PMC28

CLINICIAN REPORTED OUTCOMES: ISSUES IN THE TRANSLATION AND LINGUISTIC VALIDATION

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OBJECTIVES: The use of Clinician Reported Outcomes (ClinROs) and cognitive functioning measures in multi-national clinical trials is widespread, but the translation of such measures has often been avoided, with trial managers preferring to keep the measures in English. However, this approach is not ideal and recently the importance of translating and linguistically validating ClinROs has been highlighted. The requirements for translating and linguistically validating ClinROs have not been well documented. Usually, they are translated with a PRO translation procedure (comprising dual forward and back translations and subsequent review) with the addition of a single clinician review. This study investigates the issues surrounding the translation and linguistic validation of these ClinROs and cognitive functioning measures. **METHODS:** A review was undertaken of translation reports from past projects, including the MMSE and SCID (cognitive functioning measures), TNSN (clinician or nurse guide for assessing neuropathy) 6 Minute Walk Test (6MWT) Worksheet, (guide for clinicians to assess dyspnoea), and EORTC clinician scales. Examples of issues from the translation process were gathered. **RESULTS:** Clinical review as part of the translation process proved invaluable. Changes typically comprised alterations of specific terminology.—a clinician should also be available to aid project coordinators throughout the translation process.—Clinical review formed an essential role for advising lead translators.—One project included dual clinician reviews; this was particularly valuable since changes could be verified between reviewers. **CONCLUSIONS:** The translation and linguistic validation of ClinROs and cognitive functioning measures requires further research to determine the optimum methodology. This study found that clinical review was of the utmost importance, and that ideally dual clinician reviewers should be involved. Furthermore, translators should have experience of translating documents intended for clinical use, to ensure they are familiar with the terminology.

PMC29

USING DOZENS OF ATTRIBUTES WITHOUT INCREASING RESPONDENT BURDEN: HOW TO ADAPT LATENT VARIABLE MODELING FOR LINKING ATTRIBUTES ON SEPARATE CONJOINT SURVEYS

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Conjoint analysis is a rigorous survey technique used to understand health care preferences in the pharmaceutical and medical device industries. In a traditional conjoint study, respondents are presented with a complete profile of all of the combination of attributes and features (or levels) for a particular product or service. However, research involving a large number of attributes can be too burdensome for respondents and has been shown to elicit inaccurate responses. This study describes a procedure used to link attributes from two or more different conjoint surveys that share at least one attribute. Linked latent conjoint modeling can lessen the burden on respondents while allowing utility parameters to be estimated for a large number of attributes, all on the same interval scale. Conjoint survey data were linked using a partial profile design and parameters were calculated using maximum likelihood estimation for finite mixture modeling. Several examples demonstrating the procedures used to link choice based survey data are provided. In addition, results from a latent variable modeling of the linked survey data are reviewed. Finally, to illustrate the flexibility of latent conjoint analysis, continuous and categorical covariates were simultaneously estimated to demonstrate the usefulness of latent modeling of conjoint data.

PMC30

COGNITIVE DEBRIEFING METHODS IN TRANSLATION OF PROS: A MULTI-NATIONAL

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OBJECTIVES: Cognitive debriefing interviews are a key component of the translation and linguistic validation of PROs and a necessity when a PRO is to be used as a primary or secondary endpoint for an FDA label claim. The 2005 ISPOR principles of good practice report describes the objectives of debriefing, but little discussion has been undertaken into the methods for performing debriefing interviews as part of the translation and linguistic validation process. This abstract presents a pilot test of methodologies across countries. **METHODS:** A literature review was conducted on cognitive debriefing methodology, and different approaches were pilot tested in 10 countries. Three methodologies were selected for pilot testing: 1) Retrospective probing 2) Retrospective think aloud 3) Concurrent think aloud. **RESULTS:** The literature review highlighted the methodologies and pros and cons of different approaches to cognitive debriefing, but no research was identified that addressed the issues of particular relevance in the translation and linguistic validation process. All three processes listed above proved suitable for a methodology for linguistic validation. The Think Aloud technique provided a true sense of the respondent's understanding of the translation but its suitability was particularly subject to cultural and individual differences. Questionnaires of a personal nature (e.g. those pertaining to sex or bowel disorders) benefited from Retrospective Probing, since the patients could respond hypothetically. The Retrospective Think Aloud technique elicited more information from some respondents, since it allowed them to discuss their personal experience. Where the respondent had difficulty in understanding what was required of them, modifying the interview style proved beneficial. **CONCLUSIONS:** A combination of Retrospective Probing and Retrospective Think Aloud proved to be the optimum methodology across countries, but this was dependent on the culture, patient, and the nature of the PRO being translated.

PMC31

CONSTRUCTION OF PRIMARY HUI3 PERSON-MEAN UTILITY SCORING FUNCTION

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OBJECTIVES: To assess construction of the primary HUI3 scoring system. **METHODS:** Mean visual analogue scale (VAS) and standard gamble (SG) scores were collected in 2 face-to-face interview surveys: modeling survey (MS) for the Person-Mean utility scoring model to calculate community utilities for health states; direct survey (DS) for validation of the Person-Mean scoring model. Survey results are assessed for completeness and consistency. Completeness is evaluated by response rates and consistency by health state rankings. **RESULTS:** Completed interviews were obtained from 65% of contacted eligible subjects. Demographic distributions are similar to the underlying general population. There are 256 respondents in MS and 248 in DS. MS and DS respondents use 71% of HUI3 attribute levels in describing their own health status. Each of the 8 HUI3 attributes are reported by 35 or more respondents as being important in their preference measurements: pain (49%); vision (37%); cognition (34%); emotion (28%); ambulation (28%); hearing (17%); dexterity (17%); speech (7%). More than 70% of respondents focused on 2+ attributes. Other important preference measurement factors are self-care ability (89% of respondents), family life (76%), happiness of others (69%), ability to work current job (61%), leisure activities (42%). 83% of respondents report the interviewing did not change their opinions about the health states. Consistency of health state rankings by mean VAS and SG scores between MS and DS was 100%: PH > MA > MB > MC > Dead > Pits. MS had a missing data rate of 0.29% (17/5920) for VAS and 0.10% (1/1024) for SG. **CONCLUSIONS:** The Person-Mean HUI3 utility function is founded on a survey that was well-constructed in terms of community and attribute representation, consideration of multiple attributes and day-to-day impacts, stable opinions, and consistency of health state rankings. This evidence supports use of the primary HUI3 utility function for group-level analyses, such as allocation of societal resources.

PMC32

MINIMALLY IMPORTANT DIFFERENCE OF THE TREATMENT SATISFACTION WITH MEDICINES QUESTIONNAIRE (SATMED-Q)

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OBJECTIVES: Treatment satisfaction with drug therapies is an important patient-reported-outcome (PRO) that may help clinicians to better impact in patient health care. The Treatment Satisfaction with Medicines (SATMED-Q) questionnaire has shown appropriate psychometric properties for exploring patient's satisfaction with medicines under routine medical practice in chronic health conditions. The Minimally Important Difference (MID) of the instrument is still unknown. The goal of this research was to determine the MID values of the SATMED-Q questionnaire for the total score and domains. **METHODS:** The sample of patients (457, mean age 59 years, 53% male) used for testing psychometric properties was also used to assess MID values. Item #14 of the TSQM scale was used as an anchor reference, since it explores directly the satisfaction with medicines in a seven points ordinal response (from extremely satisfied to extremely dissatisfied). Patients were classified into four categories according with responses in this item; extremely satisfied/dissatisfied, very satisfied/dissatisfied, satisfied/dissatisfied, nor satisfied/nor dissatisfied and comparisons were carried out for the overall score and each domain of the SATMED-Q using standardized scores. The mean differences in overall score (and domains) between the neutral category and the satisfied/dissatisfied category were considered the values of MID. Effect sizes (ES) were also computed. **RESULTS:** MID for total scoring was 13.4 (ES = 0.91), while the value for domains ranged from 10.3 (medical care domain, ES = 0.43) to 20.6 (impact of daily living, ES = 0.85). Mean score differences in overall scale and domains were significant between change in satisfaction categories with respect item#14 with F values ranging from 9.7 to 74.1 ($P < 0.001$ in all cases). **CONCLUSIONS:** The SATMED-Q demonstrated to be responsive to different levels of patient's satisfaction with therapy in chronically ill subjects. Attained MID was 13.4 pts for the overall normalized scoring scale and between 10.3 and 20.6 pts for domains.

PMC33

ESTIMATING HEALTH STATE UTILITY VALUES FOR COMORBID HEALTH CONDITIONS

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OBJECTIVES: Health state utility values (HSUVs) for comorbid health conditions (CHC) are frequently estimated using data from single health conditions but there is no consensus on the most appropriate method. The objective of the study is to comparing five techniques in a single data set. **METHODS:** We use EQ-5D data from the Health Survey for England to compare results generated using the: additive, multiplicative and minimum methods, the adjusted decrement estimator (ADE), and a linear regression model; a baseline of perfect health and an adjusted baseline obtained from