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Standardization of Health-Related Quality of Life (HRQOL) Measures for Asian Populations

Cindy L K Lam, FHKAM (Family Medicine), FRCGP
Associate Professor, General Practice Unit, Department of Medicine,
The University of Hong Kong

Address for correspondence: 3rd floor, Ap Lei Chau Clinic, 161 Main Street,
Ap Lei Chau, Hong Kong.
E mail: CLKLAM@HKU.HK
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Introduction

It is now the standard for clinical trials to include quality of life as a controlling variable as well as an outcome measure (1). Quality of life (QOL) is a very broad concept that includes many dimensions some of which have little direct relationship with health care. Health care providers are mainly concerned about those aspects of QOL that are affected by health - health-related quality of life (HRQOL) (2,3). The major barrier to the use of HRQOL as outcome measures in clinical trials in Asia is a lack of instruments that can be applied to our populations. Most of the existing instruments were developed in the US or Europe and very few have been validated on Asian populations (4-7).

A few generic HRQOL measures are widely used internationally, the MOS 36 item Short Form (SF-36) Health Survey (8) is the most popular, others include the Nottingham Health Profile (9), the COOP/WONCA Charts (10), the EQ-5D (11), and the Quality of Well-being Scale (12). The SF-36 and the COOP/WONCA Charts have been translated and tested on the Chinese, Japanese and Koreans with encouraging results. The use of the same standard HRQOL measure by Western and Asian populations is necessary for pooling data in international clinical trials and comparing results of studies from different countries. This paper will describe a four-step method for the standardization of HRQOL measures for Asian populations.

Standardization of the Concepts and Content of HRQOL Measures

HRQOL_a
The core concepts of HRQOL and how they are being expressed have been identified in the Western populations (1,2), but they may not be the same as those perceived by Asian populations because of the different cultures. The use of focus group or in-depth interviews can identify the important concepts of HRQOL and how they are expressed in the population concerned (13, 14, 15, 16). Research has shown that most cultures share the same core concepts of HRQOL although the relative importance of the different concepts may vary (16). For example, social functioning is perceived to be relatively less important but eating seems to be an important function for the Chinese in Hong Kong (13,16). One can then proceed to choose a HRQOL measure that has good face validity in that its concepts and content appear to match those described by the population concerned (14,15). It is sometimes necessary to modify the content in order to achieve the conceptual equivalence (14), e.g. playing Tai-Chi is used to replace golf as an example of moderate physical activity in the SF-36.

**Standardisation of the Translation**

The translation should have semantic and functional equivalence with the original (14, 15,17). It is essential to have equivalence in conceptual meaning rather than words. The standard method is an iterative (at least double) forward and backward translations by independent qualified translators. The backward translations should be evaluated by the original author to confirm that the original meaning is preserved. The draft translation should be reviewed by panels of expert and lay people for conceptual equivalence, face validity, clarity, comprehensibility and grammatical accuracy (14,15,18).
The translation then has to be pilot tested on subjects of the target population to assess its feasibility, acceptability, relevance and clarity (14,18). It is important to identify items in the HRQOL measure that people do not understand, find difficult, irrelevant or embarrassing to answer. The methods of administration of the instrument also need to be standardized. Interviewer administration is often required for Asian populations, the intra-observer and inter-observer test-retest reliability and the operational equivalence of different methods need to be assessed (15,17,19).

The meaning of the concepts measured by the HRQOL measure need to be standardized across cultures. The relationship between the different concepts and the ranking of the items within a concept should be similar if there is conceptual equivalence across countries (17,18). Factor analysis can also be used to test if the factor components obtained from the target population fit the hypothesised factor structure (8,18).

**Standardization of the Scoring algorithm of HRQOL Measures**

Most HRQOL measures have multiple scales each of which is constructed on multiple items, e.g. the SF-36 have 8 scales each has 2 to 10 items. The construct validity of the scales must be confirmed before the standard scoring algorithm can be applied to the population concerned (14,18). The standard tests for construct validity include convergent validity, item discriminant validity, internal reliability and interpretable inter-scale correlations. Scales that do not apply weighting to items, e.g. the SF-36, should have equal item variance and item-scale correlation. Measures that apply weighting to the scores, e.g. the Nottingham Health Profile and the Quality of Well-being Scale, need standardization of the weighting by the judgement or mathematical methods (14,18).
Standardisation of the Norm References of HRQOL Measures

The measurement of HRQOL is relative rather than absolute in that there is no threshold levels of good or bad. It is more meaningful if it is interpreted in the context of the norm derived from the population concerned (18). Reference norms can be obtained for the general population or specific groups, e.g. patients with arthritis. A good HRQOL measure should have good discriminatory power between different groups and demonstrate the effects of sociodemographic factors and co-morbidity on HRQOL. Population based norms are very useful for the standardization of weighting and utility indexes, e.g. QALY, and for quality assurance(20).

Conclusion

We need a good tool in order to carve out good work. Proper Standardization of a HRQOL measure for Asian populations by the four-step method will assure the quality of the instrument and the data obtained by it.
References


