OBJECTIVES: Clinical trials of oncology products often allow crossover of control patients to the treatment arm following disease progression. This can underestimate a product's overall survival (OS) and raises challenges for cost-effectiveness analyses compared. **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. CRG001 cost $2500 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 receive palliative care. A secondary analysis allowed 50% crossover but excluded second-line costs of CRG001. Costs and outcomes were discounted at 5%. **RESULTS:** The cost per QALY gained for CRG001 compared with current care was $81,352 with no cross-over, $69,292 with 50% crossover and 40,992 with 85% crossover. In the analysis where the cost of CRG001 was excluded in crossover patients, the ratio was $140,118. **CONCLUSIONS:** The first three analyses illustrate that CRG001 cost-effectiveness decreases with increasing cross-over of gemcitabine patients, if the costs of CRG001 for crossover patients are included. In our experience, however, reimbursement agencies often require a primary analysis that excludes second-line costs of the study drug 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 excluded, adjustment of OS for crossover of gemcitabine 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

Mohamed A[1], Yang JC[1], Hauber AB[1], Liu Z[2], Wong M[3], Rogerio J[2], Garay C[2]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA,* [3]*University of Southern California, Los Angeles,, CA, USA*

OBJECTIVES: To quantify patients' benefit-risk preferences for benefits, toxicities, and serious adverse events of advanced RCC treatments. **METHODS:** Adult residents in the United States, with a self-reported diagnosis of RCC completed a web-enabled choice-format conjoint survey consisting of a series of 10 treatment-choice questions, and a pair of hypothetical RCC medication profiles. Each profile had different attributes, i.e., efficacy [PFS], tolerability [fatigue, stomach problems, mouth sores, hand-foot syndrome (HFS)], serious adverse events (lung damage and liver failure), and mode of administration. Treatment-choice questions were based on a predetermined 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% CI: 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 - 4 months), patients accepted a maximum level of lung damage risk of 1.0% (95% CI: 0.8% - 1.4%) and liver failure risk of 0.7% (95% CI: 0.4% - 1.0%). A 7-month improvement in PFS was 2 times as important as eliminating severe HFS and a 2.0% risk of lung damage ($P < 0.05$). **CONCLUSIONS:** PFS was the most important outcome for RCC patients while severe fatigue and severe stomach problems were rated as the most troublesome toxicities.

PCN156

DEVELOPMENT AND VALIDATION OF A PATIENT-REPORTED QUESTIONNAIRE TO ASSESS THE QUALITY OF LIFE OUTCOMES OF INDIAN BREAST CANCER PATIENTS

Deshpande P, Chittkathopottamal AN, Bommareddy LS, Mallasamy S
Manipal University, Manipal, Karnatak, India

OBJECTIVES: To develop and validate a patient-reported questionnaire to assess the quality of life (QOL) outcomes of Indian breast cancer (BC) patients. **METHODS:** A 27-item questionnaire was developed by literature review, patient interviews (n=6) and expert opinions (n=15). The 24-item questionnaire was finalized. Total 11 domains were considered. The questionnaire was translated to local languages and then it was administered to BC patients (n=30) irrespective staging of cancer and type of therapy. The patients were interviewed and the responses were obtained. Internal consistency, acceptability, content validity, test-retest reliability of the questionnaire was determined and assessment the scores was performed statistically. **RESULTS:** A 24-item questionnaire was developed as per literature review, patient interviews and expert opinions. Cronbach's alpha value for the questionnaire was 0.93. Patients understood the questionnaire and found the items to be relevant indicating content validity. The statistical assessment of the scores was not showing the association between scores with age or stage of BC as sample size was less. **CONCLUSIONS:** The questionnaire shows good internal consistency, acceptability, content validity and test-retest reliability. It can be used to determine the QOL of BC patients. To our knowledge there is no other questionnaire to determine the QOL outcomes of Indian BC patients. For better results the instrument is needed to be used in larger population.

PCN157

TRANSLATION AND LINGUISTIC VALIDATION OF THE FACT-TH18 FOR USE WITH CANCER PATIENTS WITH THROMBOCYTOPENIA WORLDWIDE

Arnold B, Dhar J, Parks-Vernizzi E, Debb S
FACITtrans, Elmhurst, IL, USA

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. **METHODS:** 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, Kannada, 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", "pinpoint 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 items required adjustment to translations as a result of pilot-testing. **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 HEALTHE CARE CLAIMS DATABASE

Joo S[1], Victor T[2], Gomez A[3]
[1]*Bristol-Myers Squibb Company, Pennington, NJ, USA,* [2]*Kantar Health, Princeton, NJ, USA,* [3]*Bristol-Myers Squibb Company, Princeton, NJ, USA*

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 claim 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:** Invision Data Mart 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, HVB, or HVC diagnoses and had at least 2 outpatient medical claim with an associated ICD9 code of 189.0. 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 values suggest that the overall 2010 US RCC prevalence is approximately 85k. Since there is no state level prevalence information for RCC by age and sex available, an indirect comparison was made by comparing the overall prevalence from Kantar Health (CancerMpact®). The overall prevalence estimates were similar; Kantar Health: 86,853 versus Study Estimate: 84,712. **CONCLUSIONS:** This method produced prevalence rates that take important health care related factors into 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

PIN1

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

Villa L[1], Skrepnek G[2]
[1]*University of Arizona, Tucson, AZ, USA,* [2]*University of Arizona, College of Pharmacy, Tucson, AZ, USA*

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 comorbidities analyzed included organ insufficiency/failure, cancers, heart failure, pulmonary circulation disorders, coagulopathies, fluid/electrolyte disorders, and wasting syndromes/weight loss. Outcomes of inpatient mortality and hospital charges were assessed via multivariate logistic and gamma regression, respectively, after controlling for comorbidities, patient demographics, hospital characteristics, payer, and lengths of stay. **RESULTS:** There were 1,227,718 overall inpatient cases of HIV/AIDS from 2005-2009 in the United States, averaging 44.8 (±10.7) years of age, 6.7 (±9.0) days for length of stay, and inpatient charges of $36,004 (±59,303). Mortality occurred in 41,609 cases, constituting 3.4% of all HIV/AIDS hospitalizations and averaging 47.0 (±11.1) years of age, 13.4 (±17.4) days for length of stay, and inpatient charges of $104,558 (±136,254). Fluid/electrolyte disorders