selective or non-selective and weak opioids (codeine, tramadol, dextropropoxyphene) was extracted and analysed. RESULTS: A total of 23,456 prescriptions were analysed, 18,187 prescribed to adults [18-64 years] and 5,269 to elderly 65-101 years]. The proportion of NSAID prescriptions for non-selective plus selective COX-2 inhibitors. There were 83, 92, and 91.5% of patients were prescribed an NSAID. The proportion of prescriptions for traditional non-selective NSAIDs increased from 83.9% to 90.3% from year 2004 to 2008 among adult patients and from 69.7% to 78.7% among elderly. The propor tion of prescriptions for Coxibs decreased between 2004 and 2008 and were prescribed to 3.6% of patients in this study in 2008. Co-prescription of gastroprotective therapy was made in 12-20% of prescriptions with no differences between NSAIDs, Coxibs and non-NSAID. CONCLUSIONS: In this review of NSAID prescription utilisation patterns with a diagnosis of a musculoskeletal pain shows an extensive use of anti-inflammatory agents without co-prescription of gastro-protective medication. The impact of this high utilization of NSAIDs without co-prescription of gastroprotective agents on the risk for upper gastrointestinal complications warrants further evaluation.

MAINTENANCE INFLIXIMAB DOSING AND ADMINISTRATION PATTERNS AMONG HOSPITALIZED PATIENTS WITH CROHNS DISEASE

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OBJECTIVES: U.S. Food and Drug Administration (FDA)-approved prescribing information recommends infliximab (IFX) administration at 0, 2, 6, and every 8 weeks with potential doses of 3 mg/kg. The primary objective was to compare between infliximab dosing patterns in patients with CD treated in an outpatient hospital setting. METHODS: A retrospective longitudinal analysis using the Premier Perspective Database, a U.S.-based hospital database, was conducted. Induction and maintenance infliximab dosing patterns in patients with CD were compared in a total of 18 hospitals. RESULTS: Infliximab naive patients were compared to Infliximab experienced patients; naive patients were followed for 1 year and experienced patients were followed for 2 years. Infliximab naive patients received an overall mean (SD) number of days during the index infusion of 7 (3) days. Infliximab experienced patients received an overall mean (SD) number of days during the index infusion of 7 (3) days. Infliximab naive patients were followed for an overall mean (median) of 36 (17) doses. Infliximab experienced patients were followed for an overall mean (median) of 10 (5) doses. CONCLUSIONS: Infliximab dosing patterns in patients with CD treated in an outpatient hospital setting.

SYSTHEMIC DISORDER/CONDITIONS – Conceptual Papers & Research on Methods

US COST EFFECTIVENESS ANALYSIS OF PRIMARY PROPHYLAXIS VERSUS ON-DEMAND TREATMENT IN HEMOPHILIA: DESIGN AND RATIONALE OF A COMPREHENSIVE MODEL

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OBJECTIVES: To present the design of a lifetime Markov model that compares the cost-effectiveness of primary prophylaxis versus on-demand treatment with recombinant factor VIII among children with severe hemophilia A. METHODS: Prophylactic infusions of FVIII-FS have been shown to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no pre-existing joint damage. Clinical studies have shown significant improvements in outcomes with the use of prophylactic treatment, as well as apparent gains in health-related quality of life. However, recombinant clotting factors are also associated with relatively high cost. Using a lifetime Markov model, the cost-effectiveness of primary prophylaxis treatment was compared to on-demand treatment. This model is among the few that model long-term cost and effectiveness and is unique in that it takes into account the probability of inhibitor development, use of central venous access device (CVAD), and total bleeding risk including CNS and joint bleeds. Prophylaxis treatment is assumed to be from birth until 16 years of age. Built in the model were also 5 health states: being alive, surgery, inhibitor development, disability and deceased. SUMMARY: From this model, cost-effectiveness estimations can be made for patients receiving on-demand treatment versus primary prophylaxis. Cost-effectiveness can vary by the frequencies of events between treatment arms, age where prophylaxis begins and ends, dose/frequency of factor VIII, cost of medications and key hospital-related events, and the probability of achieving specified clinical endpoints. CONCLUSIONS: The strengths and distinguishing characteristics of this model versus previously published hemophilia prophylaxis models include long-term cost and effectiveness, probability of inhibitor development, use of CVAD, and CNS bleeds. There are a few study limitations related to the lack of data for model assumptions. Obtaining stronger evidence for these parameters may substantiate or potentially improve the model results.

USING PATIENT FOCUS GROUPS TO INFORM ECONOMIC MODELING: EXPERIENCE FROM A HEMOPHILIA PATIENT FOCUS GROUP

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BACKGROUND: Decision modeling is commonly used to assess the cost-utility of drugs or technologies. For a real-world application, models should include aspects of the disease relevant to the patient. In recent years, patient focus groups have been used to help define health utility values. METHODS: Hemophilia patients attending the National Hemophilia Foundation’s 61st Annual Meeting were invited to participate in a focus group to inform the development of a decision model, evaluating prophylactic
lactic treatment of hemophilia. Patients and caregivers completed questionnaires and provided verbal feedback addressing several open-ended questions, including type and duration of bleeds, disability, impact of treatments on lifestyle and their perceptions about standard utility. RESULTS: Twenty-one patients or caregivers of children with bleeding disorders participated. Important implications for the model were: a) Patients reported that muscle bleeds can be more painful and last longer (ie, associated with lower utility) than joint bleeds, which are generally considered more disabling; b) Patients reported that the course (utility, improvement) of a typical bleed differs by the type of joint, muscle, not necessarily by bleed severity alone; c) Although patients reported a loss of utility during a bleed, they gradually regained the same level of utility/function, hence disability was not perceived as a linear process; d) Adult patients reported that nowadays, unlike them, children with hemophilia receiving prophylaxis therapy are able to play sports (ie, ice hockey), thereby improving their quality of life, an aspect not captured by standard utility instruments; e) Although caregiver-administered instruments for assessing quality of life in children with hemophilia are available, caregivers noted concern about accurately rating their child's health status based on their experience. CONCLUSIONS: Although qualitative, patients' perspectives revealed in this focus group demonstrated important utility consequences for the economic model that are not represented in the literature.

**PSY60**

LARGE-SCALE, PROSPECTIVE, OBSERVATIONAL STUDIES IN PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS: A SYSTEMATIC AND CRITICAL REVIEW.

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BACKGROUND: Observational studies, conducted appropriately, play an important role in the decision-making process providing invaluable information on effectiveness, patient-reported outcomes and costs in a real-world environment. OBJECTIVES: A systematic review of large-scale, prospective, cohort studies with the aim of (a) summarising design characteristics, the interventions or aspects of the disease studied and the outcomes measured and (b) investigating methodological quality. METHODS: We included prospective, cohort studies which included at least 100 adult patients with psoriasis or psoriatic arthritis. Studies were identified through searches in electronic databases (Pubmed, Medline, Cochrane library, Centre for Reviews and Dissemination). Information on study characteristics were extracted and tabulated and potential selection bias, defining and adjusting for confounders and losses to follow-up, and defining and describing a comparison group. CONCLUSIONS: The review highlights the need for well designed prospective observational studies on the effectiveness, patient-reported outcomes and economic impact of treatment regimens for patients with psoriasis or psoriatic arthritis in a real-world environment.

**HEALTH CARE DECISION-MAKER'S CASE STUDY POSTER SESSION**

**PCASE1**

UTILIZING EVIDENCE FROM DIFFERENT LEVELS IN THE REIMBURSEMENT PROCESS OF NEW MEDICAL TECHNOLOGIES—ADVANCED RENAL CELL CARCINOMA FIRST LINE THERAPY IN POLAND 2008–2009

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1Agency for Health Technology Assessment in Poland, Warsaw, Poland. 2Organization: Agency for Health Technology Assessment in Poland (AHTAPol) serves as an advisory body to support the Minister of Health and relevant policy makers in the decision-making process in the public sector of health care in a 38 million people country. PROBLEM OR ISSUE ADDRESSED: During 2007 in Poland, patients with metastatic renal cell carcinoma (mRCC), seventh-leading cause of death in men and in ninth-leading cause in women due to cancer, had access only to immuno- modular therapy. GOALS: Necessity of providing access to cost-effective new treatments in the first line of therapy of mRCC. OUTCOMES ITEMS USED IN THE DECISION: Clinical efficacy, safety, evidence from RCT (RCT interim analysis, patient registry), quality of life, cost-effectiveness/cost utility. IMPLEMENTATION STRATEGY: Consultative Council (CC) of AHTAPol debated on the subject multiple times and gave a new decision after each manufacturer’s submission, comprising of a new HTA report updated as soon as the new evidence was published. RESULTS: In 2008–2009, CC debated over 3 claims for the reimbursement of sunitinib and one for the reimbursement of bevacizumab in the indication: first line treatment of mRCC. The first submission on sunitinib, was based on an interim analysis of an international multicenter III phase randomized controlled trial (RCT) and 4 observational studies. The claim was rejected, on April 1, 2008, on the grounds of insufficient data on overall survival (OS) and unacceptable level of cost-effectiveness of app. USD 330 thousand per LYG, much higher than three-fold GDP recommended by WHO. The second submission, containing evidence on the grounds of unacceptably low level of submitted HTA report, especially in the sections comprising safety issues and economical analysis. Third and final submission on sunitinib was debated on March 2, 2009. CC was presented the evidence from two previous submissions and a newly published data of BC Cancer Registry—a registry of patients with mRCC. This data on practical effectiveness showing prolongation of OS, rather that unreliable evidence on efficacy derived from conference materials, persuaded CC to recommend reimbursement of sunitinib for Polish patients. After crucial decision, National Health Fund created a dedicated therapeutic program for patients with mRCC with sunitinib as a first line treatment. On December 12, 2009 CC rejected second submission of bevacizumab because there was no evidence of its superiority over already reimbursed sunitinib. LESSONS LEARNED: Utilising evidence from different levels can broaden decision maker’s perspective and justify coverage of sometimes expensive but socially demanded new treatments. In certain cases, there is a lack of evidence from the irrefutably well designed and conducted clinical controlled trials and thorough analysis of observational studies can give enough additional data to issue an informed decision. Data from large patient registries can be crucial to the decision-making process.

**PCASE2**

DEVELOPING CRITERIA FOR USE FOR CONTINUOUS GLUCOSE MONITORING (CGM) SENSORS IN A VETERAN POPULATION

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ORGANIZATION: Veteran Affairs San Diego Healthcare System (VASHDS) is a 242-bed medical facility that provides comprehensive medical, surgical, mental health, rehabilitation extended care, outpatient, and inpatient specialty services and uses a comprehensive electronic medical record system. OBJECTIVES: In 2009 VASHDS is part of the Department of Veterans Affairs which is an integrated health care organization that operates using a national formulary, provides outpatient and inpatient specialty services and uses a comprehensive electronic medical record system. The Veteran Affairs San Diego Healthcare System (VASDHS) is part of the Department of Veterans Affairs which is an integrated health care organization that operates using a national formulary, provides outpatient and inpatient specialty services and uses a comprehensive electronic medical record system. METHODS: The absence of an accepted system for evaluating appropriate utilization of disposable medical supplies present decision makers with concern for how resources are managed in this category of budget expenditures. There is no current standard in place for technology assessments for durable medical equipment (DME) requiring disposable medical supplies in a pharmacy benefit management (PBM) plan with the potential for extensive budgetary and utilization management challenges to our health care system. With the introduction of CGM to the US market, the American Diabetes Association has recognized CGM as a useful tool for clinicians and patients, describing systems and data analysis techniques. VASHDS is part of the Department of Veterans Affairs which is an integrated health care organization that operates using a national formulary, provides outpatient and inpatient specialty services and uses a comprehensive electronic medical record system. The absence of an accepted system for evaluating appropriate utilization of disposable medical supplies present decision makers with concern for how resources are managed in this category of budget expenditures. There is no current standard in place for technology assessments for durable medical equipment (DME) requiring disposable medical supplies in a pharmacy benefit management (PBM) plan with the potential for extensive budgetary and utilization management challenges to our health care system. With the introduction of CGM to the US market, the American Diabetes Association has recognized CGM as a useful tool for clinicians and patients, describing systems and data analysis techniques. GOALS: (1) Develop health technology criteria for use for CGM sensors (2) Assess diabetes outcomes after patients are approved for CGM device and sensors. OUTCOMES ITEMS USED IN THE DECISION: Clinical efficacy/effectiveness included: HgbA1c (pre-post CGM sensor utilization), incidence of hypoglycemia, and Emergency Department and hospital admissions due to hypoglycemia. IMPLEMENTATION STRATEGY: The local Pharmacy and Therapeutics (P&T) committee approved a criterion for use (CFU) for the CGM sensors that required providers to measure clinical efficacy and patient outcomes in order to facilitate the decision making process for authorization. The pharmacy service implemented the P&T committee CFU in conjunction with a medical staff reviewer from our national headquarters for approval of the DME device. RESULTS: Twelve out of 15 patients who received the CGM devices were evaluable at 6 months. All patients were on insulin (100%), most were diagnosed with type 1 diabetes (92%), 83% had hypoglycemia unawareness, and there was an average reduction of 0.13 HgbA1c following CGM intervention. No incidences of hypoglycemic events requiring hospitalizations occurred following the receipt of CGM, with 67% of patients reporting a reduction in frequency of hypoglycemic episodes. The average time to patient receipt of device was 90 days (d) SD 76 d, median 73 d) from date of provider request. Fiscal Year 2009 (FY2009) VASHDS Pharmacy budget impact was estimated as $18,480. Annualized cost for CGM device and sensors ranged from $740 to $3520 per patient based on patients refill rates in FY2009. LESSONS LEARNED: There was a gap in communication that was identified within the CGM device approval process. Final decisions by the reviewer were not communicated to the provider who initiated the request for the CGM device in a timely manner. This led to a delay in getting patients the necessary CGM devices. Hypoglycemic events that require hospitalization preventable economic burden to the PBM and society. CGM devices showed benefit in eliminating unnecessary hospitalizations due to hypoglycemia and reducing the frequency of hypoglycemic events by alerting patients of the potential danger prior to it evolving in to a major problem.