CLCLUSIONS: In general, patients who perceived themselves in better health are more satisfied with access to care than those with worse perceived health status.

DEVELOPING METHODOLOGY FOR THE TRANSLATION AND LINGUISTIC VALIDATION OF PATIENT REPORTED DIARIES

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 healthcare 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.

DEVELOPING SYMPTOM-BASED QUESTIONNAIRES FOR DIAGNOSTIC SCREENING

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.