with COPD, a total of 33.3% patients showed moderate to severe depressive symptoms and nearly 50% of cases had a marked impairment in HRQoL. Educational and occupational status, body mass index (BMI), respiratory symptoms, physical impairment and dyspnoea were associated with the diagnosis of depression in patients with COPD, whereas body mass-index, forced expiratory volume in 1 second (FEV1), dyspnoea, and sputum production were associated with patients with COPD.

CONCLUSIONS: More than one third of patients with COPD had either depression or poor HRQoL in India. The study suggest need for regular screening for depression and HRQoL in patients with COPD especially among obese and patients with compromised or severe respiratory functions.

PM02 MEASURING THE SYMPTOMS AND IMPACTS OF ENDOMETRIOSIS: PSYCHOMETRIC VALIDATION OF THE ENDOMETRIOSIS SYMPTOM DIARY AND ENDOMETRIOSIS IMPACT SCALE

Gautschi A, 1Moore AM, 1Cassio CD, 2Chen WH, 3Wichmann K, 2Harttisch C, 3Fünnlenko A, 2Seitz C, 2Gerlinger C 2
1Adelphi Values, Ballington, Cheshire, UK, 2Adelphi Values Ltd, Ballington, Cheshir, UK, 3Adelphi Values, Boston, MA, USA, 4TRT Health Solutions, North Potomac, MD, USA, 5Bayer Pharma AG, Berlin, Germany

OBJECTIVES: As a disease caused by pain, Patient-Reported Outcomes (PROs) are important for determining disease severity and evaluating the efficacy of endometriosis treatments. In the absence of existing PROs that comply with the FDA PRO Guidance, two new PROs have been developed: The Endometriosis Symptom Diary (ESD) and Endometriosis Impact Scale (EIS).

The content validity of these instruments has been demonstrated by extensive qualitative and quantitative research with women with endometriosis. The first investigation of the reliability of these scores derived from the ESD and EIS are presented herein. METHODS: Women with surgically-confirmed endometriosis (n=268) in the US and Germany participated in a 12-month non-interventional study. A range of HRQoL measures were collected from the participants throughout the study using an electronic handheld device, including: ESD, EIS, Biberoglu & Behrman Scale, Endometriosis Health Profile-30, Patient Global Improvement, and Change measures using single-item pair-difference and visual analogue scales. Pre-specified analyses were conducted to evaluate the test-retest reliability, convergent validity, known-groups validity and responsiveness of scores derived from the ESD and EIS.

RESULTS: Intra-class correlation coefficients among harmonized scores were calculated as a component of the test-retest reliability of ESD/EIS scores. Correlations between scores for the ESD/EIS and concurrent measures were consistent with a priori hypotheses, demonstrating convergent validity. Furthermore, Analysis of Covariance models revealed statistically significant (p<0.05) differences in ESD/EIS scores among participants of varying levels of symptom severity (as determined by scores on concurrent measures). Finally, observed ESD/EIS score changes in participants whose clinical status had improved (according to scores on concurrent measures) were generally greater than those who were unchanged, providing evidence of responsiveness. CONCLUSIONS: Findings support the reliability, validity and responsiveness of scores derived from the ESD and EIS. Future work will seek to explore definitions of meaningful change in ESD/EIS scores using data from clinical studies.

PM03 WHAT TYPE OF RESPONSE SCALE IS THE MOST RESPONSIVE? A COMPREHENSIVE REVIEW OF RESPONSE SCALE OPTIONS FOR PATIENT-REPORTED OUTCOME MEASURES

Rowe L1, 2Vernon MK, 3Gies KS, 3Safikhani S, 2DeLozier AM, 4McQuarrie K, 1Norquist JM, 5Cook MB
1Pfizer Inc, Tadworth, UK, 2Evidera, London, UK, 3Evidera, Seattle, WA, USA, 4Evidera, Bethesda, MA, USA, 5Lilly, Indianapolis, IN, USA, 1Janssen, Norhash, PA, USA, 2Merrick & Co Whitehouse, London, UK, 3Evidera, London, UK, 4Pfizer Inc, Tadworth, UK

OBJECTIVES: Selection of response scales for patient-reported outcome (PRO) measures is often driven by therapeutic area convention or preferences of measure developers. To help guide response scale selection, an objective of this project was to identify the responsiveness of common response scale types. METHODS: A comprehensive literature review was conducted for studies published from January 2004 through October 2014 that provided direct comparisons of responsiveness of different response scale types. Additional searches were conducted for abstracts and presentations on this topic from relevant scientific conferences. RESULTS: The most common types of response scales evaluated were the 100mm visual analog scale (VAS), the 11-point numeric rating scale (NRS), and the verbal rating scale (VRS) (with varying number of levels). Three studies directly compared responsiveness of all three types. These, one found no difference in responsiveness of the three types, one found superior responsiveness for the NRS compared to the VAS, and one found the VAS to be most responsive for one domain while the NRS was most responsive for another. Three studies compared VAS to VRS, with one finding no difference and one study each finding greater responsiveness for the VAS and a 7-point VRS, respectively. Four studies compared NRS vs. VRS, with three demonstrating no difference and one demonstrating superior responsiveness for the NRS compared to a 6-point VRS. CONCLUSIONS: There are a number of considerations in response scale selection, including target population, study design, concept of interest, recall period, data collection, and scale responsiveness. Several reviewed studies demonstrated equivalent responsiveness for the most common response scale types; however, evidence suggests the 11-point NRS may be slightly more responsive than the other response scales in some settings. Limitations of this review include its 10-year time frame and the paucity of empirical studies comparing common response scales.

PM04 PSYCHOMETRIC VALIDATION OF THE FATIGUE SYMPTOMS AND IMPACTS QUESTIONNAIRE™ (“RELATING MULTIPLE SCLEROSIS (FMS-MRS)”, 4 Hudsons 5, 1Schuler K, 1Hunsche K, 1Leist T
1Clinical Outcome Solutions, Tucson, AZ, USA, 2Acetion Pharmaceuticals Ltd, Allschwil, Switzerland, 3Thomas Jefferson University Hospital, Philadelphia, PA, USA

OBJECTIVES: Fatigue is an important symptom for multiple sclerosis (MS) patients. A new research supported initial context validity of the FMS-MRS™, the first patient-reported outcome (PRO) measure of fatigue in relapsing (RMS) or progressive (PMS) developed according to the 2009 FDA PRO guidance. To confirm appropriate- ness, validity, and reliability of the FSIQ-RMS™, further psychometric analyses were conducted. METHODS: METHODS: A cross-sectional study with 91 subjects (week 1, period 1, subdomains) and 14 Impact items (weekly recall period, 1 subdomain) was administered over 3 months (three 7-day intervals) in a multicenter, non- intervention, observational US-based study of adult patients with different disabilities (relapsing remitting, secondary progressive, progressive relapsing) and a subset of matched healthy controls (week 1 only). Data analyses included: item response and dimensionality, content and construct validity, internal consistency and test-retest reliability, as well as attribution of fatigue to RMS, (EOM) values were above 0.99 for all analyses (i.e. all adjusted analyses, for both HRQoL and disease activity scores). The primary definition for classifying respondents at risk of MS was a score > 10 on the Patient Health Questionnaire (PHQ-9). Logistic regression modeling was used to predict risk at R.M.D., or not, prior to receiver characteristic curves were produced. RESULTS: The total sample had MH scores of 48.8 and MCS scores of 48.9, similar to the normative mean for the US adult population. The percent of respondents with a PHQ-9 > 10 were 15.0%, 29.1% and 29.5% for the total sample, chronic pain alone, and chronic pain with depression, respectively. Cutoff scores (PHQ-9: 10) in the total sample for the MH domain and MCS were 43.0 and 46.0, respectively. Specificities of recommended cutoff scores for the MH domain and MCS were 78.7% and 76.1%; sensitivities were 84.9% and 88.1%. Among the subpopulation with chronic pain alone, cutoff scores for the MH domain and MCS were 41.0 and 43.1, respectively. Specificities for the MH domain and MCS were 77.9% and 73.9%; sensitivities were 78.3% and 83.4%. Trends were similar among the chronic pain with depression subsample. CONCLUSIONS: Using the PHQ-9 and the MCS we found that respondents scoring above 10 on the PHQ-9 and the MCS, respectively, are likely to be referred for a second opinion visit. Little is known about estimating utilities for comorbid (or ‘joint’) health states. Several joint health state prediction models have been suggested (for example, additive, multiplicative, best-of-pair, worst-of-pair, etc.) but no general consensus has been reached. Without preconceptions about the preferred functional form, this study explores the relationship between health-related quality of life (HRQoL) and increasing numbers of diagnoses. METHODS: We analyzed a large dataset containing respondents’ ICD-9 diagnoses and preference-based HRQoL (EQ-5D and SF-6D). Data were analyzed from the 2013 National Health and Wellness Survey (adults ≥ 18 years old, N=75,000). Respondents were classified into subpopulations based on self-report: chronic pain (n=6,679) and chronic pain receiving medication for depression (i.e. depression) (n=5,814). The primary definition for classifying respondents at risk of MS was a score > 10 on the Patient Health Questionnaire (PHQ-9). Logistic regression modeling was used to predict risk for R.M.D., or not, and receiver characteristic curves were produced. RESULTS: The total sample had MH scores of 48.8 and MCS scores of 48.9, similar to the normative mean for the US adult population. The percent of respondents with a PHQ-9 > 10 were 15.0%, 29.1% and 29.5% for the total sample, chronic pain alone, and chronic pain with depression, respectively. Cutoff scores (PHQ-9: 10) in the total sample for the MH domain and MCS were 43.0 and 46.0, respectively. Specificities of recommended cutoff scores for the MH domain and MCS were 78.7% and 76.1%; sensitivities were 84.9% and 88.1%. Among the subpopulation with chronic pain alone, cutoff scores for the MH domain and MCS were 41.0 and 43.1, respectively. Specificities for the MH domain and MCS were 77.9% and 73.9%; sensitivities were 78.3% and 83.4%. Trends were similar among the chronic pain with depression subsample. CONCLUSIONS: Using the PHQ-9 and the MCS we found that respondents scoring above 10 on the PHQ-9 and the MCS, respectively, are likely to be referred for a second opinion visit.
The data from Japan suggests that the role dimensions do not split into physical and mental health domains as they are in the United States, but other countries suggest that the PF, RE, BP, SF and MH dimensions are relevant. The role dimensions are defined and rated for different patient populations and are subject to cultural adaption for different countries. The role dimensions are validated to be relevant in different treatments and can be used to evaluate the importance of a health-related intervention focusing on different priorities in treatment decisions. Seven concepts rated as low priorities and with low importance were identified in the interventional group. The financial impact and getting a label were low priorities in treatment decisions. Seven concepts rated as high priorities in decision-making were identified from the IDIs. Researcher-caregiver agreement in concept definition was high in all three sites [13].

A72


PHM08

PHARMACISTS-LED INTERVENTIONS TO IMPROVE HEALTH-RELATED QUALITY OF LIFE OF PULMONARY TUBERCULOSIS PATIENTS IN PAKISTAN: AN INSIGHT FROM A RANDOMIZED CONTROLLED NON-ClinICAL TRIAL

Jibial M [1], Jibial MZ [2], Naas S [1], Bahari MB [1]

[1]Faculty of Pharmacy, Bahauddin Zakariya University, Multan, Pakistan. Department of Clinical Pharmacy & Pharmacy Practice, Faculty of Pharmacy, AMIST University, Kedah, Malaysia.

[2]Department of Clinical Pharmacy, School of Pharmacy and Pharmaceutical Sciences, University Malaya, Kuala Lumpur, Malaysia, Pulau Pinang, Malaysia Department of Clinical Pharmacy & Pharmacy Practice, Faculty of Pharmacy, AMIST University, Kedah, Malaysia, Faculty of Law, University of Malaya, Kuala Lumpur, Malaysia, 89Holar Hospital, Multan, Pakistan, Department of Clinical Pharmacy & Pharmacy Practice, Faculty of Pharmacy, AMIST University, Kedah, Malaysia.

OBJECTIVES: To evaluate the importance of a health-educational interventional program to improve Health-Related Quality of Life (HRQoL) among Pulmonary Tuberculosis (PTB) patients in Pakistan, under the supervision of registered hospital pharmacists.

METHODS: A health-educational intervention to improve HRQoL was offered to the PTB patients through registered hospital pharmacists. In this non-clinical randomized controlled trial, PTB patients were briefed regarding treatment and management of PTB and their HRQoL was measured by WHOQOL-BREF. Both descriptive and inferential statistics were used to determine patients’ demographic characteristics and inter-group comparisons respectively. Data was analyzed by descriptive and inferential statistics were used to determine patients’ demographic characteristics and inter-group comparisons respectively. Data was analyzed by SPSS 21.0.

RESULTS: Two groups were randomized and eighty patients were recruited for the study i.e. one hundred and forty patients in each group. Under significant differences were observed in either group for mean age, gender, education level, occupation and income whereas a significant increase (p<0.001) in the WHOQOL-BREF score was observed in the interventional group. CONCLUSIONS: HRQoL was significantly improved in the interventional group after the pharmacist-led interventional program which advocates the vital role of pharmacists in patients’ education and a better health care system of Pakistan.

PHM09

DEVELOPING SF-6D-V2: EXAMINING THE DIMENSIONALITY OF THE SF-36 USING LARGE MULTINATIONAL DATASETS

Mulhern B [1], Krazer J [2], Bjorner JB [3]

[1]University of Technology Sydney, Sydney, Australia, 2University of Sheffield, Sheffield, UK.
[3]OptumPatientInsights, Lincoln, RI, USA

OBJECTIVES: The SF-36 is a measure of health related quality of life that is widely used internationally. SF-36 produces scores for eight dimensions (physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH); vitality (VT); social functioning (SF); role emotional (RE); mental health (MH)). However there is debate about whether these dimensions are applicable cross culturally, and also to what extent the SF-36 dimensionality is different between the MI and VT dimensions. The aim was to examine the dimensionality using multinational datasets as part of the development of SF-6D-V2. METHODs: Exploratory and confirmatory factor analysis was used to examine construct validity, and was applied to patient and general population datasets from the UK, Australia, Canada, USA and Japan (n = 55,923). Analysis was carried out separately for each country, and on the combined data. The general health items were not included as the focus was the specific health areas measured by the SF-36 dimensions. Exploratory factor analysis was conducted on data from nine countries: the United States, Canada and Japan, where speaking countries suggests that the PF, RP, BP, SF and RE dimensions are generally consistent but there are inconsistencies regarding the MH and VT, where the items split into factors based on whether the item is positively or negatively worded. The data from Japan suggests that the role dimensions do not split into physical and mental constructs. Confirmatory analysis suggests that both the original seven factor model, and a model splitting MH and VT on the direction of the items, fit the data acceptably. CONCLUSIONS: There is evidence for cross cultural differences in the role functioning dimensions of the SF-36, most likely due to differences in the perception of emotional health. The inconsistency of the MH and VT items may be discovered in making treatment decisions for their child. Fourth, a final list of attributes was chosen based on the subset of attributes that had high researcher-caregiver agreement and that were a high priority. Three caregivers prioritized the concepts by selecting three items in making treatment decisions for their child. Fourth, a final list of attributes was chosen based on the subset of attributes that had high researcher-caregiver agreement and that were a high priority.

PHM10

DEVELOPMENT AND VALIDATION OF THE PROMIS NETWORK TO EVALUATE PATIENT-REPORTED HEALTH STATUS ASSOCIATED WITH CLOSTRIDIUM DIFFICILE INFECTION

Ravindra K Thavendiranathan [1], Yong NM [2], Rozgorzi S [3], Goddu S [4], Broderick KC [5], Koo JK [6], Shah DN [7], Garey KW [8]

[1]Cubist Pharmaceuticals, Lexington, MA, USA, 2University of Houston College of Pharmacy, Houston, TX, USA, 3St. Luke’s ElderCare, Houston, TX, USA, 4University of Rhode Island College of Pharmacy and Pharmaceutical Sciences and Administration University of Houston College of Pharmacy, Houston, TX, USA

OBJECTIVES: The Patient-Reported Outcome Measurement Information System (PROMIS), funded by the National Institute of Health (NIH) is a large database of measures of patient-reported health status for physical, mental, and social well-being. Use of the PROMIS tools to evaluate humanistic outcomes in hospitalized patients with Clostridium difficile infection (CDI) has not been studied. The objective of this study was to identify and validate the use of specific PROMIS network questions to evaluate patient-reported health status associated with CDI.

METHODS: This was a prospective, observational, two-center, mixed-methods study. Hospitalized adult patients with CDI were interviewed within seven days of a positive toxin test for C. difficile and again within one week of hospital discharge (N = 40). Patients were asked open-ended questions regarding their top three concerns related to CDI. Results were analyzed using ATLAS.ti 7 and classified by PROMIS domains. Based on response trends, applicable standardized questions from the PROMIS network were identified. An additional 15 patients with CDI were interviewed using the PROMIS questions to validate relevant questions.

RESULTS: Patients reported humanistic outcomes within seven days of CDI diagnosis were primarily associated with mental concerns (75%) related to anxiety and worry about future complications. Physical concerns (8%) were related to ongoing diarrhea, bowel incontinence and other abdominal complaints. Social concerns (3%) included interference with daily living and finances. Patient reported outcome responses did not change significantly during the follow-up interview. Using these responses from direct interviews of CDI patients, 18 PROMIS network questions were identified and demonstrated evidence of reliability.

CONCLUSIONS: Using the NIH PROMIS network, we identified 18 patient-reported health status questions that can be used to evaluate humanistic outcomes in patients with CDI. Future studies should use these questions to assess changes in health status of CDI patients over time.