to non-profit sector. For 2009, the market share of private for-profit health care providers increased to 30.9% (222.3 billion HUF), the local authorities had 43.8%, the central government 22.7% and the non-profit sector 2.5% market share. We found the largest increase of private for-profit health care providers in acute (from 0.8% in 2006 to 14.3 in 2009) and chronic care (from 1.1% in 2006 to 20.6% in 2009). **CONCLUSIONS:** In line with the health policy objectives between 2006-2009, we found a significant increase of private for-profit companies from health insurance financing: they doubled their market share from 15.8% (2006) to 30.9% (2009). This increase was attributed to the "functional" privatization of acute and chronic care hospitals.

PHP20

ECONOMIC EVALUATION OF POISON CONTROL CENTERS: A SYSTEMATIC REVIEW

Galvao TF[1], Silva EN[2], Silva MT[2], Pereira MG[3]
[1]*Federal University of Amazonas, University of Brasília, Brasília, DF, Brazil,* [2]*Brazilian Ministry of Health, Brasília, DF, Brazil,* [3]*University of Brasília, Brasília, DF, Brazil*

OBJECTIVES: The aim of this review is to systematically summarize and assess the existing economic evaluations of poison control centers (PCCs). **METHODS:** A literature search was performed to identify complete economic evaluations regardless of language or publication status by searching the following databases: Medline (via Pubmed), Embase, Centre for Reviews and Dissemination Databases, Cochrane Library, Cochrane Central, metaRegister of Clinical Trials, LILACS, SciELO, ProQuest, Capes (Brazilian theses register) databases and abstracts at toxicology congresses. Two reviewers assessed abstracts for inclusion and extracted the data. Two experts assessed studies' quality with a standardized tool (Drummond 2005). **RESULTS:** A total of 365 non-duplicated reports were identified, but only nine met eligibility criteria. Five studies were published in the 1990s, and four were published in the following decade. PCCs were compared to a scenario in which they did not exist. Benefits were measured as potentially avoided healthcare charges. Eight studies used cost-benefit analyses, and the other one used a cost-effectiveness approach. Only two studies did not meet at least seven of 10 quality criteria. Cost-benefit ratios ranged from 0.76 to 7.67, what means that each dollar spent on poison centers saves almost US$ 8 in other medical spending. Incremental cost-effectiveness ratios were US$ -12,000 for morbidity and -56,000 for mortality. These results indicate that a significant cost savings is realized with each successful outcome achieved by a poison center: US$ 12,000 in case of morbidity and US$ 56,000 in case of mortality. **CONCLUSIONS:** Investment in PCCs appears to be a rational public health policy. They could improve health care expenditure efficiency and contribute to the sustainability of the health system. However, the number of PCCs is decreasing in many countries.

PHP21

MEDICAL SERVICES COST INFLUENCE ON THE RATIONALITY OF NEW MEDICAL TECHNOLOGY INTRODUCTION

Kozhanova I[1], Romanova I[1], Gavrilenko L[1], Voitenkova L[2]
[1]*The Belarus State Medical University, Minsk, Belarus,* [2]*Belarusian National Technical University, Minsk, Belarus*

OBJECTIVES: To define the value medical services cost while conducting pharmacoeconomic analysis. **METHODS:** A review of pharmacoeconomic researches of 5-alpha reductase inhibitors (5-ARI) application for treatment benign prostatic hyperplasia (BPH) has been conducted. The average prices for medical services for care and treatment of BPH patients have been defined. The prices analysis of the medical services Belarusian market in a "urology" specialty has been made. The average prices comparison (in US dollars) of the actual medical services and prices taken from medical literature has been done. **RESULTS:** The foreign medical literature review of using the 5-ARI for BPH patients shows the considerable economic expenses because of an acute urinary retention hospitalization and surgical treatment necessity. The medical services cost in Belarus is considerably cheaper to compare with the costs given by foreign researchers' reviews. We have specified three procedures giving the significant contribution to the above-stated discrepancies: the urologist examination cost in the USA 9 times exceeds the similar procedure in our country (47,9$ versus 5$), transurethral resection (TURP) performance is 5 times (793$ versus 159$) and 1 day hospitalization cost without operative interventions and anesthesia is 364 times (4809$ versus 13,2$) more. **CONCLUSIONS:** Hospital services and the medical staff work high cost in western countries allows proving economically out-patient application of expensive treatment methods. The end-points choice of the events demanding hospitalizations is not optimum at making pharmacoeconomic researches in Belarus because of the low contribution in hospital expenses versus the drug therapy cost. A complex approach with integration of several economic analyses is required to introduce new expensive innovative drugs on the Belarusian pharmaceutical market.

PHP22

USE OF DECISION MODELING TO ESTIMATE THE NEGATIVE IMPACT OF TOBACCO USE ON HEALTH CARE COSTS AND HEALTH DISPARITIES IN PEOPLE LIVING WITH HIV

Burbano-Levy X, Miguez MJ, Thompson M, Medina A, Quiros C, Malow R
Florida International University, Miami, FL, USA

OBJECTIVES: After people living with HIV (PLWH) start on highly active antiretroviral therapy (HAART), rates of hospitalization for PLWH's declined, but continued still occurred at high levels. The increased prevalence of tobacco use among PLWH and paucity of current data provide the rationale to study if tobacco use might affect cost and clinical benefits of HAART among PLWH. **METHODS:** A decision-tree model guided our assessment of the impact of tobacco on costs and effectiveness of HAART by race/ethnicity. Using a payer perspective, the probabilities related with smoke habit for racial group (African-Americans, Caribbeans, Hispanics, Caucasians) were extracted from our prior tobacco study (n=560) along with the number of hospitalizations. This information along with hospital bed/day costs, provided by Jackson Memorial Hospital's patient accounting system, was used to estimate the impact of the tobacco with a 1-year time frame. Results were express as cost per hospitalizations related to smoking diseases (HRSD) **RESULTS:** Among patients receiving antiretroviral therapy, our data indicated that smoking contributed a $480,029 additional cost/year, with an average of $6,234/HRSD and an incremental cost of $ 4,750 compared to non-smokers in the same treatment group. In the Non-HAART Group, the incremental cost for smokers was $2,064,469, with an average of $8,054/HRSD and an incremental cost of $7,486. When racial group were evaluated for smoking habit, the average costs for Hispanics receiving HAART was $10,975/HRSD. African Americans despite the high cost reported for the total group had an average cost of $8011/HRSD. **CONCLUSIONS:** In PLWH receiving HAART, our analysis indicated that the benefits of HAART were negatively impacted by tobacco use and costs are increased in the smokers in both the HAART and Non-HAART groups. The data also indicated that focusing tobacco prevention efforts on minorities may maximize effectiveness in terms of disease prevention and cost reduction.

PHP23

LA ACEPTACION DE LAS VACUNAS EN LOS PROGRAMAS NACIONALES DE INMUNIZACION EN LATINA AMERICA: UN ESTUDIO COMPARATIVO

Jones K
PriceSpective Ltd., London, UK

OBJECTIVOS: A un con un precio alto, la vacuna de VPH se ha asegura do una rápida inclusión en los programas nacionales de inmunización (PNI) en economías avanzadas y emergentes. Por el contrario, otras vacunas nuevas, han encontrado una aceptación más lenta en economías emergentes. El objetivo de esta investigación es comparar el acceso al mercado de esta vacuna con los de las vacunas contra el neumococo y la del Hib, con el fin de entender los criterios subyacentes en la exitosa aceptación de una vacuna. **METODOLOGÍAS:** Cinco países de Latina América fueron considerados en este estudio. Todos los países participaron en un debate nacional de al menos dos de las vacunas sobre la inclusión en el PNI. Se recopilaron los siguientes datos: fecha de autorización comercial y de inclusión en el PNI, precio, restricciones de acceso y fuentes de financiación. Se llevó a cabo una revisión cualitativa de la literatura y de las publicaciones de los Ministerios de Salud de estos países para hacer un estudio comparativo de las tres vacunas. **RESULTADOS:** Nuestro análisis muestra en todos los países una clara diferencia entre la financiación del VPH y de las otras vacunas, con poca consistencia en el razonamiento económico y político. Por ejemplo, los altos costos se citan como barrera al acceso, sin embargo las poblaciones incluidas en los programas de vacunación del VPN son más grandes que en los países industrializados. **CONCLUSIONES:** Los factores adicionales que influyen en la aceptación de una vacuna varían dependiendo de los actores principales del debate nacional. Políticamente, las voces de los activistas contra el cáncer pueden aumentar la percepción del valor social de una vacuna en particular. Estos factores son muy importantes y van más allá de la evaluación económica del proceso de inclusión de vacunas en los PNIs.

PHP24

COMPARAÇÃO DA QUALIDADE DE VIDA ENTRE PESSOAS COM DOENÇAS CRÓNICAS E PESSOAS DA COMUNIDADE SEM DOENÇA

Pais-Ribeiro J[1], Silva I[2], Pedro L[3], Meneses R[2], Cardoso H[1], Abreu M[1], Melo V[1], Martins A[1], Martins-da Silva A[1], Vilhena E[1], Mendonça D[1]

[1]*Porto University, Porto, Portugal,* [2]*Fernando Pessoa University, Porto, Portugal,* [3]*Polytechnic Institute, Lisboa, Portugal*

OBJETIVOS: O objetivo da investigação é comparar a qualidade de vida (QOL) de pessoas portadoras de doenças crónicas com diagnóstico superior a três anos, com pessoas da comunidade sem doença, do mesmo grupo etário e género. **MÉTODOS:** Participam 603 indivíduos com 41,19 anos de idade média, escolaridade média de 9,87 anos, 72,5% mulheres, portadores de uma das seguintes doenças crónicas: epilepsia, diabetes tipo 1 e 2, cancro, miastenia gravis, esclerose múltipla, obesidade mórbida, com diagnóstico há mais de 3 anos. Depois de satisfazer as exigências éticas expressas nos códigos e na lei, avaliámos as seguintes variáveis: componentes, mental e físico, do MOS SF-36. O procedimento consistiu em subtrair o valor de cada componente da população sem doença ao da população com doença. **RESULTADOS:** No total, 28% da população com doença reportava qualidade de vida superior à dos seus contrapartes sem doença. Estes valores variavam de modo estatisticamente significativo entre doenças ($\chi 2$=0,002) com, respectivamente 10% dos participantes com miastenia gravis reportando QOL superior, 35,8% no cancro, 23,4% na obesidade mórbida, 43% na epilepsia, 22% na esclerose múltipla, 20% na diabetes tipo 2 e 32,5% na diabetes tipo 1. **CONCLUSÕES:** Os resultados mostram que uma percentagem significativa de pessoas com doenças crónicas, controladas e estabilizadas, vive com QOL superior à dos seus pares sem doença, embora esses valores variem substancialmente com a doença. A idade não se correlaciona de modo estatisticamente significativo com a diferença entre os grupos, para a componente mental e de modo estatisticamente significativo embora baixo (r=0, 14) para o componente físico: os grupos com idade mais jovem como a diabetes tipo 1 e epilepsia mostram uma maior percentagem de pessoas com melhor QOL, mas os com cancro exibem uma média de idade média mais elevada e a esclerose múltipla idade mais baixa

PHP25

VALIDITY AND RELIABILITY OF INSTRUMENTS USED FOR MEASURING PATIENT SATISFACTION WITH PHARMACEUTICAL CARE SERVICES

Sakharkar PR[1], Bounthavong M[2], Law AV[1]
[1]*College of Pharmacy, Western University of Health Sciences, Pomona, CA, USA,* [2]*Veterans Affairs San Diego Healthcare System, San Diego, CA, USA*

OBJECTIVES: Patient satisfaction is an important patient reported outcome (PRO) that is being used to document the impact of pharmacists' clinical services, especially in managing patients with chronic conditions. The purpose of this study was to review literature on the validity and reliability of published instruments that have been used to measure patient satisfaction with pharmaceutical care in the community setting. **METHODS:** A structured search was conducted in five databases (PUBMED, EMBASE, MEDLINE, PsycINFO, and OVID (1998–Feb. 2011) using keywords to identify studies that measured patient satisfaction with pharmaceutical care using survey instruments. Studies conducted outside United States, those which used non-English language questionnaire; abstracts from conferences, reviews, letters or notes were excluded. Studies reporting patient satisfaction results and/or psychometric properties were included. **RESULTS:** A total of 21 studies were identified that met the selection criteria. The pharmacy practice setting, sample size, study design in evaluating patient satisfaction varied greatly. The survey instruments differed in number of items, response scale and mode of administration. Majority of survey instrument were administered by mail. The response rate varied from relatively low to very high. Patient satisfaction was a secondary outcome in most of these studies. Majority of the studies used self developed, non-validated or modified instrument with items from preexisting instruments. Only few studies reported psychometric properties of the instrument used. Inconsistency in use of instrument measuring patient satisfaction was observed. In general, studies reviewed showed greater degree of overall patient satisfaction with the services. **CONCLUSIONS:** In majority of studies patient satisfaction was measured using non-validated instruments. There is a lack of comprehensive, valid and reliable instrument for assessing patient satisfaction with pharmaceutical care services in community setting. Use of a standardized survey instrument, sampling and study design will provide valuable insight into patient evaluation of pharmacist services.

PHP26

A SATISFAÇÃO DOS PROFISSIONAIS DE SAÚDE VS A SATISFAÇÃO DOS UTENTES EM UNIDADES DE CUIDADOS CONTINUADOS

Anjos T[1], Almeida A[2]
[1]*Santa Casa da Misericordia de Belmonte, Belmonte, Portugal,* [2]*Universidade da Beira Interior, Covilhã, Portugal*

OBJETIVOS: Esta investigação teve como objectivo identificar o nível de satisfação dos profissionais e dos utentes de unidades de cuidados continuados, a sua diferença, avaliar e identificar a influência de algumas variáveis. MÉTODOS: A metodologia utilizada foi quantitativa, descritiva e exploratória. O questionário foi composto por duas partes, questionário de Luís Graça e EORTC IN-PATSAT32, respectivamente. **RESULTADOS:** A amostra foi constituída por 41 profissionais e 30 utentes. Os resultados encontrados mostraram a consistência de 7 das 18 hipóteses formuladas. Os profissionais estavam mais satisfeitos com as dimensões "geral" e "condições de trabalho", apresentando menor nível de satisfação profissional com a dimensão "salário". Ao nível de satisfação dos utentes/clientes, estes estavam mais satisfeitos com a dimensão "satisfação com os enfermeiros", apresentando menor nível de satisfação com a dimensão "satisfação com os médicos". **CONCLUSÑES:** Os dados confirmam a existência de correlação entre as dimensões salário, tipo de vínculo, actividade profissional e estado civil com a satisfação profissional relativamente aos profissionais de saúde, relativamente aos utentes/clientes os dados confirmam a existência de correlação entre as dimensões "organização do serviço e cuidados", "enfermeiros" e "serviço hospitalar de onde teve alta" com a satisfação dos utentes/clientes, no que respeita ao serviço hospitalar de onde teve alta, esta avaliação é algo de inovador. Salienta-se o facto de os utentes/clientes e os profissionais de saúde se encontrarem na sua maioria satisfeitos, a satisfação profissional, ao contrário da satisfação dos utentes/clientes, varia em função da instituição. Será recomendável que as administrações monitorizem frequentemente a satisfação, quer dos profissionais, quer dos utentes, no sentido de ter um constante feedback, tendo conhecimento das dimensões em que há uma maior satisfação ou insatisfação, tendo assim a possibilidade de apurar/estudar alternativas para intervir no sentido de proporcionar uma maior satisfação, uma vez que a satisfação é um dos principais pontos para o sucesso de uma organização.

PHP27

THE ECONOMIC BENEFITS OF IMPLEMENTING A UNIT DOSE DRUG DISPENSING SYSTEM AT THE HOSPITAL LEVEL IN THE MEXICAN INSTITUTE OF SOCIAL SECURITY (IMSS)

Uc-Coyoc R, Pérez-Reynaud AG, Coello-Reyes LA, Rodriguez-Díaz Ponce MA
Instituto Mexicano del Seguro Social, México, D.F., México

OBJECTIVES: In Mexico, two pilot studies in public hospitals assessed the economic benefit of changing from a traditional, or ward stock, drug dispensing system to a unit dose drug dispensing system. The aim of this study is to estimate the total drug savings derived from implementing a unit dose system among hospitals at IMSS. **METHODS:** Total and average hospital drug expenditures were estimated based on hospital drug prescriptions data base for 2009. Statistical analysis was performed to test for expenditure differences among levels of health care. The percentages of economic savings derived from previous studies were used to construct three economic benefit scenarios. These were applied to the total hospital drug expenditure. The baseline scenario was obtained from studies in Mexico that reported economic savings of 40%. A minimum and maximum scenario of 14.4% and 67.7% were obtained from international studies. The exchange rate was of $12.10 pesos per dollar. **RESULTS:** The total hospital drug expenditure was of USD $499.3 millions. Most of the expenditure was derived from hospitals of general and specialized level of care. Average expenditure and drug prescription dispensed were statistically higher in the specialized compared to general hospitals (p=0.0002 and p=0.00009, respectively). The total economic drug savings from the baseline scenario considering all hospitals was of USD$199.7 millions. In the maximum and minimum scenarios, the economic savings were of USD$334.5 millions and USD$71.9 millions respectively. On average savings were higher on specialized than in general hospitals. **CONCLUSIONS:** The estimated economic benefits, derived from implementing a unit drug dispensing system in hospitals at IMSS, was equivalent to 7.9% of the 2009 institutional budget expenditure for medical related spending in the baseline scenario. This suggests that this system can contribute to the containment of costs and the rational use of medicines on behalf of the patients and institutions.

PHP28

DECENTRALISATION OF HEALTH SERVICES PLANNING AND MANAGEMENT: THE VARYING PERSPECTIVES OF HEALTH WORKERS AND COMMUNITY MEMBERS AT NANUMBA NORTH DISTRICT, GHANA

Agyei-Baffour P, Atta K, Nakua E, Owusu-Dabo E
Kwame Nkrumah University of Science and Technology (KNUST), Kumasi, Ashanti, Ghana

OBJECTIVES: To assesses the extent of varying perspectives between health workers and community members' perception of decentralization and how such variation in views could affect the effective health services planning and management in the Nanumba North District, Ghana. **METHODS:** A descriptive analytical cross sectional survey with randomly selected community members aged 18 or more years and health staff was undertaken from May – September 2009. Data collection was done with the use of questionnaire and interview guide administered by university trained research assistants to 186 respondents; 120 community members, 66 health staff who had stayed or worked in the district for the past 6-12months. Data was analysed into descriptive statistics using the Statistical Package for Social Sciences (SPSS) version 15.0. The significance or otherwise of the differences in perspectives was ascertained using chi-square or fishers exact test with p-values of 0.05 or less and at 95% confidence interval. The study had ethical clearance and Informed consent was sought from respondents. **RESULTS:** A majority of health workers were females 74.2%, and young with average of 31.5yrs (SD, 9.3) and had worked for <5yrs, 56.1%. Community members, 47.5%, were equally quite young but slightly older, mean years 34.8, (SD 8.4), than health staff, and had lived in the community for <5yrs. There was significant differences in perception between health staff of whether or not the district management team (DHMT) was decentralised, p<0.05, and in perception regarding health planning process and management of finances between health staff and community members, p<0.05. **CONCLUSIONS:** Differences in perception between health staff and community members partly account for low community involvement in health planning and management, health activities and utilisation of health service. A study involving many DHMTs will be needed to make a case for policy change as the study focused on only one district.

PHP29

PREDICTORS OF APPROPRIATE USE OF INSECTICIDE TREATED NETS IN AN URBAN COMMUNITY: THE CASE OF ASOKWA SUB-METROPOLITAN AREA, KUMASI, ASHANTI, GHANA

Agyei-Baffour P, Mantey KG, Owusu-Dabo E
Kwame Nkrumah University of Science and Technology (KNUST), Kumasi, Ashanti, Ghana

OBJECTIVES: To assesses the predictors of appropriate use of insecticides treated nets (ITNs) in the Asokwa Sub-Metropolitan Area of Kumasi, Ashanti, Ghana. **METHODS:** The research was conducted in five communities in the Asokwa Sub-

metropolitan area of Kumasi, Ghana, with randomly selected 500 mothers and caregivers, interviewed with questionnaire administration in their homes and in the health facilities. The study was conducted from May – September, 2010. The study had ethical clearance. Informed consenting processes were strictly followed. Data was analysed using descriptive statistics and logistic regression to examine the predictors of appropriate use of ITNs among children under five years at 95% confidence interval. Data was analysed into descriptive statistics using the Statistical STATA version 11 software. **RESULTS:** The study found that 50% of the participants owned ITNs, and of this only 67% used it the night before the study. Meanwhile, 21% of those who owned the nets used them occasionally. Also 39% of the total population did not own any ITN at all. The predictors of appropriate use of ITNs were found to be income levels, health seeking behaviour of caregivers and the room structure of participants. **CONCLUSIONS:** Appropriate ITN use in the study area is determined by incomes of participants, room structures, and health seeking behaviour of users. A comparative study between urban and rural communities could be useful for nationwide intervention to improve current situation.

PHP31

ANALISIS COSTO EFECTIVIDAD SECTORIAL DE 45 INTERVENCIONES SANITARIAS EN CHILE

Vallejos C[1], Castillo M[2], Puebla S[1], Orellana J[1], Reveco R[1], Valdés P[1], Alarcón A[1], Merino W[1]
[1]*Universidad de La Frontera, Temuco, Chile,* [2]*Ministerio de Salud de Chile, Santiago, Chile*

OBJECTIVOS: Apoyar la priorización de problemas de salud a ser incorporados en las Garantías Explicitas en Salud, a partir del análisis costo-efectividad de 45 intervenciones destinadas a reducir la mortalidad o discapacidad. **METODOLOGÍAS:** Análisis Costo-Efectividad Sectorial. Se definieron los procesos productivos para cada intervención (diagnóstico, tratamiento y seguimiento). Se costearon 309 prestaciones, en base a una muestra de establecimientos públicos. Los costos están expresados en moneda chilena a Junio 2009. La eficacia de cada intervención se determinó por revisión sistemática. Se construyó un modelo de historia natural (sin intervención) para cada enfermedad, y se contrastó con un modelo que incorpora la intervención. El resultado de eficacia obtenido se ponderó por adherencia, cumplimiento de prestadores, y cobertura, obteniendo así el indicador de efectividad por caso incidente tratado. Los resultados de efectividad se expresan en Disability Adjusted Life Years (DALY) evitados. Se aplica tasa de descuento (6%) para costos y resultados. El horizonte temporal se define por la expectativa de vida mediana para la cohorte de pacientes. **RESULTADOS:** Se obtiene la razón costo-efectividad de cada intervención, y se construye un ranking de costo-efectividad, identificando aquellas muy costo-efectivas, potencialmente costo-efectivas, y no costo-efectivas. Se propone un umbral de pago por DALY evitado: una intervención es muy costo-efectiva si previene 1 DALY a costo igual o inferior a 1 PIB (producto interno bruto) per cápita: potencialmente costo-efectiva si previene 1 DALY a un costo entre 1 y 3 PIB per cápita; y no costo-efectiva si el resultado es mayor. **CONCLUSIONES:** Se proporciona una metodología y resultados concretos que apoyan el proceso de toma de decisiones sanitarias en Chile. Al día de hoy, varias de las intervenciones costo-efectivas han sido incorporadas a la Ley de Garantías Explícitas. Se sugiere un umbral de pago por DALY evitado en el país para futuras decisiones.

Health Care Use & Policy Studies – Health Care Research & Education

PHP32

LINEAMIENTOS DE UNA POLÍTICA DE INVESTIGACIÓN EN SALUD EN CHILE: ACUERDOS DE LA COMISIÓN TÉCNICA DE INVESTIGACIÓN SANITARIA PARA EL PLAN NACIONAL DE SALUD 2011-2020

Espinoza MA[1], Cabieses B[2], Zitko P[3], Castillo C[3], Castillo M[3], Jeria MM[4], Valenzuela MT[4], Delgado M[3], Ramirez J[3]
[1]*Pontificia Universidad Católica de Chile, Santiago, Chile,* [2]*University of York, York, UK,* [3]*Ministerio de Salud de Chile, Santiago, Chile,* [4]*Instituto de Salud Pública de Chile, Santiago, Chile*

OBJECTIVOS: Chile ha avanzado en el desarrollo de investigación en salud (IS). Sin embargo, aún falta definir un marco conceptual que de soporte a una política de IS de largo plazo. El nuevo Plan Nacional de Salud 2011-2020 (PNS) ha incluido, por primera vez, como objetivo el desarrollo de IS en Chile. El presente reporte presenta los lineamientos directrices de la política de IS en Chile para el nuevo PNS. **METODOLOGÍAS:** El Ministerio de Salud convocó a un sub-comité de profesionales vinculados a salud para desarrollar aspectos a considerar en una política de IS. Se realizó una revisión de situación de IS en Chile, identificando elementos teóricos y empíricos centrales para fortalecer su desarrollo. A partir de múltiples encuentros de discusión temática, se definieron metas de IS al año 2020 y estrategias para su cumplimiento. **RESULTADOS:** El comité definió los siguientes cinco lineamientos: 1) La inversión en IS-aplicada debe ser consistente con objetivos de salud definidos por PNS; 2) IS se justifica desde el presupuesto de salud si permite resolver incertidumbre de la autoridad sanitaria, reduciendo el costo-esperado de decisiones incorrectas; 3) Se adopta el marco teórico de investigación traslacional que incluye distintos niveles/tipos de IS, alineados con necesidades/prioridades de la autoridad; 4) Se deben explicitar los tópicos de IS y establecer mecanismos transparentes para su priorización (priority-setting-methodology); dichos tópicos deben articularse con la evaluación de nuevas intervenciones y considerar la colaboración con sociedades-científicas; (5) Se debe potenciar la vinculación pública-académica-privada en la ejecución y financiamiento de proyectos. A partir de estos lineamientos, se definieron las metas y estrategias para IS en PNS, conforme a necesidades, restricciones y desafíos actuales del país. **CONCLUSIONES:** Este reporte destaca las bases conceptuales y lineamientos del desarrollo de una política de IS en Chile. Las metas y estrategias para el nuevo PNS son definidas a partir de esta iniciativa.

PHP33

KNOWLEDGE, ATTITUDE, AND PRACTICES (KAP) OF FOOD PRACTITIONERS ON HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) IN THE KUMASI METROPOLIS, GHANA

Agyei-Baffour P, Boateng K, Nakua E, Otupiri E, Owusu-Dabo E
Kwame Nkrumah University of Science and Technology (KNUST), Kumasi, Ashanti, Ghana

OBJECTIVES: To assess knowledge, attitude, and practices (KAP) of food practitioners on hazard analysis and critical control point (HACCP) in the Kumasi Metropolis, Ashanti, **METHODS:** A descriptive cross sectional survey with randomly selected 450 food practitioners and 50 key informants was conducted from May – September 2009. Data collection was done with the use of questionnaire and interview guide administered by university trained research assistants. Data was analysed into descriptive statistics using the Statistical Package for Social Sciences (SPSS) version 15.0. The data analysis was done at 95% confidence interval with significance level 0.05 or less and at 95% confidence interval. The study had ethical clearance and Informed consent was sought from respondents. **RESULTS:** The knowledge level of food practitioners on HACCP was extremely low, only 25% knew it. HACCP has not been widely used, less than one third, 24%, of food practitioners' use it. Little use of HACCP has negative impact on the general knowledge level and food handling practices of food practitioners, $p=0.031$. Majority have not even heard about it and therefore shows no positive signs of adherence and effort to practice. More than 85% of the respondents did not attend any educational course on food hygiene and food borne disease. **CONCLUSIONS:** There is poor knowledge on hazard analysis and critical control point among food services staff. Studies involving the use of both qualitative and quantitative research methods and environmental exposures will be helpful to design interventions to improve food hygiene.

PHP34

NECESIDADES DE INFORMACIÓN Y FORMACIÓN SOBRE FARMACOECONOMIA E INVESTIGACIÓN DE RESULTADOS PARA PROFESIONALES Y ESTUDIANTES DE FARMACIA DEL ORIENTE VENEZOLANO

Adesso G, Bastardo Y
Universidad Central de Venezuela, Caracas, Venezuela

OBJECTIVOS: Describir la necesidades sobre información y formación en Farmacoeconomia e Investigaciones de Resultados de profesionales y estudiantes de Farmacia asentados en el oriente de Venezuela. **METODOLOGÍAS:** Estudio descriptivo transversal realizado a la población asistente de la 14a reunión anual de la Federación Farmacéutica de Venezuela celebrada en el estado Anzoátegui en el mes de marzo de 2011, mediante el cuestionario desarrollado por los Consorcios de Asia y America Latina de ISPOR y, disponible en la pagina web de ISPOR para evaluar la necesidad para la investigación de farmacoeconomia e investigación de resultados. **RESULTADOS:** Del total de encuestados (N: 74), el 53% son profesionales farmacéuticos en ejercicio y el resto estudiantes de Farmacia del núcleo de oriente de la Universidad Santa Maria. La mayoría de los profesionales (66%) trabaja en establecimientos de Farmacia para la comunidad. El 83% de los encuestados señala no haber recibido actividades educativas o de formación en Farmacoeconomia e Investigación de Resultados. El análisis de costos y los estudios de costo beneficio concentran los métodos percibidos que usualmente se utilizan (41%). Un 56% de los encuestados considera que las autoridades no toma en cuenta los resultados de los estudios llevados a cabo, y un 59% se preocupa por la falta de conocimiento de los temas farmacoeconomicos en el país. Así mismo, 91% quisiera más formación educativa y aplicaciones prácticas de la disciplina. El 77% nunca ha escuchado de la existencia de ISPOR, y un 55% de los mismos estarían interesados en ser miembros del capitulo local del ISPOR. **CONCLUSIONES:** Los resultados de este estudio sugieren la necesidad de que ISPOR Venezuela siga profundizando los esfuerzos para promover la farmacoeconomia y la investigación de resultados en Venezuela y, específicamente, con los Farmacéuticos y estudiantes de Farmacia de la zona oriental del país.

PHP35

PERCEPTIONS, KNOWLEDGE AND GAPS ABOUT HTA AND HEALTH ECONOMICS BY THE BRAZIIAN MARKET STAKEHOLDERS: ISPOR BRAZIL QUALITATIVE RESEARCH

Araújo GTB[1], Fonseca M[1], Stefani SD[2]
[1]*Axia.Bio, São Paulo, SP, Brazil,* [2]*Hospital Mãe de Deus, Porto Alegre, RS, Brazil*

OBJECTIVES: Understand the Brazilian set needs about HTA and Health economics. **METHODS:** In deep interview, based on a structured questionnaire, with decision makers from the public and private set, Prescriptors, Patients group and Manufacturers. **RESULTS:** A total of 131 interviews was conducted: 60 decision makers, 50 Prescriptors, 10 patients groups and 11 manufacturers. For the decision makers and Manufacturers, HTA and Health economics its' a main issue and, despite several methodological mistakes, takes an important role on the decision and business. Patient groups and prescirptors are not very well awarned about the issues in analysis, but consider that a better knowledge about is important and can be very useful for the prescriptor and patients. For all the stakeholders, education and access to clear information was a main issue of need. **CONCLUSIONS:** Considering the rich database that this research provides and the knowledge about the needs and points to enforce, ISPOR Brazil will be able to act with more focus.

Health Care Use & Policy Studies – Health Technology Assessment Programs

PHP36

HISTORICAL AND FUTURE DRIVERS FOR HTA IN REIMBURSEMENT SYSTEMS IN MEXICO AND POLAND

Kirpekar S, Shankland B

Double Helix Consulting, London, UK

OBJECTIVES: Although HTA is well established in healthcare systems like the England & Wales National Health Service (NHS), it is increasingly used more formally in developing countries such as Poland and Mexico. The objectives of this research were to understand the drivers of decision-making and future trends in these HTA systems in relation to market access for pharmaceuticals. **METHODS:** Secondary research and structured telephone interviews with 12 key stakeholders in Poland and Mexico was carried out. The research evaluated trends in the following aspects of the systems: impact of HTA in final reimbursement decisions, positioning of HTA in the healthcare system and future trends. A comparison of the impact of HTA in Mexico and Poland was then made on a rating scale devised to account for these influencing factors. **RESULTS:** HTA in Mexico is positioned within a highly decentralised healthcare system, although its Federal Cuadro Básico is important in determining price and access for pharmaceuticals. HTA appraisals although mostly conducted by IMSS (60% of reimbursement) are also used by the other reimbursing institutions. The Polish HTA body, AHTAPol, works closely with the reimbursement process at the central level, but its ultimate influence on price and reimbursement is moderate; the majority of respondents (n=8) regarded HTA as more of a negotiating tool, as decision-making balances multiple diverse interests. **CONCLUSIONS:** HTA is seen to impact the Polish system, despite being centralised to a lesser extent than Mexico, which has a decentralised health system and a significant private sector. In addition to HTA, historical development of the health care system, external influences and financial resources are equally important drivers of access decisions.

PHP37

CROSS-CONTINENTAL COMPARISON OF HTA EVOLUTION IN EMERGING MARKETS: BRAZIL, INDIA AND POLAND

Kirpekar S, Shankland B, Dummett H
Double Helix Consulting, London, UK

OBJECTIVES: Despite universal healthcare being the common motto, healthcare systems in developing economies around the world have developed to varying extents. HTA as a concept has evolved particularly in Western European markets to ensure equity and equality of healthcare provision. Understanding the status of HTA evolution and impact on reimbursement decisions is expected to have lessons to be learnt for countries like India where non-evolution of HTA is seen. **METHODS:** Secondary research to understand the reimbursement systems publicly available information about recent reimbursement decisions was done. Primary research involved discussions with decision makers in important reimbursement bodies. Eight in-depth interviews were conducted covering individuals from a variety of backgrounds. Information was collected under headings covering current drivers, historical influences, existing issues, reasons for evolution / non-evolution of HTA and expected changes. Data was analysed qualitatively to develop results. **RESULTS:** Broadly, HTA was seen to be non-evolved in India. Majority of the market being out-of-pocket is considered the key driver where both industry and doctors are thought to generally oppose any formal technology appraisals (n=6). At the other end of the spectrum, despite having a multi-payer reimbursement system, Brazil was seen to be using HTA as a tool for reimbursement decisions widely (n=6). Poland however, despite having a well-developed HTA system was seen to use HTA more as a negotiation tool than for reimbursement decisions (n=4). **CONCLUSIONS:** A tri-directional comparison of HTA systems and their involvement in the reimbursement system showed that the reasons behind the varying level of HTA influence can be attributed somewhat to the history of the healthcare systems. There are lessons to be learned for Poland, which is a centralised system from other centralised systems like England and for India from Brazil. In-depth research involving lessons from Brazil for India is warranted.

PHP38

HEALTH TECHNOLOGY ASSESSMENT APPLIED TO MEDICAL DEVICES IN LATIN AMERICA: WHAT MUST BE ASSESSED

Gimenes F[1], de O. Machado F[2], Quiroz ME[3]
[1]*Medtronic, Sao Paulo, SP, Brazil,* [2]*Medtronic, Doral, FL, USA,* [3]*Medtronic, Colonia Juarez, DF, México*

OBJECTIVES: Analyze the health technology assessment (HTA) scenario and process to Medical Devices (MD) in Latin American and discuss the appropriateness of the present process. **METHODS:** search in Latin American and Caribbean Health Sciences Literature (LILACS), PubMed, gray literature and internet search. **RESULTS:** MD and drugs differ from their concept to usage, therefore it is important to note that is not always possible to apply the same HTA processes to both categories. In the research, we found in Latin America 12 countries with significant HTA initiatives and the majority emerged in the past decade. In total, 4 countries with published economic evaluation guidelines, 17 HTA committees and groups, 6 ISPOR chapters, the Pan American Health Organization (PAHO) HTA initiative and Mercosur HT special group. The expertise with HTA applied to drugs seems to be higher than HTA applied to MD across Latin America and this was observed in appraisals published by the main HTA agencies. Important to note the almost non existence of specific HTA guidelines to MD among HTA agencies, groups and committees. **CONCLUSIONS:** The methodological validity should consider a broader source of evidence to evaluate the efficacy of certain MD or for certain clinical indications or settings. Patient and/or investigator blinding is impractical or impossible for many MD and most surgical procedures. Observational studies should be considered as a relevant source of data for HTA, often randomized clinical trials do not provide real life data and are not always feasible technically and ethically for devices. MD has a shorter life cycle and it is not compatible with HTA cycles which can vary from 6 months to 4 years for a sound assessment. HTA agencies, committees and groups in Latin America must recognize the medical devices specificities and its market dynamics and incorporate to existing guidelines a process adequate to this category.

PHP39

GAUGING THE ROLE OF HTA IN REIMBURSEMENT DECISION-MAKING ACROSS FIVE MARKETS IN LATIN AMERICA

Dummett H, Kirpekar S, Shankland B
Double Helix Consulting, London, UK

OBJECTIVES: HTA is at different stages of development across Latin America, from Brazil's highly developed system at one extreme to Venezuela at the other, despite the existence of substantial local expertise. This study attempts to explain these disparities. **METHODS:** A total of 20 HTA reviewers and academic health economists were interviewed across Brazil, Argentina, Mexico, Chile and Venezuela to understand the parameters of the HTA system, the importance of different stakeholders within the process and the decisions influenced by HTA. **RESULTS:** HTA systems within Latin America exist at all stages of the HTA development continuum, although they are better developed than in many other developing countries. At one end sits a multi-payer, universal health system Brazil in which demonstration of cost-effectiveness is considered highly important for central funding decisions. At the other extreme sit Chile and Venezuela in which no formal role for HTA yet exists, although the speed and direction of HTA development in these two countries is likely to differ. In between sits Argentina, where HTA capability is advanced but operating within a fragmented health system. **CONCLUSIONS:** HTA is developing rapidly within the markets surveyed suggesting that private actors would be rational to invest in local expertise. However, despite formalisation, cost-effectiveness may remain only one of many decision factors. Understanding the nuances of where HTA sits in the reimbursement system and how it is applied in practice in each market is essential for maximising favourable outcomes for suppliers and providers alike.

Health Care Use & Policy Studies – Patient Registries & Post-Marketing Studies

PHP40

PROMOTING EFFICIENCY OF AVAILABLE CAPACITY IN A FRAGMENTED HEALTH SYSTEM: PATIENTS WITH DIFFERENT HEALTH INSURANCE SCHEMES ATTENDED BY MOH, MEXICO 2006-2010

Gómez-Fraga S
Mexican Ministry of Health, México, D.F., México

OBJECTIVES: In order to implement strategies that promote an efficient use of public health services and grant more access opportunities to the population, irrespective of their insurance status, estimate the volume and type of hospital care services provided by the Ministry of Health (MoH) to patients who have social security or private health insurance. **METHODS:** The exercise was made though an analysis by ICD-10 of the Hospital Discharge Automated System, which concentrates hospital activity from over 600 hospitals belonging to MoH, between January 2006 and August 2010. Patients having a social security scheme (IMSS, ISSSTE, PEMEX, SEDENA y SEMAR) or private health insurance were analyzed. **RESULTS:** A total of 11.9 million of attentions were recorded in the analyzed period, 2.2 on average per year, of which, 40 thousand (1.7%) corresponded to patients who belong to a social security institution or private health insurance. Among the institutions of origin, IMSS led the list with 45% of the total, followed by ISSSTE with 26% and private insurances with 20%. By ICD-10 chapter, *Pregnancy, childbirth and puerperium (O00-O99)* was the most demanded, with 24.5% of the total attentions. In the analysis by state, about 50% of cases came from five to seven states; in 2010 the state of Jalisco led the list with 14.5% of the total, followed by the states of Tamaulipas and Mexico, with about 7% each. Considering all the analyzed period, the most common intervention was *Single spontaneous delivery* (O80), (41% in 2010). **CONCLUSIONS:** Quantifying the MoH health care demand coming from social and private insured population and its evolution will permit the definition of better exchange planning strategies and guarantee its appropriate financial compensation. Besides analyze the exchange volume and their characteristics; establishing fees and agreements is needed to implement reimbursement systems between public sector institutions.

PHP41

MONITORING OF HPV VACCINATION EFFECTIVENESS WITHIN EUROPEAN UNION

Bielik J[1], Marušáková E[2], Glogowski C[3]
[1]*Trencin University, Trencin, Slovak Republic,* [2]*GlaxoSmithKline Slovakia, Bratislava, Slovak Republic,* [3]*GSK Commercial Sp. z o.o., Warsaw, Poland*

OBJECTIVES: The study evaluated recent data related to real impact measurement of HPV prevention or cervical oncologic diseases related to HPV infection available from publications in the EU member states. The main idea was to find out whether there is any prerequisite to evaluate the effectiveness of the preventive HPV vaccination based on the existing data and standard approaches within the EU in the future in an observational study. The second goal was to define these prerequisites in order to use them for "good practice." **METHODS:** The systematic review of PUBMED, EMBASE and CENTRAL extended to official websites of public health institutions officially published data was used. The goal was to find all papers on HPV/cervical cancer epidemiology, screening, and prevention published in years 2009- 2011, related to EU member states. Only studies related to countries from the European Union were taken into account. All relevant data were extracted and compared. Population size was derived from Eurostat. Based on this data we created the principles for evaluation of HPV screening and monitoring of quality indicators. **RESULTS:** Out of 27 EU countries, only 2 countries (Denmark and United

Kingdom) received the highest value for screening and monitoring of quality indicators. The data retrieved from their standard approaches in screening could be a baseline for the comparison between the modelling of effectiveness data and real data. New data required were defined as the condition to formulate an optimal design for valued surveillance of the effectiveness of HPV vaccination in general population. **CONCLUSIONS:** Some harmonization of screening and monitoring of active surveillance would be necessary within the EU member states in order to increase the reliability of real world data effectiveness. The proposal for defined criteria is needed for valuable evaluation the real effectiveness of HPV vaccination in general population in prospective studies.

Health Care Use & Policy Studies – Population Health

PHP42

CALIDAD DE VIDA RELACIONADA CON LA SALUD Y APOYO SOCIAL EN ESTUDIANTES DE FARMACIA EN VENEZUELA

Parra G, Bastardo Y
Universidad Central de Venezuela, Caracas, Venezuela

OBJECTIVOS: Describir la calidad de vida relacionada con la salud (CVRS) de los estudiantes de farmacia y explorar su relación con el apoyo social percibido (AS). **METODOLOGÍAS:** Una muestra al azar, de 71 estudiantes de Farmacia de la Universidad Central de Venezuela se entrevistó usando un cuestionario escrito. La CVRS fue determinada usando los cuestionarios de salud: Forma Corta 36 (SF-36) y EQ-5D. El AS se evaluó usando la Lista de Evaluación de Apoyo Interpersonal (ISEL). Estadísticos descriptivos fueron calculados para todas las variables. La asociación entre CVRS y AS se estimó mediante coeficiente de correlación de Pearson. **RESULTADOS:** La muestra estuvo formada por 53 mujeres y 18 hombres con edad promedio de 19.31 años. Los promedios obtenidos para el ISEL fueron: Emocional=76.97, Información=80.32 y Tangible=78.13. Los promedios obtenidos para el SF-36 fueron: Función Física=90.34, Rol Físico=57.75, Dolor Corporal=70.28, Salud General=68.59, Vitalidad=49.85, Función Social=67.96, Rol Emocional=50.70 y Salud Mental=62.93. Los valores obtenidos para el EQ-5D fueron: Movilidad: 87.7% sin problemas y 11.3% tiene problemas moderados; Cuidado Personal: 90.1% sin problemas y 9.9% tiene problemas moderados; Actividades Cotidianas: 64.8% sin problemas y 35.2% tiene problemas moderados; Dolor: 52.1% sin problemas y 47.9% tiene problemas moderados; Ansiedad: 53.5% sin problemas, 40.8% tienen problemas moderados y 5.6% problemas severos. Para la EQ-VAS se obtuvo un promedio de 75.48. La EQ-VAS se encontró estar asociada en forma positiva como todas las dimensiones del ISEL. **CONCLUSIONES:** Pese a limitaciones en generalizabilidad de los resultados y diseño transversal, el estudio encontró que la CVRS de los estudiantes de farmacia es buena. Los principales problemas detectados corresponden a Rol Emocional, Vitalidad, Ansiedad y Dolor. Esto resalta necesidades de atención en esta población de jóvenes universitarios. El apoyo psicosocial puede ser una opción de atención.

PHP43

EXPLORING SOCIAL DETERMINANTS OF THE HEALTH OF INTERNATIONAL IMMIGRANTS IN CHILE: THE GLOBAL HEALTH STATUS INDEX

Cabieses B, Tunstall H, Pickett K, Gutacker N, Espinoza M
University of York, York, UK

OBJECTIVES: Variations in immigrants' health-status have been observed in the past, depending on the indicator considered. This study analyzes the association between a new linear variable "Global Health-Status Index" (GHSI) generated from Exploratory Factor Analysis (EFA), and different social determinants of health (SDH) in the international immigrant population (IIP) in Chile. **METHODS:** Cross-sectional Chilean survey (CASEN-2006). From 268,873 participants, one percent were immigrants (n=1.877). Main-outcome-measure: GHSI, constructed using EFA (range=-0.82-+4.25; the higher the index, the worse the health-status). This was a linear combination of: 1) number of medical consultations, 2) number of mental consultations and 3) number of other healthcare consultations. Before EFA, Reliability-coefficient (cronbach's-alpha=0.74), constructs-validity/sampling-adequacy (Kaiser–Mayer–Olkin=0.56, Bartlett's-Sphericity-Test p-value<0.001), Minimum-loadings (above=0.30) and loadings-uniqueness (below=0.80) were assessed. They all suggested EFA was moderately suitable in the IIP. Explanatory variables: SDH: demographics (age/sex/marital-status/geographic-location), socioeconomic-status (low/medium/high), and material standards (overcrowding/sanitary-conditions/housing-quality). Analysis: Given the skewness of GHSI, weighted Generalized Linear Models (with log-link and gamma-variance function) were estimated (STATA-10.0). **RESULTS:** Age showed a positive association with GHSI in the IIP [coeff.=0.02(SE=0.003)]. Female immigrants showed a lower chance of impairing their health status [coeff.=-0.31(SE=0.07)] compared to men and this association was consistent across different SDH. Immigrants in rural settings were more likely to have a poor global health-status [coeff.=1.00(SE=0.11)]. Immigrants belonging to a minority ethnic group had a higher chance of experiencing health impairment [coeff.=1.32(SE=1.06)]. EFA was a valuable first-step towards a combined measure of health status among immigrants. GLM with log-link and gamma-variance function have been used in the past and prove useful to deal with highly skewed outcomes without requiring transformation-retransformation techniques. **CONCLUSIONS:** The Global Health-Status Index is a useful indicator of health status to study different SDH in the IIP. Demographic determinants were strongly associated with GHSI, even after controlling for socioeconomic and material SDH, and should be further addressed in Chile.

Health Care Use & Policy Studies – Prescribing Behavior & Treatment Guidelines

PHP44

CHARACTERISTICS OF PATIENTS TREATED FOR FIBROMYALGIA IN PUERTO RICO AND THE UNITED STATES: BASELINE FINDINGS OF THE REFLECTIONS STUDY (REAL WORLD EXAMINATION OF FIBROMYALGIA: LONGITUDINAL EVALUATION OF COSTS AND TREATMENTS)

Vazquez-Suarez JE[1], Able SL[2], Gatz JL[2], Robinson RL[2]
[1]*Eli Lilly and Company, San Juan, PR, USA,* [2]*Eli Lilly and Company, Indianapolis, IN, USA*

OBJECTIVES: This secondary analysis of REFLECTIONS, a prospective observational study of patients initiating on medications for fibromyalgia, compared patient, clinical, and treatment characteristics between United States (US) and Puerto Rico (PR). **METHODS:** Baseline data were collected from July 2008 through May 2010 via physician surveys, office visit forms, and telephone interviews in 58 care settings in the US and PR. **RESULTS:** Study patients included 1539 (90.5%) treated in the US and 161 (9.5%) in PR. Patient characteristics differed for mean age in years (53.8 PR vs. 50.0 US, p<.001), body mass index (30.4 PR vs. 31.4 US, p=.049) and race/ethnicity (98.1% Hispanic PR vs. 91.4% Caucasian US). Patients in PR versus the US were more likely to have a lower category of economic status and less likely to be privately insured. PR patients had more total concomitant diseases including back pain and depression (all p<.001). Times to first symptom, diagnosis, and prescription were shorter in PR than US (all p<.01). Patients in PR also reported more severe pain, pain interference, and greater disease impact via the Brief Pain Inventory and the Fibromyalgia Impact Questionnaire (all p<0.001). Treatment patterns also differed with US patients more likely to be prescribed opioids (5.6% PR vs. 26.2% US) and exercise (81.4% PR vs. 90.3% US), but less likely to be prescribed NSAIDS (55.9% PR vs. 23.6% US), (all p<.001). Despite the strong evidence for efficacy, cognitive behavioral therapy was prescribed infrequently (3.1% PR vs. 4.7% US, p=0.36). **CONCLUSIONS:** To the best of our knowledge, this is the first study to describe patient and treatment characteristics for patients with fibromyalgia in PR. Patient, clinical, and treatment characteristics of REFLECTIONS patients in PR differed in several respects from the US cohort. It is unknown whether these findings are generalizable to all fibromyalgia patients in the US and PR.

PHP46

PRÁCTICA CLÍNICA INSTITUCIONAL EN EL TRATAMIENTO DE LA DIABETES MELLITUS TIPO 2 EN MÉXICO

Juarez-Garcia A[1], Vargas-Valencia J[2], Martinez-Rivera G[1], Sotelo-Guzmán M[2], Elias-López JI[1], Zamora-Barron M[1], Rangel S[1]
[1]*Bristol-Myers Squibb, México City, D.F., México,* [2]*Econopharma Consulting S.A. de C.V., México, D.F., México*

OBJECTIVOS: Realizar un análisis de la práctica médica institucional en el tratamiento de la diabetes mellitus tipo 2 (DM2) en México. **METODOLOGÍAS:** Estudio transversal sobre los esquemas de manejo de la DM2, la recolección se realizó mediante un cuestionario estructurado en entrevista directa a 54 médicos en instituciones de salud pública (56% IMSS, 15% ISSSTE, 4% PEMEX y 26% SSA), de los cuales 37% son médico generales, 4% familiares, 15% endocrinólogos y 44% internistas, con 14.4 años IC95%(10.7-18.3) de experiencia. El 41% atiende un volumen ≤60 pacientes/año, 30%≤100 pacientes/año y el 29% >100 pacientes/año. Se reporta estadística descriptiva de los tratamientos y características poblacionales. **RESULTADOS:** Al diagnóstico, la edad promedio es de 47.7 años IC95%(43.7-51.7), 43% hombres y 57% mujeres. El 56% presenta IMC>25, 36% IMC>30, 53% hipertensión y 28% tabaquismo. Valores promedio de glucosa sérica en ayuno 205.8mg/dL, tolerancia oral a la glucosa 233.9mg/dl, Hb1Ac 9.3%, glucosa postprandial 242mg/dL, microalbuminuria 161.7mg/dL, LDL 162.5mg/dL, HDL 30mg/dL, triglicéridos 280mg/dL, colesterol 253.3md/dL y creatinina sérica 1.7mg/dL. Con un tiempo de evolución <1año 11%, de 3-5 años el 45% y >5 años el 44%. El 48% de los pacientes no presenta complicaciones, 25.8% una complicación, 13.1% dos complicaciones y 13.1% ≥3 complicaciones. Se observa una preponderancia de la monoterapia en el 86% de los pacientes con niveles <7% HbA_{1c}, principalmente metformina en el 68%; con respecto al uso de insulina, el 62% de los médicos consideran niveles ≥8.75% de HbA1c IC95%(7.92-9.58%) como criterio para indicar su uso. **CONCLUSIONES:** El diagnóstico de la diabetes en México suele ser tardío. De acuerdo a lo reportado por los médicos el 89% de sus pacientes presentan una evolución de más de 3 años y al menos una complicación el 52% de los casos. Además, el estudio sugiere una relación importante entre los niveles de HBA1c y la elección del tratamiento farmacológico.

Health Care Use & Policy Studies – Regulation Of Health Care Sector

PHP47

AVALIAÇÃO DO MERCADO DE ANTIMICROBIANOS NO BRASIL: PASSO PARA IMPLANTAÇÃO DO MONITORAMENTO E CONTROLE SANITÁRIO EM ESTABELECIMENTOS FARMACÊUTICOS

Mota DM, Araújo MAM, Santos AEG, Cunha TRP, Silva SF, Bovi RF, Alaver RT, Albo GC, Cunha JAF, Oliveira MG, Baptista FJDO, Bernardo PJB
Agência Nacional de Vigilância Sanitária, Brasília, DF, Brazil

OBJETIVOS: Avaliar o mercado de antimicrobianos no Brasil, em 2009, subsidiando a Agência Nacional de Vigilância Sanitária na implantação do monitoramento e controle do consumo desses medicamentos em farmácias e drogarias privadas. **MÉTODOS:** Estudo descritivo que congrega as áreas do conhecimento em vigilância sanitária e economia do medicamento. A seleção dos antimicrobianos foi definida a partir da lista anexa da norma regulatória (RDC n° 44/2010, atualizada pela RDC n° 61/2010). Essa norma determinou o controle sanitário por meio da retenção de receita médica nos estabelecimentos farmacêuticos e escrituração eletrônica no Sistema Nacional de Gerenciamento de Produtos Controlados (SNGPC). No Brasil,

existia uma cultura de dispensação dos antimicrobianos sob prescrição médica sem a apresentação de receita médica. Foi analisado o total e quantidade de apresentações farmacêuticas comercializadas, participação dos antimicrobianos no mercado total de medicamentos, os antimicrobianos mais vendidos no país e o custo habitante dia (CHD). **RESULTADOS:** Na norma foram definidos 119 antimicrobianos sob prescrição médica, resultando em mais de duas mil apresentações farmacêuticas vendidas no país, das quais 251 são de uso restrito aos hospitais. A quantidade comercializada ultrapassou mais de 270 milhões de unidades físicas. A participação do mercado de antimicrobianos, em termos de quantidades vendidas, foi de 9,1%. A amoxicilina (14,6%), azitromicina (8,8%) e cefalexina (7,6%) foram os antimicrobianos mais vendidos no país. O CHD foi de R$ 36,25, ou seja, para cada 1000 habitantes foram gastos de R$ 36,25 em antimicrobianos diariamente. **CONCLUSÕES:** A análise do mercado de antimicrobianos no país sinaliza para um grande volume de dados a serem escriturados no SNGPC, cuja principal finalidade é o monitoramento sanitário e farmacoepidemiológico do consumo desses medicamentos no Brasil. Essa estratégia visa ao fortalecimento da política de medicamentos e assistência farmacêutica no país, no que diz respeito ao uso seguro e racional de medicamentos no país.

PHP48

OS MOTIVOS QUE LEVAM O JUDICIÁRIO A DETERMINAR QUE OS PLANOS DE SAÚDE FORNEÇAM MEDICAÇÃO ORAL EM ONCOLOGIA

Stefani SD[1], Fonseca JRL[2]
[1]*UNIMED, Porto Alegre, RS, Brazil,* [2]*UNIDAS, Brasilia, DF, Brazil*

OBJETIVOS: Levantar as principais causas e motivos que justificaram o deferimento das liminares uma vez que, no Brasil, o fornecimento de medicação oral oncológica (QT oral) não constitui obrigatoriedade para os planos de saúde. No entanto, o Poder Judiciário tem sido acionado para demandas para o fornecimento desse tipo de terapia. **MÉTODOS:** A partir dos levantamentos realizados em decisões judiciais proferidas nos Estados de SP, MG e RJ, foram selecionadas as motivações que levaram o Magistrado à determinar o fornecimento de QT oral. Os fundamentos de cada decisão foram organizados e estratificados para análise qualitativa. **RESULTADOS:** Um total de 71 ações envolveram QT oral. Todas obtiveram (100%) de ganho de causa em favor dos pacientes. Foram identificados mais que uma justificativa em alguns casos, conforme descrito: 32 casos de deferimento por cláusulas abusivas; 07 casos onde os serviços de saúde não apresentaram cobertura securitária, incluindo drogas inovadora utilizadas anteriormente com sucesso em tratamento oncológico; 13 casos por restringir cobertura as obrigações do Rol ANS; 23 casos para Assegurar a continuidade de vida e saúde; 03 casos por descabimento e/ou interferencia de empresa de serviço na conduta médica; 01 caso de ilegitimidade passiva da operadora; 11 casos por aplicação de Jurisprudência STJ pelo fato dos Quimioterapicos, mesmo oral, fazer parte do tratamento; 01 caso por Inexistência que exclui expressamente a medicação requerida; 1 caso por Exclusão que contraria a função social. **CONCLUSÕES:** Quando acionado, o judiciário determina fornecimento de QT oral em todos casos, mesmo que os instrumentos legais ou contratos das operadoras de saúde tentem limitar tal prática. É necessária reflexão no processo de tomada de decisão dos gestores sobre esse tema, bem como a urgência de implementação de uma política racional de fornecimento QT oral, que evite instrumento judicial.

Health Care Use & Policy Studies – Risk Sharing/Performance-Based Agreements

PHP49

DEVELOPING RISK SHARING ARRANGEMENTS – POTENTIAL FOR BRAZIL AND IMPLICATIONS

Shirk RC[1], Godman B[2]
[1]*Fiocruz, Rio de Janeiro, RJ, Brazil,* [2]*Karolinska Institutet, Stockholm, Sweden*

The number of risk sharing arrangements between pharmaceutical companies, regional and national governments has been growing in recent years as authorities strive to enhance efficiency given the uncertainty of outcomes and appreciable resource implications with many new drugs. These arrangements are just being considered in Brazil. **OBJECTIVES:** Analyse risk sharing arrangements in other countries including concerns to develop a basis for future activities in Brazil. **METHODS:** Joint activities are planned including a) literature search of published papers in Europe, US, and Australia using key words including *risk sharing, coverage with evidence,price volume agreements, value-based pricing, pharmaceuticals, no cure no pay, pay back schemes, health impact* guaranteeto document existing schemes and definitions including concerns, b) an assessment of the potential legal approaches in Brazil (if different to other countries), and c) an assessment of the potential implications of such agreements to Brazilian public health/ Ministry of Health acknowledging growing resource pressures and the need to fund new products approved by the Ministry. **RESULTS:** The initial research uncovered potential definitions as well as an appreciable number of risk sharing arrangements in operation across Canada, US, Europe and Australia. These are currently being reviewed for applicability to Brazil. The findings will be discussed in more detail during the presentation as the search progresses. **CONCLUSIONS:** There is an appreciable number of risk sharing arrangements globally. However, there is confusion regarding their terminology, legal status, administration costs, benefits andransparency. These issues will be discussed in relation to Brazil to help stimulate the debate among Latin American countries and whether they should develop such schemes.

Health Care Use & Policy Studies – Conceptual Papers

PHP50

THE VALUATION OF END-OF-LIFE HEALTH GAINS

Cairns J
London School of Hygiene and Tropical Medicine, London, UK

There has been a tradition in health economics to regard all QALYs as being of the same significance and value. One example of this is the practice in economic evaluation when estimating incremental cost-effectiveness of adding together the QALYs of the entire patient group and ignoring that some patients accrue more QALYs than others and their identity. Another example concerns the use of a common cost-effectiveness threshold when making a series of recommendations across a range of clinical areas. A significant departure from this conventional approach has recently been introduced by the National Institute for Health and Clinical Excellence (NICE) in England when Appraisal Committees were instructed to treat life-extending, end of life treatments differently from other health technologies. This paper first discusses the criteria that must be fulfilled in order to qualify as an end-of-life treatment. It then reviews the ways the instruction to weight end-of-life health gains could be and has been interpreted. A key issue at the heart of the challenges of implementing this policy is whether it is the entire QALY gain or just the life extension that is to be weighted more highly. Another issue is how inappropriate double-counting of health benefits is to be avoided. The experience to date of implementing this policy with respect to about thirty drug treatments is reviewed and the implied valuation of end-of-life health gains is identified. The paper closes with an appraisal of the success of this policy innovation and discussion as to how it might be further developed and refined.

PHP51

PATIENT-CENTERED CARE: CHALLENGES FOR BRAZIL, LESSONS FOR UNITED STATES

Freitas EL, Poplavska E
University of Minnesota, Minneapolis, MN, USA

Patient-centered care is a key factor to ensure quality in the healthcare system. The USA has been struggling for a long time with its (in)ability to translate the scientific knowledge into practice and to apply the abundant technology safely and appropriately. While main issues discussed now by the USA refer to the shortage of primary care providers and needed reform that ensures appropriate reward for this practice, certainly the Brazilian Unified Health System have some experience to share, after 20 years focusing on the primary care as the chief of its healthcare system. The objective of this concept paper is to critically analyze the issues emerging from the literature related to the patient-centered care in both countries. The Patient Centered Medical Home (PCMH) in the USA and the Family Health Strategy (FHS) in Brazil claim equally to be patient-centered models of practice. However, our analysis revealed different patterns of 'patient-centeredness'. Most of the discussions around PCMH address issues of payment and organization of the healthcare providers' team that is heavily influenced by the historical structure of healthcare system; but few address, in sufficient deepness, how to improve the service that is ultimately being delivered to the patient. The FHS, by its turn, nowadays is deeply involved in discussions about humanization of care and how to articulate community participation in the policy development of healthcare strategies. In conclusion, political and budget issues are relevant in both countries, but the focus must remain on patient autonomy and participation as a way to expand the quality of a health care system truly committed to the social welfare. Furthermore, each society poses unique health care challenges. In confronting this complex and sensitive issue, it is essential to reflect on the experiences of both countries and to use the lessons learned for optimizing patient care.

Indivdual's Health – Cost Studies

PIH1

IMPACTO PRESUPUESTAL DEL USO DE LEVONORGESTREL-UIS FRENTE A OTROS TRATAMIENTOS EN MENORRAGIA IDIOPATICA EN COLOMBIA

Romero M[1], Karpf E[1], Sanabria M[1], Alvis N[2]
[1]*Fundación Salutia, Bogotá, Colombia,* [2]*Universidad de Cartagena, Cartagena de Indias, Bolívar, Colombia*

OBJECTIVOS: Realizar un análisis de impacto presupuestal del uso de Levonorgestrel-UIS (LNG-UIS) como primera opción de tratamiento en Menorragia idiopática en Colombia. **METODOLOGÍAS:** Se realizó un análisis de impacto presupuestal del uso de LNG-UIS para la población de mujeres en edad fértil para Colombia con cortes anuales. La prevalencia de la enfermedad fue obtenida de estudios clínicos. Se utilizó como base la población reportada por el Departamento Nacional de Estadística para 2010. La distribución de uso actual de LNG-UIS, Anticonceptivo Oral Combinado, Acido Tranexámico, Acido Mefenámico y Naproxeno fue establecida mediante una encuesta y posterior comité de expertos. Se modeló que las preferencias por LNG-UIS aumentarían a un 50% en los primeros 2 años y 70% en los años siguientes. Para el cálculo de costos se utilizó un modelo de Markov basado en la historia natural de la enfermedad. Los datos fueron estimados en pesos colombianos (COP) y convertidos a dólares americanos 2010 (USD) según tasa representativa media del mercado. **RESULTADOS:** Los casos esperados en un año de Menorragia idiopática serían 61,334 en mujeres en edad fértil y según los cambios en intención de uso de LNG-UIS definidos para el primer año del análisis se tendría un mayor costo de 6,4 millones de USD. A partir del segundo año el ahorro sería de 8,8 millones de USD lo que significaría un ahorro acumulado de 2,4 millones de USD. El ahorro sigue incrementándose a partir del segundo año a pesar de estimarse el incremento de población anualmente. El análisis del ahorro acumulado al final del 5 año sería 37,5 millones de USD. **CONCLUSIONES:** El uso de LNG-UIS como primera opción de tratamiento en mujeres con menorragia idiopática generaría ahorro para el Sistema General de Seguridad Social en Salud colombiano en un horizonte de análisis de cinco años.

PIH2
ADDRESSING CHILDHOOD OBESITY IN MEXICO: SAVINGS ON HEALTH CARE EXPENDITURES FROM REGULATING FOOD AND BEVERAGE SALES IN BASIC EDUCATION SCHOOLS

Guajardo-Barron VJ[1], Gutierrez-Delgado MC[1], Rivera-Peña G[2]
[1]Mexican Ministry of Health, México, D.F., México, [2]Economic Analysis Unit, México, D.F., México

OBJECTIVES: Estimate potential direct savings for the Mexican Healthcare System generated by the operation of the "Technical Guidelines for distribution of food and beverages in establishments of basic education" targeting population of 6 to 14 years of age. **METHODS:** The authors use the micro-simulation model "Chronic Disease Prevention (CDP)" developed by the OECD-WHO for projecting health gains and costs of treatment in a period of 100 years. The model was adjusted to accommodate the range of ages stated in the Guidelines and uses information of incidence, prevalence, mortality, population at risk, annual unit costs and relative risk of selected chronic diseases (diabetes mellitus type 2, hypertension, cardio- and cerebro-vascular, hypercholesterolemia) attributable to obesity as well as the treatment of obesity as disease itself for the Mexican context. Sensitivity analyses were developed for most variables used in the model. **RESULTS:** Under the base case scenario present value of potential savings in total spending on medical care associated with the implementation of the Guidelines amount to USD$1,052.2 million in 2008. Most savings are derived from averted cases of hypertension (32.7%), obesity-overweight (28.6%) and diabetes mellitus type II (17.8%). Results are robust to changes in all parameters analyzed. Amounts obtained are an underestimation of potential savings as neither expensive complications as renal failure nor other chronic diseases attributable to obesity as arthritis, colorectal or breast cancer were included. **CONCLUSIONS:** The Guidelines, developed by both Ministry of Public Education and Ministry of Health, represent a good example of cooperation among different sectors to solve a complex public health problem. Results shows the importance of implementing preventive interventions aimed at reducing the prevalence of chronic diseases related to poor eating habits, inadequate physical activity and obesity in Mexico. The implementation of the Guidelines involves significant direct savings that can be assigned to other health needs of the Mexican population.

PIH3
RESOURCE USE AND ASSOCIATED COSTS FOR THE TREATMENT OF HEAVY MENSTRUAL BLEEDING WITH LEVONORGESTREL RELEASING INTRAUTERINE SYSTEM (LNG-IUS) VERSUS HYSTERECTOMY: THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM (SUS) PERSPECTIVE

Bahamondes L[1], Bahamondes V[1], Schiola A[2], Silva AP[3], Santoni NB[3], Moura M[4], Salem J[4], Clarck L[4], Teich V[4]
[1]University of Campinas, Campinas, SP, Brazil, [2]Bayer de México, S.A. de C.V., México, D.F, México, [3]Bayer Brazil, São Paulo, SP, Brazil, [4]MedInsight Evidências, São Paulo, SP, Brazil

OBJECTIVES: To describe the resource utilization and the costs related to heavy menstrual bleeding (HMB) control with either an LNG-IUS or hysterectomy in the Brazilian Public Health System (SUS) on patients treated at the Department of Obstetrics and Gynecology, School of Medical Sciences, University of Campinas, Brazil. **METHODS:** We performed an observational retrospective descriptive study with costs evaluation and budgetary impact calculation from data extracted from medical files of patients diagnosed with HMB treated either with the LNG-IUS or hysterectomy. The measured outcomes were HMB control, LNG-IUS induced complications (expulsion, uterine perforation, pelvic inflammatory disease), LNG-IUS continuation rate and hospital costs after one year, as well as, the budgetary impact of the use of LNG-IUS in the treatment of HMB vs. hysterectomy. **RESULTS:** Two hundred sixty-seven medical files were initially retrieved for analysis. A total of 246 patients were included in this study, 122 received the LNG-IUS and 124 were treated with hysterectomy. The mean age was 39.7 years in the LNG-IUS group and 47.9 in the surgery group. Mean duration of HMB in the hysterectomy group was 3.2 years, twice that of the LNG-IUS group (1.5 years) ($p<0.01$). Of the patients treated with LNG-IUS, 88.7% maintained the device for over one year and 83.1% had success in bleeding control with this method. Fourteen patients had to have the LNG-IUS removed prior to 12 months; however, only 1.6% because of failure in bleeding control. Costs for the LNG-IUS insertion in a one-year time horizon were R$ 762.64 versus R$ 870.03 for the hysterectomy procedure. **CONCLUSIONS:** When applied to the eligible population in SUS the budgetary impact of the LNG-IUS adoption was an economy of almost R$ 3.6 million.

PIH4
ANALISIS DE COSTO-EFECTIVIDAD DEL USO DE LEVONORGESTREL-UIS FRENTE A OTROS TRATAMIENTOS EN MENORRAGIA IDIOPATICA

Romero M[1], Arango C[1], Espinel F[2], Karpf F[1], Sanabria M[1], Alvis N[3]
[1]Fundación Salutia, Bogotá, Colombia, [2]Clínica de la Mujer, Bogotá, Colombia, [3]Universidad de Cartagena, Cartagena de Indias, Bolívar, Colombia

OBJECTIVOS: Establecer la Costo-efectividad de levonorgestrel-UIS (LNG-UIS) en el tratamiento de Menorragia Idiopática comparado con otras opciones de tratamiento (Anticonceptivo Oral Combinado, Acido Tranexámico, Acido Mefenámico y Naproxeno). **METODOLOGÍAS:** Se realizo un análisis de costo-efectividad desde la perspectiva del tercero pagador evaluando como desenlace el tiempo libre de sintomatologías ganado y el número de histerectomías evitadas. Las probabilidades de transición fueron obtenidas de estudios clínicos. Se tomaron los costos directos de atención a precios del 2010. No se incluyó la Ablación endometrial por no ser de uso en Colombia Se aplico un descuento del 3% anual para costos y desenlaces. Se realizó un análisis de sensibilidad tipo Montecarlo con 2000 iteraciones y un análisis univariado tipo tornado. **RESULTADOS:** Para una cohorte hipotética de 100 mujeres y un horizonte temporal de 5 años el costo del brazo con LNG-UIS fue de 100,993 USD frente a 116,726 USD, 127,513 USD, 103,497 y 125,330 USD (Anticonceptivo Oral Combinado, Acido Tranexámico, Acido Mefenámico y Naproxeno respectivamente). Con LNG-UIS se lograron 5.413 meses sin sintomatología frente a 5.110, 4.975, 5.028 y 4791 respectivamente. Con LNG-UIS se evitaron, 77 Histerectomías frente a 58, 74,75 Y 65 respectivamente. LNG-UIS fue dominante frente a los demás comparadores para los desenlaces analizados. El análisis de sensibilidad tipo Montecarlo mantuvo dominancia del LNG-UIS en más del 99%. **CONCLUSIONES:** El uso de LNG-UIS como primera opción de tratamiento en mujeres con menorragia idiopática es la mejor alternativa por cuanto es menos costoso y más efectiva desde la perspectiva del tercero pagador en Colombia.

PIH5
REPLACING MMR BY MMRV IN MEXICO: ASSESSEMENT OF COST-EFFECTIVENESS BASED ON A DYNAMIC TRANSMISSION MODEL

Ouwens M[1], Macias M[2], Mascareñas De Los Santos AH[3], Gomez JA[4], Sauboin C[5], Carreño Manjarrez R[6]
[1]Mapi Values Netherlands, Houten, The Netherlands, [2]Instituto Nacional de Pediatría, Pediatric Infectious Diseases, México, D.F., México, [3]Servicios médicos de la Universidad Autónoma, Monterrey -Nuevo León, México, [4]GlaxoSmithKline, Victoria, Buenos Aires, Argentina, [5]GlaxoSmithKline Biologicals, Wavre, Belgium, [6]GlaxoSmithKline, México, D.F. , México

OBJECTIVES: To predict the cost-effectiveness of vaccination with measles, mumps, rubella, and varicella (MMRV) vs MMR in Mexico. **METHODS:** A dynamic mathematical model was used to reproduce the age-related incidence of varicella and zoster. The impact of introducing varicella vaccination was predicted at population-level including costs and quality of life. Empirical age-specific contact rates between individuals were used. Vaccine efficacy against varicella was assumed to be 95% after two doses (1y and 6y). We assessed the impact of vaccination in a base-case (coverage dose1: 90%; dose2: 80%) and in an optimal scenario (higher coverage dose1:95%; dose2:90% and catch-up programme); and the cost-effectiveness of replacing MMR with MMRV using 5% discount rates for benefits and costs. **RESULTS:** In the long-term, MMRV vaccination is predicted to result in a ~90% decrease in varicella incidence (with short-term epidemics due to rebound effect) and a ~90% decrease in zoster cases (with a temporary increase due to the assumption on exogenous boosting). At 1, 5, 30, and 80 years, MMRV versus MMR is predicted to result in: - more QALYs saved (31, 209, 925, and 1306); - more complications avoided (2, 6, 132, 1864); and - less deaths (0.15, 1.09, 8.39, 28.95). Despite increased vaccine costs vs MMR, MMRV was cost saving at all time points in terms of GP/outpatient, hospital, indirect, and total ($7.9, $56.5, $226.9, and $331.2 million, respectively) costs. Cost-effectiveness planes for direct and total costs indicate that MMRV would provide more QALYs than MMR, and is cost saving. These results are for the base-case scenario. For optimal scenario, results were similar or even better. **CONCLUSIONS:** MMRV vaccination should result in significant reduction in varicella and zoster cases in the long-term. We predict the replacement of MMR by MMRV to be dominant under both scenarios.

Infection – Clinical Outcomes Studies

PIN1
THE EPIDEMIOLOGIC BURDEN OF HEPATITIS C VIRUS INFECTION IN LATIN AMERICA

Szabo SM[1], Donato BM[2], Yuan Y[3], Bibby M[1], Jimenez-Mendez R[4], Levy AR[1]
[1]Oxford Outcomes Ltd., Vancouver, BC, Canada, [2]Bristol-Myers Squibb, Wallingford, CT, USA, [3]Bristol-Myers Squibb, Plainsboro, NJ, USA, [4]University of British Columbia, Vancouver, BC, Canada

OBJECTIVES: Chronic infection with hepatitis C virus (HCV) is a major and growing public health concern in many, if not all, Latin American countries. With more efficacious therapies becoming available, decision-makers require accurate estimates of disease prevalence to assess the cost-benefit ratio of new treatments for HCV infection. These estimates are challenging to derive because HCV infection often remains asymptomatic – and therefore undetected – until the liver has been seriously damaged. The objective of the study was to synthesize estimates of the epidemiologic burden of HCV from Latin America. **METHODS:** A systematic review was conducted in Medline and EMBASE by two reviewers to identify population-based estimates of HCV prevalence from Argentina, Brazil, Colombia, Mexico, Peru, and Venezuela since 2000. Studies were only included if they were considered methodologically adequate, and randomly sampled representative members of the general population. Counts and rates of positive HCV tests from national blood bank networks were also synthesized. **RESULTS:** Only one methodologically adequate Latin American population-based survey, from Mexico, was identified; the estimated HCV prevalence was 1.4% (1.1%-1.6%). Estimates of HCV prevalence among blood donors were: 0.66% (Argentina, 2008), 0.53% (Brazil, 2007), 0.57% (Colombia, 2006), 0.66% (Mexico, 2007), 0.81% (Peru, 2007), and 0.37% (Venezuela, 2005). **CONCLUSIONS:** Based on the review, Mexico is the only Latin American country with robust estimates of HCV prevalence; the potential societal burden is enormous as about 1.5% of the population is infected. Rates from blood donors underestimate true HCV prevalence; and the differences between population-based and blood donor estimates for Mexico help frame the extent of that underestimate. These population-based prevalence estimates, and the prevalence estimates from blood donors, may be useful for inclusion in disease models. Discrepancies between estimates from the different sources underscore the need for methodologically-rigorous epidemiologic studies to maximally inform decision-makers in Latin America.

Infection – Cost Studies

PIN2
FACING CRITICAL HEALTH EVENTS: ECONOMIC IMPACT OF AH1N1 FLU EPIDEMIC IN THE MEXICAN HEALTH SECTOR, 2009-2010

Gutierrez-Delgado C, Gómez-Fraga S
Mexican Ministry of Health, México, D.F., México

OBJECTIVES: Analyze the economic impact of the A-H1N1 flu epidemic for the health sector in Mexico in the 2009-2010 period, that resulted in the first pandemic of the XXI century, in order to plan the resources provision and review policies aimed to deal with similar future events. **METHODS:** The exercise had several stages. First, a collect of the expenditures incurred by the health sector at federal level between April 2009 and August 2010 was made. Second, the collected information was classified into two areas of analysis: a) health care expenditures, and b) additional costs from purchasing and application of vaccines, medical equipment, drugs and health products, federal support to states, and national media campaigns. Third, health care expenditure and expenditure by area of analysis was estimated by aggregating all costs. **RESULTS:** Total federal expenditure related to addressing the epidemic in the health sector was estimated in USD$ 733.3 million, 32% linked to health care and 93.7% exercised in 2009, corresponding to 11.2% of the total health expenditure budget for this year. This expenditure involved medical attention of 368 thousands patients, purchasing and application of 6.8 million of anti-flu seasonal vaccines and 30 million of anti-AH1N1flu vaccines. For health care, a total expenditure of USD$ 216.7 million was estimated, 80% exercised in 2009, that involves medical attention of 330 thousand patients. A total expenditure of USD$ 516.3 million was estimated for additional costs, more than 99% exercised in 2009. The main component of this area was the purchase and application of A-H1N1 flu vaccine (USD$ 228.8 million). **CONCLUSIONS:** The exercise allows knowing the mayor spending areas and generates evidence to strengthen the financial and operational planning processes to face similar health events, such as the need to anticipate resources and contingency funds in addition to administrative and operational processes.

PIN3

PURSUING FINANCIAL SUSTAINABILITY TO FULFILL THE MILLENIUM DEVELOPMENT GOAL SIX IN A FRAGMENTED SYSTEM. THE EXPERIENCE OF THE UNIVERSAL ACCESS TO ANTIRETROVIRAL DRUGS IN MÉXICO 2007-2009

Rivera-Peña G, Rios-Arenas D, Gutierrez-Delgado C
Economic Analysis Unit, México, D.F., México

OBJECTIVES: To calculate the average annual cost per ART in IMSS, ISSSTE and MoH. To analyze the financial requirements for the provision of ART through the Universal Access Program to Antiretroviral Drugs (PAUMA) lead for the MoH and its implications for drug procurement policies at national level in the short and medium terms. **METHODS:** We obtained data about patients under ART in 2007 for the three main institutions mentioned and in 2009 only for MoH. Information was analyzed to identify ART prescriptions according to official recommendations. Average annual cost of ART per patient and institution was estimated for 2007 and 2009. Projections of the financial requirements to ensure the provision of ART through the PAUMA for the period 2010-2017 were estimated. Analysis was developed in STATA 9.2. **RESULTS:** In 2007 average annual cost of ART for the three main institutions was MXP$64,800; per institution were as follow: ISSSTE MXP$74,300; IMSS MXP$67,600 and MoH MXP$61,600. Information for the MoH indicates that average annual cost of ART decreased between 2007 and 2009 by around 10.2% (in 2009 was MXP$55,300). First 20 ART options are prescribed to 80% of the patients and represent around 73% of the total costs in 2009. Projections for PAUMA in the period 2010-2017 indicate that on average annually 7,000 new patients require ART and 5,000 deaths will occurred. Assuming new cases, deaths and prices of antiretroviral drugs remain constant the average annual increase in financial requirements for PAUMA to ensure ART in the period studied will be 5.6%. **CONCLUSIONS:** Results generate evidence to strengthen the decision making, monitoring, containment costs, and purchase of antiretroviral drugs processes. It also provides information to allow policy makers optimize the use of limited public resources to support the demand for ART through the financial armor that contributes to maintain universal coverage, allowing the fulfillment of Goal 6 of the Millennium Development Goals.

PIN4

ECONOMIC IMPACT OF COMMUNITY ACQUIRED PNEUMONIA HOSPITALIZATIONS IN ADULTS IN SIX COUNTRIES IN LATIN AMERICA

Rosado-Buzzo A[1], Garcia-Mollinedo L[1], Camacho-Cordero L[1], Roberts CS[2], Mould-Quevedo JF[2], Trejo-Martinez A[1], Luna-Casas G[1]
[1]*Links & Links S.A. de C.V., México, D.F., México,* [2]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: To estimate the economic impact of community acquired pneumonia (CAP) in adults over 50 years of age in Argentina, Brazil, Chile, Colombia, Mexico, and Venezuela. **METHODS:** Local data sources were used to estimate the number of cases of hospitalized pneumonia cases from ICD-9 codes in the year 2009 in adults ≥50 years of age. CAP episodes were estimated from pneumonia proportionally by age based on prior publications that compared ICD-9 coded hospitalizations to confirmed CAP by chart review. Resource use was estimated from treatment guidelines and expert opinion and multiplied by local unit costs to derive total costs. Indirect costs to patients and caregivers were estimated by average wages times participation rate by age. Mortality cost was estimated by discounted life expectancy times wage rates and participation rates by age group. Costs were converted to USD by exchange rates to facilitate comparison. **RESULTS:** The average cost of CAP hospitalizations in adults was (USD): Argentina=$32,241; Brazil=$29,457; Chile=$26,936; Colombia=$23,656; Mexico=$21,018; Venezuela=$22,536. In adults <65 years old, indirect costs comprised 1.5% of cost associated with hospitalizations (range: 0.2% - 2.5%) and mortality costs comprised 16% (range: 3% - 24%). In adults ≥65 direct costs were over 95% of episode costs. The total cost of CAP hospitalizations in adults was (USD$Mil): Argentina=$697; Brazil=$3,624; Chile=$445; Colombia=$347; Mexico=$941; Venezuela=$387. As a proportion of the total population, CAP hospitalizations cost approximately $74 per person ≥50 years old per year (range $42-$108) and $148 per person over 65 per year (range $95-$235). **CONCLUSIONS:** CAP hospitalizations represent a significant economic burden in adults across Latin America countries. Nearly one quarter of the cost burden among adults <65 includes indirect costs, while the economic burden among older patients is driven by direct costs and high incidence.

PIN6

EVALUACION COSTO-EFECTIVIDAD DEL USO DE LINEZOLID EN EL TRATAMIENTO DE NEUMONIAS NOSOCOMIALES EN MÉXICO

Vargas-Valencia JJ[1], Sotelo-Guzmán M[1], Díaz-Ponce H[2], Galindo-Suárez RM[2], Muciño-Ortega E[2], Mould-Quevedo JF[3]
[1]*Econopharma Consulting S.A. de C.V., México, D.F., México,* [2]*Pfizer S.A. de C.V., México, D.F., México,* [3]*Pfizer, Inc., New York, NY, USA*

OBJECTIVOS: La neumonía nosocomial (NN) es la segunda causa más frecuente de infección intrahospitalaria, la infección más frecuentemente adquirida en la unidad de cuidados intensivos (UCI) y la primera causa de mortalidad por infecciones intrahospitalarias. El objetivo de esta investigación fue estimar el costo-efectividad del uso de linezolid en el tratamiento de la NN en comparación con el uso de vancomicina y teicoplanina, desde la perspectiva del Instituto Mexicano del Seguro Social (IMSS). **METODOLOGÍAS:** Se construyó un árbol de decisiones que compara el uso de linezolid inyectable, seguido por linezolid oral (600mg dos veces/día), vancomicina inyectable (1000mg dos veces/día) y teicoplanina inyectable (400mg dos veces el primer día, días subsecuentes: 400mg) en el tratamiento de NN (horizonte temporal: 38 días). Se evalúan la tasa de éxito microbiológico, los días de estancia hospitalaria (en piso y UCI) y los costos médicos directos. Se realizó una revisión de literatura para extraer la tasa de respuesta. La relación de insumos (laboratorios, consultas y medicamentos) y procedimientos, así como el manejo hospitalario se extrajó de la literatura y se complementó con opinión de expertos. Los costos corresponden al IMSS para el año 2010. Se realizó análisis de sensibilidad probabilístico. **RESULTADOS:** La tasa de éxito microbiológico del tratamiento con linezolid fue de 64%, 59.5% con vancomicina (p=0.336) y 44.1% con teicoplanina (p<0.001). Esto se refleja en una menor estancia en UCI, con 17.4 días para linezolid, 21.26 días con vancomicina y 21.82 días para teicoplanina. El costo total de tratamiento con linezolid fue $777,873.14, siendo menor respecto del de vancomicina ($865,186.96) y teicoplanina ($931,983.09). Las curvas de aceptabilidad muestran que linezolid es costo ahorrador con respecto a vancomicina o teicoplanina. **CONCLUSIONES:** En el tratamiento de las NN en el contexto del IMSS, linezolid presenta dominacia débil sobre vancomicina y dominancia absoluta sobre teicoplanina.

PIN7

COST-EFFECTIVENESS ANALYSIS OF ANTI-PNEUMOCOCCAL VACCINES VERSUS NO VACCINATION IN EL SALVADOR

Dueñas MDL[1], Lutz M[2], Morales G[2], Strutton DR[3], Roberts C[4], Cuesta G[2], Farkouh RA[3]
[1]*Hospital Centro Pediátrico, San Salvador, El Salvador,* [2]*Pfizer S.A., La Aurora, Heredia, Costa Rica,* [3]*Pfizer, Inc., Collegeville, PA, USA,* [4]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: In 2009, it was estimated that there were 12.000 to 28.000 deaths in Latin America related to Streptococcus pneumonia infections in pediatric population under 5 years old. Currently, in El Salvador, Prevenar 7 (PCV-7) is the anti-pneumococcal vaccine used. The aim of this study was to estimate the cost-effectiveness and cost-utility of immunization strategies based on pneumococcal conjugated vaccines (PCVs) in El Salvador, from an institutional perspective. **METHODS:** A decision tree model was used to asses economic and health impact of PCVs in children under 2 years old. The alternatives compared were: no vaccination (comparator), PCV-7, PCV-10 and PCV-13. The effectiveness measures were: child illness avoided, life years gained (LYs) and quality-adjusted life years (QALYs) gained. Effectiveness and utilities were obtained from literature. Local costs (expressed in 2009 $US) and epidemiology (data from 2009) were obtained from El Salvador's Ministry of Health database. The model included vaccine dosage schedules approved in WHO prequalification and/or El Salvador MoH calendar at the time of data collection (dec-2010). Univariate sensitivity analysis was performed. The time horizon was one year and the discount rate was 3%. **RESULTS:** Results show that immunization is cost-saving against no-vaccination. PCV-13 gained the highest number of QALYs (898) against PCV-10 (637) and PCV-7 (460). PCV-13 prevented 359 illnesses and gained 998 LYs. PCV-10 and PCV-7 prevented 257 and 228 illnesses and gained 707 and 511 LY's, respectively. These results were robust to variations in herd immunity and impact adjustments of PCV10 immunogenicity. **CONCLUSIONS:** In El Salvador, immunization strategies based on 7, 10 and 13-valent PCV's would be cost-saving interventions. Health outcomes and savings of PCV-13 are greater than those estimated for 7 and 10-valent PCV's.

PIN8

EVALUACION ECONOMICA DE LA EXTENSION DE PROFILAXIS CONTRA CMV DE 100 A 200 DIAS EN RECEPTORES DE TRASPLANTE RENAL CON ALTO RIESGO (D+ / R−)

Morales Buenrostro LE
Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubiran, México, DF, México

OBJECTIVOS: Traducir los beneficios clínicos de extender el período de profilaxis con Valganciclovir de 100 a 200 días en un análisis de costo-efectividad de largo plazo en la etapa postrasplante en pacientes con alto riesgo de enfermedad por Citomegalovirus (CMV) (D+ / R−). **METODOLOGÍAS:** Se utilizó un Modelo Markov para simular los costos de los diferentes estadios de la enfermedad. Los horizontes temporales evaluados son: menor a un año, un año, cinco años y diez años. La población modelada son pacientes receptores de trasplante renal (RTR) con alto

riesgo de contraer CMV. Se compararon dos esquemas de profilaxis con Valganciclovir 100 vs. 200 días. Tasa de descuento para un horizonte temporal mayor a 1 año: 3% (Aplica para costos y utilidades). Los costos médicos directos asociados con los diferentes estadios, se obtuvieron del listado de costos unitarios para el IMSS, publicados en el Diario Oficial de la Federación 2010 y el portal de compras gubernamentales Compranet. **RESULTADOS:** En el caso de receptores con alto riesgo, extender profilaxis con Valganciclovir a 200 días, muestra una notable mejoría en los resultados de salud y una baja en los costos asociados a las complicaciones por enfermedad del CMV. De una cohorte de 100 pacientes, dentro de los 2 siguientes años, se evitará la infección por CMV en 18 pacientes, adicional a esto se redujeron en un 53% el riesgo de rechazo agudo, un 28% la pérdida de la función del injerto y un 23% la probabilidad de muerte. **CONCLUSIONES:** La reducción y/o retraso de infecciones por CMV en RTR resultará en una reducción de los costos en el largo plazo. En el corto plazo se observarán menos complicaciones por la enfermedad del CMV en pacientes inmunosuprimidos y en el largo plazo se reducirá la incidencia de fallas del injerto y la probabilidad de muerte.

PIN10

EXCHANGE RATE OR POWER PURCHASE PARITY FOR ECONOMIC EVALUATION: ESTIMATING THE COSTS OF ROTAVIRUS VACCINATION IN A SIX-YEAR PERIOD CONSIDERING DATA FROM MEXICAN CHILDREN

Granados-Garcia V[1], Salinas-Escudero G[2], Martinez-Valverde S[2]
[1]*National Institute of México for Social Security (IMSS), México, D.F., México,* [2]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México, D.F., México*

OBJECTIVES: To undertake a comparison of cost effectiveness estimates in different currencies for the program of vaccination to prevent rotavirus diarrhea for children less than five years of age. **METHODS:** Cost effectiveness estimates were conducted considering yearly cohorts of children from 0 to 5 years of age for a period of 6 years (2001-2006). We used two alternatives for presenting the values of costs when transforming the Mexican pesos to dollars. In one alternative we present the costs and cost effectiveness results in US dollars (with yearly average exchange rates) and the second was the purchase power-parity factors. We compare the results obtained considering the exchange rates and PPP factors for each one year. Costs data and cost effectiveness ratios were expressed in 2006 prices. **RESULTS:** We found that the cost per DALY in base case estimate was estimated at US$ 3640 per DALY ranging between US$ 2692 and 4502. The variations of the estimates using PPP were between 48-59% larger than estimates using US dollars. **CONCLUSIONS:** Estimates of cost effectiveness using US dollars or PPP did not change the conclusion which suggest that the vaccine is cost effective by using of the rule of three times GDP per capita of the country as a threshold of the cost per DALY in low and middle-income countries.

PIN11

EVALUACION ECONOMICA DE LAS VACUNAS CONJUGADAS DE PNEUMOCOCO PARA PERU

Tirado Caballero JC[1], Navarro A[2], Castrejon MM[3], Gomez JA[4]
[1]*Complejo Hospitalario San Pablo, Lima, Peru,* [2]*GlaxoSmithKline, Lima, Peru,* [3]*GlaxoSmithKline, Panama City, Panama,* [4]*GlaxoSmithKline, Victoria, Buenos Aires, Argentina*

OBJECTIVOS: Evaluar los beneficios potenciales de la vacuna conjugada 10-valente de neumococo & proteína D de *Haemophilus influenzae* no tipificable (HiNT) (PHiD-CV) y la vacuna conjugada 13 valente de neumococo (PCV-13) para Perú. **METODOLOGÍAS:** Se utilizó un modelo Markov de cohorte. El modelo simula el impacto de la enfermedad por neumococo y HiNT (enfermedad invasiva (EI), neumonía adquirida en comunidad (NAC), y otitis media aguda (OMA)) en una cohorte peruana seguida toda la vida. La epidemiología, el manejo de enfermedad y los costos utilizados fueron específicos de Perú. El escenario base incluyó asunciones mínimas sobre las tasas de infección por HiNT. Se utilizó un esquema de vacunación 3+1, una cobertura del 95% y precios por dosis de la Organización Panamericana de la Salud (PHiD-CV: 14,85 dólares, y PCV13: 20,00 dólares). Se presentan resultados de años de vida ganados ajustados por calidad (AVACs) y costos utilizando un descuento del 3,5%, desde la perspectiva del pagador. **RESULTADOS:** El modelo estimó resultados comparables sobre mortalidad por EI y NAC para las dos vacunas, en el escenario base. Predice que las vacunas reducirían 51,5 muertes (PCV13) y 50,0 muertes (PHiD-CV) por cada 100,000 niños vacunados. PHiD-CV prevendría 364 más miringotomías y 4.403 más OMAs cada 100,000 niños vacunados versus PCV-13. Los costos médicos evitados (sin descuento) por EI y NAC prevenidas, son similares para las dos vacunas. En cambio, PHiD-CV ahorraría 1,9 veces más costos médicos por OMAs que PCV13. Ambas vacunas son costo efectivas, pero PHiD-CV generaría más AVACs ganados (378 AVACs adicionales) y sería costo ahorrativa (requiere 10 millones de dólares menos) comparado con PCV13. **CONCLUSIONES:** Ambas vacunas reducirían significativamente la enfermedad neumocóccica invasiva y la NAC siendo PHiD-CV la que generaría más AVACs ganados siendo costo ahorrativa con respecto a PCV-13, al presentar mayores efectos sobre OMA.

PIN12

ANALISIS DE COSTO-EFECTIVIDAD DEL USO DE PROTEINA C ACTIVADA (PCA) EN ENFERMOS CON SEPSIS GRAVE Y CHOQUE SÉPTICO EN LA UNIDAD DE CUIDADOS INTENSIVOS DEL HOSPITAL REGIONAL 1° DE OCTUBRE DEL ISSSTE

Villagómez A[1], García S[2], Carlos F[3], Lemus A[4]
[1]*Hospital Regional 1° de Octubre del Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, México, D.F., México,* [2]*Centro Médico Nacional 20 de Noviembre del Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, México, D.F., México,* [3]*R A C Salud Consultores, S.A. de C.V., México, D.F., México,* [4]*Universidad Anáhuac, México, D.F., México*

OBJECTIVOS: La sepsis y el choque séptico representan una de las principales causas mundiales de morbilidad y mortalidad, generando un impacto económico considerable. El objetivo fue evaluar los costos y el beneficio por reducción de mortalidad asociados con el uso de proteína C activada (PCA) en pacientes con sepsis grave o choque séptico (SGoCS) desde la perspectiva del Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (ISSSTE). **METODOLOGÍAS:** Se realizó un estudio transversal, comparativo, abierto, analítico y retrospectivo con 200 pacientes adultos con SGoCS atendidos en la Unidad de Cuidados Intensivos (UCI) del Hospital Regional 1° de Octubre del ISSSTE. La inclusión fue no aleatoria y consecutiva de enero de 2007 a diciembre de 2009. El tratamiento estándar se otorgó conforme a guías internacionales. PCA fue administrada en forma intravenosa (24 μg/kg/h) con duración total de 96 horas. Se analizó la mortalidad a 28 días de inicio del tratamiento en cada grupo. Utilizando las proyecciones del Consejo Nacional de Población y el factor de Quartin se estimó la expectativa de vida restante en los sobrevivientes (tasa de descuento=5%). Se contemplaron los costos de adquisición de PCA y estancia hospitalaria en UCI. Todos los costos se expresan en pesos mexicanos (MXN) 2010. **RESULTADOS:** Ambos grupos eran comparables: edad media 60 años, 57% mujeres, puntuación APACHE II (23.3 Vs. 24.0 en PCA y tratamiento estándar), número de órganos con disfunción (3.8 y 3.6 en PCA y tratamiento estándar). Menos muertes ocurrieron en el grupo PCA (52 Vs. 57): riesgo relativo=0.91 (IC95%=0.71-1.18). El costo por salvar una vida adicional con PCA fue $1,159,591. Los costos por año de vida ganado y por año de vida ajustado por calidad (AVAC) adicional con PCA fueron $163,324 y $272,207 respectivamente. **CONCLUSIONES:** El uso de PCA en pacientes con SGoCS constituye una estrategia costo-efectiva.

Mental Health – Clinical Outcomes Studies

PMH1

COMPARING THE EFFECTIVENESS OF PALIPERIDONE PALMITATE VERSUS OLANZAPINE PAMOATE FOR RELAPSE PREVENTION IN SCHIZOPHRENIA: POST HOC INDIRECT ANALYSIS USING PUBLISHED PLACEBO-CONTROLLED STUDIES

Einarson T
University of Toronto, Toronto, ON, Canada

OBJECTIVES: Presently, no published studies compare head-to-head long-acting injectable (LAI) antipsychotics paliperidone palmitate (PP) and olanzapine pamoate (OLANZ) for schizophrenia; therefore, this indirect analysis was undertaken to examine long-term relapse rates. **METHODS:** A priori criteria included: Patients: adults ≥18 with DSM diagnosis of schizophrenia, non-suicidal outpatients with stable disease, taking minimal other medications; Designs: placebo-controlled, double-blind, stabilized on LAIs and treated long-term; Outcome was relapse rate; Definitions: must have defined relapse and stabilization. We compared between LAI and placebo within studies using risk ratios (RR) for relapse rates derived from Kaplan-Meier curves. Bucher's method was used to compare indirectly between LAIs. **RESULTS:** We identified two similar trials, one for each LAI. At randomization, patients had similar mean±SD age (PP=39.1±11.1, OLANZ=38.9±11.2), BMI (PP=27.3±5.8, OLANZ=26.9±5.0), and PANSS-Total scores (PP=52.6±11.8, OLANZ=55.8±15.2). Research designs and definitions were also comparable. For a valid comparison, outcomes at 24 weeks were analyzed. In the PP trial (Hough; Trial PSY-3001), 206 patients received PP (50 or 100 mg Eq, which could be adjusted to 25, 50 or 100 mg Eq; average dose: 82.8 mg/4 weeks; 1.18 daily-defined-doses[DDDs]), 204 received placebo. In the OLANZ trial (Kane; Trial HGKA), 599 patients were randomized to receive OLANZ (150 mg/2 weeks, 405 mg/4 weeks, or 300 mg/2 weeks; average dose: 426 mg/4 weeks; 1.52 DDDs) and 144 received pseudo-placebo (45 mg/month), a very low clinically sub-therapeutic dose assumed to be comparable to placebo. PP had significantly fewer relapses than placebo (RR=0.31; CI95%: 0.22-0.44) as did OLANZ (RR=0.33, CI95%:0.24-0.46). The indirect RR of OLANZ versus PP was 1.06 (CI95%:0.65-1.72). However, the monthly dose was 29% higher for OLANZ (426 mg, 1.52 DDDs) than for PP (82.8 mg, 1.18 DDDs). **CONCLUSIONS:** No differences were found in 6-month relapse rates between LAIs; however, OLANZ required higher DDDs. These findings could impact outcomes from cost-effectiveness analyses.

Mental Health – Cost Studies

PMH2

THE COST-EFFECTIVENESS OF PALIPERIDONE PALMITATE COMPARED TO OLANZAPINE PAMOATE IN THE TREATMENT OF SCHIZOPHRENIA IN SWEDEN

Pudas H[1], Hemels M[2], Mehnert A[3], Druais S[4], Martin M[4]
[1]*Janssen-Cilag Oy, Espoo, Finland,* [2]*Janssen-Cilag AS, Birkerod, Denmark,* [3]*Janssen Pharmaceutica NV, Beerse, Belgium,* [4]*i3 Innovus, Uxbridge, Middlesex, UK*

OBJECTIVES: To compare from the Swedish societal perspective the cost-effectiveness of paliperidone palmitate administered monthly (75mg eq every month) (PP) with olanzapine pamoate (150mg every 2 weeks or 300mg every 4 weeks) (OP). **METHODS:** A Markov decision analytic model was developed simulating a cohort of stable schizophrenia patients transitioning monthly through different health states over a lifetime (55 years). Probability of relapse, level of adherence, side-effects (extrapyramidal symptoms, tardive dyskinesia, weight gain and diabetes) and treatment discontinuation (switch) were derived from long-term observational data. Productivity losses were included in the analysis. Costs were expressed in 2011 Swedish Kronor (1 SEK ≈ 0,159 US dollar) with costs and benefits discounted at 3%. Drug costs were derived from the Swedish Pharmaceutical Benefits agency (TLV). Primary cost-effectiveness measures were the cost / QALY gained and cost / relapse avoided. **RESULTS:** Compared to OP, PP is dominant: an increased effectiveness (additional QALYs = 2.097) and fewer relapses (0.395) at reduced costs (SEK 26 719) over a lifetime horizon. Results were robust when tested in 33 deterministic (DSA) and probabilistic sensitivity analyses (PSA) using 12 parameters with pre-

defined distributions. The model was most sensitive to change in the risk ratio of relapse and the proportion of patients changing medication. PP dominated OP in 99% of cases in QALYs gained and in 92% of cases in relapses avoided. **CONCLUSIONS:** This cost-effectiveness analysis indicates that paliperidone palmitate has both economic (reduced costs) and clinical advantages (more QALYs, fewer relapses) compared with olanzapine pamoate in the long-term treatment of schizophrenia in Sweden.

PMH3

COST-EFFECTIVENESS OF PALIPERIDONE PALMITATE FOR THE TREATMENT OF SCHIZOPHRENIA IN MÉXICO

Reyes-Lopez A[1], Querol J[2]
[1]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México, D.F., México,* [2]*Janssen de México, México, D.F., México*

OBJECTIVES: Perform a cost-effectiveness analysis of paliperidone palmitate, for the treatment of patients with schizophrenia in Mexico, from the perspective of public health care providers. **METHODS:** A Markov model with monthly cycles was developed based on the natural history of disease, to simulate cohorts of patients treated with paliperidone palmitate (PP), risperidone long-acting injectable (RIS) or oral olanzapine (OLZ), over a ten year horizon. The model captured clinical and cost parameters including adherence levels, relapse risks, treatment switch reasons, adverse events and direct medical care costs. Deterministic and probabilistic sensitivity analyses were conducted to assess the robustness of the model. **RESULTS:** Compared with RIS, PP resulted more effective and less costly, while when compared with OLZ, PP was more costly but more effective with an incremental cost-effectiveness ratio of US$ 980 per relapse avoided. When plotting an acceptability curve, PP showed a 0.90 probability of being cost-effective if a decision maker is willing to pay US$ 3775 at present value to avoid an additional relapse over a 10 year horizon. There was also a 0.32 probability of PP being considered cost-saving. Both probability results were derived from the comparison with OLZ. **CONCLUSIONS:** Since it is possible to avoid more relapses at a reasonable cost when compared with OLZ, PP represents good value-for-money for Mexican healthcare providers. On the other hand, PP is a dominant treatment alternative over RIS.

PMH4

ECONOMIC ASSESSMENT OF MAJOR DEPRESSIVE DISORDER TREATMENT UNDER DIFFERENT THERAPEUTIC CLASSES AT ISSSTE

Ramírez-Gámez J, Dueñas-Tentori H
Eli Lilly and Company, México, D.F., México

OBJECTIVES: The objective of the present study is to determine the cost-effectiveness associated with three therapeutic classes for treating major depressive disorder (MDD) from the public health care payer perspective in Mexico. **METHODS:** To evaluate health and cost outcomes, a previously published decision model was adapted in order to reflect the usual treatment practice of MDD at the Institute for Social Security and Services for State Workers in Mexico (ISSSTE) during a 3-months time horizon. The three therapeutic classes included in the present analysis are: Selective Serotonin Reuptake Inhibitors (SSRI), Tricyclics (TCA) and Serotonin-Norepinephrine Reuptake Inhibitors (SSRI). Only direct medical costs were considered either generics or branded antidepressants with patent protection. All costs are presented in 2010 US dollars (Exchange Rate 1 US:12.50 MXN pesos). **RESULTS:** Within the 3 therapeutic classes assessed, the expected value for one patient with each three options was distributed as follows: $5 001, $4 215 $4 078 for group SSRI, TCA, and SNRI, respectively. The alternative with a greater expected remission rate was the SNRI class. For every thousand patients treated with SNRI, TCA, and SSRI, 725, 718, and 665 patients are expected to accomplish remission. For each thousand patients treated with SNRI instead of TCA, there will be $ 68,272 cost savings over a period of 3 months. Likewise, when compared against SSRI, the savings generated by SNRI is more than $ 367 437 for each thousand treated patients. **CONCLUSIONS:** The results of the present analysis suggest that the SNRI as a therapeutic class in the treatment of MDD represent a dominant strategy.

PMH5

ANALISIS DE COSTO EFECTIVIDAD DEL MANEJO FARMACOLOGICO DE LA ESQUIZOFRENIA RECURRENTE EN PERU AJUSTADO POR LA ADHERENCIA AI TRATAMIENTO

Izquierdo C
Janssen, Bogotá, Colombia

OBJECTIVOS: Comparar los resultados de costo-efectividad del tratamiento de la esquizofrenia en adultos entre los antipsicoticos orales atípicos (APOA) vs. antipsicoticos de depósito convencionales (DEPOT) vs. risperidona de acción prolongada inyectable (RAPI) entre escenarios según adherencia. **METODOLOGÍAS:** Se desarrolla un modelo en Excel con variables de uso y frecuencia de los medicamentos y recursos hospitalarios, los eventos adversos más relevantes y el subsidio por incapacidad entre las alternativas disponibles para el tratamiento de la esquizofrenia. El modelo contempla switch de medicación por risperidona de acción prolongada cuando ha iniciado con antipsicoticos de depósito convencionales u orales atípicos y haloperidol o flufenazina para el caso de risperidona de acción prolongada inyectable. Horizonte temporal: dos años (un año para cada escenario), Perspectiva del tercero pagador. Indicadores de efectividad: días libres de crisis y días evitados de hospitalización. **RESULTADOS:** El modelo proyecta un porcentaje de adherencia de 89.6% para RAPI; 79.6% para DEPOT; y 69.5% para APOA. El incremento de efectividad de RAPI teniendo en cuenta los dos escenarios comparado con la opción menos costosa (risperidona oral) es de de 65 días libres de crisis y 15 días libres de hospitalizacion con un ICER en el primer caso de $65.47 y en el segundo caso de ICER de $261.67 en dos años. **CONCLUSIONES:** Risperidona de acción prolongada como primer medicamento o como switch en esquizofrenia recurrente teniendo en cuenta un primer año de mala adherencia y un segundo año con mejoría de la adherencia es una alternativa que ahorra costos en recursos hospitalarios y costo efectiva con un umbral a pagar aceptable comparándolo con el costo de un día de hospitalizacion ($300). El análisis de sensibilidad muestra robustez después de tres días en promedio de hospitalizacion en caso de recaída. (1 Dólar Americano: 2.84 Nuevos Soles Peruanos).

Muscular-Skeletal Disorders – Clinical Outcomes Studies

PMS1

META-ANALISIS DE LA EFECTIVIDAD Y SEGURIDAD DEL USO DE CELECOXIB EN EL MANEJO DEL DOLOR CRONICO VS OTROS COX-2 EN PACIENTES CON OSTEARTRITIS O ARTRITIS REUMATOIDE

Vargas-Valencia J[1], Granados-Soto V[2], Galindo-Suárez RM[3], Mould-Quevedo J[4]
[1]*Econopharma Consulting S.A. de C.V., México, D.F., México,* [2]*Centro de Investigación y Estudios Avanzados, México, D.F., México,* [3]*Pfizer S.A. de C.V., México, D.F., México,* [4]*Pfizer, Inc., New York, NY, USA*

OBJECTIVOS: Los inhibidores de la ciclooxigenasa-2 (COX-2) constituyen una alternativa para tratar el dolor asociado a artritis reumatoide u osteoartritis. El objetivo de esta investigación fue identificar las diferencias en efectividad y seguridad de celecoxib vs otros inhibidores de la COX-2 al tratar el dolor en pacientes con osteoartritis o artritis reumatoide. **METODOLOGÍAS:** Se realizó una búsqueda de literatura publicada de enero 2000 a diciembre 2010. Se incluyeron ensayos aleatorizados, doble ciegos y placebo-controlados, que especifican la evaluación de la intensidad del dolor mediante escala visual análoga (EVA) e incidencia de eventos adversos (EA) gastrointestinales y cardiovasculares (hipertensión, edema y cardiopatía congestiva), en pacientes con clase funcional I-III, con dolor ≥40EVA y 3 meses previos con sintomatología. Se excluyeron aquellos que investigaron dosis de inhibidores de la COX-2 diferentes a las terapéuticas (Celecoxib 200mg/día, Etoricoxib 30-90mg/día y Lumiracoxib 100-200mg/día). Para la cuantificación del efecto de los inhibidores de la COX-2, se definió la diferencia media en la reducción en la calificación de EVA con respecto a placebo y se evaluó mediante análisis de varianza. La razón de momios para estimar el incremento en riesgo de presentar EA's, se estimó mediante la prueba Mantel-Haenszel. Se consideró el modelo de efectos aleatorios y pruebas de heterogeneidad. **RESULTADOS:** La reducción absoluta en la escala del dolor a 12 semanas con respecto a placebo fue 14.18% IC95% [10.48-17.87] con Celecoxib (P<0.00001); 12.70% IC95% [7.67-17.73] con Etoricoxib (P<0.00001) y 9.47% IC95% [7.17-11.77] con Lumiracoxib (P<0.00001). Celecoxib redujo el dolor crónico en 4.71% IC95% [0.36,9.06] (P=0.03) respecto a Lumiracoxib. La diferencia con Etoricoxib no fue significativa (P=0.64). La diferencia en la incidencia de EA's entre los inhibidores de la COX-2 y placebo no fue significativa. **CONCLUSIONES:** Celecoxib constituye una alternativa farmacológica segura para el manejo del dolor crónico asociado a osteoartritis o artritis reumatoide y ofrece mayor reducción del dolor vs Lumiracoxib.

PMS2

OSTEOPOROSIS MEDICATION MIGHT HELP REDUCE THE INCIDENCE OF SECOND HIP FRACTURES?

Sebestyén A[1], Sándor J[2], Betlehem J[3], Boncz I[3]
[1]*South-Trasdanubian Regional Health Insurance Fund Administration, Pécs, Hungary,* [2]*University of Debrecen, Debrecen, Hungary,* [3]*University of Pécs, Pécs, Hungary*

OBJECTIVES: The aim of the study is to evaluate, that the pharmacologic treatment for osteoporosis after primary hip fracture can reduce the risk of subsequent femoral neck fracture in patients aged over 60 years? **METHODS:** In this retrospective study the data derive from the financial database of the Hungarian National Health Insurance Fund Administration. The study includes patients over 60 years following primary treatment of femoral neck fracture (S7200) discharged from inpatient care institutions in 2000. Pathologic hip fractures, fractures that emerged from high-energy trauma, fractures that happened in hospitals, and patients who died within 1/2 years after primary hip fracture were excluded from the analysis. The follow up period was 8 years. We evaluated data according to sex, age, type of living place, type of hospital treated the primary fracture, type of primary femoral neck fracture, absence or presence of accompanying diseases, type of surgical intervention for primary fracture, and antiosteoporotic pharmacologic treatment after primary fracture. The effects of prognostic factors were evaluated by Cox proportional hazard regression analysis (HR, 95 % CI, p) **RESULTS:** The 2778 patients were observed for 13,488.92 person-years. During the observation period 320 second hip fracture (11.5 %) were identified, giving an overall incidence of 0.024 per person-year. The significant predictors (0.05>p) are presented: Gender: female/male HR: 1.5289; Age: 80-89y/60-69y HR:1.4910; Residence: capital/village HR:1.4980; Type of surgical intervention: arthroplasty/osteosynthesis HR:1.4136; Osteoporosis medication: duration<2years/none HR:0.5100, duration>2 years/none HR:0.5261. The references is marked with underline. **CONCLUSIONS:** The risk of second hip fracture was the highest in female, in older age-group, in patient after arthroplasty, in patient with capital residence and in patient without pharmacologic treatment for osteoporosis. In addition the osteoporosis medication can reduce the risk of subsequent femoral neck fracture.

Muscular-Skeletal Disorders – Cost Studies

PMS3

IMPACTO ECONOMICO DE LA OSTEOPOROSIS Y DE LAS FRACTURAS POR FRAGILIDAD EN EL INSTITUTO MEXICANO DEL SEGURO SOCIAL

Clark P[1], Carlos F[2], Chico G[1], Galindo-Suarez RM[3]
[1]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México, D.F., México,* [2]*R A C Salud Consultores, S.A. de C.V., México, D.F., México,* [3]*Pfizer, Inc., México, D.F., México*

OBJECTIVOS: La osteoporosis (OP) y fracturas por fragilidad (FF) aumentarán considerablemente en los próximos años. El objetivo fue identificar los costos directos médicos asociados al tratamiento de estas condiciones en personas de 50-99 años del Instituto Mexicano del Seguro Social (IMSS) durante 2010. **METODOLOGÍAS:** La prevalencia de OP fue estimada con base en literatura publicada y datos nacionales de población y cobertura del IMSS. La herramienta FRAX® se utilizó para estimar la probabilidad de presentar alguna de las principales FF (cadera, columna, antebrazo y húmero) en población mexicana con diagnóstico de OP (T-score promedio=-3.0) y ningún factor clínico de riesgo. En el portal de transparencia IMSS se consultaron los gastos en bisfosfonatos, calcio, calcitriol y calcitonina. Mediante una búsqueda bibliográfica se identificaron datos publicados sobre costos de atención aguda de FF en el IMSS, cifras que fueron actualizadas a diciembre de 2010 aplicando la inflación acumulada en el periodo correspondiente (2007-2010). Se consideraron los costos potenciales de diagnóstico así como el seguimiento durante un año en pacientes con OP y los generados por sesiones de rehabilitación y consultas externas para las FF tomando en cuenta la literatura disponible, entrevista a expertos y costos unitarios del IMSS. **RESULTADOS:** Un total de 659,182 (17.4%) mujeres y 188,196 hombres (6.0%) conformaron la prevalencia de OP en derechohabientes de 50-99 años. El gasto en atención no farmacológica para OP superó 616 millones de pesos mexicanos (MXN). El gasto en adquisición de medicamentos para OP fue estimado en 72.8 millones MXN. Los costos totales de las 9488 FF ascendieron a 513 millones MXN. Así, el impacto económico de la OP y las FF en el IMSS para el año 2010 fue de 1202.30 millones MXN, equivalente al 0.4% de los ingresos del instituto. **CONCLUSIONES:** La OP y FF imponen un elevado costo económico al IMSS.

PMS4

ECONOMIC EVALUATION OF POST-OPERATION ORTHOPEDIC SURGERY OF ANTACID, ANTIHEMETIC AND ANALGESIC MEDICATION AFTER KETOPROPHENE, KETOROLAC, PARECOXIB AND TENOXICAM IN BRAZILIAN PATIENTS

Fujii RK[1], Mould-Quevedo JF[2]
[1]*Pfizer Pharmaceutics inc., São Paulo, SP, Brazil,* [2]*Pfizer, Inc., New York, NY, USA*

OBJECTIVES: To evaluate the use of 'antacid, antihemetic and adjuvant analgesic opiates and non-opiates' (AAA) after using intravenous ketoprophene (100mg/day), ketorolac (90mg/day), parecoxib (40mg/day) or tenoxicam (40mg/day) in post-operative orthopedic surgery at five Brazilian private hospitals. **METHODS:** Medical charts were accessed and selected based on the use of ketoprophene, ketorolac, parecoxib or tenoxicam at the immediate post-operative period and based on the existence of hospital's billing information. 400 medical charts from November 2010 were evaluated and 121 cases were recruited. Data regarding the regular use of AAA was gathered and grouped by age, sex, length of stay (LOS) at nursing ward and intensive care unit, and number of hours at the immediate post-operative observation room. Ketoprophene, ketorolac, parecoxib and tenoxicam groups were compared using unpaired t-tests with 95% confidence interval. **RESULTS:** Average age was 51.1 (±13.1)yrs and 60% were female. Average LOS at nursing ward, ICU and immediate post-operative rooms were 3.7 (±2.8) days, 0.8 (±1.1)days, and 95 (±36)min, respectively. Ketoprophene, ketorolac, parecoxib and tenoxicam for overall users represented 39.7%, 28.9%, 19.0% and 12.4% respectively. Ketorolac group exhibited to use more adjuvant non-opiate analgesics than parecoxib and tenoxicam groups($p<0.05$). Only parecoxib was found to have significantly less use of antacid and antihemetic medications when compared to others treatments($p<0.004$). Other parameters didn't present meaningful differences. Total mean treatment daily costs considering drug equipment resulted in US$28.2; US$ 34.3; US$27.1 and US$32.9 corresponding to ketoprophene, ketorolac, parecoxib and tenoxicam, respectively. Mean AAA daily estimates costs were US$9.0 (±4.8); US$11.0 (±5.7); US$5.3 (±4.1) and US$7.5 (±4.9), respectively. Potential cost savings per patient regarding the reduction of AAA by replacing all alternatives with parecoxib was estimated in US$37.2. **CONCLUSIONS:** Parecoxib users undergoing orthopedic surgeries showed the least use of antacid and antihemetic medications generating savings in the Brazilian private setting.

PMS5

ANALISIS DE COSTO-EFECTIVIDAD DE AGENTES BIOLOGICOS EN EL TRATAMIENTO DE PACIENTES CON ARTRITIS REUMATOIDE ACTIVA Y RESPUESTA INSUFICIENTE A FARME TRADICIONALES DESDE LA PERSPECTIVA DEL SISTEMA PUBLICO DE SALUD EN MÉXICO

Carlos F[1], Aguirre A[1], Peláez-Ballestas I[2], Ramos E[1]
[1]*R A C Salud Consultores, S.A. de C.V., México, D.F., México,* [2]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México, D.F., México*

OBJECTIVOS: Un número importante de pacientes con artritis reumatoide (AR) presenta respuesta insuficiente a fármacos antirreumáticos modificadores del curso de la enfermedad (FARME) tradicionales. El objetivo fue comparar los costos y la efectividad de utilizar FARME biológicos en esta población, desde la perspectiva del sistema público de salud en México. **METODOLOGÍAS:** Se realizó una búsqueda sistemática, identificándose 23 estudios clínicos controlados, con asignación aleatoria y a doble-ciego que evaluaron el uso de tocilizumab, infliximab, etanercept, adalimumab y abatacept en dosis recomendadas para la población objetivo. El horizonte temporal fue seis meses. La medida de efectividad consistió en la proporción de pacientes con mejora de 70% en la respuesta, según criterios del Colegio Americano de Reumatología (ACR70), parámetro considerado proxy de remisión. Mediante una comparación indirecta se calcularon las tasas ajustadas de ACR70 para cada agente biológico. Únicamente se analizaron costos de adquisición y administración de FARME biológicos con base en la duración de los ensayos. Los costos de infliximab, etanercept y adalimumab, además del costo unitario por infusión fueron obtenidos de fuentes oficiales; Roche México proporcionó los precios de tocilizumab y se estimó que el costo de abatacept en instituciones de gobierno es 40% más bajo que en el sector privado. Todos los costos se expresan en pesos mexicanos (MXN) 2010. **RESULTADOS:** El costo fue más bajo con tocilizumab ($57,420) que con etanercept ($62,354), infliximab ($65,527), adalimumab ($73,359) y abatacept ($74,925). La mayor proporción ajustada de pacientes con respuesta ACR70 se obtuvo con tocilizumab (30.74%), seguida de adalimumab (22.05%), abatacept (14.84%), etanercept (14.79%) e infliximab (12.80%). El costo por lograr un ACR70 fue notablemente más bajo con tocilizumab ($186,783) que con el resto de las alternativas (rango: $332,699 a $511,820). **CONCLUSIONES:** Tocilizumab representa una estrategia dominante para el tratamiento de pacientes adultos con AR y respuesta insuficiente a FARME tradicionales.

PMS6

HEALTH CARE RESOURCE UTILIZATION OF THAI HIP FRACTURE PATIENTS IN PUBLIC HOSPITAL: COST OF ILLNESS ANALYSIS AT CHIANGRAI HOSPITAL

Srisawi K[1], Thepnamwong J[1], Sukwong DP[1], Reungjarearnrung K[3]
[1]*Chaiangraiprachanukroh Hospital, Chiang Rai, Thailand,* [3]*Bumrungrad Hospital, Wattana, Bangkok, Thailand*

OBJECTIVES: Hip fracture incidence in Thailand is rising and triggers an increased healthcare resource demand. This research is to examine hip fracture incidence at Chiangraiprachanukroh hospital and associated hospital costs. **METHODS:** Patients with hip fracture coded S720-S722 (ICD-10) aged 50 or older, were recruited from January to December 2009 together with co-morbidities, type of hip fracture and management (surgical & nonsurgical discharge) and a follow-up over one year. All direct hospital costs at provider's perspective were retrieved from hospital database. Statistical analysis employed unpaired t-test, Mann-Whitney U test for comparison of costs and their associations to type of fracture and management. **RESULTS:** A total of 121 patients with hip fracture were screened. Patients' mean age (SD) was 77.0 (11.6) years and 57% were male. (N=68). The mean days follow-up (SD) and mean hospitalization (SD) was 90.7 (15.1) and 7.3 (7.9) respectively. At screening, 56% of patients had co-morbidities (N=67). The average hospitalization costs were 20,936 THB. The cost of all type of drugs was below 11% of total cost of illness. It ranged from 2.5% to 10.7% for surgical and non-surgical discharge and from 4.8% to 9.6% for inter-trochanteric and femoral neck fracture respectively. Patients with femoral neck fracture (N=33, 27%) and inter-trochanteric fracture (N=88, 73%) had similar mean age ($p=0.612$) and hospitalization length ($p=0.480$). The associated mean hospital costs were 34,397 THB and 15,887 THB respectively. Patients with surgical discharge (N=34, 28%) and non-surgical discharge (N=87, 72%) had similar hospitalization length ($p=0.490$). The associated mean hospital costs were 55,268 THB and 7,273 THB respectively. Overall hospital costs ranges from less than 10,000 to 156,529 THB with median of 7,260 THB per patient/year. **CONCLUSIONS:** Patients admitted for hip fracture, femoral fracture and surgical management increase hospital costs over short-term in public hospital. Regardless of context, cost of drugs was marginal among hospital costs of hip fracture.

PMS7

DIRECT TREATMENT-COST OF PATIENTS WITH RHEUMATOID ARTHRITIS IN MEDELLIN, COLOMBIA

Montoya N[1], Gómez L[1], Vélez M[1], Rosselli D[2]
[1]*Medicarte, Medellin, Colombia,* [2]*Universidad Javeriana, Bogotá, Colombia*

OBJECTIVES: To analyze clinical variables and direct costs of a sample of patients with rheumatoid arthritis from a specialized pharmacotherapeutic management center in Medellin, Colombia. **METHODS:** We reviewed 408 clinical files of the period 2007-2009 collecting clinical information and direct costs from the perspective of a local private health insurer. **RESULTS:** 337 women (82.6%), average age 49.8 (range 4-91). Almost one half of the patients (183, 44.8%) in this sample received biological therapy during this period. Overall, average monthly cost increased from Col$1.31 million (around US$650) in 2007, to Col$1.71 million (~US$850) in 2008, and Col$1.99 million (~US$1000) in 2009; 87.9% of this cost is represented by pharmaceuticals. **CONCLUSIONS:** Costs of treatment are increasing, despite the implementation of cost-containing strategies; pharmaceuticals represent an important proportion of total cost.

PMS8

COST-EFFECTIVENESS ANALYSIS OF ETANERCEPT VERSUS AVAILABLE ANTI-TNF AND IL-6 BLOCKERS FOR TREATING RHEUMATOID ARTHRITIS IN GUATEMALA

Lutz M, Cuesta G, Morales G
Pfizer S.A., La Aurora, Heredia, Costa Rica

OBJECTIVES: Rheumatoid Arthritis (RA) affects approximately 0.4% of the Latin American population over 16 years old. Due to its chronic and progressive condition, RA has an important economic and social impact. The aim is to assess the cost-effectiveness of etanercept in the treatment for moderate to severe RA, with previous antirheumatic drugs (DMARDs) failure, in comparison with the rest of anti-TNF and IL-6 blockers products available in Guatemala, from the healthcare payer's perspective. **METHODS:** A decision tree model was used to compare the costs and effectiveness of the alternatives, all in combination with methotrexate, in the treatment of RA in adult population of Guatemala. The alternatives included were: etanercept (comparator), adalimumab, infliximab and tocilizumab. The effectiveness measures were: American College of Rheumatology (ACR) Response Criteria ACR<20 and ACR<70. Quality utilities were obtained from Health Assessment Questionnaire (HAQ). Local costs (2011 US$) were obtained from Guatemala's Ministry of Health databases. The outcomes were express in costs of success with ACR20 and ACR70 and QALYs gained. Univariate sensitivity analysis was performed. The time horizon was 2 years. Discount rate was 5% for costs and health outcomes. **RESULTS:** Results showed that etanercept gained the highest number of

QALYs (1.5423) in comparison with adalimumab (1.5048), infliximab (1.4299) and tocilizumab (1.4955). Etanercept appeared as the least expensive alternative at both ACR<20 ($69,410.32) and ACR<70 ($176,178.43). The highest costs were obtained by infliximab, ACR<20 ($139,291.80) and ACR<70 ($612,236.06). Cost-effectiveness analyses exhibited etanercept as the dominant strategy. Acceptability curves showed that at the willingness-to-pay of US$8,000/QALY, the probability that etanercept is cost-effective met 100%. PSA results support the robustness of these findings. **CONCLUSIONS:** Etanercept is the most cost-effective alternative for treating RA against other anti-TNF and IL-6 blockers. According to <3 GDP per capita ($5,200; 2010) threshold of Guatemala, etanercept is a cost-effective treatment for RA.

PMS9

WHAT IS THE VALUE OF THE NEW KID ON THE BLOCK?: TOCILIZUMAB VERSUS ABATACEPT FOR RHEUMATOID ARTHRITIS IN COLOMBIA

Alfonso-Cristancho R[1], Aiello EC[2], Roa CN[3], Valencia JE[3]
[1]*University of Washington, Seattle, WA, USA,* [2]*Bristol-Myers Squibb, Buenos Aires, Argentina,* [3]*Bristol-Myers Squibb, Bogotá, Colombia*

OBJECTIVES: Determine the cost-effectiveness of abatacept or tocilizumab in patients with rheumatoid arthritis (RA) with inadequate response to methotrexate (IR-MTX) in Colombia. **METHODS:** A patient-level simulation based on the Birmingham Rheumatoid Arthritis Model was adapted to the clinical practice patterns and demographic characteristics of the patients and validated by clinical experts in Colombia. The functional disability was assessed using the Health Assessment Questionnaire (HAQ); the mean scores and the distribution were derived from subjects screened to participate in clinical trials in Latin America. The effect of biologic therapy was assessed using changes in HAQ scores for the first 6 months based on a mixed treatment comparison and then projected over time. Direct medical costs were calculated from private and public providers, and the information system of the Ministry of Social Protection (SISMED). A 20-year time horizon and the payer's perspective were assumed. Costs and health outcomes were discounted at 3% annually. Sensitivity analyses were performed to the main parameters of the model. **RESULTS:** A hypothetical cohort of 1,000 patients with RA - IR MTX followed for 20 years or until death, the mean direct medical costs per patient for abatacept were U$132,654 (129,198-145,203), compared to U$283,753 (275,809-315,551) for tocilizumab. For the group of subjects treated with abatacept, 84% of these costs were associated with the drug; for tocilizumab, 93% of the costs are associated with the drug. The mean number of life years were 29.27 (28.45-30.15) and 29.25 (28.43-30.13) for abatacept and tolicizumab respectively. The mean number of QALYs (discounted) by abatacept, and tocilizumab were: 7.21 (7.02-7.42), and 7.15 (6.96-7.37) respectively. Using abatacept as the reference treatment, tolicizumab provided less utility at a higher cost, being dominated by abatacept. **CONCLUSIONS:** For the treatment of RA in patients with IR MTX in Colombia, the use of abatacept, as the reference treatment, is dominant over tocilizumab.

PMS10

COST-EFFECTIVENESS OF DULOXETINE COMPARED TO PREGABALINE IN PATIENTS WITH FIBROMYALGIA FROM THE PUBLIC HEALTH CARE SYSTEM PERSPECTIVE IN MÉXICO

Ramírez-Gámez J, Dueñas-Tentori H
Eli Lilly and Company, México, D.F., México

OBJECTIVES: Fibromyalgia (FM) is a disease with a great economic impact not only related to the costs associated but also to the loss of productivity. Effective treatment options in the Mexican market are few. The objective of the present analysis is to assess the cost-effectiveness of duloxetine in the treatment of patients with FM versus pregabalin. **METHODS:** Alternatives to compare were: (1) duloxetine 60 mg / day and 120 mg / day and (2) pregabalin 300 mg / day and 450 mg / day. A decision tree model was developed with a 12 weeks time horizon in which patients maintained response, lost response or dropped out. Relative rates of response for other comparators over placebo were extracted from a systematic review of published randomized controlled studies for achieving a reduction of 30% in the Brief Pain Inventory average pain severity score or a "much improved" or "very much improved" rate in the Patient Global Impression of Improvement (PGI). Resource use associated with fibromyalgia management was estimated from published studies and costs were estimated from the Mexican Public Healthcare Payer perspective at 2010 USD prices. **RESULTS:** In the base case duloxetine 60 mg/day versus the two indications of pregabalin were compared considering the price per milligram for the 14 and 28 tablets of 75 mg presentations of pregabalin. In this case, duloxetine is a dominant strategy versus pregabalin in 3 out of four scenarios and highly cost-effective when compared duloxetine 120mg/day versus pregabalin 300mg/day. Further analysis (considering presentation 14/28 tablets of 150 mg of pregabalin), shows that duloxetine is a highly cost-effective alternative with cost-effectiveness ratios of $34-405 USD range per one additional response. **CONCLUSIONS:** Results suggest duloxetine is a dominant and highly cost-effective alternative compared with pregabalin at therapeutic doses published in studies of comparable design in patients with FM.

PMS11

REVIEW OF THE STUDIES ON ECONOMIC EVALUATION OF TREATMENT FOR POSTMENOPAUSAL OSTEOPOROSIS

Brandão CMR[1], Acurcio FDA[2]
[1]*Universidade Federal de Minas Gerais, Contagem, Minas Gerais, Brazil,* [2]*Universidade Federal de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil*

OBJECTIVES: The use of economic evaluation studies has been increasingly common, especially in the field of osteoporosis, in which there is wide a variation in effectiveness and costs of therapeutic strategies. Aiming to identify relevant studies, there was a complete review of the economic evaluations, conducted in Brazil and abroad, focusing on the treatment of postmenopausal osteoporosis to support decision-making on health policies in Brazil and Latin America. **METHODS:** There was a search on PubMed and the national scientific journals until February 2011. We used the keywords {osteoporosis} and {postmenopausal or post-menopausal} and {cost effectiveness or cost benefit or cost utility or Economic Evaluation}. **RESULTS:** 147 titles and abstracts were found. After careful selection, 29 articles remained for analysis. We found great variability in the methods of studies related to the specific issues of each country (demographic and epidemiological factors), associated with the perspective adopted, the prices, the valuation of health states by population (utility) and according to factors inherent to economic modeling. Most studies that compared treatment strategies with no treatment at all, found a reasonable incremental cost-effectiveness ratio (ICER), according to the willingness to pay of each country. The interventions have become more cost-effective with increasing age, decreasing bone mineral density and the presence of previous fractures. In general, bisphosphonates were the strategies that were evaluated the most and they showed better results in ICER's. Teriparatide was not cost-effective. Studies evaluating hormone replacement therapy found good ICER, but call attention to the increased risk of breast cancer. Vitamin supplementation, strontium ranelate, raloxifene, and denosumab were evaluated and showed variable results depending on the perspective, of the country and the assumptions. **CONCLUSIONS:** It was not possible to extrapolate any of the results to the population of Brazil or countries of Latin America, limiting its use to decision makers in yours different locations.

PMS12

EVALUACION ECONOMICA DE RITUXIMAB VERSUS ANTI-TNF EN PACIENTES CON ARTRITIS REUMATOIDE Y FALLA PREVIA A ANTI-TNF EN MÉXICO

Carlos F[1], Clark P[2]
[1]*R A C Salud Consultores, S.A. de C.V., México, D.F., México,* [2]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México, D.F., México*

OBJECTIVOS: Aproximadamente 30% de los pacientes con artritis reumatoide (AR) tratados con inhibidores del factor de necrosis tumoral (anti-TNF) no alcanzan una mejora de al menos 20% en los criterios del Colegio Americano de Reumatología (ACR). El objetivo fue determinar la relación costo-utilidad de diferentes opciones de tratamiento en pacientes con AR y falla a anti-TNF, desde la perspectiva del sistema público de salud en México. **METODOLOGÍAS:** Se utilizó un modelo de microsimulación (horizonte temporal de por vida) para comparar 12 diferentes secuencias de tratamiento en un millón de pacientes (edad: 40 años, 70% mujeres, peso corporal 66.67kg). En las secuencias, rituximab (2 infusiones de 1g por curso, administrados cada 9 meses) podía ser utilizado inmediatamente tras la falla de un anti-TFN (infliximab, etanercept o adalimumab) o hasta después de agotar los 3 anti-TNF. Mediante una comparación indirecta de 23 ensayos clínicos, se determinaron las respuestas ACR ajustadas para cada agente. Un panel integrado por diez expertos y literatura publicada sirvió para determinar el consumo de recursos. Se consultaron costos unitarios oficiales. Analizamos los costos de adquisición e infusión de medicamentos (incluyendo metotrexato), el costo ambulatorio por respuesta ACR y el costo hospitalario según puntaje HAQ (Health Assessment Questionnaire). **RESULTADOS:** Los costos acumulados de por vida (descontados a una tasa anual de 3%) fueron más bajos para todas las secuencias en las que rituximab fue administrado como primera opción ante una respuesta insuficiente al tratamiento con un anti-TNF. Los ahorros oscilaron entre $6904 y $16,411 pesos mexicanos por paciente. Las mayores diferencias en calidad de vida a favor de iniciar con rituximab se obtuvieron cuando se comparó contra iniciar con infliximab. **CONCLUSIONES:** Este estudio sugiere que iniciar terapia con rituximab inmediatamente después de la primer falla a anti-TNF es una estrategia costo-efectiva en lugar de continuar con otro agente anti-TFN.

PMS13

ECONOMIC MODEL OF WORKPLACE IMPACTS OF ANTI-TNF THERAPY FOR RHEUMATOID ARTHRITIS IN BRAZIL

Teich V[1], Chaves L[2], Birnbaum H[3], Pike C[3], Waryas C[3], Cifaldi M[4]
[1]*MedInsight Evidências, São Paulo, SP, Brazil,* [2]*Abbott Laboratories, São Paulo, SP, Brazil,* [3]*Analysis Group, Inc., Boston, MA, USA,* [4]*Abbott Laboratories, Abbott Park, IL, USA*

OBJECTIVES: To estimate employer productivity offset costs when using Tumor Necrosis Factor inhibitors (TNF-i) therapies for treatment of Rheumatoid Arthritis (RA) using an economic model that encompasses a broad set of workplace costs from RA. **METHODS:** A customizable model of the workplace impacts of alternative RA treatments was calibrated with Brazilian specific parameters based on data from literature, clinical trials, and government sources. The workplace model included employment sector wages to allow for comparisons across industries. Costs of medical leave absenteeism/disability, reduced productivity, job turnover, and work-equipment adaptations were calculated for RA employees on the TNF-i versus other traditional DMARDs RA treatments. Employer costs of RA workers on TNF-i versus traditional DMARDs were compared. **RESULTS:** Across all industries in Brazil, the annual workplace cost of employees with RA was R$4,839 for employees on adalimumab (23% of wages) versus R$8,679 for employees on traditional DMARDs therapies (42% of wages). The R$3,839 offset reduction in employer costs for RA workers on adalimumab included reduced medical leave (R$764) and RA-related job turnover (R$1,076), and higher productivity (R$1,999). Savings per RA worker on adalimumab ranged from R$2,597 (19% of wages) in the waste treatment sector to R$26,312 (19% of wages) in the petroleum product manufacturing sector. **CONCLUSIONS:** RA imposes a large financial burden on employers in Brazil. This burden is substantially less for employees treated with adalimumab than for employees treated with traditional DMARDs as a result of the higher productivity,

lower turnover, and lower absenteeism associated with adalimumab use. Employer savings from adalimumab use varies across industries in Brazil. High-wage sectors, such as the petroleum industry, have both larger absolute costs associated with RA and larger absolute savings from adalimumab use than do low-wage sectors, such as waste treatment.

Neurological Disorders – Cost Studies

PND3

ESTIMACIÓN DEL PROCESO DE PROCURACIÓN DE ÓRGANOS DE PACIENTES CON MUERTE CEREBRAL EN MÉXICO 2009

Camacho Chairez A, Gutierrez C
Mexican Ministry of Health, México, D.F., México

OBJECTIVOS: Estimar el costo del proceso de procuración de órganos de pacientes con muerte cerebral dentro de las instituciones públicas del Sector Salud en México para identificar los costos en que incurren los hospitales involucrados (donador y receptor). Lo anterior debido a que el Centro Nacional de Trasplantes (CENATRA) ha identificado que la falta de incentivos económicos para los hospitales donadores, disminuye la posibilidad de obtener órganos de aquéllos pacientes que presentan muerte cerebral. **METODOLOGÍAS:** El costo del proceso de procuración de órganos se estimó tomando como referencia el protocolo técnico del CENATRA de México. Los costos de baterías de laboratorio, de gabinete y de operación durante el proceso se obtuvieron de fuentes de información tanto de instituciones públicas del Sector Salud, como de empresas privadas proveedoras de servicios al Sector. Los supuestos básicos son: todas las actividades del proceso se enfocan a una procuración multiórganica (6 órganos) y que el tiempo estimado del proceso es de 36 horas. **RESULTADOS:** El costo total del proceso de procuración multiorgánica es de $47,572.50 pesos mexicanos (PM). Por órgano el costo es de $7928 PM, del cual el 77.67% es incurrido por el hospital donador ($6159 PM), mientras que el 22.33% restante por el hospital receptor ($1770 PM). Los rubros que implican más del 80% del costo del proceso son el día terapia intensiva y de hospitalización (59.65%), mientras que el 22.15% es representado por el gasto en viáticos y alimentación para el personal médico necesario dentro del proceso. **CONCLUSIONES:** Los resultados permiten identificar los costos en que incurre cada una de las partes que intervienen dentro del proceso de procuración de órganos, a considerarse en la implementación de políticas públicas que incentiven el proceso a nivel nacional.

PND4

EL IMPACTO ECONOMICO DEL TABAQUISMO EN EL DESARROLLO DE LA ENFERMEDAD VASCULAR CEREBRAL EN UN CENTRO NEUROLOGICO DE TERCER NIVEL

San-Juan D[1], Quintana Carrillo R[2], Arauz Góngora A[1], López de Santiago I[1], Aguire-Cruz L[1], Corona T[1], Reynales Shigematsu L[3]
[1]*Instituto Nacional de Neurología y Neurocirugía, México, D.F, México, México,* [2]*Instituto Nacional de Salud Pública, México, D.F., México,* [3]*Instituto Nacional de Salud Pública, Cuernavaca, Morelos, México*

OBJECTIVOS: Estimar los costos directos de atención médica de la enfermedad vascular cerebral (EVC) atribuidos al tabaquismo en un centro neurológico de tercer nivel. **METODOLOGÍAS:** Se estimaron los costos de salud directos por ictus atribuidos al tabaquismo en 297 pacientes atendidos en el Instituto Nacional de Neurología y Neurocirugía (INNN) en 2009. Metodología: Cost of Illness y microcosteo. Perspectiva de costeo: proveedor. La utilización se estimó con base en los procedimientos médicos registrados en el expediente clínico. Se utilizó la fracción atribuible al tabaco de la EVC para estimar los costos del tabaquismo. Los costos están expresados en pesos mexicanos ($) y en dólares americanos (USD) del 2009. **RESULTADOS:** El costo total de la EVC atribuible al tabaco durante el 2009 fue de $13,995,388.8 (1,071,123.2 USD). La hemorragia subaracnoidea fue la más costosa. El costo promedio anual por paciente relacionado con el tabaquismo de las hemorragias intracerebral y subaracnoidea fue, respectivamente, $35,396.2 (2,709.2 USD) y $66,890.5 (5,119.5 USD). El costo promedio anual asociado al tabaquismo de la EVC de un paciente en el INNN fue de $45,242.6 (3,462.6 USD). **CONCLUSIONES:** Este es el primer estudio que evalúa y confirma los altos costos directos de la atención médica de los pacientes con EVC atribuidos al tabaco. Si de los 297 pacientes atendidos en el INNN durante 2009, 149 no hubieran fumado, el Instituto podría haber asignado en su mejor uso alternativo los $13,995,188.8 (1,071,123.2 USD). La metodología empleada nos provee un gran nivel de especificidad de los datos relacionados con los servicios médicos y financieros utilizados por el paciente con EVC durante el año analizado.

Research on Methods – Databases & Management Methods

PRM2

EROS: A NEW SOFTWARE FOR EARLY STAGE OF SYSTEMATIC REVIEWS

Glujovsky D, Bardach A, García Martí S, Comandé D, Ciapponi A
Institute for Clinical Effectiveness and Health Policy (IECS), Buenos Aires, Argentina

OBJECTIVES: The workload of the initial phases of the process of developing a systematic review (SR) is often underestimated. The screening and quality assessment of studies, usually done by pairs of independent reviewers, is not only time-consuming, but it also is complicated, tiresome, and prone to mistakes. A computer-software designed to cope with the initial phases of a SR would be of great help. There is a generalized lack of development in this regard, and the available options are not very accessible or affordable. The objective of this study is to show the advances in the development of EROS (Early Review Organizing Software), a web-based software for the initial phases of a SR process. **METHODS:** We developed an online software that helps in performing the first stages of a SR: importation of citation from a reference manager software or directly after a search in several medical electronic databases (PubMed, EMBASE, LILACS, etc), screening by title/abstract, first agreement, uploading of full-text, screening by full-text (tracking exclusion reasons), quality assessment (second and third agreement respectively), and distribution of full-text for data collection. **RESULTS:** EROS is currently being used in the simultaneous conduction of more than 20 systematic reviews. Its main characteristics are: a) ability to manage multiple projects; b) differentiation of roles assigned to reviewers, administrators and librarians; c) multi-language environment in each review; d) adequate, equitable and timely delivery of full-texts for evaluation and data abstraction; e) real-time tracking of the whole process for each role; f) building the study flowchart; g) possibility to work simultaneously in different SR's stages; and h) configurable inclusion/exclusion criteria and other relevant features. **CONCLUSIONS:** A computerized SR tool in the initial phases like EROS saves time, reduces workload for each involved role, and probably enhances SR's methodological quality.

Research on Methods – Statistical Methods

PRM3

DIMENSIONALITY OF COMORBIDITIES IN HEATH RELATED QUALITY OF LIFE COMORBIDITY INDEX

Ou HT[1], Bagozzi RP[2], Erickson S[2], Mukherjee B[2], Piette JD[2], Balkrishnan R[2]
[1]*University of Michigan College of Pharmacy, Ann Arbor, MI, USA,* [2]*University of Michigan, Ann Arbor, MI, USA*

OBJECTIVES: To assess comorbidity patterns among 25 comorbidity candidates in the Health-related Quality of Life Comorbidity Index. **METHODS:** Using the MarketScan™ Medicaid database from 2003 to 2007, type 2 diabetes patients were targeted. Patterns of comorbidities were analyzed via confirmatory factor analyses for four subgroups: male, female, black and white. Three models were compared: a uni-dimensional model, a 2-dimensional model in which 15 and 10 disorders represented physical and mental domains of comorbidities, respectively, a multi-dimensional model in which the dimensions were formed based on tetrachoric correlation matrices. Predictive performances of three comorbidity structures were assessed using regression analyses for four types of outcomes: physician adherence to diabetes care guideline, patient adherence to oral antidiabetic medication, health care utilization and costs. The STATA™ and LISREL™ software were utilized. **RESULTS:** 9,830 patients were included and majority of them was female (73%) and white (62%). A 7-factor (category) structure was noticeable in the correlations among comorbidity candidates across subgroups. Arrhythmias, heart failure, and ischemic heart disease formed a heart disease category; asthma and obstructive pulmonary disease formed a lung disease category; rheumatoid arthritis, osteoarthritis and nontraumatic joint disorders formed a rheumatic disease category, degenerative neurologic disorders and headaches formed a neurologic disease category, esophageal disorders, gastric and duodenal ulcer formed a gastric disease category, hepatitis, biliary and liver disorders formed a liver disease category, anxiety, depression, affective disorders, schizophrenia, other psychoses formed a mental disease category. The 7-category model provided best model fit across subgroups and better predictive performance across different health care outcomes. Based on a 7-category model, individual comorbidity categories demonstrated differential impacts for a given outcome. **CONCLUSIONS:** Instead of one composite comorbidity score, using comorbidity categories had better risk adjustment and provided insightful information about differential impacts of different features of comorbidities for further developing efficient comorbidity management strategies.

PRM4

A MIXED-EFFECTS PIECEWISE LINEAR MODEL OF THE RATE OF LUNG FUNCTION DECLINE BEFORE AND AFTER INHALED CORTICOSTEROIDS IN AN OBSERVATIONAL STUDY OF CHILDREN WITH CYSTIC FIBROSIS

Pasta DJ, Rasouliyan L
ICON Late Phase & Outcomes Research, San Francisco, CA, USA

OBJECTIVES: To evaluate the change in the rate of lung function decline before and after initiation of inhaled corticosteroids (ICS) in children enrolled in the Epidemiologic Study of Cystic Fibrosis (ESCF) through a multivariable mixed-effects piecewise linear model. **METHODS:** The primary outcome measure was the long-term rate of change in percent predicted forced expiratory volume in 1 second (pp FEV_1). Patients aged 6-17 years who had been enrolled in ESCF for 2 years, when initially treated with ICS therapy, were selected if they remained on treatment for at least 80% of their visits during the following 2 years. A comparator group included patients aged 6-17 who did not receive ICS for 4 consecutive years. The index date was defined as date of ICS initiation (ICS group) or the patient's even-numbered (8th-16th) birthday (comparator group). For each patient we estimated the annual rate of decline in pp FEV_1 before and after index using a mixed-effects piecewise linear model adjusted for age, gender, pulmonary exacerbations, routine therapies, and nutritional supplements. Model results were used to draw comparisons within and between study groups. **RESULTS:** Before initiation of ICS, mean FEV_1 decline was -1.52 pp/year (95% CI: -1.96, -1.08 pp/year). After initiation of ICS therapy, mean FEV_1 decline was -0.44 pp/year (95% CI: -0.85, -0.03 pp/year), which was a significant change ($p=0.002$). In contrast to our observations in the ICS group, patients in the comparator group had a mean FEV_1 decline of -1.01 pp/year (95% CI: -1.27, -0.75 pp/year) before index, which marginally worsened ($p=0.046$) after index to -1.44 pp/year (95% CI: -1.70 to -1.19 pp/year). **CONCLUSIONS:** Initiation of ICS was associated with a significantly slower subsequent rate of FEV_1 decline in children with cystic fibrosis. Mixed-effects piecewise linear models are valuable for analyzing observational studies by demonstrating changes in key disease measures corresponding to the times of interventions.

Research on Methods – Conceptual Papers

PRM5

INCORPORATING EQUITY INTO DEVELOPING AND IMPLEMENTING EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

Eslava-Schmalbach JH, Sandoval Vargas G, Mosquera PA
Universidad Nacional de Colombia, Bogotá, Colombia

BACKGROUND: Clinical practice guidelines (CPG) are useful tools for clinical decision making, processes standardization and quality of care improvements. The current General Social Security and Health System (GSSHS) in Colombia is promoting the initiative of developing and implementing CPG based on evidence in order to improve efficiency and quality of care. The reduction of inequalities in health should be an objective of the GSSHS. **OBJECTIVES:** The main propose of this analysis is to argue why it is necessary to consider the incorporation of equity considerations in the development and implementation of clinical practice guidelines based on the evidence. **METHODS:** A series of reflections were made. Narrative description was used for showing the arguments that support the main findings. **RESULTS:** Among the main findings are: 1) Differential effectiveness by social groups of interventions could diminish final effectiveness of CPG in the GSSHS; 2) To not consider geographical, ethnic, socioeconomic, cultural and access diversity issues within the CPG could have a potential negative impacts of the CPG; 3) Overall effectiveness of GPC could be better if equity issues are included in the quality verification checklist of the guideline questions; and 4) Incorporating equity issues in the process of developing CPG could be cost effective, because improve overall effectiveness of CPG. **CONCLUSIONS:** To include equity issues in CPG and can help in achieving more equitable health outcomes. From this point of view CPG could be key tools to promote equity in care and health outcomes. Keywords: health inequalities, clinical practice guidelines, essay (Source: MeSH, NLM).

PRM6

TRANSLATION OF PATIENT-REPORTED OUTCOMES MEASURES TRANSLATABILITY REVIEW AND ITEM DEFINITION

Arnold BJ[1], Correia H[2], Pérez B[1], Lent L[1]
[1]*FACITtrans, Elmhurst, IL, USA,* [2]*Northwestern University, Chicago, IL, USA*

Translatability Review and Item Definition documents are key components to any successful Patient Reported Outcome (PRO) translation and are especially relevant in item banking initiatives. Translatability review helps to ensure concepts, constructs and phrasing in the source language are appropriate for translation into other languages and for multicultural contexts. Identifying potential issues during item development can result in improvement of the source item. When modification of the source is not possible or necessary, translatability review can be seen as a first step towards identifying acceptable translation alternatives which can be used by linguists. The assessment of item translatability before the translation process begins also facilitates the creation of item definitions, a critical tool for increasing translation accuracy. The Item Definition document refers to the identification and clarification of concepts the items are trying to measure. The development of item definitions is an iterative process combining efforts by translation coordinators and item/questionnaire developers as well as input from linguists. These steps are especially essential in item banking initiatives in which items are frequently made available by different developers and sources on behalf of varying patient populations, with disparate answer categories. As translation of PRO measures is much more than just a literal, word for word translation process, these steps are fundamental in furthering the equivalence, comparability and data poolability of translated language versions. This presentation will provide information regarding when to carry out these steps, how to carry them out and who should be involved in them. Linguistic issues such as, but not limited to, sentence structure, register and ambiguity will be discussed. Examples from National Institutes of Health Spanish translation projects Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) and The Patient-Reported Outcomes Measurement Information System (PROMIS) will be highlighted.

Respiratory-Related Disorders – Cost Studies

PRS1

BUDGET IMPACT ANALYSIS OF FLUTICASONE FUROATE (FFNS) IN TREATMENT OF ALLERGIC RHINITIS PATIENTS IN MEXICO

Rely K[1], Salinas GE[2], Anaya P[3], Alexandre PK[4]
[1]*CEAHealthTech, México, D.F., México,* [2]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México, D.F., México,* [3]*GlaxoSmithKline México, México, D.F., México,* [4]*Johns Hopkins University, Baltimore, MD, USA* **OBJECTIVES:** To estimate the 5-year projected impact on the annual pharmacy budget for allergic rhinitis (AR) patients in Mexico. **METHODS:** Mexican prevalence and treatment data for AR patients were obtained from published and nonpublished sources. The model considered 2 scenarios—without (pre) and with (post) FFNS. Market share data for corticosteroid treatment options for AR pre-FFNS and in the first year post-FFNS were obtained from nonpublished, real-world drug utilization data collected by GSK. Market shares for the second until fifth years post- FFNS were forecasted by the study authors. Drug costs were based on the Mexican Social Security Institute (IMSS). Wholesale Acquisition Cost was accessed on March 2010. The results for each indication were analyzed individually and summed to reflect the total impact of FFNS. Results were also considered on a per member per month (PMPM) basis to examine the relative impact on the plan. Sensitivity analyses were performed by varying several model input parameters. **RESULTS:** The estimated prevalence of AR in 2010 was 10%. In the year after its introduction, 60% of the AR population filled a prescription for FFNS. The estimated total cost for AR treatment prior to introduction of FFNS was $ 552 million and (532 to $ 384 million post FFNS. The incremental decrease in pharmacy benefit cost was ($ 20 to $ 84 millions) in 2010 dollars. These reductions translated to a medical care cost saving of $ 266 millions over 5 years. **CONCLUSIONS:** Model results suggest that increasing the use of fluticasone furoate decreases total budget costs due to decreased acquisition drug costs.

PRS2

COSTOS DE ATENCION MEDICA ATRIBUIBLES AL CONSUMO DE TABACO EN MÉXICO

Reynales-Shigematsu L[1], Quintana Carrillo R[2]
[1]*Instituto Nacional de Salud Pública, Cuernavaca, Morelos, México,* [2]*Instituto Nacional de Salud Pública, México, D.F., México*

OBJECTIVOS: Estimar la carga económica, en términos de costos de atención médica que las enfermedades atribuibles al consumo de tabaco representan para el sistema de salud Mexicano. **METODOLOGÍAS:** La estimación del costo directo de atención médica atribuible al tabaquismo se realizó con las enfermedades: CP, IAM, EPOC y EVC, en 2009. Instituciones de salud participantes: institutos nacionales (INNN, INCAN, INER e INCAR), Hospital Central Militar (HCM), Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (sólo incluye al CMN "20 de Noviembre" y al HRZ "1°. de Octubre" del ISSSTE) e Instituto Mexicano del Seguro Social (IMSS). El análisis de costos fue realizado desde la perspectiva del proveedor de servicios, utilizando la metodología *Cost of Illness*, basada en la prevalencia así como la creación de un panel de expertos multidisciplinario, que clasificó la atención médica: Ambulatoria, Urgencias, Hospitalización, Quirófano, Unidad de Cuidados Intensivos, Quimioterapia, Cuidados Paliativos y Radioterapia. Finalmente empleamos la fracción atribuible por tabaco para estimar dichos costos. Los costos están expresados en pesos mexicanos ($) y en dólares americanos (USD) del 2009. **RESULTADOS:** Los costos institucionales de atención médica por tabaquismo ascendieron a $459,026,446.2 (35,131,636.3 USD); Institutos Nacionales, $92,016,175.0 (7,042,467.4 USD); HCM, $103,483,466.1 (7,920,117.7 USD); ISSSTE y $9,564,089,959.0 (731,988,608.4 USD); IMSS, respectivamente. Los costos nacionales por tabaquismo oscilaron entre $30,213,184,046.5 (2,312,369,147.7 USD) y $44,484,500,278.1 (3,404,625,802.9 USD). El IAM y el CP fueron los más caros. **CONCLUSIONES:** Nuestros resultados muestran la elevada carga económica que representan para el sistema de salud mexicano el tabaquismo y son evidencia científica sobre la magnitud del problema. Como las enfermedades asociadas al tabaquismo son prevenibles, una adecuada política de salud para el control del tabaco, produciría una reasignación de los recursos económicos que actualmente se destinan al tratamiento de las enfermedades provocadas por el tabaco hacia otros programas institucionales.

PRS3

COSTOS DE ATENCION MEDICA DE LA ENFERMEDAD PULMONAR OBSTRUCTIVA CRONICA ATRIBUIBLES AL TABACO

Ramirez-Venegas A[1], Quintana Carrillo R[2], Sansores R[1], Hernandez-Zenteno R[1], Reynales Shigematsu L[2]
[1]*National Institute of Respiratory Diseases, México, D.F., México,* [2]*National Institute of Public Health, Cuernavaca, Morelos, México*

OBJECTIVOS: Estimar los costos directos de atención médica de la Enfermedad Pulmonar Obstructiva Crónica (EPOC) asociados al consumo de tabaco, en el Instituto Nacional de Enfermedades Respiratorias. **METODOLOGÍAS:** Durante el 2009 se estimaron los costos directos de la EPOC de los pacientes que fueron atendidos en el año 2008 en el Instituto. El análisis de costos se hizo desde la perspectiva del proveedor de servicios, considerando el enfoque de la metodología *Cost of Illness* (COI), basada en la prevalencia así como la creación de un panel de expertos multidisciplinario, que clasificó la atención médica en 4 eventos: Ambulatoria, Urgencias, Hospitalización y Unidad de Cuidados Intensivos. Finalmente empleamos la fracción atribuible por tabaco para estimar los costos por consumo de tabaco. El costo además se estimo de acuerdo a la gravedad de la enfermedad con los criterios GOLD. **RESULTADOS:** El costo anual de la EPOC atribuible al tabaco fue de $36 millones. El costo promedio por paciente, de acuerdo a GOLD fue de $30 mil; estadio I, $37 mil; estadio II, $84 mil; estadio III y $288 mil; estadio IV. Entre más grave fue la enfermedad, (III y IV) mayores costos resultaron. **CONCLUSIONES:** La evaluación económica de los costos directos que ocasiona el EPOC debido al tabaquismo, confirma la gran carga económica que representan estos pacientes para el presupuesto del INER y del sistema de salud mexicano. Estos resultados proveen suficiente evidencia científica para apoyar la implementación de políticas del sector salud relacionadas con el tabaco.

PRS4

ECONOMIC EVALUATION OF THE USE OF PALIVIZUMAB AS PROPHYLACTIC TREATMENT FOR THE REDUCTION OF COMPLICATIONS ASSOCIATED WITH RESPIRATORY SYNCYTIAL VIRUS IN PRE-TERM PATIENTS

Mayen-Herrera E[1], Buesch K[2], Cortina D[3]
[1]*Abbott Laboratories de México, México, D.F. México,* [2]●●●, [3]●●●

OBJECTIVES: To determine the incremental cost-effectiveness ratio (ICER) of the use of palivizumab as prophylaxis for the reduction of complications associated with respiratory syncytial virus (RSV) in pre-term patients <29 weeks of gestational age (WGA) under the Mexican public health sector perspective. **METHODS:** A cost-utility model was developed based on a decision tree that evaluated both scenarios of prophylaxis and no-prophylaxis. Epidemiological and cost data were obtained from different Mexican sources such as the Mexican Institute of Social Security (IMSS) by analysing birth rates. Clinical effectiveness was obtained from the international literature (Cardiac Synagis Study Group, The IMpact-RSV Study Group MEDI-493 Study Group). Prophylaxis therapy consisted of 5 applications of palivizumab during the winter season in Mexico. The dose scheme considered was 15 mg/kg. The effectiveness outcomes were quality adjusted life years (QALYs). Since

the study was conducted under the public health perspective, only direct medical costs associated with the RSV treatment were evaluated (hospitalization, emergency room, drugs, and prophylaxis). For resource utilisation purposes, an expert panel of paediatricians with experience in RSV infection was convened. Drug and medical attention costs were discounted by using a 3% discount rate and are reported in local currency. Acceptability curves of the probability of palivizumab to be cost effective were calculated. The threshold included in the study for cost-effectiveness comparisons, is the proposed by the World Health Organisation (3 times the gross domestic product per capita). **RESULTS:** The ICER per QALY for the study group was MXN $219,150. The acceptability curves showed a 75% probability of palivizumab to be cost effective when employing a 3 times GDP threshold. **CONCLUSIONS:** The use of palivizumab represents a cost-effective alternative for the prophylaxis of complications associated with RSV infection, under the public health perspective in Mexico for patients <29 WGA.

PRS5

COST-EFFECTIVENESS OF VARENICLINE VS EXISTING SMOKING CESSATION STRATEGIES IN DOMINICAN REPUBLIC USING THE BENESCO MODEL

Lutz M, Morales G, Cuesta G
Pfizer S.A., La Aurora, Heredia, Costa Rica

OBJECTIVES: In Dominican Republic, the economic burden of tobacco has not been assessed. The aim of this study was to evaluate the cost-effectiveness of varenicline compared to other existing strategies for smoking cessation within a 5-year time horizon in an adult population cohort from Dominican Republic using the healthcare payer's perspective. **METHODS:** The Benefits of Smoking Cessation on Outcomes (BENESCO) simulation model was used for an adult cohort in Dominican Republic (n=6,528,125). Smoking cessation therapies compared were: varenicline (0.5 – 2 mg/day) versus bupropion (300 mg/day); nicotine replacement treatment (NRT) (5-10 mg/day) and unaided cessation. Effectiveness measures were: Life-Year gained (LYG) and quality-adjusted life-year gained (QALY's). Resource use and costs data were obtained from Dominican Republic's Ministry of Health and Social Security databases (2009). The model used a 3% discount rate for costs (expressed in 2009 US dollars) and health outcomes. Probabilistic sensitivity analyses (PSA) were conducted and acceptability curves were constructed. **RESULTS:** Varenicline reduced smoking-related morbidity, mortality and healthcare costs. After 5 years, mortality in the varenicline arm was reduced by 67, 86 and 163 deaths compared with bupropion, NRT and unaided cessation, respectively. The net average cost per additional quitter showed that varenicline was cost-saving against competing alternatives. Varenicline exhibited 145, 188 and 355 more QALYs against Bupropion, NRT and unaided cessation, respectively. Cost-effectiveness analyses showed that varenicline was the dominant strategy. At a willingness-to-pay of US$8,000/QALY, the probability that varenicline is cost-effective met 100%. PSA results support the robustness of the findings. **CONCLUSIONS:** Smoking cessation therapy with varenicline is cost-saving in Dominican Republic. These results could help to reduce the tobacco related disease burden and align cost-containment policies.

PRS6

COST-EFFECTIVENESS OF FLUTICASONE FUROATE COMPARED WITH MOMETASONA FUROATE FOR THE PRIMARY TREATMENT OF ALLERGIC RHINITIS PATIENTS

Rely K[1], Alexandre PK[2], Anaya P[3], Salinas GE[4]
[1]*CEAHealthTech, México, D.F., México,* [2]*Johns Hopkins University, Baltimore, MD, USA,* [3]*GlaxoSmithKline México, México, D.F., México,* [4]*Hospital Infantil de México Federico Gómez, Secretaría de Salud, México, D.F., México*

OBJECTIVES: To evaluate the cost-effectiveness of fluticasone furoate vs. mometasone furoate in the treatment of ocular symptoms in allergic rhinitis patients in Mexico. **METHODS:** A decision-analytic model was developed to estimate the cost-effectiveness of fluticasone furoate versus mometasone furoate. Patients initiated on treatment either completed initial therapy or switched to second line therapy due to non-response. Probability of a switch and resource use was based on expert panel and literature. Costs were based on local drug acquisition costs, local cost estimates for outpatient and hospitalization. Effectiveness was defined as the net improvement in Total Ocular Symptom Score (TOSS) at 12 weeks from Keith PK. 2009 study. The analysis was carried out from the perspective of the Mexican health care system and all costs are reported in 2010 US dollars. **RESULTS:** The corresponding health effects were 0.47 net improvement TOSS for fluticaone furoate and 0.31 for mometasone furoate regimen. The mean total cost of the fluticaone furoate regimen was $ 627 compared with $ 827 for the furoate mometasone regimen. Treatment with fluticasone furoate compared to treatment with mometasone furoate was less costly and resulted in a greater net improvement of TOSS. Probabilistic sensitivity analyses demonstrated that the cost savings observed were maintained over a wide range of alternative values for costs and resource utilization. **CONCLUSIONS:** Cost-effectiveness analysis indicated the dominance of fluticasone furoate over mometasone furoate because of both lower costs and greater efficacy. Cost savings with fluticasone furoate were attributable to lower drug acquisition costs. In addition, a net improvement in ocular symptoms may be expected in allergic rhinitis patients.

PRS7

ESTUDIO DE COSTO-EFECTIVIDAD DE BECLOMETASONA VS CICLESONIDA COMO MEDICAMENTOS CONTROLADORES EN EL MANEJO DEL ASMA EN PACIENTES QUE ASISTEN A CONSULTA EXTERNA DE NEUMOLOGÍA PEDIÁTRICA EN EL HOSPITAL UNIVERSITARIO CLÍNICA SAN RAFAEL DE BOGOTÁ COLOMBIA, JULIO A DICIEMBRE 2010

Hinestrosa F[1], Pedraza AM[2]
[1]*Grünenthal Colombiana S.A., Bogotá, Colombia,* [2]*Hospital San Rafael, Bogotá, Colombia*

OBJECTIVOS: Desarrollar un estudio de costo-efectividad que compare Ciclesonida con Beclometasona en el control del asma. **METODOLOGÍAS:** Estudio Costo-Efectividad, de cohortes, observacional, analítico, con información recolectada prospectivamente, realizado desde la perspectiva institucional, incluyó pacientes pediátricos con diagnóstico de asma no controlada admitidos durante Julio de 2010 los que recibieron Ciclesonida o Beclometasona como único medicamento controlador. Se realizó seguimiento por 6 meses, basados en datos reportados por la literatura se utilizó el porcentaje de pacientes libres de crisis asmáticas como variable para el cálculo del tamaño muestral, la muestra necesaria fué de 20 pacientes por cada alternativa, se incluyeron 94 pacientes con edades entre los 1 y 15 años, 47 recibieron Beclometasona y 47 Ciclesonida. La asignación fue de manera aleatoria. La variable primaria de efectividad fue definida como el porcentaje de pacientes libres de crisis durante el periodo de estudio, se definieron como variables generadoras de costo uso de medicamentos y estancia hospitalaria. Se calculó la razón costo-efectividad incremental y se realizó un modelo mediante un árbol de decisión. **RESULTADOS:** 17 pacientes estuvieron libres de crisis en el grupo de Beclometasona, los costos de utilización de medicamentos en este grupo fueron de $7255.564 pesos colombianos, los costos de hospitalización se calcularon en $38,568.200, los costos totales ascendieron a $45,823.764 ($25,188.67 dólares). En el grupo de Ciclesonida, 45 pacientes estuvieron libres de crisis, los costos por utilización de medicamentos fueron de $14,982.172, los costos derivados de hospitalización se calcularon en $92,200, los costos totales alcanzaron los $15,074.372 ($8291.73 dólares). La razón costo-efectividad incremental de Beclometasona versus Ciclesonida fue de -1'098.192. **CONCLUSIONES:** Al utilizar Ciclesonida el hospital encuentra ahorros de $1098.192 pesos por cada paciente libre de crisis, desde la perspectiva del hospital, el manejar un paciente con Beclometasona representa un costo adicional de $1,098.192 que se podrían ahorrar si el paciente fuese manejado con Ciclesonida.

PRS8

COST-EFFECTIVENESS OF AN AMBULATORY PROGRAM OF PULMONARY REHABILITATION FOLLOWING ACUTE EXACERBATIONS OF COPD IN COLOMBIA

Giraldo LF, Brito KP, Rodriguez P
Universidad de La Sabana, Chia, Cundinamarca, Colombia

OBJECTIVES: To evaluate the economic benefits of an 8 week Ambulatory Pulmonary Rehabilitation Program (PR) plus GOLD based standard treatment (ST) vs. ST without PR of COPD patients after an acute exacerbation of the disease in the Colombian Health Care System (CHCS). **METHODS:** Direct costs of ST and of PR were calculated according to tertiary level university hospital's registries during one year and CHCS's drugs prices; these costs and QALY were estimated for one year by a Markov chain model based on Seymour's study (Thorax, 2010) findings of health care utilization and probability of death. Univariate sensitivity and probabilistic analysis were performed by Monte Carlo method. **RESULTS:** Following acute exacerbation of COPD the annual cost of PR plus ST was COL$ 4,594,407,00 (US$ 2,483.46) vs. an annual cost of ST without PR of COL$ 9,124,326.00 (US$ 4,932.07). QALY of PR plus ST patients: 0.86577; QALY of ST without PR: 0.852979. Mean cost-effectiveness of PR plus ST: COL$5,306,729.00 (US$ 2,868.50) per QALY, cost-effectiveness of ST without PR:$10,697,014.00 (US$ 5,782.17) per QALY. There was absolute dominance of PR plus ST vs. ST without PR in all scenarios. In the sensitivity analysis the absolute dominance is maintained for any cost of PR program < COL$ 5,302,428.00 (US$ 2.866,18). **CONCLUSIONS:** Global costs of Pulmonary Rehabilitation plus Standard Treatment are much lower than Standard Treatment without Pulmonary Rehabilitation for patients after an acute exacerbation of COPD. Pulmonary Rehabilitation is a highly cost-effective treatment for these patients in the CHCS and probably in many other countries with similar socio-economic level, specially of Latin America.

Respiratory-Related Disorders – Patient-Reported Outcomes & Preference-Based Studies

PRS9

DISPONIBILIDAD A PAGAR POR UN METODO EFECTIVO PARA DEJAR DE FUMAR: EVIDENCIAS A PARTIR DE LA ENCUESTA GLOBAL DE TABAQUISMO EN ADULTOS MÉXICO 2009

Heredia I, Serván E, Reynales LM, Bautista S
Instituto Nacional de Salud Pública, Cuernavaca, Morelos, México

OBJECTIVOS: Estimar la máxima disponibilidad a pagar (DAP) por un tratamiento efectivo de cesación tabáquica entre fumadores mexicanos e identificar los factores sociodemográficos, de la historia de fumador y de su entorno asociados a esta valoración. **METODOLOGÍAS:** Se realizó un estudio observacional de tipo transversal. La muestra de análisis estuvo constituida por 777 fumadores que participaron en la Encuesta Global de Tabaquismo en Adultos, México 2009. Se realizó un análisis descriptivo y de asociación estadística que permitió caracterizar a los fumadores y su DAP con base en variables socioeconómicas, demográficas, de su historia de tabaquismo y de su entorno. **RESULTADOS:** El 74.4% de los fumadores eran del sexo masculino, 51.4% consumía cigarrillos con una frecuencia diaria. Los fumadores tenían más de 15 años fumando, 58.6% había realizado intentos previos de cesación y alrededor del 10% conocía de la existencia de centros de ayuda para dejar de fumar. En promedio, la DAP por un método efectivo de cesación fue $2573 pesos mexicanos. En los hombres, la DAP fue 2056 pesos menor que en las mujeres. A mayor educación y mayor nivel socioeconómico (NSE), la DAP de los fumadores aumentó en todos los modelos estimados. **CONCLUSIONES:** Las estimaciones del presente estudio sugieren que los fumadores mexicanos que desean dejar de fumar revelan, en términos monetarios, una alta valoración por un método de cesación efectivo. Los fumadores del sexo masculino muestran un comportamiento

más "egoísta" que las mujeres fumadoras. En México, se requiere de la implementación de un mayor número de acciones encaminadas a apoyar a los fumadores en su intento por abandonar la adicción al tabaco, fortaleciendo y ampliando la oferta de programas de cesación, así como el acceso a los tratamientos farmacológicos logrando una cobertura universal mediante la incorporación de las diferentes alternativas farmacológicas al cuadro básico de medicamentos del sector salud.

Sensory Systems Disorders – Cost Studies

PSS1

EVALUACION ECONOMICA DE FOTOTERAPIA DE BANDA ANGOSTA O FOTOQUIMIOTERAPIA PARA EL TRATAMIENTO DE PSORIASIS DESDE LA PERSPECTIVA DEL INSTITUTO MEXICANO DEL SEGURO SOCIAL

Carlos F[1], Ramos E[1], Llorens F[2], Ruiz L[2]
[1]*R A C Salud Consultores, S.A. de C.V., México, D.F., México,* [2]*Tecnologicos Dalup S. De R.L. De C.V., México, D.F., México*

OBJECTIVOS: La psoriasis es una enfermedad cutánea que en sus formas moderadas-graves afecta la expectativa y calidad de vida. El objetivo fue evaluar costos y desenlaces en salud de diversas modalidades de tratamiento de psoriasis de grado moderado-severo desde la perspectiva del Instituto Mexicano del Seguro Social (IMSS). **METODOLOGÍAS:** En un modelo Markov se compararon: fototerapia de luz ultravioleta de banda angosta (UVB-NB); fotoquimioterapia PUVA; metotrexato (MTX); ciclosporina (CsA); infliximab (INF); etanercept (ETA); adalimumab (ADA). Se contemplaron dos horizontes temporales: período de evaluación (12-16 semanas) seguido de un período de 10 años donde los respondedores continúan tratamiento. Cada ciclo anual los pacientes enfrentan riesgo de muerte y de abandono por pérdida de eficacia o por eventos adversos. Se analizaron los costos de adquisición y administración de terapias, monitoreo de pacientes y costo adicional por falla terapéutica. Mediante revisión sistemática se identificó el cambio en el puntaje PASI (Psoriasis Area Severity Index) asociado con cada estrategia y su efecto en calidad de vida. Los costos se expresan en pesos mexicanos (MXN) 2010. **RESULTADOS:** El costo total acumulado por paciente es más bajo cuando se utiliza PUVA ($589,636); MTX ($602,045) o UVB-NB ($602,749) que cuando se emplea CsA ($644,268) o algún agente biológico: $919,292 (ETA); $1,048,781 (ADA) y $1,190,837 (INF). La mejor respuesta se obtuvo con ADA e INF. El costo más bajo por categoría de respuesta (moderada o buena) se encontró con PUVA, seguido de UVB-NB, MTX y CsA. En todos los casos, los agentes biológicos condujeron a un costo por respuesta notablemente más elevado. UVB-NB y PUVA fueron dominantes (menos costosos y con más años de vida ajustados por calidad) con relación a MTX, CsA y ETA. **CONCLUSIONES:** UVB-NB y PUVA representan las alternativas más costo-efectivas y potencialmente costo-ahorradoras al compararse con otras modalidades de tratamiento utilizadas actualmente en IMSS.

PSS2

ENCOURAGING THE EFFICIENCY OF THE NATIONAL TRANSPLANT PROGRAM: ESTIMATING THE COST OF CORNEAL TRANSPLANT TO BE FINANCED BY PUBLIC INSTITUTIONS IN THE HEALTH SECTOR IN MEXICO

Camacho A, Gutierrez C
Mexican Ministry of Health, México, D.F. México

OBJECTIVES: Estimate the cost of procurement-surgery-follow up for corneal transplant to be covered by public institutions in Mexico, in the context of the National Transplant Program. The estimation is important, because according to economic evaluation studies in Mexico, corneal transplant is considered a very cost effective intervention. However, there is a considerable list of patients awaiting corneal transplant. This situation urges forward the Ministry of Health to analyze the various aspects involved in the corneal procurement-transplant process. **METHODS:** A micro-costing was developed considering the clinical treatment protocol developed by the collegiate body of the General Health Council of Mexico. The protocol includes three phases: preoperative, surgery and follow-up. Each phase requires a number of studies, medical supplies, medicines and medical staff. The unit cost of required inputs are obtained from the public health sector. **RESULTS:** The total cost of the procurement-surgery-follow up of corneal transplant, was US$2037. The phase that represents the lowest percentage of total cost is the preoperative (13.4%), the greatest cost comes in the stage of surgery with US$1042 (46.4%). This stage includes the most expensive supply (trephine) as well as the cost of the procurement process. Finally, the follow up phase amounts to US$722 which represents the cost of medical visits and drug therapy for one year. **CONCLUSIONS:** The results allow estimating the total cost of corneal transplant in the context of public institutions in Mexico. This estimate provides vital information for the decision making process of developing sustainable strategies for the abatement of the list of patients waiting for corneal transplantation.

PSS3

UN ESTUDIO DE COSTO-EFECTIVIDAD PARA EVALUAR EL TRATAMIENTO CON N-ACETIL CISTEÍNA EN PACIENTES CON ESCLEROSIS SISTÉMICA

Lopez JA[1], Briones B[2]
[1]*Sandoz México, México, D.F., México,* [2]*Novartis Farmaceutica, México, D.F., México*

OBJECTIVOS: La terapia con N-Acetil Cisteína ha demostrado ser eficaz y segura en pacientes con Esclerosis Sistémica (ES). El objetivo de este análisis es comprobar la costo-efectividad de la adición de N-Acetil Cisteína al tratamiento estándar para ES. **METODOLOGÍAS:** Este es un estudio de costo-efectividad desde la perspectiva institucional del Instituto Mexicano del Seguro Social (IMSS). Se evaluó el tratamiento estándar a base de prednisona 10 mg/d y penicilamina 300 mg/d en comparación con el mismo tratamiento más la adición de N-Acetil Cisteína 1.8 g/d durante seis meses. La medición de eficacia utilizada fue la mejora en capacidad vital (CV), medida por espirometría; los datos de eficacia fueron obtenidos de estudios publicados. Los costos y la utilización de recursos fueron obtenidos de la institución; todos los costos están expresados en Pesos Mexicanos y son vigentes para el 2010. El horizonte temporal fue de 6 meses, por lo cual no se utilizó tasa de descuento. Se realizó un análisis probabilístico de sensibilidad a través de una simulación de Monte Carlo con 100,000 iteraciones para corroborar la robustez del modelo. **RESULTADOS:** El análisis reveló un índice de costo-efectividad de $9898.74 para el grupo que recibió el tratamiento estándar más la adición de N-Acetil Cisteína, en comparación con un índice de $7158.09 para el grupo que sólo recibió el tratamiento estándar, lo cual nos da como resultado un índice incremental de costo-efectividad de $2740.65, que es el costo por cada unidad adicional de eficacia con la adición del tratamiento de N-Acetil Cisteína. **CONCLUSIONES:** La adición de N-Acetil Cisteína al manejo de pacientes con ES supone un incremento en la eficacia y una mejora en la capacidad vital, que conlleva un costo adicional de $2740.65 por cada unidad adicional de eficacia, convirtiendo a N-Acetil Cisteína en un tratamiento costo-efectivo.

Sensory Systems Disorders – Patient-Reported Outcomes & Preference-Based Studies

PSS4

DEVELOPMENT OF A QUESTIONNAIRE ASSESSING THE BURDEN OF ICHTHYOSIS IN INFANTS

Taieb C[1], Dufresne H[2], Bodemer C[2]
[1]*PFSA, Boulogne Billancourt, France,* [2]*Hopital Necker, Paris, France*

OBJECTIVES: To explore the handicap, in the largest sense, generated by ichthyosis using a questionnaire to express the burden of the illness on the daily life of patients and their family, in order to anticipate and treat it more effectively. **METHODS:** The questionnaire was developed following a strict methodological process involving a multidisciplinary team incorporating various players (doctors, nurses, social workers) who are involved in the treatment of patients and caring for their families in order to guarantee its credibility and reliability. A review of the literature and discussions with the children and their families were conducted in order to identify the concepts related to the pathology. **RESULTS:** Exploratory assessments showed that the concept of burden could be structured around 5 components: feeling of pain, daily life, family and personal relationships, work and psychological impact. 96 preliminary items were identified at the end of the first discussion. A first analysis managed to reduce these items to 40 whilst conserving the 5 components but making it easier to use the analysis. The creation of a "child module" aimed at children who are able to provide answers independently proved necessary. **CONCLUSIONS:** Chronic pathologies such as ichthyosis, which remains a rare and incapacitating illness, are difficult to assess by clinical or quality of life aspects alone as their impact can be multidimensional. Although there is no specific quality of life questionnaire, several existing questionnaires attempt to assess one or other of these components; our questionnaire entitled "Family Burden Ichthyosis" takes them all into consideration in order to explain every angle of the handicap generated.

Systemic Disorders/Conditions – Cost Studies

PSY1

EPIDEMIOLOGY AND SOCIOECONOMIC BURDEN OF OVERWEIGHT AND OBESITY IN ARGENTINA

Elgart JF, Gonzalez L, Caporale JE, Pfirter G, Gagliardino JJ
CENEXA - Centro de Endocrinología Experimental y Aplicada (UNLP-CONICET La Plata, Centro Colaborador OPS/OMS), La Plata, Buenos Aires, Argentina

OBJECTIVES: Obesity is a global epidemic with a heavy socio-economic burden. This study estimates such burden in Argentina and provides useful evidence to design prevention, control and treatment strategies for obesity and other cardiovascular risk factors (CVRFs). **METHODS:** Descriptive statistical analyses of the National Survey of Risk Factors (2005) to identify associations between overweight/obesity (classified according to BMI values and WHO criteria) and demographic/epidemiological characteristics. It estimates fatal events, cost of premature deaths (human capital approach) and loss of healthy life years due to overweight and obesity. Differences in means and proportions were verified using Student's t test, ANOVA and Chi2. **RESULTS:** The national prevalence of overweight and obesity was 34.8% and 14.8%, respectively; age range of the adult overweight/obesity population was 35-64 years; obese people were older than normal weight and overweight (49.4 vs. 38.7 and 47.3, respectively); 16.2% of the obese people had unsatisfied basic needs (15.1% in overweight people). Prevalence of obesity (15.2%) was lower than that of overweight (21.6%) in university students. Obesity was frequently associated with other CVRFs, being hypertension the most frequent one (48.1%). The association with two o more CVRFs was greater in obese than in overweight people (23.3% vs. 16.6%), with 14.776 deaths due to overweight/obesity. The statistical value of life in Argentina was $39,174. The cost attributable to premature deaths due to obesity/overweight was $190.5 millions (70% due to overweight). We estimate 596.704 lost healthy life years due to overweight/obesity. **CONCLUSIONS:** Implementation of effective strategies for the prevention and treatment of overweight and obesity is necessary to decrease their high socioeconomic costs and their negative impact upon lost healthy life years.

PSY2

ESTIMACIÓN DEL IMPACTO FINANCIERO EN LA SALUD DE LA POBLACIÓN MEXICANA DERIVADO DE LA OBESIDAD Y EL SOBREPESO, 2000-2017

Guajardo-Barron VJ, Gutierrez-Delgado MC
Mexican Ministry of Health, México, D.F., México

OBJECTIVOS: Estimar el impacto financiero de la obesidad y el sobrepeso en los aspectos de muerte prematura y gasto total de la atención médica en el contexto mexicano para el periodo 2000-2017. **METODOLOGÍAS:** Se desarrollan diversos escenarios en un modelo de proyección que emplea información de incidencia, prevalencia, población expuesta al riesgo, costo anual unitario y fracción de enfermos y muertes atribuibles a obesidad y sobrepeso, esperanza de vida e ingresos promedios. **RESULTADOS:** El ingreso perdido por muerte prematura asociada a cuatro enfermedades seleccionadas atribuibles a obesidad y sobrepeso se estimó en 25,099 millones de pesos en 2008 afectando a 45,504 familias. La estimación para 2017 fluctúa entre 30,394 millones y 101,086 millones de pesos afectando a 68,471 familias. El gasto total anual en la atención médica de cuatro enfermedades seleccionadas atribuibles a obesidad y sobrepeso en 2008 asciende a $42,246 millones. Este monto representa el 33.2% del gasto público federal en atención médica presupuestado en ese año. En 2017 se estima que dicho gasto fluctúe entre $77,909 millones y $101,281 millones en pesos de 2008 que representarían entre el 61.2% y 79.5% del gasto público federal en atención médica del presupuesto 2008. Nótese que el gasto total en atención médica esta subestimado en al menos 6433 millones de pesos al no incluir complicaciones derivadas de las enfermedades seleccionadas. Además no incluye el gasto en la atención médica de la obesidad y el sobrepeso como enfermedad, estimado en alrededor de 19,688 millones de pesos. **CONCLUSIONES:** De los resultados se evidencia la necesidad de definir e implementar una serie de políticas preventivas encaminadas a reducir la incidencia de obesidad y sobrepeso en la población mexicana. Asimismo se requiere un seguimiento integral de la población enferma para controlar la aparición de complicaciones que implique un ahorro potencial al sistema mexicano de salud.

PSY3

USE OF A DISCRETE EVENT SIMULATION MODEL TO ESTIMATE LONG TERM ECONOMIC OUTCOMES OF BARIATRIC SURGERY IN MORBIDLY-OBESE, TYPE-2 DIABETIC PATIENTS IN MEXICO

Zanela OO[1], Cabra HA[1], Anaya P[2], Rodriguez S[1], Melendez G[2], Rupprecht F[3]
[1]*Johnson & Johnson Medical, México, D.F., México,* [2]*Fundación Mexicana para la Salud AC, México, México,* [3]*Ethicon Endo-Surgery, Mission Viejo, CA, USA*

OBJECTIVES: Estimate return of investment (ROI) time for bariatric surgery as treatment for morbidly obese, type-2 diabetic (T2D) patients *versus* conventional, non-surgical approach from a Mexican third level public hospital perspective. **METHODS:** The individual experience of a morbidly-obese patient was assessed using a discrete event simulation model built in Arena™. Patients were created with unique, randomly assigned baseline characteristics, cloned and sent to either bariatric surgery (BS) or conventional treatment – pharmacologic treatment of associated comorbidities and lifestyle modifications (control arm). The only comorbidity considered was T2D. Preoperative prevalence and up to year 2 recovery rates were taken from a published meta-analysis. Prevalences for years 2-10 were assumed constant, as literature suggests T2D does not relapse after year 2 post surgery. Patients in control arm were not allowed to experience comorbidity recovery. Additional assumptions include infrastructure restrictions, no perioperative complications and short term mortality; 5% of patients in control group were allowed to have bariatric surgery after year 5. Considered costs included the bariatric procedure and T2D pharmacologic treatment, taken from public institution's DRG list. Simulation was run with 150 patients for 10 years and 10 iterations using a 4.5% annual discount rate. Results are shown in years and 2011 inflation-adjusted MXP; 95% confidence intervals were estimated. **RESULTS:** Average 10-year accumulated costs were $108,744 ($108,302 – $ 109,186) for a BS patient and $222,555 ($222,062 - $223,048) for a control patient. ROI on BS was achieved on year 4.55 (4.52 – 4.58). Cost differences are due to the reduced resource utilization after BS resulting from T2D resolution. **CONCLUSIONS:** Investment in BS offsets its cost and is recouped within a reasonable time, thus allowing institutions to reduce the burden imposed by T2D morbidly obese patients. Long-term data for other associated comorbidities is needed, as their inclusion in the analysis could modify ROI time.

PSY4

MODELO DE COSTO BENEFICIO DE LIDOCAINA EN PARCHE AL 5% VERSUS PREGABALINA 300 MG Y 600 MG AL DÍA PARA EL TRATAMIENTO DE LA NEURALGIA POSTHERPÉTICA

Rojas LA[1], Martinez JA[2]
[1]*Universidad de La Sabana, Chía, Cundinamarca, Colombia,* [2]*Grünenthal Colombiana S.A., Bogotá, Colombia*

OBJECTIVOS: Estimar el costo-beneficio (CB) de usar lidocaína parche 5% para el tratamiento de la Neuralgia Post-Herpética (NPH) comparado con pregabalina cápsulas de 300mg y 600mg al día desde la perspectiva del pagador en el sistema de salud de Colombia. **METODOLOGÍAS:** Se construyó un modelo teórico de análisis de decisión con base en el costo-beneficio de usar lidocaína en parche 5% y pregabalina 300mg/día y 600mg/día para el tratamiento de la NPH, simulando 1000 pacientes adultos en un horizonte temporal de un mes, utilizando el software DPL v7; tomando como variable de desempeño el costo total del tratamiento (costo del medicamento para la enfermedad + costo de tratamientos complementarios + costo de tratamiento de reacciones adversas). El criterio de decisión será el medicamento que produzca menos efectos adversos relacionados con el tratamiento y que genere menores costos totales. Como análisis de sensibilidad se empleará una simulación de Montecarlo, modificando la variable de costo de tratamiento. **RESULTADOS:** Los costos totales del tratamiento mensual en moneda local fueron: lidocaína 5% 1 parche/día $386.809,48; lidocaína 5% 1/2 parche/día $196.553,62; pregabalina 150 mg bid fue $232.700,19 y pregabalina 300 mg bid $326.912. Desde la perspectiva de costo integral, la alternativa menos costosa fue pregabalina 150 mg dos veces al día. Simulando en DPL, el uso de medio parche de lidocaina 5% presenta mejor relación costo/beneficio frente a pregabalina. **CONCLUSIONES:** Según el modelo de costo-beneficio, para la NPH se recomienda iniciar tratamiento con pregabalina 150mg via oral cada 12 horas. En caso de presentarse reacción adversa, iniciar medio parche o parche completo de lidocaína al 5%, si no hay alivio usar pregabalina 300mg al día, dosis con la que es necesario evaluar el perfil de seguridad. Este trabajo puede ser el fundamento de establecer si Lidocaina 5% en parche puede favorecer la calidad de vida de los pacientes que requieran tratamiento para la NPH.

PSY5

ESTUDIO COSTO-EFECTIVIDAD DEL PARCHE DE LIDOCAÍNA COMO TERAPIA ADYUVANTE A PREGABALINA Y GABAPENTINA EN EL MANEJO DEL DOLOR NEUROPÁTICO PERIFÉRICO EN EL HOSPITAL SAN JOSÉ DE BOGOTÁ D.C. ENERO-DICIEMBRE 2010

Hinestrosa F[1], Garzon L[2]
[1]*Grünenthal Colombiana S.A., Bogotá, Colombia,* [2]*Hospital San José, Bogotá, Colombia*

OBJECTIVOS: Desarrollar un estudio costo-efectividad que compare Pregabalina y Gabapentina con y sin la terapia adyuvante del parche de Lidocaína en dolor neuropático periférico. **METODOLOGÍAS:** Estudio costo-efectividad, observacional, descriptivo, con recolección retrospectiva de información, desde la perspectiva institucional, incluyó historias clínicas de pacientes con dolor neuropático periférico que utilizaron bien sea Pregabalina ó Gabapentina para el control del dolor con y sin el parche de Lidocaína como medicamento adyuvante y que asistieron a clínica de dolor entre Enero y Diciembre de 2010.La variable primaria de efectividad fue definida como el número de pacientes que presentaron mejoría significativa del dolor en el periodo de estudio, previamente definido como alivio de tres o más puntos en la escala visual análoga, se definieron como variables generadoras de costo el uso de medicamentos, estancia hospitalaria y atención por profesionales de la salud. Se calculó la razón costo-efectividad incremental para cada alternativa, el análisis de sensibilidad se hizo al variar 20% el costo más relevante, se realizó análisis de decisiones mediante un modelo de Markov. **RESULTADOS:** Se encontró que 49 pacientes utilizaron Gabapentina, 52 Lidocaína + Gabapentina, 57 Pregabalina y 59 Lidocaína + Pregabalina. Un total de 23 pacientes presentaron mejoría significativa en el grupo de Gabapentina, 43 con Lidocaína + Gabapentina, 38 con Pregabalina y 55 con Lidocaina + Pregabalina . Los costos totales ascendieron a $315.846.279 pesos con Gabapentina, $302.547.985 con Lidocaína+Gabapentina, $310.729.129 con Pregabalina y $292.478.627 con Lidocaína + Pregabalina, La razón costo-efectividad incremental de Gabapentina versus Lidocaína + Gabapentina fue de -664.914. la de Pregabalina versus Lidocaina + Pregabalina -1.073.558. **CONCLUSIONES:** La adición del parche de lidocaína a la terapia regular con gabapentina y pregabalina demostró una relación de costo efectividad favorable en ambas situaciones, se encontró que al comparar entre la terapia adyuvante a gabapentina y pregabalina fue la adición a pregabalina la que reflejo mayores beneficios.

PSY6

ESTUDIO DE COSTO-EFECTIVIDAD DE BUPRENORFINA TRANSDÉRMICA VERSUS OXICODONA ORAL Y FENTANILO TRANSDÉRMICO EN EL MANEJO DEL DOLOR CRÓNICO NO ONCOLÓGICO EN EL HOSPITAL SAN JOSÉ DE BOGOTÁ D.C. ENERO-DICIEMBRE 2010

Hinestrosa F[1], Garzon L[2]
[1]*Grünenthal Colombiana S.A., Bogotá, Colombia,* [2]*Hospital San José, Bogotá, Colombia*

OBJECTIVOS: Desarrollar un estudio de costo-efectividad que compare Buprenorfina transdérmica con Fentanilo transdérmico y Oxicodona oral en el manejo del dolor crónico no maligno. **METODOLOGÍAS:** Estudio costo-efectividad, observacional, descriptivo, con recolección retrospectiva de la información, realizado desde la perspectiva institucional, incluyó historias clínicas de pacientes con dolor crónico no maligno que utilizaron bien sea Fentanilo ó Buprenorfina ó Oxicodona para el control del dolor y que asistieron a clínica de dolor entre Enero y Diciembre de 2010.La variable primaria de efectividad fue definida como el número de pacientes que presentaron mejoría significativa del dolor en el periodo de estudio, previamente definido como alivio de tres o más puntos en la escala visual análoga, se definieron como variables generadoras de costo el uso de medicamentos, la estancia hospitalaria y la atención por profesionales de la salud. Se calculó la razón costo-efectividad incremental para cada alternativa, el análisis de sensibilidad se hizo al variar en un 20% el costo más relevante, se realizó análisis de decisiones mediante un modelo de Markov. **RESULTADOS:** Se encontró que 147 pacientes utilizaron Oxicodona, 121 Fentanilo transdérmico y 132 Buprenorfina transdérmica. Un total de 115 pacientes presentaron mejoría significativa en el grupo de Oxicodona, 104 en el grupo de Fentanilo y 117 en el de Buprenorfina. Los costos totales ascendieron a $400.224.615 pesos colombianos en el grupo de Oxicodona, $398.902.388 en el grupo de Fentanilo y $396.875.234 en el grupo de Buprenorfina. La razón costo-efectividad incremental de Oxicodona versus Buprenorfina fue de -1'013.577. La de Oxicodona versus Fentanilo -120.202 y la de Fentanilo versus Buprenorfina -257.644. **CONCLUSIONES:** El Fentanilo y la Buprenorfina se asociaron a valores favorables al compararse con Oxicodona, ambas alternativas se mostraron costo-efectividad significativa en el escenario estudiado, el desempeño de Buprenorfina transdérmica fue ligeramente superior al de Fentanilo transdérmico.

PSY7

COST OF MANAGING BLEEDING-RELATED EPISODES (BRE) FOR ROMIPLOSTIM VERSUS STANDARD OF CARE (SOC) IN PATIENTS WITH CHRONIC IMMUNE THROMBOCYTOPENIA (ITP) IN MEXICO

Arocho R[1], Northridge K[2], Rivera Hurtado R[3], Chavez JG[4]
[1]*Amgen, Inc., Barcelona, Spain,* [2]*Outcomes Insights, Inc., Westlake Village, CA, USA,* [3]*Amgen México, México, D.F., México,* [4]*National Institute of México for Social Security (IMSS),*

Tlalnepantla de Baz, Edo., México, D.F., México

OBJECTIVES: ITP, an autoimmune disorder characterized by isolated thrombocytopenia, puts patients at risk of BRE, the management of which can pose a high economic burden. The novel TPO-mimetic romiplostim is recommended for treatment of adult patients with chronic ITP. We compared BRE rates, and the costs of managing BRE in Mexico, for romiplostim versus SOC in adult patients with chronic ITP. **METHODS:** BRE rates were obtained from two randomized placebo-controlled trials in splenectomized and non-splenectomized patients. BRE were categorized as: outpatient minor bleed, bleed requiring immunoglobulin treatment, or bleeding-related hospitalizations. BRE costs were calculated by splenectomy status and treatment group, with unit costs obtained from the 2010 Official Price List of the Public Healthcare System in Mexico. The frequency of each BRE was multiplied by its managing cost and this total cost divided by the total number of patient-weeks in each treatment arm to obtain an average cost per patient per week. The average cost per patient per week was then extrapolated to the treatment duration of 52 weeks. **RESULTS:** The analysis included 62 non-splenectomized (41 romiplostim, 21 SOC) and 63 splenectomized patients (42 romiplostim, 21 SOC), with a total of 2,715 patient-weeks on study. Romiplostim yielded a 55% reduction in all BRE (95% CI: 41% to 65%) and an 88% (95% CI 80% to 93%) reduction in those requiring immunoglobulin treatment. The estimated yearly BRE management cost per non-splenectomized patient was MXP$33,103 for romiplostim and MXP$162,720 for SOC. The estimated yearly BRE management cost per splenectomized patient was MXP$31,328 for romiplostim and MXP$283,246 for SOC. **CONCLUSIONS:** Romiplostim is an important therapeutic alternative for adult patients with chronic ITP which reduces the incidence of BREs compared to SOC, and lowers BRE management costs for the Mexican Public Healthcare system.

PSY8

TWO ANALGESIC TECHNIQUES AFTER CESAREAN DELIVERY: A COST-EFFECTIVENESS ANALYSIS STUDY

Farshchi A, Abdollahi Asl A
Tehran University of Medical Sciences, Tehran, Iran

OBJECTIVES: The study was designed to compare two analgesic regimens administered after cesarean delivery in a routine hospital setting with respect to patients' perceptions of their pain relief and the impact of analgesic technique on hospital costs. **METHODS:** This study was undertaken based on our previous paper that evaluated postoperative pain in a double-blinded, randomized, single-dose comparison of the monoaminergic and μ-opioid agonist tramadol, 100 mg (Group T) and piroxicam 20 mg (Group P) given IM alone- single dose in 150 patients who had elective cesarean delivery. All patients were assessed at 0, 6, 12 and 24 hours post operation for pain degree (by Visual Analogue Score: VAS 1-10), nausea and vomiting. Our outcomes were the power of drug to reduce pain and our costs came from drug prices. Incremental Cost-Effectiveness Ratio (ICER) was calculated. **RESULTS:** There was no significant difference between the efficacy of tramadol and piroxicam injections ($P>0.05$). Side effects were similarly minimal with all treatments. Total costs in P group were $16.33 and in T group were $47.52. **CONCLUSIONS:** In this study, ICER showed that analgesic effect of piroxicam is more cost-effective than tramadol.

PSY9

EVALUACIÓN ECONÓMICA DE DIETA INMUNOREGULADORA (INMUNEX PLUS®) EN PACIENTES MEXICANOS

Soto Molina H
Iteliness SA de CV, México D.F., México

OBJECTIVOS: Realizar un análisis costo efectividad del uso de una dieta Inmunoreguladora (DI) con aporte de antioxidantes y glutamina, Arginina, Nucleótidos y Ácidos grasos omega 3, en dosis terapéuticas; utilizado como apoyo nutricional enteral en pacientes críticos en comparación con el tratamiento sin apoyo nutricio inmunogénico (NDI), desde la perspectiva del IMSS. **METODOLOGÍAS:** Se realizó un análisis de costo-efectividad, para ello, se construyó un árbol de decisiones. Se realizó una revisión sistemática para determinar la eficacia (porcentaje de pacientes libres de complicaciones) y los días de estancia hospitalaria. Se midieron costos médicos directos por medio de un panel de expertos. En la valuación de costos se utilizaron tarifas vigentes aplicables a los servicios médicos proporcionados por el IMSS. Todos los costos están expresados en pesos mexicanos de 2010. Se realizó un análisis de costo efectividad incremental, análisis de sensibilidad y un análisis de impacto presupuestal. **RESULTADOS:** Los pacientes con DI tienen una mayor eficacia promedio (68.76% versus 57.80%, $p<0.001$) y un menor costo promedio por paciente ($490,602 PMX versus $504,876.54) que los pacientes NDI, este menor costo se debe a una reducción 3.3 días de estancia hospitalaria que tienen los pacientes con DI versus pacientes con NDI. Los ahorros en el presupuesto para el IMSS, al utilizar la dieta inmunogénica en el tratamiento de 100 pacientes sería $1,427,436.35. El análisis de sensibilidad corroboró la validez del modelo. **CONCLUSIONES:** La dieta Inmunoreguladora produce una reducción significativa de complicaciones mayores (infecciones nosocomiales, falla multi-orgánica, abscesos intra-abdominales, dehiscencia de anastomosis, entre otros). Al usarla se obtiene una disminución significativa de los costos totales y días totales de estancia hospitalaria, por lo cual es una opción eficiente en este tipo de pacientes mexicanos.

PSY11

EVALUACION ECONOMICA DEL USO PROFILACTICO DE PEGFILGASTRIM EN PACIENTES CON QUIMIOTERAPIA MILOABLATIVA PARA EVITAR LA NEUTROPENIA FEBRIL

Morgan-Villela G
Instituto Mexicano del Seguro Social, Guadalajara, Jal, México

OBJECTIVOS: Evaluar si el uso profiláctico de Pegfilgastrim ofrece mejores resultados en términos de salud y gasto asociado a la incidencia de la neutropenia febril (NF) asociada a la quimioterapia mielosupresora con respecto a Filgastrim y a no usar profilaxis. **METODOLOGÍAS:** Análisis de minimización de costos basado en un árbol de decisiones de tres alternativas profilácticas: Pegfilgastrim, Filgastrim y no-profilaxis. La medida de efectividad fue la incidencia de NF en pacientes que reciben quimioterapia. Pegfilgastrim de acuerdo a literatura, reduce el riesgo relativo de desarrollar nuetropenia febril en un 90% y Filgastrim la reduce en un 39%. Se consideraron los siguientes costos médicos directos: costos de medicamentos, consultas, estudios clínicos, hospitalización y procedimientos. Dichos costos se tomaron de las tarifas vigentes para 2010 aplicables a los servicios médicos proporcionados por el IMSS. **RESULTADOS:** Tomando en cuenta un total de 1000 pacientes hipotéticos con un riesgo del 20% de desarrollar NF, si dividimos equitativamente los pacientes (33% Pegfilgrastim, 33% Filgrastim, 33% sin Profilaxis), el uso de Pegfilgastrim hace que sólo 7 pacientes presenten NF, y se incurrirá en un costo total de $5.6 Mio MXP; mientras que el uso de Filgrastim hace que 40 pacientes presenten NF y 66 pacientes desarrollan NF cuando no se usa profilaxis, con costos totales de $7.8 y $10.5 Mio MXP. **CONCLUSIONES:** En conclusión, podemos afirmar que el uso de Pegfilgatrim en forma profiláctica disminuyen los costos de atención de los pacientes con cáncer que reciben quimioterapia mieloablativa en nuestro país, además de ser una molécula que incurre en menores costos para las instituciones, y claramente presenta un beneficio para los pacientes. El uso de Pegfilgastrim es un medicamento dominante comparado con Filgastrim y el no uso de profilaxis.

PSY12

LAPAROSCOPY VERSUS OPEN ROUX-EN-Y GASTRIC BYPASS FOR MORBID OBESITY: COST-UTILITY ANALYSIS

Silva EN[1], Silva MT[1], Elias FTS[1], Laranjeira FO[1], Mottin CC[2]
[1]*Mexican Ministry of Health, Brasília, Brazil,* [2]*Pontifical Catholic University of Rio Grande do Sul, Porto Alegre, RS, Brazil*

OBJECTIVES: To estimate the incremental cost-utility ratio (ICUR) of laparoscopy versus open Roux-en-Y gastric bypass for morbid obesity in the Brazilian Public Health System (SUS) perspective. **METHODS:** We performed a cost-utility model using a decision tree for the SUS perspective as the payer of the health services, with a one-year follow-up. The cost and complication rates information were obtained from a retrospective cohort ($n>1000$) at a Brazilian center that is renowned for bariatric surgery, and from the SUS database. More specifically, we used an adjustment factor to convert the average value charged in private health plans due to the absence of actual costs for laparoscopic surgery in the SUS (unlisted). The mortality data, conversion probability (for video to open) and years with quality-adjusted life year (QALY) were from literature. A tornado diagram was created, which encouraged univariate and bivariate analyses to explore sensitivity. **RESULTS:** The ICUR was R$ 84.678/QALY. The QALY and the costs of laparoscopic or open surgery were the variables most sensitive to the model. **CONCLUSIONES:** Compared with open surgery, the laparoscopic approach does not appear cost-effective within the SUS perspective, assuming the cost-utility threshold recommended by WHO (R$ 49,242.90). From the bivariate sensitivity analysis related to quality of life, the laparoscopic approach becomes costeffective if there is a favorable difference in quality of life of at least 20%, keeping the other variables constant. Moreover, in the bivariate sensitivity analysis related to costs, laparoscopy would be cost-effective if its cost to the SUS were reduced by R$ 8,100.00, keeping other variables constant.

Systemic Disorders/Conditions – Patient-Reported Outcomes & Preference-Based Studies

PSY13

EFECTO DE UN PROGRAMA DE ATENCIÓN FARMACÉUTICA PARA PACIENTES CON SOBREPESO Y OBESOS

Alfonzo N[1], Bastardo YM[2]
[1]*Proveeduria Farmaceutica IPP, Caracas, Venezuela,* [2]*Universidad Central de Venezuela, Caracas, Venezuela*

OBJECTIVOS: El propósito de este estudio es describir los efectos de un programa de Atención Farmacéutica para pacientes con sobrepeso y obesos que asisten a la Proveeduría Farmacéutica IPP-UCV en términos de perdida de peso y calidad de vida relacionada con la salud (CVRS). **METODOLOGÍAS:** Pacientes adultos con sobrepeso y obesos recibieron Atención Farmacéutica por un periodo de 6 meses en la Farmacia Comunitaria ubicada dentro del Campus de la Universidad Central de Venezuela. El cuestionario de salud EQ-5D que comprende un sistema descriptivo de cinco dimensiones y una escala visual analógica (EQ VAS) fue utilizado para medir la CVRS. **RESULTADOS:** Un total de 83 pacientes (68 mujeres y 15 hombres) con una edad promedio de 49.86 años (DE= 15.73) completaron el cuestionario durante el periodo de la intervención. El peso, diámetro de cintura y las puntuaciones obtenidas en la EQ-5D antes y después de la intervención fueron comparados. Una mejora en calidad de vida fue observada en todas las dimensiones del EQ-5D y en la EQ-VAS. Una diferencia estadísticamente significativa en peso (-5.44 kg) y diámetro de cintura (-5.48 cm) fue observada al final de la intervención. **CONCLUSIONES:** Un programa de Atención Farmacéutica permite alcanzar una mejora en la calidad de vida relacionada con la salud y en los resultados clínicos en pacientes con sobrepeso y obesos.

Urinary/Kidney Disorders – Cost Studies

PUK1

COMPARISON OF DIRECT MEDICAL COST OF DIALYSIS IN A MEXICAN COHORT EITHER ON PERITONEAL OR HEMODIALYSIS

Mayen-Herrera E[1], Cortes M[1], Marx SE[2], Sterz R[2]
[1]Abbott Laboratories de México, México, D.F., México, [2]Abbott Laboratories, Abbott Park, IL, USA
OBJECTIVES: End-stage renal disease (ESRD) poses a high medical and economic burden on healthcare systems. Information on direct medical costs for dialysis patients in Mexico is comparatively sparse. **METHODS:** Data was collected retrospectively on 40 patients on automated peritoneal dialysis (APD) and 40 patients on hemodialysis (HD) from institutional databases of two hospitals of the Mexican Institute of Social Security (IMSS). Patient follow up ranged from 3 months up to 67 months. Resources captured in the study were: medications, dialysis procedures, laboratory and diagnostic tests, hospitalizations and medical consultations, blood and hemoderivatives and catheter procedures. Drug and medical services costs were calculated using information from the Mexican Government website (http://web.compranet.gob.mx) based on 2010 fees. All costs were converted into US dollars (1USD = 12.54 Mexican pesos). **RESULTS:** Forty patients on peritoneal dialysis (APD, age 50 ± 15.6, 40% female) and 40 patients on hemodialysis (HD , age 47 ± 17.3 years , 42,5 % female). Total annual costs were: USD 12,589 (APD), USD 7,541 (PD). Dialysis: USD 1,058 (APD) , USD 13,739 (HD). Hospitalization: USD 6,212 (APD), USD 6,128 (HD). Medication: USD 5,043 (APD), USD 7,580 (HD). Costs for complications: USD 5,586 (APD) and USD 3,943 (HD). **CONCLUSIONS:** Dialysis patients either on peritoneal or hemodialysis present a high cost burden to the Mexican Health system. Medication and hospitalization costs constitute a major part of the total costs. Further investigations are needed to understand how to optimize care to avoid some of these costs.

PUK2

COST PER SUCCESSFUL RESPONSE OF STANDARD TREATMENT PLUS CINACALCET VERSUS STANDARD TREATMENT ALONE IN PATIENTS WITH SECONDARY HYPERPARATHYROIDISM IN MEXICO

Arocho R[1], Ianazzo S[2], Rivera Hurtado R[3], Paniagua Sierra JR[4]
[1]Amgen, Inc., Barcelona, Spain, [2]AdRes Health Economics & Outcomes Research, Torino, Italy, [3]Amgen México, México, D.F., México, [4]National Institute of México for Social Security (IMSS), México, D.F., México
OBJECTIVES: Secondary Hyperparathyroidism (SHPT) is a common complication of chronic kidney disease. Abnormal levels of Parathyroid Hormone (PTH), Calcium (Ca) and Phosphorus (P) are associated with an increased risk of cardiovascular death and fracture. The aim of the study was to assess the cost per successful response with standard treatment (ST)+Cinacalcet versus ST alone (vitamin D sterols and chelated phosphates) in patients with SHPT in Mexico. **METHODS:** A decision analytic model was developed to calculate and compare the costs per successful response with Cinacalcet in adult patients with SHPT to whom a specific scheme of ST has been prescribed. The successful response was defined as the balance (normal levels) in all target parameters: PTH, Ca, P and Ca x P. ST was defined as one of the following combinations: Paricalcitol IV + Chelated Phosphate (PCP), Chelated Phosphate + Calcitriol (CPC) and Paricalcitol + Calcium Carbonate (PCC). Unit costs were gathered from the 2010 Official Price List of the Public Healthcare System in Mexico. **RESULTS:** According to the literature, 16% of patients achieve the targets in all parameters when ST is given. The addition of Cinacalcet increases this proportion up to 60%. Considering PCP as the ST, the cost per response was MXP$32,750 vs MXP$16,945 with Cinacalcet+PCP; CPC showed a cost per response of MXP$22,156 vs MXP$15,509 with Cinacalcet+CPC; finally, PCC reflected a cost per response of MXP$14,850 vs. MXP$12,091 with Cinacalcet+PCC. **CONCLUSIONS:** The addition of Cinacalcet to any ST combination represents a strategy which results to lower cost per responder principally due to two factors: the reduction of 50% in ST concomitant drugs and the higher response rates in achieving targets for all biochemical parameters.

PUK3

COST-EFFECTIVENESS OF ANEMIA TREATMENT IN DIALYSIS PATIENTS IN BRAZIL

Silva FHCV[1], Vianna CMDM[2], Silva FVC[3]
[1]Agência Nacional de Saúde Suplementar, Rio de Janeiro, RJ, Brazil, [2]Universidade do Estado do Rio de Janeiro, Rio de Janeiro, RJ, Brazil, [3]Universidade Estadual do Rio de Janeiro, Rio de Janeiro, RJ, Brazil
OBJECTIVES: This study sought to determine the cost-effectiveness of anemia treatment in dialysis patients for Brazilian Public Health System. Two alternatives were compared: a new drug, the *Continuous Erythropoietin Receptor Activator*, CERA, recently registred in Brazil, and another one, provided nowadays by the National Health System, Epo-rHu (Recombinant Human Eythropoietin). **METHODS:** A Markov cohort of dialysis patients treated with CERA and Epo-rHu for four years was used to perform the base case analysis. The model outputs were QALYs and costs. The quality of life associated with each drug was measured by interviews applied to health care professionals. These interviews were previously submitted and approved by the local ethics committee. A sensitivity analysis was applied to the model to test it, varying the values of drugs dosage, costs, discount rate and effectiveness. **RESULTS:** The average quality of life assigned by health care professionals to the patients treated with Epo-rHu, CERA and to kidney transplant receptors were respectively 6,3, 7,8 and 9,3. The model showed that Epo-rHu treatment was more cost-effective than CERA treatment. The cost-effectiveness ratio of Epo-rHu therapy was R$ 21.052,00. In addition, the cost per QALY gained of CERA therapy was R$ 72.974,00. **CONCLUSIONS:** Anemia treatment with CERA is associated with improvement in quality of life compared to Epo-rHu therapy. However, the new drug is not more cost-effective than the drug provided by the Brazilian Public Health System.

PUK4

COSTO-EFECTIVIDAD DE INTERVENCIONES PARA INSUFICIENCIA RENAL CRÓNICA TERMINAL EN MÉXICO

Arredondo A[1], De icaza E[2]
[1]Instituto Nacional de Salud Pública, Cuernavaca, Morelos, México, [2]Servicios de Salud del DF, México, D.F., México
OBJECTIVOS: Análisis de costo-efectividad en intervenciones para pacientes con insuficiencia renal crónica terminal (IRCT) en términos de los costos económicos de cada intervención, los años de vida ganados y la calidad de vida que generan tres alternativas comparables y mutualmente excluyentes: diálisis peritoneal continua ambulatoria (DPCA), la hemodiálisis (HD) y el trasplante renal (TR). **METODOLOGÍAS:** El diseño del estudio fue de tipo longitudinal. Los costos de cada intervención se determinaron mediante la técnica de manejo de caso promedio. Las medidas para evaluar los criterios de efectividad elegidos fueron la probabilidad de sobrevida y el Año de Vida Ajustado por Calidad (QALY, Quality-Adjusted Life Year) medido por el Indice de Rosser. **RESULTADOS:** Los costos de manejo anual de caso en US $ fueron: diálisis peritoneal $470.00, hemodiálisis $802.00 y trasplante $231,00. En cuanto a la efectividad, la sobrevida del injerto de trasplante renal resultó de 89,9% y 79,6% a uno y tres años respectivamente, mientras que los pacientes sometidos a DPCA tienen una sobrevida de 86,2% y 66,9% a un año y a tres años respectivamente. En cuanto a los QUALY's, los resultados para cada intervención fueron: DPCA 0,879; HD 0,864; y para el TR 0,978. **CONCLUSIONES:** La intervención más costo-efectiva resultó el trasplante renal con un coeficiente de 3088,69, seguido de la DPCA y la hemodiálisis, cuyos coeficientes fueron de 6416.95 y 11.147,68 respectivamente. Por lo tanto se recomienda promover y utilizar el trasplante renal como la intervención más costo-efectiva para pacientes con IRCT. Los resultados del coeficiente costo-efectividad identificado desde una perspectiva clínica y económica, constituyen un aporte relevante para la búsqueda y el logro de la eficiencia de los recursos que se asignan para producir servicios de salud para pacientes con IRCT, cuyas demandas están en competencia con otras enfermedades crónicas e infecto-contagiosas.

PUK5

ANÁLISIS COMPARATIVO DE COSTOS DEL TRATAMIENTO PARA LA ANEMIA RENAL CON METOXI POLIETILENGLICOL-ERITROPOYETINA BETA (MIRCERA®) VS. ERITROPOYETINA ALFA

Medina Gómez JL
Instituto Mexicano del Seguro Social, Puebla, México
OBJECTIVOS: Evaluar si el uso de Metoxi polietilenglicol-eritropoyetina beta (MPG-beta) ofrece mejores resultados en salud y gasto con respecto a la eritropoyetina alfa. **METODOLOGÍAS:** Análisis de costo-efectividad incremental basado en un árbol de decisiones para simular los costos del tratamiento, con un horizonte temporal de 12 meses (costos en valor nominal). La dosis mensual de agentes estimulantes de la eritropoyesis se ajustó de acuerdo con los niveles de hemoglobina; sí la concentración es mayor a 12 g/dl 20,000 UI/mes de Eritropoyetina alfa o 0.6 mcg/kg/mes de MPG-beta, para 11-12 g/dl 26,00 0UI/mes de Eritropoyetina alfa o 1.2 mcg/kg/mes de MPG-beta y para concentraciones menores a 11 g/dl 32,000 UI/mes de Eritropoyetina alfa o 1.5 mcg/kg/mes de MPG-beta. Cada escenario tiene un costo basado en la atención habitual de estos pacientes. Los costos de los insumos se tomaron de las tarifas vigentes para 2010 aplicables a los servicios médicos proporcionados por el IMSS. Se evaluaron los riesgos de no estar en un intervalo ideal de Hemoglobina (11-12.5 g/dl), también conocido como excursiones de la hemoglobina y su costo asociado. **RESULTADOS:** MPG-beta mantiene en forma más estable la concentración de hemoglobina al compararse con Eritropoyetina alfa, de tal forma que a los 6 meses de tratamiento permanecen en el intervalo ideal 94% vs. 5% con Eritropoyetina alfa. Con el uso de Eritropoyetina alfa hay mayor riesgo de tener excursiones, y por consecuencia se incurre en mayores costos anuales (67,612 vs. 63,931). El análisis costo-efectividad incremental muestra un incremento de 83% en efectividad y un ahorro por paciente de 3,681 utilizando MPG-beta en comparación con Eritropoyetina alfa, esto derivado de la estabilidad de la hemoglobina. El ICER es de -12,901 unidades. **CONCLUSIONES:** Estos resultados demuestran que MPG-beta ofrece mejores resultados en salud y costos posesionándose como un tratamiento costo-ahorrador.

ISPOR 3RD LATIN AMERICA CONFERENCE DISCLOSURE INFORMATION FOR RESERCH PRESENTATIONS

The International Society for Pharmacoeconomics and Outcomes Research asked all abstract contributors to disclose financial support for their research.
The following financial support was declared:

Reference Code	Financial Support
CN1	Global Health Research Initiative, Ottawa, Canada; ANVISA - OPS, Brasilia, Brazil
CN2	Consejo Mexicano Contra el Tabaquismo en colaboración con el Instituto Nacional de Salud Pública, México, D.F., Mexico
CN3	None
CN4	None
CV1	Boehringer Ingelheim, Bogota, Colombia
CV2	Eli Lilly and Company, México, D.F., Mexico
CV3	None
CV4	None
EX2	AstraZeneca Pharmaceuticals, Macclesfield, UK
EX3	None
EX4	None
HS1	Pan American Health Organization, Washington DC, USA
HS2	Convenio OPS / MPS Colombia, Bogota, Colombia
HS3	Pan American Health Organization/World Health Organization, through its Country Office, Belize, Belize
HS4	Consejo Mexicano Contra el Tabaquismo en colaboración con el Instituto Nacional de Salud Pública, México, DF, Mexico
IN1	Pfizer S.A. de C.V., México, D.F., Mexico
IN2	Capes, Brasília, Brazil
IN3	None
IN4	Pfizer Inc, New York, NY, USA
PCN1	GlaxoSmithKline, Wavre, Belgium
PCN2	None
PCN3	Novartis, Bogota, Colombia
PCN4	Novartis, Bogota, Colombia
PCN5	Novartis, Bogotá D.C., Colombia
PCN6	BMS, Bogota, Colombia
PCN7	None
PCN8	None
PCN9	Amgen Mexico, Mexico City, Mexico
PCN10	Bayer Colombia, Bogota, Colombia
PCV1	Covidien, Mansfield, MA, USA
PCV2	AstraZeneca, Mexico D.F., Mexico
PCV3	AstraZeneca, Sao Paulo, Brazil
PCV4	CONACYT, México, D.F., Mexico
PCV5	Bayer Brasil, São Paulo, Brazil; MedInsight Evidências, São Paulo, Brazil
PCV6	Bayer Brasil, São Paulo, Brazil; MedInsight Evidências, São Paulo, Brazil
PCV7	Eli Lilly and Company, México, D.F., Mexico
PCV8	Bayer Brasil, São Paulo, Brazil; MedInsight Evidências, São Paulo, Brazil
PCV9	None
PCV10	Sandoz Mexico, Mexico City, Mexico
PDB2	None
PDB3	Eli Lilly and Company, México, D.F., Mexico
PDB4	Secretaria de Estado da Saúde de Minas Gerais, Belo Horizonte, Brazil
PDB5	Johnson & Johnson Medical Mexico, Mexico City, Mexico
PDB6	Novo Nordisk International Affairs, Buenos Aires, Argentina
PDB7	Bristol-Myers Squibb, Buenos Aires, Argentina
PDB8	CONACYT, México D.F., Mexico
PDB9	Novonordisk Colombia, Bogota, Colombia
PDB10	Eli Lilly, México, D.F., Mexico
PDB11	ELi Lilly and Company, México, D.F., Mexico
PGI1	Cellerix SA, Tres Cantos, Spain
PGI2	Abbott Laboratories, Abbott Park, Chicago, IL, USA
PGI3	BMS, Bogota, Colombia
PGI4	UCB, Braine l, Alleud, Belgium
PHP1	None
PHP2	None
PHP3	Roche International, Montevideo, Uruguay
PHP4	None
PHP5	None
PHP6	None
PHP7	None
PHP8	None
PHP9	FCT, Lisboa, Portugal
PHP10	None
PHP11	None
PHP12	None
PHP13	None
PHP15	None
PHP16	None
PHP17	None
PHP18	Instituto Mexicano del Seguro Social, Mexico, D.F., Mexico
PHP19	None
PHP20	MCT/CT-Saúde and MS/SCTIE/DECIT, via CNPq (Edital 67/2009) - Public funding, Brasilia, Brazil
PHP21	None
PHP22	James & Esther King Biomedical Research/ The Florida Department of Health, Lee's Summit, MO, USA
PHP23	None
PHP24	FCT, Lisboa, Portugal
PHP25	None
PHP26	None
PHP27	None
PHP28	None
PHP29	None
PHP31	Ministerio de Salud de Chile, Santiago, Chile
PHP32	None
PHP33	None
PHP34	None
PHP35	Pfizer, Sao Paulo, Brazil
PHP36	Double Helix Consulting, London, UK
PHP37	Double Helix Consulting, London, UK
PHP38	Medtronic, Doral, FL, USA
PHP39	Double Helix Consulting, London, UK
PHP40	None
PHP41	GlaxoSmithKline, Bratislava, Slovak Republic
PHP42	Universidad Central de Venezuela, Caracas, Venezuela
PHP43	Scholarship Beca Chile, Santiago, Chile
PHP44	Eli Lilly and Co., Indianapolis, IN, USA
PHP46	Bristol-Myers Squibb de México, Mexico, D.F., Mexico
PHP47	None
PHP48	None
PHP49	None
PHP50	London School of Hygiene and Tropical Medicine, London, UK
PHP51	None
PIH1	Bayer, Mexico, D.F., Mexico
PIH2	None
PIH3	MedInsight Evidências, São Paulo, Brazil
PIH4	Bayer, Mexico, D.F., Mexico
PIH5	GlaxoSmithKline, Wavre, Belgium
PIN1	Bristol-Myers Squibb, Wallingford, CT, USA
PIN2	None
PIN3	None
PIN4	Pfizer Inc, New York, NY, USA
PIN6	Pfizer S.A: de C.V., México, D.F., Mexico
PIN7	Pfizer, La Aurora, Costa Rica
PIN8	None
PIN10	None
PIN11	GlaxoSmithKline, Rio de Janeiro, Brazil
PIN12	None
PMH1	Janssen, Beerse, Belgium
PMH2	None
PMH3	Janssen de México, México, D.F., Mexico
PMH4	ELi Lilly, Mexico, D.F., Mexico
PMH5	Janssen, Bogota, Colombia
PMS1	Pfizer S.A. de C.V., México, D.F., Mexico
PMS2	None
PMS3	Pfizer, Mexico, D.F., Mexico
PMS4	Pfizer Pharmaceutics inc., New York, NY, USA
PMS5	Productos Roche, S.A. d C.V., México, Mexico
PMS6	None
PMS7	Abbott, Bogota, Colombia
PMS8	Pfizer, La Aurora, Costa Rica
PMS9	BMS, Bogota, Colombia
PMS10	Eli Lilly, México, D.F., Mexico
PMS11	Fapemig, Belo Horizonte, Brazil
PMS12	Grupo Roche, S.A. de C.V., México, D.F., Mexico
PMS13	Abbott Laboratories, Abbott Park, IL, USA
PND3	None
PND4	Consejo Mexicano Contra el Tabaquismo en colaboración con el Instituto Nacional de Salud Pública, México, D.F., Mexico
PRM2	None
PRM3	None
PRM4	Genentech, Inc., South San Francisco, CA, USA
PRM5	Universidad Nacional de Colombia, Bogota, Colombia
PRM6	None

Reference Code	Financial Support
PRS1	GSK, Mexico, Mexico
PRS2	Consejo Mexicano Contra el Tabaquismo en colaboración con el Instituto Nacional de Salud Pública, México, DF, Mexico
PRS3	Consejo Mexicano Contra el Tabaquismo, Mexico, D.F., Mexico
PRS4	Abbott Laboratories de Mexico, Mexico City, Mexico
PRS5	Pfizer, La Aurora, Costa Rica
PRS6	GSK, Mexico, D.F., Mexico
PRS7	Grünenthal Colombiana S.A., Bogotá, Colombia
PRS8	Universidad de La Sabana, Chia, Colombia
PRS9	Fundación Bloomberg, New York, NY, USA
PR1	GlaxoSmithKline, Tres Cantos, Spain
PR2	National Institute for Health Research, London, UK
PR3	Ministry of Health, Santiago, Chile
PR4	Universidad de Guadalajara, CD. Guzman, Mexico
PSS1	TECNOLOGICOS DALUP S. DE R.L. DE C.V., México, D.F., Mexico
PSS2	None
PSS3	Sandoz Mexico, Mexico City, Mexico
PSS4	PFSA, Boulogne, France
PSY1	None
PSY2	None
PSY3	Johnson & Johnson Medical Mexico, Mexico City, Mexico
PSY4	None
PSY5	Grünenthal Colombiana S.A., Bogotá, Colombia
PSY6	Grünenthal Colombiana S.A., Bogotá, Colombia
PSY7	Amgen Limited, Thousand Oaks, CA, USA
PSY8	None
PSY9	PISA Farmacéutica, México, D.F., Mexico
PSY11	None
PSY12	None
PSY13	None
PUK1	Abbott Laboratories, Mexico City, Mexico
PUK2	Amgen, Mexico City, Mexico
PUK3	None
PUK4	None
PUK5	None
QA1	GSK, Buenos Aires, Argentina
QA2	Productos Roche Colombia, Bogota, Colombia
QA3	Boehringer Ingelheim, Bogota, Colombia
QA4	MEDTRONIC, Mexico City, Mexico
RM1	Mexican Ministry of Health , Mexico City, Mexico; Panamerican Health Organization, Mexico City, Mexico; National Council on Science and Technology, Mexico City, Mexico
RM2	None
RM3	None
RM4	Fondo Nacional de REcursos, Montevideo, Uruguay
TP1	Merck and Co., Inc., Whitehouse Station, NJ, USA
TP2	Bristol-Myers Squibb de México, Mexico, D.F., Mexico
TP3	Bristol-Myers Squibb, Mexico, Mexico
VA1	Ministerio de la Proteccion Social, Bogota, Colombia
VA2	Pfizer S.A., Bogota, Colombia
VA3	GSK, Middlesex, UK
VA4	None

ISPOR 3RD LATIN AMERICA CONFERENCE RESEARCH ABSTRACTS AUTHOR INDEX

GUIDE FOR AUTHORS

Value in Health is a peer-reviewed publication of the International Society for Pharmacoeconomics and Outcomes Research. Its mission is to provide a forum for the advancement and dissemination of knowledge and research in pharmacoeconomics and the health-related outcomes of disease and treatment processes. The journal therefore solicits original contributions in applied and theoretical pharmacoeconomics, and in the theory, measurement, and analysis of the health-related outcomes relevant to forwarding scholarly and public dialogue about the assessment of value in health and health care. In keeping with its broad mission, *Value in Health* will also accept methodology papers and critical reviews of empirical and theoretical literature in pharmacoeconomics and outcomes research.

Value in Health does not consider papers reporting data series or data sets that do not include appropriate statistical confidence intervals and/or other measures of statistical imprecision. *Value in Health* also does not consider papers reporting modeling results that do not include sensitivity analysis of key and influential model parameters.

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission or during the review process. Authors wishing to pursue a professional English-language editing service should make contact and arrange payment with the editing service of their choice. For more details regarding the recommended services, please refer to http://support.elsevier.com/.

I. ETHICS IN PUBLISHING

For information on Ethics in Publishing and Ethical guidelines for journal publication see http://www.elsevier.com/publishingethics and http://www.elsevier.com/ethicalguidelines.

II. CONFLICT OF INTEREST

All authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. See also http://www.elsevier.com/conflictsofinterest.

III. SUBMISSION DECLARATION

Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere including electronically in the same form, in English or in any other language, without the written consent of the copyright-holder.

IV. RETAINED AUTHOR RIGHTS

As an author you (or your employer or institution) retain certain rights; for details you are referred to: http://www.elsevier.com/authorsrights.

V. FUNDING BODY AGREEMENTS AND POLICIES

Elsevier has established agreements and developed policies to allow authors whose articles appear in journals published by Elsevier, to comply with potential manuscript archiving requirements as specified as conditions of their grant awards. To learn more about existing agreements and policies please visit http://www.elsevier.com/fundingbodies.

VI. MANUSCRIPT SUBMISSION AND SPECIFICATIONS

To submit a manuscript to *Value in Health,* please go to: http://mc.manuscriptcentral.com/vih. For assistance, authors may contact the *Value in Health* editorial office at: viheditor@ispor.org.

If submissions are larger than 500 KB, they should be compressed using PKZIP or WINZIP.

Authors will be required to assign copyright of their papers. Copyright assignment is a condition of publication and papers will not be passed to the publisher for production unless copyright has been assigned. An appropriate copyright assignment form can be found at the following address: http://www.ispor.org/publications/value/Value-In-Health-Copyright-Transfer-Form_2011.pdf. A faxed copy of this completed and signed form is acceptable; fax to 609-219-0774 or email to: viheditor@ispor.org.

If excerpts from other copyrighted works are included, the author(s) must obtain written permission from the copyright owners and credit the source(s) in the article. Elsevier has preprinted forms for use by authors in these cases: please consult http://www.elsevier.com/permissions.

Each Submission should contain separate documents as follows:

i. COVER LETTER. The cover letter should include: 1) title of the manuscript; 2) name of the document file(s) containing the manuscript and the software (and version) used; 3) name and all contact information for the corresponding author and a statement as to whether the data, models, or methodology used in the research are proprietary; 4) names of all sponsors of the research and a statement of all direct or indirect financial relationships the authors have with the sponsors; and 5) if applicable, a statement that the publication of study results was not contingent on the sponsor's approval or censorship of the manuscript.

ii. TITLE PAGE. The title page should contain the following: 1) title; 2) full names (first and surname) of all authors including academic degrees and affiliation(s); 3) name, mailing and email addresses, telephone and fax numbers of corresponding author (with whom all correspondence will take place unless other arrangements are made); 4) all sources of financial or other support for the manuscript (if no funding was received, this should be noted on the title page); 5) at least four key words for indexing purposes; and 6) a running title of not more than 45 characters including spaces.

iii. MANUSCRIPTS. Manuscripts must be written in English, typed in either Microsoft Word (Version 5.0 or later) or WordPerfect (version 5.1 or later). Please note that Word 2007 is not yet compatible with journal production systems. Unfortunately, the journal cannot accept Microsoft Word 2007 documents until such a time as a stable production version is released. Please use Word's 'Save As' option therefore to save your document as an older (.doc) file type. Manuscripts should be in 8.5x11-inch page format, double-spaced with 1-inch margins on all sides and size 10 font (Arial or Times New Roman fonts are preferred). Minimal formatting should be used, i.e., no justification, italics, bold, indenting, etc. There should be no hard returns at the end of lines. Double-spacing after each element is requested (e.g., headings, titles, paragraphs, legends). There is no limit on manuscript length, but length in terms of clarity and conciseness will be considered in the editorial process. The 'Uniform Requirements for Manuscripts Submitted to Biomedical Journals' should be consulted for specific style issues not addressed here (www.acponline.org, Ann Intern Med 1997;126:36-47).

a. ABSTRACT. An abstract of 250 words or less is required, summarizing the work reported in the manuscript. Original research manuscripts should use a structured format for the abstract, i.e., Objectives, Methods, Results, and Conclusions.

b. TEXT. The body of the manuscript should be divided into sections that facilitate reading and comprehension of the material. This should normally include sections with the major headings: Introduction, Methods, Results, Conclusions, Acknowledgments (if needed), and References. There should be no footnotes. Figures (inclusive of figure legends) and Tables must be submitted each as separate documents.

c. REFERENCES. References should be listed in a separate section and numbered consecutively with Arabic numerals in the order in which they are cited in the text. Citing unpublished or non-peer-reviewed work such as abstracts and presented papers is discouraged. Personal communications may be indicated in the text as long as written acknowledgment from the authors of the communications accompanies the manuscript. Reference style should follow that of *Index Medicus*. Spell out single-word journals and abbreviate all others according to the style of *Index Medicus*. If there are more than four authors, use only the names of the first three, followed by et al.

The three most common types of references are illustrated below for example.

Journal article: Surname and initials of author(s), title of article, name of journal, year, volume number, first and last page.

Arocho R, McMillan CA. Discriminant and criterion evaluation of the U.S.-Spanish version of the SF-36 Health Survey in a Cuban-American population with benign hyperplasia. Med Care 1998;36:766–72.

Book: Surname and initials of author(s)/editor(s), title and subtitle, volume, edition (other than first), city, publisher, year.

Johnston J. Econometric Methods (3rd ed.). New York: McGraw-Hill, 1984.

Chapter in Book: Surname and initials of author(s), title of chapter, author(s)/editor(s) of book, title of book, volume, edition (other than first), city, publisher, year.

Luce BR, Manning WG, Siegel JE, et al. Estimating costs in cost-effectiveness analysis. In: Gold MR, Siegel JE, Russell LB, et al., eds., Cost-effectiveness in Health and Medicine. New York: Oxford University Press, 1996.

iv. TABLES. Tables should be clearly labeled, neatly typed, and easy to

understand without reference to the text. Each should be double-spaced and presented on a separate page. Statistical estimates should indicate parameter estimates and, as appropriate, t ratios or standard error, statistical significance, sample size, and other relevant information. All abbreviations must be explained below each table. Each table should be numbered and have a self-explanatory title.

v. FIGURES. Figures should each be submitted as a separate image file, not embedded in the manuscript document or in a slide presentation. Cite figures consecutively, as they appear in the text, with Arabic numbers (Figure 1, Figure 2, Figure 3A, etc.). If, together with your accepted article, you submit usable color figures then the Journal will ensure, at no additional charge, that these figures will appear in color on the Web (e.g., ScienceDirect and other sites) regardless of whether or not these illustrations are reproduced in color in the printed version. There will be a charge for color reproduction in print; you will receive information regarding the costs from Elsevier after receipt of your accepted article. Please indicate your preference for color in print or on the Web only. Each figure must be assigned a brief title (as few words as possible, and reserving abbreviations for the legend) as well as a legend. The corresponding legend should be typed double-spaced on a separate page. All symbols, arrows, and abbreviations must be explained in the legend. Please submit files with a resolution of at least 300 DPI. Line artwork should contain a resolution of least 1000 DPI. Elsevier recommends submitting figures in the following formats: TIFF, JPG, EPS, and PDF. Please be sure to delete any identifying patient information such as name, social security number, etc. Photographs in which a person's face is recognizable *must* be accompanied by a letter of release from that person explicitly granting permission for publication in the Journal. For any previously published material, written permission for both print and electronic reprint rights must be obtained from the copyright holder. For further explanation and examples of artwork preparation, see Elsevier's Author Artwork Instructions at **www.elsevier.com/artwork**.

vi. SUPPLEMENTARY MATERIAL. You may submit appendixes that describe either methods or results in more detail if these are needed for clarity of understanding by either peer reviewers or readers. If appropriate, materials suitable for Web publication but not print publication (eg, audio or video files, see below) can also be submitted. If you do so, indicate the particular reasons for the appendix and whether you are submitting it for possible Web publication or simply for peer review purposes. *Value in Health* accepts audio and video files as ancillaries to the main article. Audio files should be in .mp3 format; the recommended upper limit for the size of a single file is 10 Mb. Video files should be submitted in .mpg or .mp4 format; the recommended upper limit for the size of a single file is 10 Mb. Any alternative format supplied may be subject to conversion (if technically possible) prior to online publication.

vii. SURVEY INSTRUMENT. For papers analyzing preferences, *ViH* requires the submission of a copy of the survey instrument (translated into English in case of different original language) used to generate the preference data. This is to help in the review process and the survey instrument need not appear in a final publication. If the authors wish the questionnaire to be published with the paper, it should be submitted through ScholarOne Manuscripts as part of the paper. If they do not wish it to be published, it should be submitted through ScholarOne Manuscripts as Supporting Information and then will be sent to the reviewers as a reviewer's appendix.

VII. DATA, MODELS, AND METHODOLOGY

All authors must agree to make their data available at the Editor's request for examination and re-analysis by referees or other persons designated by the Editor. All models and methodologies must be presented in sufficient detail to be fully comprehensible to readers.

VIII. AUTHOR ANONYMITY

From September 15, 2003, it is the policy of *Value in Health* that peer review of submitted manuscripts is double blinded, i.e., the reviewers do not know the names of the authors of manuscripts and the authors do not know the names of the reviewers. Blinded reviews are common practice at many important scientific and medical journals.

IX. THE REVIEW PROCESS

All manuscripts deemed appropriate for *Value in Health* after initial screening will be reviewed by at least two peer reviewers. The objective of the journal is to complete peer review and reach editorial decision within ten to twelve weeks of submission, at which time the corresponding author will receive written notification, including anonymous reviewer commentary.

X. AUTHOR TRACKING SERVICES

Authors may track accepted articles at http://www.elsevier.com/trackarticle and set up e-mail alerts to inform them when an article's status has changed. Contact details for questions arising after acceptance of an article, especially those relating to proofs, will be provided by the publisher.

XI. PROOFS

Proofs will be sent electronically to the Authors to be carefully checked for printer's errors. Substantive **changes or additions to the edited manuscript cannot be allowed at this stage.** Corrected proofs should be returned to the publisher within 2 days of receipt.

XII. OFFPRINTS

The corresponding author, at no cost, will be provided with a PDF file of the article via e-mail. For an extra charge, paper offprints can be ordered via the offprint order form which is sent once the article is accepted for publication. The PDF file is a watermarked version of the published article and includes a cover sheet with the journal cover image and a disclaimer outlining the terms and conditions of use.