medical device, whilst crucial for late-stage reimbursement decisions, is often neglected by developers early on due to lack of data. The headroom method has been proposed as a way to integrate economic evaluation into early go/no-go decisions. By estimating the maximum reimbursable price (MRP) for a new device idea and comparing this with forecasted developer's costs, R&D resources can be channelled toward innovations for which future returns appear feasible. The aim of this study was to evaluate the method by applying it retrospectively to a large and diverse set of case studies, and comparing predicted 'headroom' with actual market success, within the UK setting. **METHODS:** The method was applied systematically to twenty devices/diagnostics invented in the past, retrieved from the UK national horizon scanning centre (NHSC)'s 2000-2009 database; literature searches were date restricted to mimic the information available at the 'concept stage' of development. Each case study was followed up to observe the product's actual market success or failure compared with the estimated 'headroom' and the development decision this would have engendered, in order to explore the method's predictive value. **RESULTS:** Headroom correlated with subsequent market success in 85% of cases. Headroom is most easily elicited where the change proposition of the innovation is straightforward (e.g. direct replacement technologies); diagnostic equipment posed particular difficulties. When the numerical headroom assessments were considered alongside unquantifiable factors identified relating to the clinical and market context, the method offered a good indication of future market potential. **CONCLUSIONS:** Despite the strong advocacy of early economic evaluation, the literature lacks a critical appraisal of any such method. This study for the first time explores the potential implications of basing development decisions on the headroom method, thereby assessing its potential value to stakeholders.

PRM23

COST-EFFECTIVENESS VERSUS PATIENT ACCEPTABILITY: THE EXEMPLAR OF CFS/ME

Richardson G[1], Epstein D[2], Wearden A[3]
[1]University of York, York, UK, [2]University of York, York, York, UK, [3]University of Manchester, Manchester, UK

Nurse-led self-help treatments for people with chronic fatigue syndrome/myalgic encephalitis (CFS/ME) have been shown to be effective in reducing fatigue but their cost-effectiveness is unknown. **OBJECTIVES:** To determine the cost-effectiveness of alternative treatment options for people with CFS/ME in a primary care setting. Design and setting Cost-effectiveness analysis conducted alongside a single blind randomised controlled trial comparing pragmatic rehabilitation (PR) and supportive listening (SL) delivered by primary care nurses, and treatment as usual (TAU) delivered by the general practitioner (GP) in North West England. **METHODS:** A total of 296 patients aged 18 and over with CFS/ME diagnosed using the Oxford criteria. A within trial analysis was conducted comparing the costs and quality adjusted life years (QALYs) measured within the time frame of the trial. **RESULTS:** Treatment as usual is less expensive and leads to better patient outcomes compared with Supportive Listening. Treatment as usual is also less expensive than Pragmatic Rehabilitation. PR was effective at reducing fatigue in the short term, but the impact of the intervention on QALYs was uncertain. However, based on the results of this trial, PR is unlikely to be cost-effective in this patient population. **CONCLUSIONS:** This analysis does not support the introduction of SL. Any benefits generated by PR are unlikely to be of sufficient magnitude to warrant recommending PR for this patient group on cost-effectiveness grounds alone. However, dissatisfaction with current treatment options means simply continuing with 'treatment as usual' in primary care is unlikely to be acceptable to patients and practitioners.

PRM24

METHODS FOR ANALYSIS OF CENSORED COST DATA

Jönsson L
OptumInsight, Stockholm, Sweden

OBJECTIVES: To review published methods for estimating expected lifetime costs in presence of censoring, to compare results with different methods and offer suggestions for use in future research. **METHODS:** We searched the literature for published methods for analysing cost data in presence of censoring. Methods were assessed and compared with Monte-Carlo simulation using a hypothetical dataset, introducing various degrees of censoring. All calculations were performed in STATA 11.2. **RESULTS:** Different methods have been proposed to estimate lifetime costs in presence of censoring. In the most commonly used methods, time is divided into periods, the mean cost is estimated for each period and expected costs estimated as a weighted sum across periods. However, the task of determining the period length is normally left to the analyst. If time periods are too long information risks being lost, while very short but frequent periods impedes calculation speed. An alternative approach is proposed, which avoids the arbitrary choice of period length. **CONCLUSIONS:** Expected lifetime costs can be estimated through a weighted sum of all observed costs, with weights constructed by the Kaplan-Meier survival probability and the number of patients at risk at the time each cost was incurred. This avoids constructing time periods with arbitrary length and potentially improves calculation speed or accuracy.

PRM25

ISSUES AND UNCERTAINTIES IN COMBINATIONS OF DIAGNOSTIC TECHNOLOGIES: A CASE STUDY IN EPILEPSY SURGERY

Hinde S, Soares MO, Palmer S
University of York, York, North Yorkshire, UK

OBJECTIVES: There exists very little in the way of current guidelines or literature as to the combination and sequence of visualisation technologies (invasive or non-invasive) that should be used for the visualisation of seizure focus in patients with refractory epilepsy being considered for surgery. This lack of guidelines is typical in many diagnostic technologies. This study seeks to both create an explanatory analytical framework to demonstrate the variety of technologies, sequences and combinations available before epilepsy surgery is conducted, as well as focussing on the more general questions of the difficulties associated with the evaluation of diagnostic technologies and consider the role of methods to characterise uncertainty in economic evaluations. **METHODS:** The decision analytical framework consisted of three different potential strategies that could be employed in order to elicit the most accurate information given an appropriate cost-effectiveness threshold. This framework was used to consider the wider difficulties and sensitivities of the analysis of diagnostic technologies in combination. **RESULTS:** The analytical framework section of this study found that (assuming an initial MRI and video-EEG) a strategy of FDG-PET being the first test being performed, followed by invasive EEG if the result of the test does not lead to a clear decision on whether the patient should proceed to surgery was optimal. **CONCLUSIONS:** In a general context, we found that in the evaluation of combinations of diagnostic technologies it is important not only to consider the added value of each individual test but also the correct combination and order in which the tests are employed. In addition the evaluation of diagnostics will always be highly sensitive to the cost-effectiveness of the subsequent treatment.

RESEARCH ON METHODS - Databases & Management Methods

PRM26

THE USE OF CLAIMS-BASED CHA2DS2-VASC AND ATRIA SCORES TO PREDICT STROKE/SYSTEMIC EMBOLISM AND BLEEDING RATES AMONG ANTICOAGULATED PATIENTS WITH ATRIAL FIBRILLATION (AFIB) IN A PHARMACY-BENEFIT MANAGEMENT (PBM) ENVIRONMENT

Malone DC[1], Charland SL[2], Agatep BC[2], Herrera V[2], Hawk GS[2], Schrader BJ[2], Stanek EJ[2]
[1]University of Arizona, Tucson, AZ, USA, [2]Medco Research Institute, LLC/an Express Scripts Company, Bethesda, MD, USA

OBJECTIVES: There is limited information associating CHA2DS2VASc and ATRIA scores among patients newly prescribed an anticoagulant and stroke/systemic embolism (SysEmb) and bleeding event rates in the real-world. **METHODS:** A retrospective analysis of a de-identified, pharmacy-medical claims database was conducted in patients with atrial fibrillation (AFIB) and new to dabigatran or warfarin (no drug 6-months prior) from 1/1/10-2/28/11. Patients had continuous eligibility of 12 months prior to and 4 months post initial anticoagulation claim date. Patients' CHA2DS2VASc, and ATRIA risk scores were determined using demographic data and ICD-9/CPT codes (≥2 separate dates) in the prior 12 months. Stroke/SysEmb risk was classified by CHA2DS2VASc score as: low-risk=0-1, moderate-risk=2, and high-risk ≥2. Bleeding risk using ATRIA score was classified as: low-risk=0-3, moderate-risk=4, and high-risk ≥5. Stroke/SysEmb and bleeding events rates/100 patient years were based on ICD-9 codes in the 4 months post anticoagulant initiation. **RESULTS:** A total of 8,162 patients (warfarin=7,072 and dabigatran=1,090) were analyzed: age=75±11 years (82% ≥65 years); 57% were male; with a CHA2DS2VASc and ATRIA risk scores of 3.8±1.7 and 2.8±1.9, respectively. At 4 months, Stroke/SysEmb and overall bleeding event rates were 5.9% (95%CI 5.4% - 6.4%) and 11.1% (95%CI 10.4% - 11.8%) respectively. As CHA2DS2VASc or ATRIA scores increased, so did the rates for Stroke/SysEmb or bleeding events: Stroke/SysEmb low-risk: 0.88% (95%CI 0.18% - 1.58%), moderate-risk: 1.76% (95%CI 0.95% - 2.57%) and high-risk: 7.05% (95%CI 6.43% - 7.67%); bleeding by ATRIA, low-risk: 8.62% (95%CI 7.93% - 9.31%), moderate-risk: 16.79% (95%CI 14.15% - 19.43%) and high-risk: 21.69% (95%CI 19.21% - 24.17%). **CONCLUSIONS:** Increasing CHA2DS2VASc and ATRIA scores were associated with greater rates of Stroke/SysEmb or bleeding events in this real-world, anticoagulant-treated population. Using claims-based CHA2DS2VASc and ATRIA scoring as a screening tool may identify patients at risk of thromboembolic and bleeding events when initiating anticoagulation therapy.

PRM27

EVALUATING EUROPEAN DATA SOURCES FOR ASSESSING REAL-WORLD EFFECTIVENESS OF NEW ANTI-DIABETIC DRUGS

Moïse P[1], Andreykiv M[2], van Engen A[2], Wimbush AJ[3], Richards A[3], Ploug UJ[4]
[1]Quintiles Global Consulting, Levallois-Perret, Ile-de-France, France, [2]Quintiles Global Consulting, Hoofddorp, Noord-Holland, The Netherlands, [3]Novo Nordisk A/S, Zurich Oerlikon, Switzerland, [4]Novo Nordisk A/S, Søborg, Denmark

OBJECTIVES: Real-world data sources (RWD) provide an important means for assessing the real clinical outcomes and value of newly marketed drugs. We aimed to develop a methodology to ascertain the feasibility of RWD in Europe to evaluate the effectiveness of new anti-diabetic drugs. **METHODS:** We searched a proprietary database of European RWDs and publicly available RWD initiatives (including TRANSFoRm and ISPOR international digest of databases). Additional RWDs were identified by literature search with PubMed and Google. A scoring algorithm was developed to prioritize RWDs on the basis of availability of relevant attributes. Each of 11 attributes was scored on a scale depending on the data to be captured and weighted based on the attribute's importance. According to our scoring algorithm, a database could achieve a maximum of 70 points and a minimum of 50 points to be sufficient for evaluating effectiveness. **RESULTS:** We identified 42 RWDs with the potential for evaluating the effectiveness of anti-diabetic drugs and selected 25 for scoring after obtaining additional information. The scoring algorithm allowed us to prioritise RWDs based on 3 key attributes: 1) number of patients prescribed the drugs; 2) completeness of data for key parameters for which effectiveness was to be evaluated (e.g. lab and biometric values); 3) non-parameter attributes (country scope, ability to link to other RWDs, access and cost). The algorithm yielded 16 RWDs meeting the predefined threshold of 50 points for evaluating effectiveness. However, further assessment indicated low feasibility of the 16 RWDs without linkage. **CONCLUSIONS:** We developed a unique and systematic approach to evaluating European RWDs; however, the main limitation of our methodology was the