OBJECTIVES: Clinical trials of oncology products often allow crossover of control patients to the treatment arm following disease progression. This can underestimate the true treatment effect due to the loss of patients to follow-up and introduces analysis challenges for cost-effectiveness studies. METHODS: A lifetime model compared the cost-effectiveness of a hypothetical pancreatic cancer therapy (CRG001) to gemcitabine. Gemcitabine survival data were derived from published studies. A hazard ratio of 0.55 was assumed for CRG001 while the costs were $5000 every 2 weeks for a maximum of 12 cycles and gemcitabine cost $200 every 1 week for a maximum of 24 cycles. Analyses were conducted: 1) 0%, 2) 50%, and 3) 85% crossover of gemcitabine patients to CRG001. Patient crossover occurred at the time of disease progression. Crossover patients received the CRG001 hazard ratio. Patients progressing in CRG001 were assumed to continue with CRG001. In our experience, however, reimbursement agencies often refuse to base a primary analysis that excludes second-line costs of the drug study for patients that cross-over. This analysis yields a high ratio that could lead to a negative reimbursement decision. In this case, where second-line CRG001 costs are included, adjustment of OS for crossover of gemcitabine-alone patients is required. Overall, consideration must be given to the extent and potential impact of crossover when conducting cost-effectiveness analysis of new oncology products.

PCN155
PATIENT BENEFIT-RISK PREFERENCES FOR ADVANCED RENAL CELL CARCINOMA TREATMENTS: RESULTS FROM A CONJOINT ANALYSIS STUDY

OBJECTIVES: To assess economic and clinical characteristics of severe comorbidities in hospitalized patients with HIV/AIDS. METHODS: The TRANSLATION AND LINGUISTIC VALIDATION OF THE FACT-TH18 FOR USE WITH CANCER PATIENTS WITH THROMBOCYTOPENIA WORLDWIDE

OBJECTIVES: Translation of patient reported outcomes (PRO) measures is an essential component of the research methodology required when preparing for multinational clinical trials. One such measure is the Functional Assessment of Cancer Therapy-Thrombocytopenia 18 questionnaire (FACT-TH18), which evaluates the quality of life (QOL) of cancer patients with thrombocytopenia. This study set out to linguistically validate the FACT-TH18 scale for use in China, Greece, Hong Kong, Japan, India, Israel, Korea, Taiwan and Thailand. The combined sample consisted of 160 patients (81 males/79 females) diagnosed with thrombocytopenia. Patient mean age was 46 years, and at the time of administration, 146 patients were receiving treatment. The sample consisted of patients who speak Arabic, Chinese, Traditional-Chinese-Simplified, Greek, Gujarati, Hebrew, Hindi, Japanese, Korean, Malayalam, Marathi, Punjabi, Tamil, Telugu and Thai. The FACT-TH18 was translated based on the established FACIT methodology. Patients completed the respective translated questionnaire corresponding to their primary language and then participated in a cognitive interview to determine if there were any problems with the translations or item content. Quantitative analyses were performed on the combined sample and participant comments were analyzed qualitatively in order to confirm the validity of the translations. RESULTS: During the translation process terms such as “petechiae”, “pointing bruising” and “platelet transfusions” proved difficult to translate. The FACT-TH18 translations proved relevant to patients from a wide range of countries and were well understood. Very few issues required adjusted wording during translation as a result of linguistic challenges. CONCLUSIONS: The FACT-TH18 demonstrated linguistic validity across all 16 languages. The translations are considered acceptable for PRO assessment in international research and clinical trials.

PCN158
PROJECTING STATE LEVEL ESTIMATES FOR RARE DISEASE USING CENSUS DATA AND HEALTH CARE CLAIMS DATABASE

OBJECTIVES: Estimating prevalence rates for rare medical conditions such as renal cell carcinoma (RCC) at state level by age and sex is difficult due to the paucity of available data resources. Available information may be fragmented because of a lack of national level surveillance. The use of commercial medical claims data alone is insufficient for estimation because the use of these data tends to result in biased estimates due to business practices of managed care organization. METHODS: In case-data and the US census data were used to address this problem. The study inclusion criteria for defining RCC patients was age of 18 years or older without prior history of HIV/AIDS, HBV, or HCV diagnoses and had at least 2 outpatient medical claim with an associated ICD9 code of 189. First, we estimated prevalence rates for the medical conditions by state, age, and sex using ICD9 codes from the commercial data (2002-2010). Then, reanalyzed using post-stratification weights derived from the 2010 Census data to reflect the state, age, and sex distribution of the US population. RESULTS: The sum of the adjusted state population weights yielded a total that was similar to the 2010 US census data, and adjusted weights that suggest the overall and state-level prevalence is approximately 85%. Since there was no state level prevalence data, for RCC per year by age and sex available, an indirect comparison was made by comparing the overall prevalence from Cancer Health (CancerPmacs)®. The overall prevalence estimates were similar, Kantor Health: 86,853 versus Study Estimate: 84,712. CONCLUSIONS: This method produces prevalence rates that take into account differences in the state population size. Further, this method allows us to account in the estimation process. We recommend the use of this combined approach for the estimation of prevalence rates of rare disease conditions and procedures.

INFECTION – Clinical Outcomes Studies

PCN1
OUTCOMES ASSOCIATED WITH SEVERE COMORBIDITIES IN HOSPITALIZED CASES OF HIV/AIDS

OBJECTIVES: To assess the quality of life outcomes of Indian breast cancer patients. METHODS: Deshpande P, Chittkathopottamal AN, Bommareddy LS, Mallasamy S

OBJECTIVES: To assess economic and clinical characteristics of severe comorbidities during inpatient hospitalizations in persons with HIV/AIDS. METHODS: The Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (H-CUP) Nationwide Inpatient Sample (NIS) was used in this retrospective database study spanning 2005-2009. Inpatient cases of HIV/AIDS among persons 18 years of age or older were used as inclusion criteria. Key clinical outcomes were: 1) length of stay, 2) total cost, 3) number of complications (liver failure), 4) modes of administration. Treatment-choice questions were based on a predefined experimental design with known statistical properties. Random-parameters logit was used to estimate relative preference weights for each attribute level, mean relative importance weights, and calculate risk tolerance for each adverse event for different improvements in PFS. RESULTS: A total of 272 respondents completed the survey. A 7-month improvement in PFS was the most important attribute. Remaining attributes were ranked in decreasing order of importance: eliminating severe fatigue (7.0; 95% CI: 4.6-9.4), eliminating severe stomach problems (7.0; 95% 4.7-9.3), eliminating a 2% liver-failure risk (6.1; 95% CI: 4.0-8.2), eliminating severe mouth sores (5.7; 95% CI: 3.7-7.7), eliminating severe HFS (4.5; 95% CI: 2.7-6.4), eliminating a 2% lung-damage risk (4.1; 95% CI: 2.5-5.8), and switching from infusion once a week to 1 pill once a day (2.5; 95% CI: 1.4-3.6). To increase PFS by 1 month (baseline:3-4months), patients accepted a maximum of 4.0-8.2), eliminating severe mouth sores, hand-foot syndrome (HFS), serious adverse events (lung damage and severe stomach problems were rated as the most troublesome toxicities.