has been conducted in a rigorous manner and that linguistic validation interviews have been conducted in the target country. The objective of this study was to ascertain whether there are particular areas of concern with respect to using these PROs outside of North America and Western Europe. METHODS: Specialists in outcomes research from four centers in Eastern Europe, Asia and Africa completed a questionnaire and interview about difficulties which occur with the cultural relevance of concepts included in PROs and other health questionnaires. RESULTS: Numerous cultural and linguistic issues became apparent, including: 1) The concept of witchcraft is particularly important in many places in Africa; 2) Japanese people have a tendency to be more positive about their disease or emotional health which may affect their responses to measures; 3) the concept of family is much more important in some countries, e.g., Malaysia and Ukraine; 4) the idea of ‘God’s will’ is particularly important to the people; people think about health in an abstract way; 5) women rarely play sports (a topic sometimes included in PRO measures); and questions about alcohol use cannot be used in Islamic countries. CONCLUSIONS: A number of issues should be considered during the subsequent development of PRO measures. This can be achieved using an extended translatability check which would include representatives from countries outside of North America and Western Europe to help bridge the gap between the cultural specificity of a sequentially developed measure and a cross-culturally developed measure.

**QUALITATIVE METHODS IN PRO RESEARCH: DEVELOPMENT OF A METHODS MATRIX**

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OBJECTIVES: Qualitative research methods are pivotal to PRO research and the importance of these methods has been highlighted by the FDA draft guidance. The objective of this study was to conduct a review of qualitative methods used in PRO research and social research, to evaluate the methods for application in PRO research, and to develop a methods matrix to enable the selection of the most appropriate methods in a given situation. METHODS: A search was conducted in Medline to identify methods of data collection and analysis in general, and to identify those methods applied to PRO research since the publication of the FDA draft guidance in February 2006. Qualitative research methods falling were evaluated according to the requirements for valid and reliable PRO research and a methods matrix was prepared. RESULTS: A wide variety of methods were used in health and social research, to evaluate the methods for application in PRO research. CONCLUSIONS: The ways in which qualitative research methods are applied in PRO research are varied, with some emergence in recent years of alternative theoretical approaches. The results matrix provides a useful and practical reference to enable selection of a range of qualitative methods for application to solve specific PRO research requirements.

**THE ADVANTAGES OF A CENTRALIZED DISSEMINATION STRATEGY FOR HEALTH OUTCOMES INSTRUMENTS AND THEIR TRANSLATIONS: THE ADVANTAGES OF A CENTRALIZED DISSEMINATION STRATEGY FOR HEALTH OUTCOMES INSTRUMENTS AND THEIR TRANSLATIONS**

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?MAR Research Trust, Lyon, France; ?Pennsylvania State University, University Park, PA, USA OBJECTIVES: From November 2007 to December 2009 the ZBI had been translated into a number of languages and translated versions and a harmonised version was produced. The harmonised version was translated into English by the Spanish speaking authors and used as reference for further versions. Two independent English native translators created two translated versions and a harmonised version was produced. The harmonised version was then pilot tested on 20 chronic patients. Suggested modifications were introduced and a final version was shaped. The final version was compared with the reference translation and back-translated into Spanish by two other independent translators native in Spanish. RESULTS: Meaningful differences were found between the two translations, especially when referring to undesirable effects, medication-treatment, disease-illness-medical condition, leisure and labour. Slight differences were also found on the words used to anchor the Likert response scales. Suggestions from the pilot sample advised to introduce examples accompanying questions about physical activity, free time activities, daily activities and personal hygiene, in order to illustrate questions. Nevertheless, the questionnaire was found easy to answer and to understand, and completion times were similar to those found with the original instrument. CONCLUSIONS: An English version of the SATMED-Q questionnaire is now available with linguistic validity ensured. Although psychometric properties should now be assessed, this new version allows beginning the cultural validation process and can be safely used as a bridge instrument towards other languages.

**CORRELATION BETWEEN ADHERENCE RATES MEASURED BY MEDICATION EVENT MANAGEMENT SYSTEM AND SELF-REPORTED QUESTIONNAIRES: A META-ANALYSIS**

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OBJECTIVES: This study performed meta-analysis examining the correlations of measurements of medication adherence (medication event monitoring system (MEMS) and self-reported questionnaires) using published study reports. METHODS: The literature search was performed from 1980–2009 using PubMed, PubMed In Process and Non-Indexed, OVID MEDLINE, PsyCINFO (EBSCO), CINAHL (EBSCO), OVID HealthStar, EMBASE (Elsevier), and Cochrane Database. English, Spanish, and French were used: patient compliance, medication adherence, treatment compliance, drug monitoring, therapy, treatment, electronic, desktop, computer, computer, monitoring, drug, drugs, pharmaceutical preparations, compliance, and medications. Studies were included if the correlation coefficient (Pearson correlation coefficient (r) or Spearman rank correlation coefficient (r_s)) between adherences measured by both MEMS and self-reported questionnaires were available or could be calculated. A meta-analysis was conducted to pool the correlation coefficients using random-effect model. RESULTS: A total of 11 studies (N = 1684 patients) met the inclusion criteria. The mean adherence measured by MEMS was 74.9%, ranging from 66.8% to 84.0% by self-reported questionnaire, from 76.5% to 93.5%. The correlation between adherence measured by MEMS and self-report questionnaires ranged from 0.24 to 0.87. Seven (63.6%) articles reported r values whereas 4 studies (36.4%) had r_s values. The combined effect size for 11 studies was 0.45 (p = 0.001, 95% CI: 0.34–0.56). The subgroup meta-analysis on the studies reporting r_s and r, correlation revealed the effect size 0.46 (p < 0.001, 95% CI: 0.33–0.59) and 0.43 (p = 0.001, 95% CI: 0.23–0.64), respectively. CONCLUSIONS: The correlation between adherence measured by MEMS and self-reported questionnaires tends to be moderate. Therefore, self-reported questionnaires give good estimate of patient medication adherence. However, MEMS and self-reported questionnaire should be used complementary to get accurate measure for patient adherence.

**EXAMINING MASLOW’S HIERARCHICAL THEORY OF NEEDS BY USING THE ITEMS OF THE WHOOQL-BREF**

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OBJECTIVES: Over the last few decades, many theories have been developed for the basic needs of human beings. Specifically, Maslow’s hierarchical model offered a sounder theoretical basis for theory of needs. The aim of this research was to examine whether the items of quality of life (based on the WHOQOL-BREF Taiwan version) fit the framework of Maslow’s hierarchy of needs. METHODS: This study used 13,008 participants aged from 20 to 65 from the 2001 National Health Interview Survey (NHIS) in Taiwan. The items of the WHOQOL-BREF were categorized according to Maslow’s five hierarchical levels of needs: physiological needs, safety needs, love and belonging needs, esteem needs and self-actualization needs. Structural equation modeling (SEM) was conducted to test the hierarchical model. RESULTS: The results showed that the model of Maslow’s hierarchy of needs did not fit the real data well if all of the items of the WHOQOL-BREF Taiwan version were used. However, after deleting several misfit items, the model can be fitted well. In general, the deleted items were comparatively far from the definition of Maslow’s hierarchical model. CONCLUSIONS: The study showed that partial items from the WHOQOL-BREF fit...