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PMC85

THE TRANSLATION AND LINGUISTIC VALIDATION OF THE PAR-ENT-QOL QUESTIONNAIRE

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OBJECTIVES: The PAR-ENT-QoL was developed in French. It is designed to assess the effect on family life of children's Rhinopharyngitis and otitis. This study's first objective was to produce a US English version to be used as the basis for other, conceptually equivalent and culturally relevant, translations and then to perform these. **METHODS:** An unusual methodology was employed to create the US English version: 2 translations into English, reconciliation by a bilingual native English consultant based in France, 'back' translations into French, back translation review, developer review, cognitive debriefing interviews with 5 members of the target population, 2 proofreadings; with input at every stage from both consultants. The translations from English employed a standard methodology: 2 forward translations, reconciliation, 2 back translations, back translation review, or in-country review; developer review, cognitive debriefing interviews as before, 2 proofreadings. **RESULTS:** Numerous cultural and linguistic issues arose, some of them particular to this methodology: •In US English "Rhinopharyngitis" and "otitis" were not understood by the general population so an explanation was added in the first instance. •Some in-country consultants were fluent in French so they worked directly from the English and used the French version as a guide. •'Vous' in French means 'you' but can be singular or plural. In the context this was translated as 'you or your partner'. •The French 'contrarié' covers numerous English meanings including "upset" and "frustrated" – after developer input, 'upset' was used. **CONCLUSIONS:** The simplest way of performing translations from a non-English original questionnaire is to create an English version as a basis for other translations. This now exists, and the PAR-ENT-QoL has been rigorously translated and linguistically validated into 16 languages. A number of cultural and linguistic issues became apparent and were resolved. The measure is now appropriate for use in multinational trials.

PMC86

THE IMPACT OF DISEASE ADAPTATION ON GENERAL POPULATION VALUES

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Health care resource allocation uses values for hypothetical health states elicited from the general population rather than patient values. The drawback is that respondents from the general population may not consider possible adaptation to the disease. This study aimed to investigate whether initial health state values change after the respondents were informed about disease adaptation. Three rheumatoid arthritis (RA) states of different severities were used as a demonstration. **METHODS:** Participants (n = 156) were randomly allocated into two groups: Uninformed and Informed. Each group completed two identical valuation tasks, consisting of rating and time trade-off (TTO) exercises, and underwent an adaptation exercise (AE), where participants first listened to recordings of patients discussing how they adapted to RA and then were guided to reflect upon this information. The Uninformed Group valued the three states, underwent the AE, and then completed a second set of valuations. The Informed Group started with the AE, then the first valuations; this was followed by a presentation of patient values of RA states and finally a second set of valuations. **RESULTS:** For most health states, a statistically significant change between each pair of valuations was observed for both groups. For example, the TTO values of the Uninformed Group for the severe RA state were 0.24+/–0.49 and 0.43+/–0.52, while the Informed Group valued the same state at 0.33+/–0.52 and 0.41+/–0.51. This indicated that both the AE and the patient values influenced the valuations. When comparing the first TTO valuation of both groups, only the mild state showed a statistically significant difference ($p < 0.10$). Specifically, the Uninformed Group valued this state at 0.80+/–0.26 whereas the Informed Group valued it at 0.87+/–0.20. **CONCLUSIONS:** The results revealed that both the administration of the AE and the presentation of the patient values informed the participants which, in turn, influenced their valuations.

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Study Design

PMC87

COMPARING CHART REVIEW AND MODIFIED DELPHI PANEL RESOURCE DATA COLLECTION METHODS: THE COST OF TREATMENT FOR MULTIPLE MYELOMA IN SWEDEN

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OBJECTIVES: Compare modified Delphi-panel survey methodology with a chart review study on resource data collection and costing. **METHODS:** Results from a published chart review on the cost of treatment of multiple myeloma in Sweden 2001 – 2005 is compared with a modified Delphi-panel (2008) set up in accordance to Evans et al. (1997, 2000). The panel consisted of four responding haematologists at different university hospital clinics. Costs in year 2008 prices. **RESULTS:** Background patient characteristics differences between the chart review and Delphi-panel were; gender: 3%, share aged above 65: –28%, mean number of co-morbidities at diagnose: –6%, clinical trial participation: 383%. As expected, the treatment regimen options in 2008 had changed considerably since the chart review with the introduction of thalidomide, bortezomib and lenalidomide, resulting in chemotherapy drugs representing the single greatest increase with Euro1164 (1013%). Consistent with the lower mean age in the Delphi-panel (68 vs. 76) stem cell transplantation showed an increase with Euro698 (303%) and blood cell enhancing drugs with Euro471 (682%). Given the patient characteristics, we saw an expected moderate increase in costs for outpatient visits, laboratory- and diagnostic tests. Mean total cost per patient-month was estimated to Euro4800 in the Delphi panel, or 59% higher than in the chart review. **CONCLUSIONS:** In therapeutic areas where treatment practice is undergoing rapid changes and treatment guidelines are well accepted and complied with, expert opinions can be a valuable source to capture changes from a well-defined but outdated baseline. However, the recruitment of representative respondents is important to avoid bias in patient selection and treatment practice. We believe our Delphi panel estimation of health care resource utilisation captures the development of MM-treatment in Sweden since the results were in line with our expectations on cost item development compared to the chart review given the patient characteristics.

PMC88

AN EXPLORATORY ANALYSIS OF REASONS BEHIND PREMATURE TERMINATION OF RANDOMIZED CONTROLLED TRIALS

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OBJECTIVES: The objective was to identify the reported factors leading to the premature termination of randomized controlled trials (RCTs). **METHODS:** A clinical trial registry (clinicaltrials.gov) was searched on December 15, 2008 for identification of RCTs with recruitment status "terminated". The RCTs submitted to the registry on or after January 1, 2004 were analyzed. Submission details were reviewed to identify the reason for premature termination along with other study details. Reasons for termination were categorized according to the pre-specified categories. Descriptive statistics were used where appropriate. **RESULTS:** A total of 1162 RCTs that met inclusion criteria were analyzed. Reason for premature termination of trial was reported in 656 (56.45%) trials. The most frequent reasons cited for the premature trial termination were: recruitment issues (244 trials), action based on interim analysis (68 trials), sponsor's decision (63 trials), efficacy related issues (44 trials) and safety concern (39 trials). These together were responsible for premature termination of about 70% trials. Results of terminated trials were made available on the registry for only 144 (12.39%) trials. Sponsor's decision was reported as responsible for the termination of twice as many trials during phase III or IV compared to the earlier phase of development (13.5% vs. 6.5%). Out of the 78 large trials (estimated enrolment >500) reporting termination reasons, sponsor's decision (24.4%) was the most frequent reason followed by action based on interim analysis (20.5%) and efficacy and safety related issues (11.5% each). **CONCLUSIONS:** Reporting of reasons for premature termination of RCTs was low with very few reporting the results on the registry. Slow recruitment and results of interim analysis were the major factors contributing to premature termination of RCTs, where reasons were reported.

PMC90

MANAGING STUDY PARTICIPANT RECRUITMENT SITES: METHODS FOR OPTIMIZING SUBJECT RECRUITMENT AND RETENTION THROUGH PRIVATE PRACTICE OFFICES

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Recruiting study subjects via private physician offices is a common research practice because such sites offer several benefits, including existing infrastructure and patient volume. Yet researchers face many challenges with achieving a sufficient sample size and retaining subjects when managing multiple physician offices as a study sites. Many physician offices lack the resources to manage the administrative workload associated with subject recruitment and retention. There are strategies researchers can employ to optimize recruitment and retention efforts when contracting with multiple physician offices. We launched a study in October 2008 to examine outpatient treatment outcomes among a sample of patients seeking treatment for opioid dependence. In order to achieve a sample size of 2000 patients, we targeted several hundred physicians across the United States that have been certified by the DEA to prescribe buprenorphine. A variety of methods were used to maximize study enrollment. Study site physicians were required to attend training about the study and received written training materials. Initially, online informed consent was required. However, paper-based informed consent options were added during the recruitment period to accommodate offices without internet access. Furthermore, we offered to provide these offices with internet-equipped laptops so patients could enroll at the time of their office visit. Physicians received a bi-weekly progress report detailing enrollment status for the study as a whole and for individual study sites. Repeated, targeted outreach to physicians with zero or few patients enrolled was conducted. As a result of these efforts, we were able to meet study recruitment goals. Groups that conduct clinical trials or other patient outcomes studies will benefit from employing similar strategies when managing multiple physician sites for subject recruitment and retention.