potential values. RESULTS: Frequency distribution of the EQ5Dindex was tri-modal and difficult to describe in summary statistics. In all, 27 possible values (11%) were responsible for 92% of all observations, 14 possible values had no observations, and 24.7% of returns had an EQ5Dindex of 1.0. There are a number of categories that are rarely used e.g., severe mobility problems and severe self care problems. There was a close correlation between weighted scale and simple addition of responses (R² = 0.87). There were 6.8% of responses with an EQ-5D index ≤0.0. There was a low correlation between the EQ5Dindex with the general health question of the SF36 and the arbitrary, continuous valuation of health status above. The ranking of mean estimates was intuitively correct. CONCLUSIONS: The number of theoretical values that are represented was sparse. The EQ-5D distribution results in no easily describable parametric distribution, and the correlation with other general health measures was low. Given that these subjects are hospital treated, too many may have a health status of 1.0, and too many are also in a health status notionally equal to or worse than death. Decisions based on the EQ5Dindex now have enormous health and commercial implications. The EQ5D classifies the right health factors but the sensitivity and scoring methods need urgent revaluation: good but needs improving.

**Abstracts**

**PMC18**

**HEALTH UTILITIES INDEX (HUI) ON-LINE QUESTIONNAIRE SYSTEM: CRITERION VALIDITY OF MULTI- AND SINGLE-ATTRIBUTE UTILITY SCORES**

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OBJECTIVES: To assess the criterion validity of HUI Mark 2 (HUI2) and Mark 3 (HUI3) utility scores from a new, centralized on-line questionnaire administration system. METHODS: The system presents HUI questionnaires to patients and provides results to clinicians by email. Questionnaire results include responses and 32 derived variables (14 attribute levels; two overall health state vectors; 14 single-attribute utility scores; and two multi-attribute utility scores of health-related quality of life (HRQL)). SPSS code, validated to Health Utilities Inc. decision tables for determining attribute levels and published utility functions, is the criterion method for determining HUI derived variables. Testing used a data set that included questionnaire response combinations for all HUI2 and HUI3 attribute levels. Criterion validity was evaluated using percent exact agreement, and single-measure intra-class correlation coefficients (ICC), between scores from the new system and scores from the criterion method. RESULTS: The test data set generated 240 utility scores. There was exact agreement for 99.2% (n = 238) of the scores. Disagreement was limited to HUI2 sensation (ICC = 0.803, p < 0.01), and HUI2 overall HRQL (ICC = 0.966, p < 0.01), scores in one test case. Results were received by email from the on-line system within approximately one minute of completing each questionnaire. There were no missing or incomplete questionnaire data from the on-line system. CONCLUSION: The results indicate that most of the utility scores from the new on-line questionnaire system have criterion validity and there is a problem with the coding algorithm for at least one set of questionnaire response combinations associated with HUI2 sensation. The coding problem should be corrected, and more rigorous testing should be completed, before public release of the system. The system should be considered an alternative to traditional methods for future HUI data collection, especially for applications requiring immediate results such as clinical settings.

**PMC19**

**IMPROVING THE SCALING PROPERTIES OF THE PSYCHOLOGICAL GENERAL WELL-BEING SCALE (PGWB)**

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OBJECTIVES: To apply item response theory (IRT) to PGWB data to determine whether the instrument provides unidimensional assessment of well-being; identify a revised version of the measure. METHODS: The PGWB is a widely used patient-completed generic measure of well-being that, to date, has not been subjected to item response theory (IRT) assessment. The UK version of the PGWB was used. It consists of 22 items, each with five response options. The measure was completed by two patient groups, 103 patients with rheumatoid arthritis and 96 with adult growth hormone deficiency. Data were subjected to Rasch Analysis using RUMM 2010. RESULTS: Analysis revealed problems with the five option scoring system for four of the items. Three methods of analysis were followed to obtain the best fit of data: 1) rescaling of disordered items and deletion of any further misfitting items; 2) collapsing response options into three categories and rescaling further misfitting items; and 3) deletion of disordered items and any further misfitting items. The first approach gave the best fit of the data to the Rasch model in terms of overall and individual item fit and person-item separation. Three other items were then removed due to poor item fit. Subsequently, fit to the Rasch model was good, in terms of overall Item-Trait Interaction (Chi² = 128.87, df = 95, p = 0.001), Item Fit (mean = 0.156, SD = 1.592), Person Fit (mean = -0.294, SD = 1.297) and person Separation Index (0.955). CONCLUSION: Application of Rasch analysis to PGWB data identified a new version of the instrument consisting of 19 items with good scaling properties. Use of the new version would improve the accuracy with which well-being is assessed in clinical studies. It is recommended that the new version is tested with other disease groups to determine whether the scaling properties are maintained.

**PMC20**

**RELATIONSHIP BETWEEN PATIENT SATISFACTION AND PERCEIVED HEALTH STATUS**

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OBJECTIVE: To examine the relationship between patient satisfaction with access to care and their perceived health status. METHODS: Information on patient satisfaction with access to care and perceived health status along with their demographics was extracted for people 35–64 years of age, from the Household Component of 1999 Medical Expenditure Panel Survey. Descriptive statistics were used to illustrate the characteristics of the study population. Multiple regression analysis was applied to examine the relationship between patient satisfaction and their self-rated health status controlling for age, gender, race, marital status and education level. All analyses used STATA 8.0 which is designed to analyze weighted data. RESULTS: A total of 8746 patients met the study inclusion criteria and were included in the study. Of these patients, 53% were females, 69.3% were married and 82% were Caucasian. The majority (44.9%) had a high school diploma and 14.5%, 6.9% and 1.7% held BS, MS and Ph.D. degrees, respectively. Patients who rated their health better scored higher in their satisfaction with access to care. In addition, higher satisfaction was found in patients with the following characteristics: being older, female, Eskimo, married and with higher education. Asian and Hispanic patients scored lower in satisfaction than Caucasian patients. CON-
CLUSIONS: In general, patients who perceived themselves in better health are more satisfied with access to care than those with worse perceived health status.

PMC21
DEVELOPING METHODOLOGY FOR THE TRANSLATION AND LINGUISTIC VALIDATION OF PATIENT REPORTED DIARIES
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OBJECTIVES: To build on recent discussion within the ISPOR QoL/SIG group and develop methodology for the translation and linguistic validation of patient diaries. There is a considerable body of literature in support of a rigorous methodology for the translation and linguistic validation of PROs. Typically this methodology involves forward translation, back translation, developer review and pilot testing, with ongoing harmonisation between translated versions. This methodology aims to achieve linguistic equivalence—essential if data from multinational trials are to be pooled. Recent discussion within the ISPOR QoL/SIG group has focused on whether this same methodology should also be applied to patient diaries. Patient diaries are designed to be completed at time intervals, and thus erroneous information or wording might be repeated, something unlikely to occur in other PROs. METHODS: Relevant literature on translation and linguistic validation of PROs was reviewed. Several translated patient diaries were analysed for their content and for concepts that proved problematic in translation. The results were discussed and form the basis of this paper’s findings and recommendations. RESULTS: A number of translation difficulties were encountered with patient diaries. These can be broadly categorized as follows: a) psychological concepts regarding patient thoughts and feelings; b) clinical information, e.g. country-specific names for drugs; c) references to country-specific health care and welfare systems; and d) miscellaneous linguistic ambiguities. Involvement of psychological concepts indicates a need for pilot testing with patients. The presence of clinical information and references to country-specific health care and welfare systems indicates that clinical personnel should be involved in translation. CONCLUSIONS: A concept elaboration stage, to review diary content and identify translation difficulties, is needed before a translation methodology is selected for patient diaries. This approach will lead to the selection of appropriate methodology and result in a translation that is faithful to the concepts within the source language.

PMC22
DEVELOPING SYMPTOM-BASED QUESTIONNAIRES FOR DIAGNOSTIC SCREENING
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OBJECTIVES: For many chronic diseases diagnosis is often delayed or missed, leading to delayed or inappropriate intervention and increasing the burden of disease on the patient. Symptom-based questionnaires represent an efficient approach to early identification and screening. We report an approach to developing diagnostic questionnaires based on patient-reported information. METHODS: Based upon a comprehensive literature review and input from an advisory board of specialists and generalists, a pool of candidate questions is established. Item reduction is carried out using a small group of patients with known diagnosis, and the reduced item set is prospectively tested against a gold standard using subjects at risk, but whose diagnostic status is not known to the investigators. Responses are analyzed using a split-sample technique. Bivariate and multivariate methods identify question items that may be eliminated from the question pool. Prototype questionnaires are developed using one sample, and tested for performance characteristics using the other sample. A scoring system is designed to optimize clinical goals and facilitate easy scoring and interpretation. RESULTS: Using this approach, diagnostic instruments have been developed for COPD case-finding and for differential diagnosis between COPD and asthma. These instruments have achieved sensitivities of 54–82%, specificities of 58–88%, positive predictive values of 30–78%, and negative predictive values of 71–93%, which are comparable to other widely accepted case-finding tools. CONCLUSIONS: Symptom-based questionnaires provide rapid, inexpensive tools that can efficiently improve early diagnosis, encourage care-seeking among patients, and provide useful information to patients and physicians. In addition to office based case-finding applications, other potential uses include population or workplace screening, or as an adjunct to public awareness campaigns. Using an internet platform, screening can be standardized over wide areas which may include multiple countries.

PMC23
TRANSLATABILITY ASSESSMENT: A NEW APPROACH TO INTERNATIONAL QUESTIONNAIRE DEVELOPMENT
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OBJECTIVES: The last 20 years have seen the development of numerous PRO measures. Mostly however, within and for one culture. Based on the assumption that the original concepts are universally appropriate, instruments destined for international use are translated following a standardized procedure (linguistic validation). As this process reveals the interdependence of translation and original, the importance of integrating an international component into the design of instruments emerges. This can be achieved through the Translatability Assessment of a pre-final original questionnaire. The presentation will illustrate methodology and advantages of this new approach. METHODS: A translatability assessment can be defined as an international critical review of a pre-final original in collaboration with the developer. In the absence of international development, this may be a cost and time effective compromise between the WHO approach to instrument development and translation. The translation process usually reveals difficulties when adapting the format, instructions, concepts, idiomatic expressions, response scales or demographic items to different languages. The translatability assessment proposes to review these aspects and suggest re-formulations in the original considering the context and constraints of other languages/cultures. RESULTS: Several examples of the impact of the Translatability Assessment on the original wording will be given. For instance, although the term “work” in English may refer both to a paid job and voluntary work, other languages may require different expressions to convey this global notion. The reference to “daily activities” may be an alternative facilitating international harmonization across languages and pooling of data. Similarly, reference to “patient initials” being inappropriate for Chinese languages, replacing the original with “patient record number” can improve international acceptability. CONCLUSIONS: The Translatability Assessment may be a practical and easy way to integrate an international component in the design of new measures, thereby facilitating the subsequent translation by anticipating and solving its difficulties.