entertainment function. The three domains were moderately correlated with each other (r = 0.5 to 0.6, p < 0.001). Muscle strength was weakly related with limitations in gross motor function (r = 0.20, P < 0.001), and social and entertainment function (r = 0.13, P < 0.001). However, this did not significantly correlate with limitation in fine motor function (r = 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 has three domains, of which the gross motor function domain and social and entertainment function domain are weakly related with muscle strength.

PHS1

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

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OBJECTIVES: To investigate issues in translating a Patient-Reported Outcomes (PRO) instrument containing idiomatic terms 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 source 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 term 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 collections forms were analyzed to assess the 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, required an average of two to three revisions, as opposed to non-idiomatic questions which required one revision or less. For example, “stepping on toes” was revisited 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, as well as reviewing for 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.

PHS2

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

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OBJECTIVES: Patient Reported Outcomes (PROs) play an important role in evaluating the quality of life of patients and comparing efficacy 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 developed by analyzing existing clinical studies. Key physicians and 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. PROCIDM design was developed based on secondary research and primary interviews. RESULTS: PROCIDM was designed to capture patient reported outcomes data such as Quality of Life (using five attributes), adverse events (six commonly reported AE), medications and OTC drugs history, PSA antigen score, past surgery and radiation therapy and record of physician appointments. Patients could enter data into PROCIDM using web or phone (iphone or android) based systems. Data from PROCIDM could be emailed by patient to provider or could be downloaded by tethering phone to computer. Pilot data was captured by testing PROCIDM with physicians and patient advocacy groups. Based on interviews, PROCIDM was rated superior and highly useful in providing current chronic disease management tools. Patient outcomes data would be collected from a planned IRB approved study. CONCLUSIONS: PROCIDM 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.

PHS3

ASSESSMENT OF PRO LABELS CLAIMS GRANTED BY THE FDA AS COMPARED 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 relating to PRO label claims across 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 (44%) were granted at least one PRO claim by the EMA, as compared with 19 (14%) 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. 6%, p = 0.03). Additionally, claims were more likely to exceed one revision for PRO claims 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.

PHS4

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

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OBJECTIVES: A recent review (Gnanasakthy, 2012) has shown that about 24% of New Drug Applications (NDAs) and Biologic License Applications (BLAs) approved by the FDA (50% of OECD) between 2006-2008 included at least one patient-reported outcome (PRO) label claim, and most claims (74%) were granted for primary endpoints that were also primary endpoints. Claims based on primary endpoints are likely to be fully promoted by the manufacturer, however, the extent to which manufacturers promote claims based on secondary or nonprimary 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 PharmaVox 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 claims 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 1,200 times (39% fewer distributions). Only 49% of 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.

PHS5

CROSS-CULTURAL PRO ANALYSIS IN HEALTH TECHNOLOGY ASSESSMENTS

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OBJECTIVES: IFORQ has focused on patient reported outcomes (PROs) since the second annual European Congress in 1998, but the prevalence of PROs in product evaluation for Health Technology Assessments (HTAs) is not well studied. This study examines the prevalence of PROs for reviews published by nine agencies in 2005-2011: PBAC, CADTH, HAS, IQWIG, SMC, NHS Scotland, NICE, DERP, AHRO. METHODS: Analysis of all HTA reports from 2005-2011 in the aforementioned agencies’ disease areas: and compared between products (4% to 70%). 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.