were evaluated based on US and European PRO/HRQOL guidance criteria. RESULTS: The model was fitted in WinBUGS; with the constraint that increasing EDSS score is associated with a disimprovement in quality of life. The mapping between disease severity and cost values are applied to each EDSS state in the model. Using EQ5D-5L results structured on health states reflecting progressing disease severity, represented by scores on the Expanded Disability Status Scale (EDSS) 0-9, whereby single utility and cost values are applied to each EDSS state in the model. The application of one linear model to the data was not justified. The greatest utility decrease was between EDSS 6 and 7 (0.15) and EDSS 7 and 8 (0.41). CONCLUSIONS: The decline in HRQL in MS is multifactorial, but can be explained primarily by the severity of the disease. The application of one linear model to the data was not justified. The piecewise regression improved model efficiency and reduced sampling variability by utilizing the trends in utility decline between EDSS states.

P4116

PAINTER AND PATIENT PERCEPTIONS OF MEDICATION VALUE AND THE ROLE OF PATIENT-REPORTED OUTCOMES

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OBJECTIVES: To explore how patients and payers perceive value and risk and investigate the role of patient-reported outcomes. METHODS: Quintiles surveyed a variety of US and UK stakeholders including: an online survey of payers (US managed care, UK National Health Service, and a telephone survey of adults being treated for a chronic disease. RESULTS: Between January and March 2012, 144 payers (75 US, 72 UK National Health Service) and 1009 patients (509 US and 500 UK) were surveyed. In general, payers were more optimistic that the quality of health care would be improved 10 years from now than patients (68% US / 66% UK payers vs. 59% US / 38% UK patients). From the payer perspective, over 80% of payers support use of risk sharing for: 1) population-based performance guarantees (i.e., coverage dependent on meeting a benefit target) and 2) Coverage with Evidence Development (CED) (i.e., future approval based on real-world evidence). High coadministration costs (66%), difficulties in agreeing on definition of success (67%), and difficulties in accurately measuring treatment success (63%) are among main problems. With 77% of US and 73% of UK payers supporting the shift to a more patient-focused approach to treatment assessment, measures of cost that are the most commonly used to assess risk/benefit (60% and 71% respectively). Patients are in agreement with payers that PROs are most important in how they evaluate the value of medicines (51% US, 60% UK). Other important drivers of patient value: helping people live longer (16% US, 24% UK) and affordability (25% US, 2% UK). CONCLUSIONS: Payers and patients agree that use of PRO data is critical to assessing value and benefit-risk for prescription medicines. The shift to
patient-centered treatment assessments and growth in risk sharing assessments will further increase the need for real-world FRO data.

PRM117

EXPLORING PATIENT PERCEPTIONS OF, AND PREFERENCES FOR, PAIN RESPONSE SCALARS

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OBJECTIVES: Scales measuring perceptions of pain can include numeric rating scales (NRS), visual analogue scales (VAS) and descriptor scales using words (adjective). With the increased use of electronic data capture in clinical trial settings, such scales have been migrated to numerous platforms. After conducting a brief literature review, there was found to be a lack of research on the impact that migration of such pain scales can have on the efficacy of the scales. The objective of this study was to deploy three pain scales in different formats and on different platforms to determine which provides the best fit for a psoriatic arthritis (PsA) cohort using daily pain. METHODS: Twelve participants diagnosed with a range of conditions resulting in pain were interviewed in a qualitative interview setting. All participants completed three pain scales in different formats: NRS (11-, 9-, and 7-point scales); VAS (horizontal/vertically, portrait/landscape) and adjective scale (increasing/decreasing severity). All scales were presented in three modes of administration: paper, handheld device and tablet device. Participants were asked about perceived differences and their preferences of the different scales, formats, and modes of administration. RESULTS: The NRS and adjective scale were preferred equally (n = 5). Participants expressed a higher level of preference for the 11-point NRS and increasing severity adjective scale, across all administration modes. In contrast, the VAS was the least preferred scale (n = 7) due to difficulty with interpretation. Participants expressed no usability problems with the tablet or handheld devices, but the tablet was preferred overall because of the bigger screen. CONCLUSIONS: Although the sample size makes generalising these findings difficult, this exploratory study suggests that the preferred pain scales may provide higher quality data as they are easier to interpret, and therefore minimise error and patient burden. Further evidence, particularly quantitative, is required to support these preliminary findings.

PRM118

METHODOLOGY FOR NEUROPSYCHOLOGICAL ASSESSMENT WORLIST ADAPTATION

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OBJECTIVES: Effective translation and adaptation of neuropsychological assessments is paramount to the successful collection of data in a global context. The structure and content of neuropsychological assessments requires specific processes for translation and adaptation to ensure appropriate understanding in each target language. Word list adaptation requires particular consideration, as various criteria must be met within and between wordlists – including but not limited to frequency, familiarity and cultural relevance to the target population, number of syllables, and avoidance of homonyms and repeated words. This review highlights important considerations for creation of target language word lists, and solutions for determining appropriate adaptation methodologies. METHODS: A review of previously published neuropsychological assessments, such as the ADAS, PC-SRT, RBANS, MoCA, and MMSE., was performed. A review of translation procedures, developer involvement, guidelines for adaptation, translation methodology, linguistic decisions, and word list creation was conducted. RESULTS: Key solutions to effective adaptation of word lists are developed. 1) Develop the English word lists and assessment, 2) Create clear guidelines for adaptation of word lists in collaboration with the developer, if guidelines are not already available, 3) Employ a specialized project team of project managers, native-speak medical linguists, and native-speaking neuropsychologists possessing extensive expertise in the relevant neuropsychological assessments. 4) Depending upon the assessment and the context of use, additional testing of the word lists with local populations to ensure comprehension may be warranted. CONCLUSIONS: Neuropsychological assessments and word lists require specialized translation and adaptation methodologies to ensure appropriate comprehension by the target population. Developer involvement in the creation of adaptation guidelines, and neuropsychologist involvement in the adaptation process are critical to ensuring adaptation is conducted appropriately. Further research is required to outline clear guidelines for using existing adaptation methodologies to conduct additional testing of the word lists with local populations to ensure comprehension.

PRM119

MAPPING BETWEEN COMPOSITE MEASURES IN PSORIATIC ARTHRITIS AND THE SF-6D: ANALYSIS FROM THE GRACE DATASET

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OBJECTIVES: Mapping or cross-walking is an accepted methodology for calculating utilities. Different models have been proposed for mapping from disease-specific quality-of-life (QOL) measures to generic QOL measures. Much of this work has been done using data from rheumatoid arthritis cohorts and using measures specific to RA. The objectives of this study are to test various statistical models to determine which provides the best fit for a psoriatic arthritis (PsA) cohort using both newly developed composite disease measures and established measures. The study also aimed to determine whether the composite disease measures provide a better estimate of utility over other measures and whether the composite disease measures influence the relationship between the PRO measure and QOL. METHODS: The data was made available from the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) which collected data from an international cohort of PsA patients. Different regression models were used to estimate the relationship between the generic QOL measure, SF-6D and disease specific measures (HAQ, Composite Disease Activity Index (CDAI), Psoriatic Arthritis Disease Activity Score (PASDAS) and the Arithmetic Mean Desirability Function Score (AMDF). Model fit was determined using the R2 statistic, root mean square error, Akaike information criterion (AIC) and pseudo R2 values. RESULTS: The optimal model for each of the disease specific measures and SF-6D was a multiple regression model. The difference in model fit between the linear and multiple regression models was greatest for the composite disease measures specific to PsA. The CDAI and SF-6D provided the best fit to utility score theory, followed by the HAQ and PASDAS. CONCLUSIONS: PsA is a heterogeneous disease for which composite disease measures may be more appropriate than measures such as the HAQ. This study provides mapping coefficients, allowing utility estimation from these measures which may be collected in trials where no preference-based utility measure has been used.

PRM120

PATHWAYS TO EFFECTIVE CLINRO DOSSIER DEVELOPMENT

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OBJECTIVES: To highlight some of the common areas that require particular attention when preparing clinical outcome assessment (COA) dossiers, suitable for FDA regulatory label claims, with a particular focus on clinician-reported outcome (ClinRO) measures. The FDA has provided guidance for the use of Patient-Reported Outcome measures in clinical trials to support label claims (FDA, 2009). Although several authors have indicated that the standards used to evaluate PRO’s will apply to all COA’s (Burke, 2011; Gwaltney, 2012), the FDA have not published guidelines on ClinRO measures to support label claims. This is surprising given that the ratio of label claims based on ClinRO is approximately three ClinRO’s to every PRO measure (Burke, 2010). METHODS: We conducted a review of the literature to ascertain the general level of use of ClinRO’s and to find examples of widely used ClinRO’s. The available evidence for these ClinRO’s was then compared by the standards of the PRO guidance document, specifically in relation to content and construct validity, reliability and other psychometric properties. RESULTS: The literature review revealed that ClinRO’s are common endpoints in clinical trials. However, it was also apparent from the sample of ClinRO’s reviewed, that there is a failure to meet the evaluative standards prescribed by the FDA particularly in being “well defined and reliable”. CONCLUSIONS: ClinRO’s used as endpoints in clinical trials to support FDA label claims may lack the required evidence set out in the FDA PRO guidance document. Specifically, many ClinRO’s have been developed by clinicians, and widely accepted by clinical peers, without undergoing psychometric evaluation. If the FDA were to evaluate ClinRO’s to the same standards as PRO’s, the ratio of label claims between ClinRO’s and PROs may decrease significantly.

PRM121

BURDEN OF OSTEOARTHRITIS: DEVELOPMENT OF A QUESTIONNAIRE

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OBJECTIVES: Osteoarthritis (OA) also known as degenerative arthritis or degenerative joint disease, is a group of mechanical abnormalities involving degradation of joints. The daily-life of OA patient is considerably disturbed. The burden’s concept assesses the individual burden, measuring the patient's disability generated by the patient-centered treatment assessments and growth in risk sharing assessments. Key solutions to anticipate difficulties and thus provide better care have been developed. The development of this questionnaire we propose here was inspired by the construction of general QOL measures to generic QOL measures which provides mapping coefficients, allowing utility estimation from these measures which may be collected in trials where no preference-based utility measure has been used.

PRM122

ATOPIC DERMATITIS ON FAMILIES: CREATION OF A SPECIFIC BURDEN QUESTIONNAIRE

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OBJECTIVES: Although it has been shown that the burden of atopic dermatitis (AD) is not adequately assessed, to our knowledge, no validated questionnaire exists to assess this burden. The aim of this study was to develop a specific questionnaire to assess the burden generated by AD on families from a patient’s perspective. METHODS: A specific questionnaire was created by a group of experts (Dermatologists, Therapeuticians, Psychologists, Biostatisticians) in order to investigate the burden of AD on families. In order to do this, a specific interview was performed to families from a dermatological center. RESULTS: A questionnaire has been created. Our next objective is to develop the “BONeS” in German, Italian and Spanish with a cross cultural validation.

PRM123


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