choice instrument to elicit women’s tradeoff preferences for various treatment attributes, including both benefits and risks for therapies to relieve vasomotor symptoms. The survey was administered to 500 US women between the ages of 46 and 60, randomly sampled from a large internet consumer panel. Two survey versions were administered to split samples. The versions were identical except that risk descriptions incorporated relative risks in one version and absolute risks in the other version. Ordered-probit importance weights for various health states and risks were estimated from the resulting tradeoff data.

RESULTS: We found that the risk description did not affect ordered-probit estimates of respondents’ preferences for risk of fracture and heart attack, but did affect preferences for the risk of breast cancer. Subjects who received the relative-risk versions indicated that a decrease in risk of breast cancer from 3.9% to 2.3% was 64% more important than subjects who received the absolute-risk version. Conversely, subjects who received the absolute-risk version were more concerned about relieving vasomotor symptoms. Relieving the severity of hot flashes was 44% more important, reducing the frequency of hot flashes was 40% more important, and reducing the frequency of night sweats was 50% more important for subjects who received the absolute-risk version than for subjects who received the relative risk version.

CONCLUSION: Although health professionals presumably interpret clinical relative-risk results in the context of the base prevalence of a condition, laypersons often do not have access to base-rate information. Our results suggest that more careful characterization of adverse-event risks is important in helping women make fully informed choices among alternative treatments for vasomotor symptoms.

NEW WEIGHTS FOR OLD: A SCALE OF VALUES FOR EQ-5D HEALTH STATES
Kind P, Macran S, Hennessy S
University of York, York, UK

OBJECTIVES: EQ-5D is one of the most widely used index measures of health-related quality of life. Ten years have passed since the first UK national survey that established preference weights for EQ-5D health states. That protocol elicited values for 45 of the 245 possible EQ-5D health states. Values for the remaining health states were interpolated from estimation models based on the values for directly observed states. The process of model construction and testing was onerous and labour intensive. Estimated values remained largely untested as replication studies are virtually non-existent. This paper reports on an alternative approach in which values for ALL health states are elicited.

METHODS: The standard questionnaire used to value EQ-5D health states records VAS ratings on a 0–100 scale, for 16 health states presented as two groups of eight on consecutive pages. The logically best and worst health states are repeated on each page. A value for dead is also elicited in each questionnaire. For this study, 21 versions of the questionnaire were designed, each presenting 14 different states. Questionnaires were mailed to 1100 individuals selected randomly from the electoral registers of England and Wales. RESULTS: A response rate of 62% was achieved (n = 685). Mean VAS scores from this survey were similar to those elicited ten years earlier although the value for dead was 45% higher than its predecessor. A smooth, well-behaved set of values for all 245 states was derived using OLS regression (r² = 0.974, p < 0.001). Transformed to a 0–1 scale, values were systematically higher than the corresponding TTO weights used as standard in NICE appraisals reporting EQ-5D. Only 12 states demonstrate negative values.

CONCLUSIONS: Traditional interview-based procedures are costly. This study demonstrates the feasibility of postal survey methods and simultaneously poses a dilemma for end-users. Are contemporary VAS-based values preferable to decade old TTO-based values?

THE CONTENT VALIDITY OF CLINICIAN DERIVED PATIENT REPORTED OUTCOMES (PRO) MEASURES: THE ROLAND MORRIS DISABILITY QUESTIONNAIRE
Horowicz-Mehler N1, Evans CJ1, Abez L2, West C3, Copley-Merriman K3
1Mapi Values, Boston, MA, USA; 2Mapi Values, Cheshire, UK; 3Pfizer Inc, Ann Arbor, MI, USA

OBJECTIVES: The FDA currently requires patient interviews in the process of developing a new PRO measure. In the past, many questionnaires were developed based solely on clinician expertise and patient involvement in the creation of items was nonexistent. In order to ensure existing questionnaires are accepted by the FDA, it is necessary to confirm the content validity of
questionnaires that were not based on patient interviews. The 25 and 18 item RMDQ is a measure of pain and function widely used in low back pain (LRP) trials that was based solely on clinician involvement. METHODS: Two US focus groups (n = 15) and one UK focus group (n = 7) were asked to complete the problem elicitation technique (PET) alongside the RMDQ to determine the relevance of items. The PET measures the importance of concepts based on a series of questions rating the importance of each item on a five-point likert response continuum. To ensure the RMDQ was not missing any relevant items participants were asked several open-ended questions. RESULTS: Participants confirmed the content validity of the RMDQ by identifying four areas of importance: pain/discomfort, activities of daily living, sleep problems and emotional impact. Based on the PET, all RMDQ items were rated as moderately to extremely important (item score range of 3.57–4.36 on a one—five scale). Items rated least important were the same items removed in the 18 item version. In the open ended questions, sleep disturbances was consistently mentioned as a primary area of concern. CONCLUSIONS: The PET augmented by open-ended questions is a valid method for confirming the content validity of questionnaires that did not include patient involvement in their development. These findings support the continued use of the RMDQ in LBP trials; however, consideration should be given to including additional sleep questions or measuring this concept separately.

Respiratory Diseases

QUALITY OF LIFE IN ASTHMA PATIENTS IS AFFECTED BY HOME TELEMANAGEMENT

Joshi A, Amelung P, Finkelstein J
University of Maryland, Baltimore, MD, USA

OBJECTIVES: To determine whether Home Automated Telemanagement (HAT) affects disease-specific Quality of Life (QOL) in adult asthma patients. METHODS: Fifty adult patients with mild persistent to severe asthma were randomly assigned to an intervention or control group and were followed for 12 months. The patients in the control group received regular care. The HAT system assisted clinicians in setting up individualized action plans and helped asthma patients in following their action plans at home using peak flow meter and a laptop connected with a hospital. RESULTS: Both intervention and control group patients had similar baseline demographic characteristics with regard to their asthma severity, action plan use, computer skills and the quality of life. After 12 month follow-up the mean total QOL score in the intervention and the control group was 20.2 ± 0.9 and 16.9 ± 1.3 respectively. The difference was significant (p < 0.0001) at the alpha level of 0.05. Analysis of the symptoms domain of the asthma quality of life showed improved score 3.3 ± 0.4 in the intervention group compared to the control group 4.4 ± 0.6 (p < 0.05). The activities domain of the QOL showed an improvement in the activities in the intervention group 5.1 ± 0.2 compared to the control group 3.7 ± 0.3 (p < 0.05). There was a statistically significant difference (p < 0.05) in the emotions domain of the QOL; the mean score in the intervention group was 4.8 ± 0.2 whereas the mean score in the control group was 4.4 ± 0.4. The environment domain in the intervention group was 5.1 ± 0.3 compared to 4.4 ± 0.5 in the control group (p < 0.005). CONCLUSION: Disease-specific quality of life in asthma patients is positively affected by Home Telemanagement.

ASSESSING HEALTH-RELATED QUALITY OF LIFE USING THE SF-12V2 FOR PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Martinez RJ1, Raczek AE2, DeRosa MA2, Girts TK2, Phillips AL3
1University of Michigan, Ann Arbor, MI, USA; 2QualityMetric Incorporated, Lincoln, RI, USA; 3Boehringer Ingelheim, Ridgefield, CT, USA

OBJECTIVES: To assess health-related quality-of-life (HRQOL) for patients with chronic obstructive pulmonary disease (COPD). METHODS: In Spring 2004, 700 patients cared for by pulmonologists or general practitioners at 12 sites across the US completed a 90-item survey that included the SF-12v2 and pre-/post-bronchodilator spirometry. COPD was defined as post-bronchodilator Forced Expiratory Volume in one second/Forced Vital Capacity (FEV1/FVC) <70%. Descriptive statistics for SF-12v2 measures were calculated for mild (FEV1 >80% predicted) and moderate/severe (FEV1 <80% predicted) COPD. Disease burden was estimated by adjusting general population normative data from the 1998 National Survey of Functional Health Status (NSFHS) to age and sex characteristics of the COPD sample. Multivariate and univariate analyses of variance (MANOVA, ANOVA) F-statistics were used to test for differences between patients’ HRQOL and adjusted norms. RESULTS: Based on spirometry, 36% (N = 249) of patients had COPD (20% mild, 80% moderate/severe). Patients with COPD were less likely to describe their health as very good or excellent (20.5% vs. 36.8%, p < 0.001), and more likely to describe their health as fair or poor (33.3% vs. 23.4%, p < 0.005) compared to those without COPD. MANOVA revealed a significant difference between the full profile of SF-12v2 scales for COPD patients and the US general population (p < 0.001). Adjusted norm comparisons revealed that patients with mild COPD had significantly lower (mean, SD) Role Physical (41.9, 11.1; p < 0.02) and Physical Component Summary (PCS) (41.0, 12.0; p < 0.02) scores. Moderate/severe COPD patients had large, statistically significant decrements across all SF-12v2 measures. Differences from normative values were most notable for Physical Functioning (38.2, 12.8; p < 0.001), PCS (38.9, 11.7; p < 0.001), General Health (40.8, 11.2; p < 0.001), and Role Emotional (43.0, 13.0; p < 0.001). CONCLUSION: Compared to the US general population, COPD has a significant impact on a patient’s HRQOL, notable with mild disease and pronounced at higher severity levels.

ESTIMATING THE COST-EFFECTIVENESS OF FLUTICASONE PROPIONATE FOR TREATING CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Briggs A1, Wang H2, Gagnon YM2, Spencer S1, Gale G2, Spencer M1, Burge S2
1University of Oxford, Oxford, United Kingdom; 2Oxford Outcomes (Canada) Ltd, Vancouver, BC, Canada; 3Brunel University, Uxbridge, UK; 4Birmingham Heartlands Hospital, Birmingham, UK; 5GlaxoSmithKline, London, UK

OBJECTIVES: To explore the cost-effectiveness of fluticasone propionate (FP) for the treatment of chronic obstructive pulmonary disease (COPD), we estimated costs and quality adjusted life years (QALYs) over three-years, based on an economic appraisal of a previously reported clinical trial (ISOLDE). METHODS: Results from the initial analyses of the trial data showed significant improvements with FP in reducing the rate of exacerbations from COPD, in slowing the rate of decline in health status and a trend towards improved survival. A recently