entertainment function. The three domains were moderately correlated with each other (PCC=0.5 to 0.6, p<0.001). Muscle strength was weakly related with limitations in gross motor function (PCC=0.20, P>0.001), and social and entertainment function (PCC=0.13, P>0.001) but not significantly related with limitation in fine motor function (PCC=0.06, p=0.09). CONCLUSIONS: These findings suggest that in a sample of US elderly aged 60-80 years the NHANES physical function limitation questionnaire was three domains, of which the gross motor function domain and social and entertainment function domain are weakly related with muscle strength.

PH51

ACHIEVEMENT OF CULTURAL EQUIVALENCY WHEN TRANSLATING A PATIENT-REPORTED OUTCOMES (PRO) INSTRUMENT CONTAINING ENGLISH-US IDIOMATIC TERMS AND COLLOQUIALS

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OBJECTIVES: To investigate issues in translating a Patient-Reported Outcomes (PRO) instrument containing idioms and colloquialisms of English-United States origin. Idiomatic items present an adaptation challenge for translators, generally requiring additional rounds of discussion and revision. The Linguistic Validation process allows a local and difficult subject to be adapted while maintaining validity of data when pooling across different countries and cultures. METHODS: Prior to translation into 25 languages, a survey research expert defined each idiomatic item in the PRO for the translation team. Additionally, all back-translated documents were reviewed to determine the rate and difficulty of revision of idiomatic items, and cognitive debriefing interview data collection forms were analyzed to ascertain comprehension of adapted idiomatic terms by subjects and to make translation revisions as needed. RESULTS: As observed, linguists were successful in adapting the idiomatic source to their target language and culture (idiomatic items, however, ever, required an average of two to three rounds of back-translation as opposed to non-idiomatic questions which required one revision or less. For example, "stepping on toes" was revised two to three times on average across languages, resulting in cultural adaptations such as "climbing over others" in Spanish or "trample on others" in Arabic.

Furthermore, when testing the translated instruments, in each instance where a subject encountered an adapted idiomatic item, it was understood 97.7% of the time. CONCLUSIONS: A PRO containing English-United States colloquialisms faces challenges in producing a validated translation. Defining idiomatic items prior to translation would, as well as reviewing and discussion, revision and analysis of back-translated idioms. While idiomatic items can be beneficial to the source text in terms of patient comprehension, their inclusion is shown to mandate several more rounds of discussion and review during the translation process in order to achieve appropriate levels of conceptual equivalence.

PH52

ELECTRONIC PATIENT REPORTED OUTCOMES AND DATA TOOL FOR CHRONIC DISEASE MANAGEMENT (PROCIDIM): CASE IN POINT PROSTATE CANCER

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OBJECTIVES: Patient Reported Outcomes (PROs) play an important role in evaluating patient quality of life in comparative effectiveness of various treatments. Another potential use of PROs is for chronic disease management, which can provide useful data to physicians and patients. We developed a novel web and phone based PROs tool for management of prostate cancer disease. METHODS: PRO methods for prostate cancer were analyzed by reviewing published clinical studies. Patient advocacy groups were interviewed to obtain their input for design of PROS disease management tool. Recent technologies for developing such tools were reviewed by analyzing available electronic PRO tools. PROCIDIM design was developed based on secondary research and primary interviews. RESULTS: PROCIDIM was designed to capture patient reported outcomes data such as Quality of Life (using five attributes), adverse events (six commonly reported AEs), medications and OTC drugs history, PSA antigen score, past surgery and radiation therapy and record of physician appointments. Patients could enter data into PROCIDIM using web or phone (iphone or android) based systems. Data from PROCIDIM could be emailed by patient to provider or could be downloaded by tethering phone to computer. Pilot data was captured by testing PROCIDIM with physicians and patient advocacy groups. Based on interviews, PROCIDIM was rated superior and highly usable by physicians compared to current chronic disease management tools. Patient outcomes data could be collected from a planned IRB approved study. CONCLUSIONS: PROCIDIM is a valuable tool to capture several patients reported outcomes and data for chronic disease management. Such tools could be used for collecting data for disease management, clinical trial and for observational studies for various chronic diseases.

PH53

ASSESSMENT OF PRO LABELS CLAIMS GRANTED BY THE FDA AS COMPARABLE TO THE EMA

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OBJECTIVES: In 2009, the United States (US) Food and Drug Administration (FDA) issued a formal guidance for the use of patient-reported outcomes (PRO) in support of labeling claims, whereas the European Medicines Agency (EMA) offers insight in a 2007 reflection paper in lieu of formal guidance. To evaluate and describe decision making by the FDA and EMA, a review of PRO label claims granted for new molecular entities and biologic license applications from 2006 through 2010 was conducted. The purpose of this research was to evaluate consistencies and discrepancies between the 2 agencies and their future implications for regulatory agencies.

METHODS: A listing was created of drug approvals granted by both the FDA and the EMA. PRO claims were compared using US Drug Approval Packages and European Public Assessment Reports packages to determine any instances where claims made for the same product by the same company were similar or different. RESULTS: A total of 75 products were identified as having been approved by both agencies. Of these, a total of 35 (40%) were granted at least one PRO claim by the EMA, as compared with 14 (19%) by the FDA. Most claims in the US focused on signs and symptoms; however, claims in the European Union were more likely to include higher-order concepts such as health-related quality of life (HRQL) and functioning (29% vs 19%). In instances where only one claim was granted by both agencies. CONCLUSIONS: The EMA is more likely than the FDA to grant PRO claims and to grant claims for higher-order constructs such as HRQL and functioning. Additionally, there appears to be poor concordance between claims granted by both agencies, which may demonstrate a need for sponsors to develop agency-specific PRO strategies.

PH54

PROMOTION OF PATIENT REPORTED OUTCOMES (PRO) LABEL CLAIMS BASED ON NON-PRIMARY ENDPOINTS

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OBJECTIVES: A recent review (Gnanaskathy, 2012) has shown that about 24% of New Drug Applications (NDAs) and Biologic License Applications (BLAs) approved by the FDA (FDA) between the years 2006-2011 included at least one patient-reported outcome (PRO) label claim, and most claims (74%) were granted for PRO endpoints that were also primary endpoints. Claims based on primary endpoints are likely to be fully promoted by the manufacturers, however, the extent to which manufacturers promote claims based on secondary PRO endpoints is unknown. The purpose of this review is to assess the extent of promotion of PRO label claims for six products with nonprimary PRO endpoints. METHODS: All six pharmaceutical products that received PRO label claims based on nonprimary PRO endpoints between 2006 and 2008 were reviewed. Promotional documents distributed in the US by the manufacturers of these drugs between the year of launch and 2011 were identified from a PharmaVoxx database. To assess the intensity of promotional activity, circulation of these documents was calculated based on quarterly distributions. Two researchers reviewed the documents using standard criteria. Promotional activities based on nonprimary PRO endpoints were compared with total number of messages. Disease-awareness and management documents and all videos, CDs, and DVD were excluded. RESULTS: Manufacturers of the six products distributed a total of 973 unique promotional documents 2998 times. Messages based on primary endpoints were distributed 1,798 times, whereas messages relating to secondary PRO endpoints were distributed 1200 times (40% vs 33% distributions). Messages relating to PROs were targeted mostly at patients and consumers (65%) and physicians and health care professionals (34%). CONCLUSIONS: Promotion of PRO messages based on nonprimary endpoints is much lower than those based on primary endpoints, indicating that manufacturers do not always optimize the potential of PRO messages.