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

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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

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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?

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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

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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

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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

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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

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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?

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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?

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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

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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

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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-