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 11 countries in Eastern Europe, Asia, 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 medications; 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 way people think about things in Saudi Arabia and Sudan; 5) Saudi Arabian and Sudan 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 sequential 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

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research methods are pivotal to PRO research and the importance of these methods has been highlighted by the FDA draft guidance.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and analysis in general, and to identify those methods applied to PRO research since the publication of the FDA draft guidance in February 2006.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 used in health and social research, which are in the broad category of qualitative methods for data collection and analysis. With some approaches, e.g. thematic analysis and grounded theory, there is a need for a tightening of definition in order to reduce some of the ambiguity around methods. In PRO research, each qualitative method is used in concept exploration, selection of PROs, translation of PROs, migration from paper to ePRO, and development/modification of PROs (content validity evidence) among other areas. The results matrix identifies which qualitative methods are the most appropriate for use in specific areas of 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 the 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: A CASE EXAMPLE WITH THE ZIBI BURDEN INTERVIEW (ZBI)

OBJECTIVES: To calculate the correlation coefficient between the ZBI English version translated into Spanish and back-translated into English by two other translators and a harmonised version was produced. The harmonized 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 harmonized version was used as the pilot sample of 20 charts. Critical 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 MONITORING SYSTEM AND SELF-REPORTED QUESTIONNAIRES: A META-ANALYSIS

OBJECTIVES: This study performed meta-analysis examining the correlations of measurements of medication adherence (medication event monitoring system [MEMS] and self-reported questionnaires) used 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 Databases. Selected studies were used: patient compliance, medication adherence, treatment compliance, drug monitoring, drug therapy, electronic, digital, computer, monitor, monitoring, drug, drugs, pharmaceutical preparations, compliance, and medications. Studies were included if the correlation coefficients [Pearson correlation coefficient (r) or Spearman rank correlation coefficient (τ)] 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 of adherence measured by MEMS was 74.9%, ranging from 66.2% to 84.9% and 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 τ values. The combined effect size for 11 studies was 0.45 (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 WHOQOL-BREF

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 with the framework of Maslow’s hierarchy of needs. METHODS: This study used 13,008 participants aged from 20 to 63 from the 2001 National Health Interview Survey (NHIS) in Taiwan. The items obtained from 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 missfit 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
with the framework of Maslow's hierarchy of needs. In conclusion, Maslow's hierarchy of needs was partially supported by the WHOQOL-BREF.

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CLASSIFYING PATIENT REPORTED OUTCOMES: DEVELOPMENTS IN THE FIELD SUGGEST A NEW TAXONOMY
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OBJECTIVES: The FDA proposed the term 'patient reported outcomes' in 2001 which grouped concepts such as quality of life (HRQL), satisfaction and preference together in terms of their role in regulatory approval. Since then there have been notable developments in the field, not least the much wider use of stated preference methods such as conjoint analysis. METHODS: ISPOR's Patient Preference Conjoint Analysis Working Group convened a team to develop a new taxonomy to characterise the different approaches used to capture patient based data. A thorough review of different patient reported methods was undertaken, and based upon discussion and further expert review, a taxonomy of methods based was developed. RESULTS: Several groups of methods emerged from the review which reflected both the underlying data that the method produces and also the audience of the data—regulators, payers, policy makers and decision makers. Group 1 (Classic PRO) includes different psychometric approaches, commonly based upon Likert scale responses. This group includes measures of HRQL, symptoms and treatment satisfaction. Group 2 (Stated preference) describes ordinal methods including conjoint analysis (discrete choice, graded pairs) and willingness to pay methods. Group 3 (Cardinal utility) describes cardinal methods of capturing health outcomes often used in economic evaluation. Each group of methods also has naturally different audiences. CONCLUSIONS: The FDA's simple classification of measures as PROs does not reflect the diversity and applications of patient reported data. The proposed taxonomy we believe reflects important differences in methods and also the different uses of data.

THE EVOLVING HEALTH ECONOMICS EVALUATION PARADIGM AND THE ROLE OF THE QALY
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The quality-adjusted life year (QALY) is a unit of measurement which combines the length and quality of life in a way which reduces the number of dimensions which must be taken into account in an economic evaluation. In simple cost utility analysis (CUA) the problem of allocating scarce resources is reduced to two steps: ranking projects by their cost per QALY and deciding upon a threshold cost per QALY above which projects will not be funded. Over time there has been increasing dissatisfaction with the perceived excessive simplicity of the approach. Partly this has arisen over technical questions which instrument should be used to measure QALYs (the SG, TTO, etc.), should the QALY be replaced by the healthy-year equivalent (HYE) or is there additive separability between health states; are valid QALY league tables achievable. However there has also been increased questioning of the value basis of the QALY. Should 'utility' incorporate an individual or social perspective (like the person trade off (PCTO)) or economic values revert to the older concept of hedonic, rather than preference / utility (i.e., subjective well-being), but, perhaps most fundamentally, can QALYs be abstracted from other values relating to the distribution of benefits between patients with dissimilar problems, and disregard characteristics of services except that they add utility or quality of life? A systematic review was performed a systematic literature search to identify studies in which various methods for documenting benefit were applied and different target populations were investigated. Standardised, selected studies are presented, whose incremental cost-utility-ration have an wide scatter related to the documenting. Depending on the documenting method, indication-dependent trends are found for effective size and direction of QALYs. RESULTS: The studies identified show that the variation in methods for documenting QALYs even within the same intervention trial considerably reduces its comparability. It is also not easily possible for decision-makers to make a decision based on these results. The documenting methods used clearly create different constructs that apparently display different levels of responsiveness in the same indication (e.g. rheumatoid arthritis, sleep apnoea, macular degeneration, oral anticoagulation). In the indication comparison, a clear trend could not be determined for the effective size in the results in relation to the documenting used. CONCLUSIONS: If the legal conditions are satisfied and a consistent decision using cost utility analyses in one indication area is possible, the documenting method for utilities must be standardised. This could be directed indication-specific towards an optimum correspondence with the responsiveness of validated, disease-specific quality of life documenting instruments.

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WHICH HEALTH ECONOMIC APPROACHES FOR WHICH DECISION-MAKING SUPPORT IN METASTATIC CANCER? A LITERATURE REVIEW AND FRENCH EXPERT OPINIONS
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Conventional health economic tools are not adapted to the very specific problems of metastatic cancer treatment. The objective of this study was to analyze the methodological tools used in published economic evaluations for metastatic breast cancer (empirical studies) and for all metastatic cancer treatments (methodological studies). Results of a systematic literature search (Medline, Embase, Cochrane Library, Pascal, HTA databases) since 1990 were completed by expert interviews (oncologists, health economists, decision-makers). 535 abstracts were screened and 80 selected, excluding: clinical trials with no economic analysis, alternative treatments to chemotherapy, early stages of cancer, any metastatic cancer with no specific and/or original methodology and/or endpoints. According to a pharmacoeconomic quality checklist, 37 were analyzed. The review showed a majority of studies in breast cancer with low level of evidence and only two prospective studies. More than half of the studies were cost-utility analyses. Endpoints combine quality of life and other indicators: QALY (Quality-Adjusted Life Years), Q-TWIST (Quality-Adjusted Time Without Symptoms and Toxicity), QAPFY (Quality-Adjusted Progression-Free life Years), QADs (Quality-Adjusted Days of life). We did not find any specific criterion to the metastatic state. Experts recommend the use of multi-dimension criteria comprising direct and indirect costs, efficacy and quality of life data integrating patient preferences; thresholds of resource availability should be defined according to treatment strategies and population subgroups (performance status, age, illness severity). This study underlines the need to develop tools for more rigorous and raises the issues of economic rationality in the health care decisions in France. Although some countries have chosen arbitration (QALY, Efficiency Frontier per pathology), France has not chosen a valid method for resources allocation.