



Review Article

Methodological issues in measuring health-related quality of life

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ABSTRACT

Modern medicine has made significant progress in screening, diagnosis, and treatment, but the objectives of treatment have been a subject of debate. The question “Should the focus be on the quantity or on the quality of survival?” still prevails. Nowadays, health-related quality of life (HRQOL) has become an important index in medical treatment and clinical care. The health care system focuses on improvement in quality of life and health which are influenced by illness. The emphases of this article are on the definition and concepts of HRQOL. We discuss the methodological issues in the measurement of HRQOL including: (1) objectivity versus subjectivity, (2) generic versus specific, (3) unidimensional versus multidimensional, (4) self-report versus proxy report, (5) reliability, (6) validity, and (7) the selection of HRQOL measures. Subsequently, the importance of HRQOL in the treatment of a disease is also addressed. Copyright © 2012, Buddhist Compassion Relief Tzu Chi Foundation. Published by Elsevier Taiwan LLC. All rights reserved.

1. Introduction

Quality of life (QOL) is an amorphous concept and is still taken to refer to the conceptions of the goodness of life [1]. It is a concept that broadly covers all the aspects of human experience about the necessities of life, and is characterized as individuals' subjective well-being with general measures of how happy and/or satisfied they are with their life as a whole [2]. There are broad notions of QOL that encompass satisfaction about housing, employment, standard of living, marriage, interpersonal relationships, religion, and environment [3]. However, the health care system and its providers do not take responsibility for all these global human concerns, and therefore a distinction is made with regard to health-related quality of life (HRQOL) [2].

In a survey that was conducted to find out the five most important things in life, the respondents suggested health as one of the most importantly valued states [4]. Most QOL researches in the medical and health care fields are related to health status, and HRQOL has become increasingly important in health care and clinical investigations.

Although QOL and HRQOL are often used interchangeably to refer to the same concept, there are differences between the two. As

described previously, QOL is a broad concept covering all aspects of human life, whereas HRQOL focuses on the effects of illness and specifically on the impact of treatment on QOL [5]. HRQOL is a reflection of the way that individuals perceive and react to their health status and the nonmedical aspects of their lives, which include health-related factors, such as physical, functional, emotional, and mental well-being as well as nonhealth-related elements, such as job, family, friends, and other situations in life [6]. Regarding health outcomes, most indicators reflect a disease model, but HRQOL provides a comprehensive evaluation encompassing all the important aspects of QOL related to health. It has generated a new focus on a broader, more positive concept of health, rather than a narrow, negative focus (disease based) [7].

2. The characteristics of HRQOL

The concept of HRQOL is based on the concept of health and QOL, which is influenced by an individual's experiences, beliefs, expectations, and perceptions [8]. Good health is not only the absence of disease or infirmity but also a state of complete physical, mental, and social well-being [9]. HRQOL is a double-sided concept that includes both positive and negative aspects of health. The negative aspect includes disease and dysfunctions, whereas the positive aspect encompasses feelings of mental and physical well-being, full functioning, physical fitness, adjustment, and efficiency of the mind and body [10].

HRQOL is a multidimensional dynamic concept [11] and includes multiple components, such as an individual's physical

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health, psychological state, level of independence, and social relationships, and their relationships to the salient features of their environment [12]. These are health related to the extent they are influenced by illness, injury, and treatment [13]. In addition, it is a dynamic concept resulting from past experience, present circumstances, and expectations for the future [10]. Perception and achievement of HRQOL are not only dependent on an individual's physical condition but are also dependent on the preferences and priorities in life [14]. HRQOL can be recognized as a dynamic concept representing an individual's responses to the physical, mental, and social effects of illness which influence the extent to which personal satisfaction with life circumstances can be achieved, and which allows favorable comparison with others according to the selected criteria [15]. The dimensions of HRQOL encompass consequences for the daily lives of individuals, including health perceptions, functional status, symptoms, and their preferences and values [16].

HRQOL is sometimes confused with health status or functional status [17]. Illness has a pervasive effect that seeps into all areas of life, but HRQOL does not depend on measuring physical health status alone [18]. In fact, HRQOL and health status are two distinct constructs. There is no concordance between patients' ratings of health status and global HRQOL. For example, in one study, 43% of patients with poor physical functioning actually rated their HRQOL as good [19]. Furthermore, patients' ratings of their health and global HRQOL seem to be influenced by different factors. While perceived health status was greatly affected by physical functioning, it is less affected by emotional well-being. However, global HRQOL was influenced more by emotional well-being than physical functioning [20]. HRQOL encompasses not only perceived health status but also broad aspects of life.

3. The methodological issues in measuring HRQOL

Over the last three decades, the application of HRQOL measures to different diseases, conditions, and populations has increased. However, some criticism exists, for example, in the lack of conceptual clarity and measurement feasibility [21,22]. It is essential to define and operationalize HRQOL. The field of HRQOL assessment has become more sophisticated and methodologically rigorous [23]. Eiser and Morse (2001) reviewed HRQOL-relevant literature and provided performance characteristics for good measurement of HRQOL. The measurement should cover the full spectrum of behaviors that are thought to contribute to HRQOL (e.g., psychological, physical, social functioning), and include a generic core and disease-specific items. The usability of the instrument must be considered (e.g., the language, reading level, and burden to staff); it should be brief and easy to administer with proper reliability and validity for the groups of patients it is to be used [24].

Fitzpatrick and colleagues (1998) have also developed the following criteria to assess the standard of HRQOL measures: reliability, validity, precision (measures can distinguish health and illness), responsiveness (measures can detect clinically important changes), acceptability (patients are willing to complete measures), and feasibility (the timing and cost of measures are reasonable) [25]. In the following section, important issues in measuring HRQOL are addressed, including: (1) objectivity versus subjectivity, (2) generic versus specific, (3) unidimensional versus multidimensional, (4) self-report versus proxy report, (5) reliability, (6) validity, and (7) the criteria for selecting HRQOL.

3.1. Objectivity versus subjectivity

HRQOL includes both subjective and objective components [8,26–28]. Assessment of objective functioning and subjective

well-being involves different definitions and methodologies [28]. Subjective well-being has multiple facets, which depend on reactions in multiple physiological and psychological systems [29]. Subjective assessment includes the individual's perception or appraisal of HRQOL, such as emotional levels, satisfaction of life, and well-being [8,30]. Objective functioning is important in defining an individual's degree of health or ability, and an individual's subjective perceptions translate objective functioning into the HRQOL experienced [8]. In contrast, objective assessment focuses on what the individual can do, such as walking or self-care ability, and symptoms, such as pain, fatigue, or weakness.

A combination of HRQOL assessment and objective clinical indicators has become popular in evaluating the effectiveness and appropriateness of medical treatment and health-service methods [31]. HRQOL instruments can be used to assess the ripple effect of disease and symptoms on all aspects of life, and not just on a narrowly focused measure of target symptoms [23]. HRQOL assessment can incorporate these two characteristics.

3.1.1. Generic versus specific measures

A generic measure is referred to as a broad outcome indicator including physical, mental, and social health; a specific measure is used to assess only disease- or condition-related attributes [10]. Generic instruments are health profiles and utility measures [18]. In general, generic HRQOL measures should contain the dimensions of physical, emotional, and social functioning, as well as global perceptions of health and well-being [32]. Generic measures can be used to compare different types and severities of disease, treatments, or interventions, and their variations across demographic and cultural subgroups [18].

Unlike generic measures, a specific measure focuses on a special area of primary interest, where the instrument may be specific to the disease (e.g., cancer or heart disease), to a population of patients (e.g., children or elderly), to a certain function (e.g., sleeping or eating), or to a problem (e.g., pain) [18]. Disease-specific measures are used to assess a specific population or disease, with the goal of measuring responsiveness or clinically important changes [13,33]. Selection of different measures depends on the research objectives, patients' characteristics, and applications of measures in clinical research, practice, or policy analysis [13]. It is recommended that generic measures need to be supplemented with disease-specific measures to address clinically important positive and negative changes [18,33].

3.1.2. Unidimensional versus multidimensional measures

The results of HRQOL measures can be reported either as a single composite score or as a profile score [6]. Unidimensional measures use a single global question to present the overall HRQOL status [23]. The single item asks patients to evaluate their overall QOL status. For example, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) has one item which asks "How would you rate your overall quality of life during the past week?" [34] and the Functional Assessment of Cancer Therapy-Generic (FACT-G) has one item which states "I am content with the quality of my life right now" [35].

However, HRQOL is inherently multidimensional [28]. A domain or dimension refers to the area of behaviors or experience that researchers or physicians are trying to measure [18]. A majority of HRQOL instruments separately measure each domain by asking specific questions pertaining to its most important components [8]. There are several major HRQOL measures with international versions and norms that focus not only on overall HRQOL but also on specific domains. Examples of such measures are the EORTC QLQ-C30 [34,36], FACT-G [35], Short Form-36, [37,38], and World

Health Organization Quality of Life Assessment [39,40] (Table 1). These results can provide a health profile that measures various aspects of health status, for example, physical, psychological, and social functioning [6,8,41].

3.1.3. Self-report versus proxy report

The question arises about who should assess HRQOL. Sometimes researchers and physicians obtain HRQOL ratings from proxies instead of patients, because of the patients' physical conditions and limited time availability. For example, patients with terminal illness may be too weak to complete the instrument and children may be too young to understand the meaning of the items mentioned on the report. Therefore, views from caregivers or relatives are useful in understanding the HRQOL of such patients. However, the debate here is whether a proxy's rating can accurately represent a patient's HRQOL.

In one study, the Sickness Impact Profile was used to assess terminally ill patients (who still could complete the questionnaire) and the views of close relatives. The results of this study showed that only moderate correlation ($r = 0.55$) exists between the two ratings [42]. Therefore, it can be concluded that the relation between self- and proxy reports varies depending on the domains of measurement and the relationships between the proxy and patient [18]. One study found a high correlation in physical functioning between self- and proxy reports, but it did not find any significant correlation in psychosocial aspects [43]. In general, it is recommended that HRQOL ratings be obtained directly from patients, and researchers and physicians should limit inferences based on ratings provided by proxies or caregivers [5,18].

3.1.4. Reliability

Reliability refers to the stability and equivalence of repeated measures of the same concept [2]. A reliable questionnaire means it is accurate over time [44]. Generally, the various types of reliability for HRQOL measures are internal consistency, test–retest reliability, and inter-rater reliability [24].

Internal consistency refers to the homogeneity of items, that is, the extent to which the items of a domain or scale measure the same concept or construct. Cronbach α is the most widely used

statistical test to assess internal consistency [45]. Test–retest reliability refers to the stability of the measure over time, where two sets of scores that are administered on different occasions are positively correlated [44]. Inter-rater reliability refers to the consistency of measures between different raters, which is normally assessed using the κ statistic [46]. The minimum level of reliability depends on the type of analysis. In general, reliabilities in the 0.50–0.70 range are acceptable for making comparisons between groups [47].

3.1.5. Validity

Validity is the extent to which a test measures the construct it purports to measure [48]; for example, the HRQOL questionnaires should measure the status of HRQOL rather than some other criterion [24]. The various types of validity are content validity, criterion validity, and construct validity. Content validity refers to judgments about the extent to which the content of the measure logically includes a complete assessment of the characteristics or domains it is intended to measure [24]. Criterion validity is the extent to which a score corresponds to an accurate measure or a gold-standard measure. Construct validity refers to the extent to which a measure is a good representation of the construct. Convergent validity and discriminant validity are the two types of construct validity. In addition, factor analysis, confirmatory factor analysis, and multitrait-multimethod modeling are methods used for establishing construct validity [49].

3.1.6. Selection of HRQOL measures

Although many different instruments for measuring HRQOL are available, there is no best tool in an absolute sense, and there are only tools best suited to a particular condition [11]. The criteria for selecting and judging the appropriateness of measures include the following: (1) *appropriateness*: match of a measure to the specific purpose and questions of research; (2) *reliability*; (3) *validity*; (4) *responsiveness*: sensitivity to changes in important aspects; (5) *precision*: the number and accuracy of the distinction made by the measure; (6) *interpretability*: the meaning of scores; (7) *acceptability*: how acceptable is the completion of a measure for respondents; and (8) *feasibility*: the extension of effort, burden, and

Table 1
The characteristics of HRQOL measures.

	EORTC QLQ-C30	FACT-G	SF-36	WHOQOL
Number of items	30	27	36	100
Domains	Five functional scales: physical, role, social, emotional, and cognitive Symptoms: pain, fatigue, nausea/ vomiting, dyspnea, insomnia, appetite loss, constipation, diarrhea Financial impact Global QOL/general health	Physical well-being Emotional well-being Functional well-being Social and family well-being	Physical health: Physical functioning Role limitation (physical) Bodily pain General health Mental health: Role limitation (emotional) Vitality Mental health Social functioning	Physical domain Psychological domain Social domain Environmental domain
Reliability and validity	Cronbach $\alpha = 0.54$ – 0.86 . Construct validity (interscale correlations) and discriminant validities (between different diseases, performance status, and health status) were assessed.	Test–retest reliabilities = 0.72–0.92. Criterion-related validity (correlation with SF-36 and ECOG performance status), convergent and divergent validity (mood, interpersonal support, and social desirability), and discriminant validity (different treatment groups) were assessed.	Most reliabilities of all subscale >0.8. Content validity, construct validity (principal component factor analysis), and discriminant validity (groups with different physical/mental health status and severity) were assessed. Short form: SF-12 (12 items).	Cronbach $\alpha = 0.73$ – 0.85 ; Test–retest reliabilities = 0.66–0.87. Discriminant validity (healthy and unhealthy individuals) and construct validity (confirmatory factor analysis) were assessed. Short form: WHOQOL-BREF (28 items).

EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; FACT-G = Functional Assessment of Cancer Therapy-Generic; HRQOL = health-related quality of life; SF-36 = Short Form-36; WHOQOL = World Health Organization Quality of Life Assessment.

disruption to staff arising from using a measure [25]. Three possible methods can be used to improve HRQOL measures, namely, using global ratings, allowing supplemental items, and rating severity and importance [6].

4. The importance of HRQOL

HRQOL measures can be used to evaluate different methods of symptom management [50] and the effects of treatments [51] by incorporating physical indices such as survival rates, response rates, and mortality rates. There are three reasons why researchers and physicians should focus on HRQOL. First, HRQOL is useful in understanding the patient's point of view about the disease and the treatment methods applied. Second, there is value in understanding the "normal" process of adjustment to disease and treatment, and by implication, what is abnormal and when intervention is necessary. Third, HRQOL is an important consideration when comparing different treatments methods and evaluating interventions [11,52].

HRQOL measures can be one of several end points in clinical trials to help decide on the optimal treatment for patients and families [53–56]. HRQOL measures can help to clarify the trade-offs between treatments and interventions with major benefits and health-related outcome costs [5]. In particular, if the primary goal of treatment is to improve the way patients are feeling, it is imperative to measure HRQOL directly and use the results in clinical decision-making [5]. More importantly, HRQOL assessment is changing the medical paradigm from a disease-centered approach to a patient-centered approach [51], as well as addressing positive elements of life [29].

Effective and efficient methods of assessment, such as short forms or screening tools, can be developed and used in clinical care [57]. In addition, the integration of survival time and HRQOL into quality-adjusted life years can be useful for making clinical decisions about a specific treatment method and evaluation of health care service [58].

5. Conclusion

In summary, HRQOL has become an important end point in medical care and clinical trials [5,55]. It coordinates both objective functioning and subjective evaluations about an individual's health. Directly assessing a patient's experience with disease and treatment is also important for the comprehensive understanding of health status. Health care providers and researchers should provide conceptual and operational definitions of HRQOL, as well as specific domains of measurement [6,20]. Moreover, measures of HRQOL should consider the individual's social and material contexts [21].

HRQOL is an integrative index which combines objective functioning and subjective well-being, and may be presented in a health profile or a multidimensional format. The HRQOL rating should be assessed by patients directly. Individuals may simultaneously evaluate all dimensions to formulate the overall judgment; therefore, in the context of chronic disease, HRQOL is the appraisal outcome based on psychological functioning and to a lesser degree on physical functioning [20]. It can be considered as a representation of health outcomes instead of providing information on the pathology or the underlying disease state [59]. Measures of health outcomes should incorporate physical indices and the individual's perspectives as a outcome of adjustment.

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