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 attended. Important implications for the model were: a) Patients reported that muscle bleeds can be more painful and last longer (i.e., 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 (joints, muscles), 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 (i.e. ice hockey), thereby improving 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 adults 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 quality assessment, using a checklist of 18 questions, was conducted. RESULTS: Thirty five papers covering 16 cohorts met the inclusion criteria. There were 10 treatment-related studies, only 2 of which provided a comparison between treatments, and 6 non-treatment studies which examined a number of characteristics of the disease including mortality, morbidity, cost of illness and health-related quality of life. All studies included a clinical outcome measure and 11 included patient-reported outcomes, however only two studies reported information on patient utilities and two on costs. Quality range from 41% to 89%. Studies did well on a number of quality assessment questions including having clear objectives, documenting selection criteria, providing a representative sample, defining interventions/characteristics under study, defining and using appropriate outcomes, describing results clearly and using appropriate statistical tests. The quality assessment criteria least adhered to involved questions regarding sample size calculations, describing 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 regimes 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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**ORGANIZATION:** 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 immunomodulatory 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 inter rim analysis, patient registry), quality of life, cost-effectiveness/cost utility. **IMPLEMENTATION STRATEGY:** Consultative Council (CC) of AHTAPol debated on the subject multiple times and given a new decision after each manufacturer’s submission. Considering a new HTA report updated as soon as the new information was published RESULTS: In 2008–2009, CC debated over 3 claims for the reimbursement of bevacizumab and one for the reimbursement of sunitinib in the indication: renal cell carcinoma. 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 insubstantial level of cost-effectiveness of app. USD 330 thousand per LYG, much higher than three-fold GDP recommended by WHO. The second submission together with final results of the III phase trial available as conference presentation and abstract, was also rejected by CC on October 28, 2008. Claiming that a conference presentation and abstract are not sufficiently reliable evidence, CC concluded, muscle, not rence was presented and cost-effectiveness remained unacceptable high. Meanwhile, August 6, 2008, CC rejected submission of bevacizumab 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 bevacizumab 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, CC recommended by WHO. The second submission, containing evidence from the first phase trial available as conference presentation and abstract, was also rejected by CC. **LESSONS LEARNED:** Utilizing 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, spinal cord injury, and extended care services for over 57,000 veterans. VASHDS is part of the Department of Veterans Affairs which is an integrated healthcare care organization that operates using a national formulary, provides outpatient and inpatient specialty services and uses a comprehensive electronic medical record system. **PROBLEM OR ISSUE ADDRESSED:** 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 are now faced with identifying the specific utility of this new technology for their patient population. **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: HbA1c (pre-post CGM 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 (CUF) 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 CUF 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% HgA1c 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 76.4, 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 $5320 per patient per calendar year. With consideration of different levels of reliable evidence, the potential to avoid potentially 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.