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

*Houyou C, Taib C, Wild D*

*Objective:* The PAR-ENT-QoL was developed in French. It is designed to assess health states, a statistically significant change between each pair of valuations was of the PAR-ENT-Qol was translated into English version: 2 translations into English, reconciliation by a bilingual native English consultant in France, 'back translations' into French, back translation review, developer reviewed professional review, finalizing interviews with 5 members of the target population with the original version as a guide. A new version in French including 'upset' was used. **Conclusion:** The simple way of performing translation was to make a free translation of the original version as a starting point 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.

**THE IMPACT OF DISEASE ADAPTATION ON GENERAL POPULATION VALUES**

*McGregor L, Sowton EM, Tuchouy A, O’Catriona A, Brazier JE* 

*University of Sheffield, Sheffield, South Yorkshire, UK*

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 was aimed to investigate whether initial health state values change after the respondents were informed about disease adaptation. Three rheumatoid arthritis (RA) states of mild to severe severity 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 on 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 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. **Conclusion:** 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**

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

*Ghahreman O, Ljung B, Lithner M, Aschan J, Mallingvist UH, Persson S* 

*The Swedish Institute for Health Economics, Lund, Sweden, Janssen-Cilag AB, Solentuna, Sweden; Sahlgrenska University Hospital, Gothenburg, Sweden*

**Objective:** Compare modified Delphi-panel survey methodology with a chart review on resource data collection and costing. **Methods:** Results of an 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 hematologists at the major university hospital clinics. Costs in year 2008 prices. **Results:** Background patient characteristics differ between the chart review and Delphi panel were: gender: 3%, share aged above 65: -28%, mean number of co-morbidities at diagnosis: -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.

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

*Daniel S, Ubehadi BS, Singh N, Narvekar P, Blunder M* 

*Hershey Health Private Limited, Chandigarh, India*

**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 identified RCTs with recruitment status ‘terminated’. The RCTs submitted to the registry on or before 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 465 (56.4%) 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 141 (12.3%) trials. Sponsor’s decision was the most common reason (24.4%) then followed by action based on interim analysis (20.5%) and efficacy and safety related issues (11.5%). **Conclusion:** 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.

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

*Jennessinger G, Ruetsch C* 

*Health Analytics, LLC, Columbia, MD, USA*

**Objectives:** To identify sites participating in clinical trials. **Methods:** 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 was used to maximize study enrollment. Study site physicians were required to attend training about the study and receive 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 physician offices 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.