PATIENT SATISFACTION COMPARISONS BETWEEN PEDIATRICIANS AND OTHER PCPS: A MULTILEVEL CROSS-NATIONAL WEB BASED SURVEY STUDY

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OBJECTIVES: Very few studies have tried to evaluate comparative patient ratings of physician satisfaction across specialties. We examined the differences in physician satisfaction reported by patients accessing care from pediatricians versus other primary care physicians. METHODS: We conducted a cross sectional, national web based survey study consisting of anonymous patients who rated their physicians on the basis of their visit. RESULTS: We received a total of 7104 patient responses. The survey was user friendly, validated and helped patients identify their physicians as per specialties and rate them on a scale of 0 (“not at all satisfied”) to 10 (“extremely satisfied”). The association of physician satisfaction between pediatricians and non-pediatricians was assessed using hierarchical linear model (HLM). RESULTS: Using 6982 patient survey responses, we matched 2724 PCP visits with a similar number of visits to pediatricians. After controlling other variables, pediatricians were associated with higher satisfaction, on average, than other PCPs (r = 0.39, p < 0.000) holding all other factors in the model constant. However, pediatricians were associated with lower time spent with patients (r = -1.1, p = 0.045). After controlling for other variables, waiting time was negatively associated with patient satisfaction (r = -0.37, p < 0.000). CONCLUSIONS: Our study finds that pediatricians are associated with higher patient satisfaction score than non-pediatricians. Increased time spent with the patient by pediatricians convinced to other PCPs to be the driver of satisfaction, on average, than other PCPs.

ISSUES IN THE TRANSLATION AND LINGUISTIC VALIDATION OF EPRO AND IVRS INSTRUMENTS

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OBJECTIVES: EPRO and IVRS PRO instruments are increasingly used in clinical trials. As a result translations of such instruments are also increasingly required. Whilst the approach recommended in the ESPOR translation task force paper (Wild et al. 2005) should still be used, EPRO and IVRS instruments present some unique challenges during their translation and linguistic validation. This study seeks to clarify what some of those challenges are, and how to meet them. METHODOLOGY: Oxford Outcomes translation and linguistic validation projects involving ePRO/IVRS were reviewed to produce a list of tips on how to best localise such instruments. RESULTS: Shortening of limited screen space and positioning of response options were issues which was more idiomatic. The expression was substituted with ‘You do it by [. . .]’, using a capitalised definite article (‘THE’), others placed ‘ONLY ONE’ in brackets to denote the existence of a single response option. CONCLUSIONS: Our study finds that pediatricians are associated with higher satisfaction, on average, than other PCPs (r = 0.39, p < 0.000) holding all other factors in the model constant. However, pediatricians were associated with lower time spent with patients (r = -1.1, p = 0.045). After controlling for other variables, waiting time was negatively associated with patient satisfaction (r = -0.37, p < 0.000). CONCLUSIONS: Our study finds that pediatricians are associated with higher patient satisfaction score than non-pediatricians. Increased time spent with the patient by pediatricians convinced other PCPs to be the driver of satisfaction, on average, than other PCPs.

THE TRANSLATION AND LINGUISTIC VALIDATION OF THE EQ-5D ELECTRONIC VERSION (EQ-5D EPRO)

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OBJECTIVES: The objective of this study was to produce translations of the EQ-5D version of the EQ-5D that are conceptually equivalent to the original and other language versions, ensuring that the resulting translations are suitable for use in the ePRO format. METHODS: The methodology employed for the EQ-5D was: 1) forward translation; 2) review, developer review, linguistic validation interviews with 5 respondents (a mix of lay people and patients), second developer review and 2 proofreadings. RESULTS: The translation process highlighted numerous issues: 1) ‘Tap’, meaning to press lightly on the screen with a stylus, proved problematic in translation. In some languages, a literal translation would result in the patient touching the screen too lightly, not understanding that pressure was required. In other languages, there was no exact translation available. ‘press’ or ‘touch with the stylus’ were used as alternatives (French and Russian respectively), ensuring that patients could navigate the platform; 2) In some Romance languages, the emphasis of ‘tap ONE box’, meaning only one, became lost due to the languages’ requirement of an article. Some translators used a capitalised definite article (‘THE’), others placed ‘ONLY ONE’ in brackets to denote the existence of a single response option. 3) The Eastern European translators maintained that there is no literal translation of ‘heading’, in the context of a title with sentences underneath. To render the intended meaning, they used ‘the text in bold’ or ‘in each of the groups’; 4) Some languages found ‘Please do this by [. . .]’ a difficult construction to translate directly and colloquially. The expression was substituted with ‘You do it by [. . .]’, which was more idiomatic. CONCLUSIONS: The EQ-5D ePRO has been translated and linguistically validated using a rigorous translation process. A number of cultural and linguistic issues became apparent and were resolved. The method is now appropriate for use in multinational trials.

SUPPLEMENTAL METHODOLOGY FOR TRANSLATING INSTRUMENTS DEVELOPED IN A LANGUAGE OTHER THAN ENGLISH

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OBJECTIVES: Procedures used to linguistically validate PROs are well documented for instruments originally developed in English. However, methodology concerning non-English based measures is largely uncharted. This paper outlines the challenges associated with translating PROs developed in a language other than English and recommends supplemental methodology for improving this process. METHODS: To establish guidelines for translating non-English PROs, several case studies of previous validations were performed. Techniques used to validate the Cancer Dyspnoea Scale (Japanese) were compared to those used for the Pain Detect Scale (German), DN4 Questionnaire (French), and the Hôtel Dieu 16 (French). All questionnaires were translated from their source language into US English. The DN4 was subsequently translated into Dutch, while the CDS was translated into seven additional languages. Special attention was paid to maintaining conceptual equivalence, addressing colloquialisms native to the development setting and compensating for differing grammatical constructs. RESULTS: Methods for English-PROs poses numerous problems. Since most translators and project managers are English-based, an English adaptation of the instrument may need to be created prior to moving forward with other translations. Extreme care must be taken to accurately interpret all of the source instrument’s concepts. Recommended enhancements to the standard validation process include: assigning a project manager skilled in the source language to oversee all subsequent translations; creating a concept elaboration guide for both the original instrument and the English translation; conducting a specialized training session with translators to review the development of the original document; ensuring a high quality translation; placing extra emphasis on the meaning of colloquialisms and the formulation of response sets. CONCLUSIONS: Linguistically validating PRO questionnaires developed in non-English settings presents special challenges. Evidence suggests that, in such situations, standard procedures may be insufficient to produce conceptually equivalent translations acceptable for use in multinational clinical trials. In such cases, expanded procedures are recommended.

VALIDITY OF SELF-REPORT WITH RESPECT TO PRESCRIPTION MEDICATIONS AMONG PREGNANT WOMEN


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OBJECTIVES: Accuracy of self-report regarding prescription medication use among pregnant women is largely unknown. Accurate self-reported information is needed for medication reconciliation purposes, clinical management, clinical teratology research, and monitoring of adherence. This study examines the accuracy of self-reported medication use by pregnant women for medications used chronically and episodically or intermittently during pregnancy. METHODS: This was a cross-sectional analysis of data collected through the University of New Mexico (UNM) cohort study, “Safety of Medication and Perception of Teratogenicity” (SMART). Pregnant women recruited from UNM prenatal care clinics and were asked to report all medications they took since their last menstrual period. The analysis was limited to women enrolled in the first year of the study who had at least one prescription for diabetes or opioid analgesics medications (representative of chronic and acute medication use, respectively). The accuracy of agreement between self-report and medical records for each medication class was estimated by simple (k) and prevalence and bias adjusted (PABAK) kappa. Information from the medical records was used as the ‘gold-standard’. RESULTS: A total of 92 pregnant women were included in the analysis. Agreement for diabetes medications was near perfect (k = 0.87; PABAK = 0.91); whereas poor-to-moderate concordance was observed for opioid analgesics (k = 0.29; PABAK = 0.57). Among antidiabetic medications, concordance was highest for biguanides (k = 0.90; PABAK = 0.93) and lowest for sulfonylureas (k = 0.83; PABAK = 0.87); whereas among opioid analgesics, highest agreement was observed for strong agonists (k = 0.51; PABAK = 0.56) and lowest for moderate/low agonists (k = 0.06; PABAK = 0.39). CONCLUSIONS: This study suggests poor accuracy of self-report with respect to prescription medications used as short courses or intermittently during pregnancy. Therefore, in clinical trials and the development of self-report measures, the accuracy of agreement between self-report and medical records needs to be supplemented by other sources. Accuracy of self-report for medications used chronically is acceptable.

REPORTED OUTCOME RECALL PERIODS IN LIGHT OF THE FINAL FDA GUIDANCE

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OBJECTIVES: The selection of the most appropriate recall periods for PROs has been a topic of much debate since the release of the draft FDA PRO guidance in February 2006. The final PRO guidance (December 2009) provides more insight into the way
that the FDA will evaluate PRO recall periods. This study reviews the literature around PRO recall periods in the light of the final guidance and provides recommendations to sponsors wishing to obtain FDA label claims on the basis of PRO endpoints. METHODS: A literature review was conducted in Embase and Medline, with further searches such as the shift from management to patient of the relevant papers in the process searched. Forty four papers were reviewed with reference to section D3 of the FDA final PRO guidance, the research was summarized and a set of recommendations were developed. RESULTS: Psychological literature identifies that recall of complex information is problematic, e.g. limited and selective memory and systemic biases. The majority of empirical work with PROs focuses on the measurement of pain with some evidence from fatigue measurement. Whilst most studies focus on symptoms, others examine HRQoL, adherence and treatment satisfaction. Empirical research suggests a lack of evidence for the relationship between actual experienced symptoms and recalled symptoms, with variability in patient attention to the recall period instruction. Recall is significantly influenced by the concept being measured and attributes of the patient at the time of assessment. The findings from the research are in line with the FDA concerns and their present action on PRO recall periods. The final FDA PRO guidance takes a considered approach to PRO recall periods in light of available research. Recommendations are presented on how best to select and justify the most appropriate recall period for a PRO measure in order to support regulatory review of drug approval label claims.

DETERMINING MISSING DATA RULES FOR PROS: ALPHA-IF-ITEM-DELETED

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Missing outcomes data in clinical trials can be detrimental to identifying important treatment effects because power is reduced and uncertainty is increased. Although missingsness at the scale level for patient-reported outcomes (PROs) (e.g., due to attrition) is a considerable challenge to measurement in longitudinal clinical trials, missingsness at the item level for PROs (e.g., due to omission) can be more easily overcome and a reliable scale score calculated. The FDA PRO Guidance states that the maximum tolerable number of missing item-level responses should be determined during the instrument development process, but no particular method is advocated, and instrument developers often recommend arbitrary guidelines. Although a number of methods exist for examining the effect of missing data on scale precision, one simple approach is to calculate Cronbach's coefficient alpha sequentially as each item is deleted from the item set. The order in which items are removed from the item set is based on deleting the item with the largest contribution to alpha (i.e., alpha-if-item-deleted). When Cronbach's alpha for the set of remaining items falls below a priori identified threshold (e.g., 0.70), the number of items to assess from the scale minus one is the maximum number of responses that can be missing for a scale score to be reliably calculated for a subject. We explored this approach with several validated instruments and found that the developer's guidelines are often stricter than the alpha-if-item-deleted method. Broader application of the Cronbach's alpha approach would result in fewer missing PRO scale scores, increased statistical power, reduced uncertainty, and additional information with which to assess treatment effects.

TAPPING INTO A NEW DATA COLLECTION PARADIGM: USING DIRECT TO PATIENT PROGRAMS FOR MORE COST EFFECTIVE STUDY MANAGEMENT

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OBJECTIVES: 1) Understand how to navigate the regulatory environment, manage patient safety profiles, and achieve optimal process effectiveness in designing a Direct to Patient study; 2) Gather information on leveraging integrated technologies to support these studies; and 3) Learn key challenges and solutions from early Direct to Patient study implementations METHODS: The presentation will outline how to best design Direct to Patient studies to collect the right patient outcome data that will drive the most useful analysis. The presentation will look at the use of patient reported data to drive enrollment at the IND stage. Various methods of collecting patient data directly will be reviewed. RESULTS: Many questions are arising as the industry embarks on Direct to Patient programs, including how to navigate the regulatory environment and various controls and guidelines. Other issues include how to address the changing role of investigators in this study model. Optimal roadmaps for designing Direct to Patient studies will be discussed, including the implementation of a flexible clinical and medical infrastructure to monitor patient participation. Issues such as the shift from site management to patient management, the process for management from recruitment to retention, and the processes for adverse event follow-up will be discussed. The optimal use of technology, such as portals, Randomization and Trial Supply Management technologies and ePRO data collection tools, will be explored. The use of EDC in Direct to Patient programs will be discussed along with the right application of web-based and new social media tools. CONCLUSIONS: The increased need to have more outcomes and effectiveness data along with mounting pressure on the biopharmaceutical industry to contain costs have forced the industry to look at new ways to collect patient outcomes data efficiently. There is a trend toward designing studies that reach out to patients directly in new ways, while at the same time eliminating costs and intermediaries associated with traditional studies.