



A systematic review: How to choose appropriate health-related quality of life (HRQOL) measures in routine general practice?

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Abstract: In more recent times, health-related quality of life (HRQOL) measurements have formed an important part of assessing the quality of routine care in general practice. For a measure to have clinical usefulness it must not only be valid, appropriate, reliable, responsive, and capable of being interpreted, but it must also be simple, fast to complete, easy to score, and provide useful clinical data. The Two-step method of choosing appropriate measures is introduced. Then through comparison of generic instruments with disease-specific instruments, we can conclude that sometimes a combination of generic and disease-specific HRQOL measures may be more appropriate for monitoring changes in a patient's health status due to an intervention.

Key words: Health-related quality of life (HRQOL), Generic, Disease-specific, Measure, General practice

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INTRODUCTION

The ultimate goal of health care is to maintain or improve the quality of life of people. Health is an important determinant of a person's quality of life although it is not the only one. Other factors such as culture, religion, environment, education and finance can also affect quality of life but they are often beyond the scope of health care. Health-related quality of life (HRQOL) is the main concern of health care professionals and is becoming an important health outcome indicator (Greenfield and Nelson, 1992; Wilson and Cleary, 1995; Lam, 1997). Some reasons are as follows: The byproduct of advances in medical science and technology is an increasing number of people living with chronic diseases and disabilities. The change in our population's morbidity pattern has called for a paradigm shift in how we should evaluate outcomes of illness and care. Is it worthwhile to keep

a comatose person alive on a respirator? Is renal transplant a better treatment than haemodialysis for patients with renal failure? Is one particular health care delivery system better for patients with chronic diseases than another? Traditional indicators like mortality rates and objective clinical parameters are no longer adequate for answering these questions.

The main barrier to the use of HRQOL as an outcome indicator is the lack of a common definition and measuring standard. Major breakthroughs in the conceptualization of HRQOL and standardization of measures resulted from works by Lohr (1988), Bergner *et al.*(1976) and the medical outcome study by Ware and Sherbourne (1992) in the last two decades. Function is the most essential dimension of HRQOL and should include physical, social and role function. The other essential dimensions are mental health and general health perception. Vitality, pain and cognitive function are also important domains of HRQOL (Wilson and Cleary, 1995). As pointed out by Guyatt *et al.*(1993), HRQOL is a concept that tries to embrace the spirit of the WHO definition of health

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(including physical, emotional, and social well being) (WHO, 1948) by including both personal health status and social well being when assessing health. Evaluation of HRQOL should be subjective, that is the person being assessed rates his own status (Lam, 1997).

Wide application of HRQOL measure has been found in western countries. Cited in over 5000 published articles since 1988 (Bowden and Foy-Rushby, 2003), HRQOL measures have been mainly applied in the fields of the following aspects (<http://www.sf-36.org/tools/SF36.shtml#VERS2>). First is in the fields of research and clinical practice: incorporating the patient's voice into health care decision-making has dramatically changed the dynamics of clinical practice and outcomes research. To deal with this paradigm shift, clinical decision-makers are now looking for practical and cost effective tools to monitor health on a larger scale as well as more precise tools that meet the clinical standards of accuracy necessary for individual patient assessment. The implications of these trends for patient screening and health outcomes monitoring are significant. Second is in the fields of clinical trials: pharmaceutical companies now recognize the need to define benefits more broadly than traditional clinical endpoints by including patient-reported outcomes (PROs) in clinical trials. Given the astronomical costs associated with drug development and testing, clinical trials depend on reliable and scientifically valid health outcomes measurements that are acknowledged and accepted by the Food and Drug Administration (FDA) (<http://www.sf-36.org/tools/SF36.shtml#VERS2>). Third is in the fields of risk prediction and disease management: data from patient-based health surveys add significant value because they improve risk prediction, service planning, and outcomes monitoring efforts, and ensure that program planning and evaluation efforts incorporate the patient's perspective. Besides, cross-cultural comparison of HRQOL is a hot research point (Ware et al., 1998; Keller et al., 1998; Alonso et al., 2004; Tseng et al., 2003).

Many HRQOL instruments have been developed in the last decade but most of them are in English. Application of such instruments to non-English speaking population requires careful translation and cross-cultural validation. One needs to evaluate whether the content, concept, construct and scoring method of an instrument are valid and whether it is

acceptable to our population. The International Quality of Life Assessment (IQOLA) Project has developed a standard method for cross-cultural applications of an HRQOL instrument. It consists of three stages (Bullinger et al., 1998): Firstly, rigorous translation and evaluation procedures to ensure conceptual equivalence and respondent acceptance; secondly, formal psychometric tests of the assumptions underlying item scoring and construction of multi-item scales; thirdly, examination of the validity of the scales and the accumulation of normative data and evaluating the equivalence of interpretation across countries. The first two stages are essential before the instrument can be applied to the population concerned and the third is for developing a reference norm for meaningful interpretation of data obtained from specific patient groups.

With worldwide research of HRQOL measures, China has made some progress particularly in the fields of HRQOL's Chinese translations and its relevant researches. Li et al. (2002; 2003) established the normalization of the Chinese version of the SF-36 and made psychometric testing among the general population in Hangzhou City of Zhejiang Province. Besides Li and Jiang (2002) tested the reliability, validity and responsiveness of the Chinese SF-36 scales in hemodialysis patients. Those series of researches indicated that the Chinese version of the SF-36 Health Survey Scale has achieved conceptual equivalence and satisfied the psychometric scaling assumptions well enough to warrant wide use in China. Furthermore, Wang (2004) did some research on Cross-cultural HRQOL measurement among patients in general practice with the SF-36, which promoted international cooperation in the fields of HRQOL research.

HOW TO CHOOSE APPROPRIATE HRQOL MEASURES IN ROUTINE CLINICAL PRACTICE?

Self-evaluated HRQOL is most valid for patients in general practice, whose illnesses are rarely lethal but often dysfunctional. It has been used as a screening instrument for physical, psychological, role functioning and social problems in patients with chronic diseases so that appropriate interventions can

be resorted to. It can assess the quality of our care from the patients' point of view and has been shown to be more sensitive than objective indicators in predicting mortality, detecting functional impairment, determining consultation rates and showing the effectiveness of treatment in patients with chronic diseases (Meadows *et al.*, 1998; van Manen *et al.*, 2003; Wensing *et al.*, 1997).

In more recent times, health outcome measurements have formed an important part of assessing the quality of routine care in general practice, especially in the impact of chronic diseases on HRQOL of patients in primary care (Janse *et al.*, 2004; Bentsen *et al.*, 1999; Lam and Lauder, 2000). This represents a shift from assessment based on traditional clinical criteria, towards a focus on the needs and outcome in terms of the patients' experience in defining appropriate goals for treatment, and assessing the effectiveness of the treatment. This is especially relevant for the management of patients with chronic diseases, where evidence-based care requires increasingly complicated and expensive interventions, ongoing support of self-management, and close monitoring of health outcomes (Wagner, 2001). HRQOL measures have many potential uses in aiding routine general practice. They can be used to prioritize problems, facilitate communication, screen for potential problems, identify preferences, monitor changes or response to treatment, and train new staff (Higginson and Carr, 2001).

Which instrument should be used to measure HRQOL in the clinical setting? Barriers to the routine clinical use of HRQOL measures include concerns about cost, feasibility, and clinical relevance (Higginson and Carr, 2001). For a measure to have clinical usefulness it must not only be valid, appropriate, reliable, responsive, and able to be interpreted, but it must also be simple, quick to complete, easy to score, and provide useful clinical data. Higginson and Carr (2001) provided step-by-step methods of choosing a QOL measure and introducing it into general practice:

The first step: Questions to ask when choosing a HRQOL measure for use in clinical practice

1. Are the domains covered relevant?
2. In what population and setting was it developed and tested, and are these similar to those situations in which it is planned to be used?

3. Is the measure valid, reliable, responsive, and appropriate?

4. What were the assumptions of the assessors when determining validity?

5. Are there floor and ceiling effect—that is, does the measure fail to identify deterioration in patients who already have a poor quality of life or improvement in patients who already have a good quality of life?

6. Will it measure differences between patients or over time and to what extent?

7. Who completes the measure: patients, their family, or a professional? What effect will this have—that is, will they complete it?

8. How long does the measure take to complete?

9. Do staff and patients find it easy to use?

10. Who will need to be trained and informed about the measure?

The second step: Introducing an HRQOL measure into clinical practice

1. Review who is using which measures internally and externally;

2. Choose a measure;

3. Decide whether other outcomes also need to be monitored;

4. Involve staff and patients;

5. Adapt the measure for local use and requirements;

6. Identify a leader of the project;

7. Assign responsibilities (decide who will be doing what);

8. Agree on a timetable;

9. Test when and where the measure will be completed;

10. Prepare and test paperwork;

11. Plan and begin training in both the use of the measure and associated clinical skills;

12. Agree on start date and review period;

13. Begin using the measure;

14. Review its use in the first week and month and then at regular intervals;

15. Review individual patients' results and group results to improve care;

16. Modify measure as patients and staff feel appropriate for improving the use of the measure or make other changes.

COMPARISON OF GENERIC INSTRUMENTS WITH DISEASE SPECIFIC INSTRUMENTS

It is also important that the meaning is universally understood by all who might want to use the instruments and that the product has cultural applicability beyond English. In clinical practice, the definition of the instrument aims not only to give the General Practitioners (GPs) a clear understanding of what is being measured, but how it is used and the implications for its future use. Currently, some generic instruments are widely used to measure HRQOL in general practice. For example, the MOS 36 item Short Form Health Survey (SF-36) and the Dartmouth COOP functional health assessment Charts/WONCA (COOP/WONCA Charts) are two popular generic HRQOL instruments for people living in community (van Weel *et al.*, 1995; Ware and Gandek, 1998; Gandek and Ware, 1998). Both of them include most of the essential concepts of HRQOL and have been shown to be suitable for cross-cultural applications. The SF-36 is more comprehensive than the COOP/WONCA Charts and its scores can be parametric statistical tests, but it may be too long for routine clinical use and its scoring method is more complicated. On the other hand, the COOP/WONCA Charts are ideal for routine use in general practice because it takes less than 5 min to complete and the scoring method is very straightforward. The scores of the COOP/WONCA Charts are non-parametric, which limits the scope of statistical analysis. Use of HRQOL as an outcome indicator of illnesses and care for Chinese population will bring our health care closer to its ultimate goal of improving the quality of life of people.

HRQOL is a multidimensional concept, and different aspects of quality need different methods of measurement (Asadi-Lari *et al.*, 2004; Campbell *et al.*, 2001). HRQOL measuring instruments can be generic or disease specific. Generic instruments have the advantages of being applicable to all persons irrespective of their type or number of illness but they may not be sensitive to some problems unique to particular diseases. Instruments specific to a particular disease, e.g. AIDS are more specific and sensitive but they make comparison between different patient groups difficult. Furthermore, the results of disease specific instruments are difficult to interpret in per-

sons with multiple diseases. The choice of instrument must be settled by consensus within the general practice community. In deciding what health outcome measures to use, GPs need to consider whether the measurement tools will be 'all inclusive' (for use in all types of general practice), or 'unique' (for use in specific areas, such as elderly patients). Sometimes a combination of generic and disease HRQOL measures may be more appropriate for monitoring changes in a patient's health status due to an intervention.

Measurement of HRQOL in general practice allows GPs to follow the progress of individual patients over time. Review over time is particularly useful for patients who have more than one health problem, or when the illness cannot be cured. In addition, viewing aggregated health outcomes data helps GPs identify the kinds of patients that make a long-term commitment to their practice and provides information about patterns of attendance over time. By identifying who uses services of GPs and why, GPs can begin to understand the nature of the quality of services they provide (Saltman *et al.*, 1998).

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