has been estimated from clinical trials data. The cost of general practitioner visits, specialist visits, hospitalizations and emergency department visits were included. Costs and utility values associated to various health states were taken from the published literature. RESULTS: Lacosamide adjunctive therapy was associated with 6.78 avoided seizures and a gain of 38 quality adjusted life-years (QALYs) compared to the standard therapy arm within the two-year timeframe. Treatment with lacosamide was associated with a cost of $223 per seizure avoided, and $39,574 per QALY gained versus standard therapy over two years and falls within accepted thresholds of cost-effectiveness in the United States. Results calculated for 6-, 12- and 18-month follow-up showed respective incremental cost-utility ratios of $55,465, $46,587 and $44,559 and cost per seizure avoided of $731, $305 and $260. Using a willingness-to-pay threshold of $50,000 per QALY, 77% of the simulations fell below this threshold. For example, achievement of an MPR threshold of at least 0.5 was associated with $1524 lower total charges (P = 0.260 – 0.679). Larger reductions in total direct medical charges, excluding drugs, were seen with higher MPR thresholds, For example, achievement of a threshold of 0.7, 0.8 or 0.9, respectively, associated with an odds ratio of 0.62 (10-14 HDPM), 0.53 (15-19 HDPM), 0.53 (20-23 HDPM), and 0.52 (24+ HDPM) reductions fell below this value after 2 years of treatment.

The pooled trial cohort of 1384 patients (857 with BOTOX® and 527 with placebo) was included in the Migraine Prophylaxis Treatment Effectiveness Study (PREEMPT) trial population. The PREEMPT clinical trial program was considered to ascertain relevant HDPM to define migraine health states. Subsequently, pooled trial data were used to estimate transitions between health states per 12-week treatment cycle for patients with chronic migraine. Up to 24 weeks follow-up data is available from the PREEMPT phase 3 trials, with an additional 32 weeks of open-label data for BOTOX® treated patients. All available data from the PREEMPT trials were used to model transitions. A Bayesian approach with a Dirichlet distribution was used to perform sensitivity analyses of these health state transitions.

RESULTS: Patients who experienced by patients with chronic migraine (~15 headache-days per month) can be used to calculate transition probabilities that may be applied to cost-effectiveness modeling. METHODS: Published literature, headache treatment guidelines, health utility, and health resource utilization, as well as the baseline distribution of HDPM in the pooled Phase 3 Research Evaluating Migraine Prophylaxis Therapy (PREEMPT) clinical trial program were considered to ascertain relevant HDPM to define migraine health states. Conclusively, patients with chronic migraine (~15 headache-days per month) can be used to calculate transition probabilities that may be applied to cost-effectiveness modeling. RESULTS: Defined meaningful health states based on published literature and where necessary, expert opinion. Health states defined by the number of headache-days per month (28 days, HDPM) experienced by patients with chronic migraine (~15 headache-days per month) can be used to calculate transition probabilities that may be applied to cost-effectiveness modeling. METHODS: Published literature, headache treatment guidelines, health utility, and health resource utilization, as well as the baseline distribution of HDPM in the PREEMPT clinical trial program were considered to ascertain relevant HDPM to define migraine health states. Subsequently, pooled trial data were used to estimate transitions between health states per 12-week treatment cycle for patients with chronic migraine. Up to 24 weeks follow-up data is available from the PREEMPT phase 3 trials, with an additional 32 weeks of open-label data for BOTOX® treated patients. All available data from the PREEMPT trials were used to model transitions. A Bayesian approach with a Dirichlet distribution was used to perform sensitivity analyses of these health state transitions. RESULTS: Patients who experienced by patients with chronic migraine (~15 headache-days per month) can be used to calculate transition probabilities that may be applied to cost-effectiveness modeling. RESULTS: Defined meaningful health states based on published literature and where necessary, expert opinion. Health states defined by the number of headache-days per month (28 days, HDPM) experienced by patients with chronic migraine (~15 headache-days per month) can be used to calculate transition probabilities that may be applied to cost-effectiveness modeling.
CONCLUSIONS: Resource utilization and costs associated with migraine increased with greater headache frequency. Treatments that reduce headache frequency have the potential to have a positive economic impact by reducing costs associated with migraine care.

PND33 UTILIZING A PAPER STANDARD GAMBLE INSTRUMENT TO ASSESS HEALTH UTILITY IN PATIENTS WITH HEMOPHILIA B

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OBJECTIVES: To conduct a pilot study examining the validity and reliability of a paper-standard gamble (PSG) instrument and to administer the validated PSG among persons with hemophilia B enrolled in the Hemophilia Utilization Group Study (HUGS-Vb). METHODS: Fifteen pharmacy students were enrolled in this pilot. We presented a hypothetical scenario describing a patient with severe hemophilia to each participant, followed by three tests: (1)Standard Gamble (SG) using the probability wheel, (2)PSG and (3)Visual Analog Scale (VAS), each administered in random order. PSG was re-administered after two weeks to assess test-retest reliability. The validated PSG was subsequently administered to participants enrolled in HUGS-Vb, a prospective, multicenter study collecting utilization and other data associated with hemophilia B in the United States. Participants or their parent(s) completed a demographic questionnaire, the PSG and the EQ-5D. A PSG scenario based on actual demographic and clinical characteristics was created for each participant. Predicted SG did not differ significantly from 0 (p = 0.124). PSG was significantly correlated with SG (r = 0.769, p < 0.0008) and VAS (r = 0.534, p = 0.0450). PSG re-test score was 0.79 ± 0.13 and test-retest ICC was 0.85 (95% CI: 0.63-0.94; p < 0.0001). Of 71 HUGS-Vb participants, 32 (45%) were adults, 38 (54%) had severe hemophilia. Mean age was 21.8 years (range 16-41). Mean PSG and VAS scores were 0.46 ± 0.15 and 76.4 ± 14.6, respectively, with weak correlation between the two (r = 0.142; p = 0.0452) in the full sample. Adult PSG and EQ-5D scores were 0.87 ±0.18 and 0.85 ±0.16, respectively, with correlation r = 0.348 (p = 0.0506). CONCLUSIONS: A paper-based standard gamble instrument may be a valid, reliable alternative to SG for measuring health utility in hemophilia patients.

PND34 MAPPING THE INSOMNIA SEVERITY INDEX (ISI) TO THE EQ-5D UTILITIES

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OBJECTIVES: To map the Insomnia Severity Index (ISI) to the EQ-5D utilities. METHODS: A cross-sectional, online survey was conducted among adult US residents with self-reported sleep problems. Respondents provided demographic, comorbidities, and sleep-related information and, completed the ISI and the EQ-5D and the SDS, a seven-item instrument measuring perceived insomnia severity. Each ISI item is scored from 0-4 with minimum total score of 0 (no insomnia) and a maximum of 28 (most severe insomnia). Respondents can be classified into four ISI categories (0-7: no clinically significant insomnia, 8-14: subthreshold insomnia, 15-21: moderate insomnia, 22-28: severe insomnia). Generalized linear models were used to map the seven ISI items (Model 1), the ISI summary scores (Model 2), and the four ISI clinical categories (Model 3) onto EQ-5D utilities. Predictions were estimated using 50/50 split sample validation. Model fits were assessed using mean of 28 (most severe insomnia). Respondents can be classified into four ISI categories (Model 1: 0-7, Model 2: 8-14, Model 3: 15-21, Model 4: 22-28) severe insomnia), respectively. Generalized linear models were used to map the seven ISI items (Model 1), the ISI summary scores (Model 2), and the four ISI clinical categories (Model 3) onto EQ-5D utilities. Predictions were estimated using 50/50 split sample validation. Model fits were assessed using mean squared error (MSE) and distributional quality of predicted values. RESULTS: Respondents (n = 2,842) were predominantly middle-aged, female, Caucasian, with a 1:1 sex ratio. Mean sleep duration was 7.8 ± 1.9 hours, mean ISI score was 14.1 (±4.8). Predicted mean utilities were (0.765 ± 0.18) across all models, overlapping with observed utilities (0.765 ± 0.18). Using Model 1, predicted utilities increased linearly with improving ISI (0.493 if ISI = 28; 1.00 if ISI = 0, p < 0.001). In Model 2, each unit decrease in ISI summary was associated with a 0.022 (p < 0.001) increase in utility. Predicted utilities were 0.868, 0.809, 0.722 and 0.579 for no clinical, subthreshold insomnia, moderate insomnia and severe insomnia, respectively (Model 3). The SG/MLE between predicted and observed utilities were good in all models (Model 1: 0.25, Model 2: 0.70, Model 3: 0.006). Especially when predicting utilities >0.40 (MSE: 0.016-0.050). MSEs were higher when predicting lower utilities (MSE: 0.138-0.156). CONCLUSIONS: Linear relationships were found between ISI and utility. These relationships should be used to estimate the impact of insomnia-associated treatment effects on utilities.

PND35 CREATION OF A WEB-BASED MULTIPLE SCLEROSIS PATIENT-REPORTED OUTCOMES RESEARCH PROGRAM

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OBJECTIVES: To create and implement a secure web-based research program that collects and tracks validated patient-reported outcomes (PROs) for multiple sclerosis (MS) patients and their healthcare providers (HCP). METHODS: The MS Health program can be accessed through a HIPAA secure website, www.mymseven.org. A pilot study to evaluate the My MS Health program has been IRB-approved. Assessment of inclusion/exclusion criteria, enrollment, and informed consent with an electronic signature occurs through this secure web-site. Enrolled patients are prompted to complete a series of nine validated PRO surveys that measure MS specific symptom status, functional status, and quality-of-life, and results are immediately available. Patients may elect to have their HCP access to their real-time PRO results electronically. Aggregate data analysis can be performed on the entire PRO data set. RESULTS: Preliminary results indicate the study was just right, and 91% felt the website was easy to use (4.5 ± 1.05). In addition, 92% reported they would likely continue participating in the program (4.0 ± 1.11) and 78% reported they would likely recommend My MS Health to others (3.8 ± 1.48). CONCLUSIONS: Preliminary results indicate My MS Health is an efficient and user friendly technology platform that patients will continue to use. Future evaluations will assess the impact of using the program on patient and HCP communication.