

## ISSUES IN THE DEFINITIONS OF HRQoL

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Submitted: 2011-07-12

Accepted: 2011-08-30

Published online: 2011-12-15

### Abstract

Within literature there exists confusion about the health-related quality of life (HRQoL) concept. However, clarity in the meaning of HRQoL is critically important, because confusion hinders progress in research and applications in clinical practice. HRQoL is used as an umbrella term to cover a wide range of patient reported outcomes including measures of health status, living conditions or well-being. The paper reviews the literature and discusses the important issues regarding the conceptualisation of health related quality of life in health sciences. It provides a brief description of historical development; concepts/definitions and clinical application HRQoL in health care and research. The aim of this paper is to discuss controversies or contradictory issues that currently exist concerning HRQoL and its measurement. The author proposes that future debate around HRQoL should focus from HRQoL instruments/measures to issues in HRQoL conceptualisation.

**Key words:** *health related quality of life; quality of life; health; patient reported outcomes*

### Abbreviations:

HRQoL – health-related quality of life  
PROs – patient-reported health outcomes  
QoL – quality of life  
QALY – quality adjusted life years  
SWB – subjective well-being

### INTRODUCTION

Traditional medical evaluation of patient outcomes with chronic diseases focuses primarily on “hard” clinical outcome measures, such as clinical symptoms, lab parameters, disease complications or compliance with various aspects of a treatment regimen. However, clinicians, researchers and policymaker have come to realise that these outcomes are not adequate in assessing the impact of a disease or its treatment in a patient’s daily life. From the point of view of the patient, relevant health outcomes include

not only physiological measures, but also subjective factors such as disease self-management burden, social and role functioning, burdens in performing daily activities etc. (Watkins and Connel 2004). Information about these outcomes can usually be supplied most accurately by the patients themselves.

More recently, there has been a growing body of research concerning endpoints that are assessed directly by patients and can be termed “patient-reported health outcomes” (PROs). It is an umbrella term used for all patient-based assessments. The U.S. Department of Health and Human Services, The United States Food and Drug Administration (2009) defined PRO as “a measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient’s health condition without amendment or interpretation of the patient’s response by a clinician or

anyone else". Examples of PROs are outcomes such as health status, health utilities, adherence to treatment, patient satisfaction with healthcare and quality of life.

Quality of life (QoL) represents an important aspect of PROs in current health care and health management. Interest in quality of life assessment has continued to increase in recent years. International activities also illustrate the increasing importance of QoL assessment and research (Grant and Dean 2003). The United States Food and Drug Administration use QoL measurements in the process of approving new drugs. National and international groups advocating QoL assessment in clinical trials research have recognised its importance (Grant and Dean 2003). Interest in QoL research has resulted in a major shift in randomised clinical controlled trials. In addition to clinical trials, QoL assessment has evolved into a primary outcome measure in health services research, acute care, and chronic illness (Grant and Dean 2003). This evolution coincides with recent economic changes and pressures to reconcile quality care and cost effectiveness (Zebrack 2000, Omery and Dean 2004).

Today QoL assessment measures are now routinely used to evaluate the human and financial costs and benefits of different health programmes and medical interventions (Galloway et al. 2005). A PubMed/MEDLINE database search for the term "quality of life" identified over 57,742 articles for the last five-year period.

### **Development of the health-related quality of life construct**

When defining QoL as it applies to health care, the term Health-related Quality of Life (HRQoL) is commonly used to focus on the effects of illness and treatment (Ferrans 2005). The WHO definition (WHO 1948) of health was an important milestone in the development of QoL studies within health care (Galloway et al. 2005). HRQoL is a primary component of QoL and is considered to be an important construct in describing one's overall condition within the health context (Fayers and Machin 2000, Schlarman et al. 2008).

Cummins and Lau (2006) note that during the 1970s, researchers from the three disciplinary areas of economics, health care

and the social sciences were all developing alternative conceptualisations of the population "life quality". This resulted in three distinct forms of measurement, as follows:

- *Quality Adjusted Life Years (QALY)*: a product that shares the disciplines of economics and medicine.
- *Health-related Quality of Life (HRQOL)*: a product of the discipline of medicine.
- *Subjective well-being (SWB)*: a product of social sciences.

While each of these three approaches includes measures of health, their methodologies are so different from one another as to yield indexes that have remarkably little in common (Cummins and Lau 2006). Within medicine, nursing or in the health care area in general, QoL has been operationalised via the HRQoL construct. Over the past 30 years, HRQoL has evolved into a respect construct for evaluating the effectiveness of treatment in health care (Ferrans 2005).

### **Purpose of HRQoL measurement**

QoL is proposed as a goal for health care (Omery and Dean 2004), as an endpoint (Gotay et al. 1992), as an outcome of treatment, and as a means of rank-ordering treatments for allocating resources. The conceptualisation and measurement of QoL are vital to health policy, evaluation research, and clinical decision making (Omery and Dean 2004).

The use of HRQoL instruments is particularly important in chronic conditions where a major objective of management is to arrest or reverse the decline in function and quality of life. Given the wide-ranging effects that chronic conditions and their treatment can have on quality of life it is perhaps not surprising that there have been a large number of attempts to develop patient-assessed health outcome measures (Garratt et al. 2002).

During the last 15 years there have been numerous attempts to develop patient-assessed measures of health outcome for specific diseases (disease-specific HRQoL instruments and situation-specific instruments) that can be used in clinical practice or research. Many controversies currently exist concerning HRQoL and its measurement (King 2003). How we define and measure the HRQoL of individuals

reflects much of the ongoing debates related to QoL in general. A more basic question is, *Why should we study or use the concept of HRQoL?* This answer may be examined at the level of the individual, the health care providers, or national health care policy (Spilker 1990, King 2003). When addressing the question at the level of a patient with chronic disease, the answer is to improve the quality of the individual's life and treatment. When evaluating a particular therapy, health care providers may evaluate QoL in clinical trials to differentiate between two therapies. Health care providers are concerned with QoL because it may alter prescribing habits, treatment regimens, and the decision to cease treatment. At the national health care policy level, QoL is an important concept used to improve the allocation of insufficient health care resources to solve all the health care problems (Spilker 1990).

There are several reasons why QoL assessment is included in health care. HRQoL outcomes may be included in clinical trials of treatments with curative or palliative intent, in improving symptom relief, care, or rehabilitation. Another reason for assessing HRQoL is to establish information about a range of problems that affect patients. Information about QoL may facilitate patient communication, and help to determine patient preferences (Fayers and Machin 2000) and establish a therapeutic relationship. Despite its importance, there is still no consensus on the definition or proper measurement of QoL (Speight and Shaw 2007). There is a very wide range of definitions and interpretations of QoL (Haas 1999). HRQoL can be considered as a latent theoretical construct which cannot be measured directly but only indirectly using indicators (Bullinger and Ravens-Sieberer 1995). Within the literature there exists confusion about what QoL is, what *contributes* to QoL, and what the *outcomes* of QoL are (Hagerty et al. 2001). There has also been a tendency to conflate QoL with other concepts, and to use the different concepts interchangeably. The most cited examples of these are life satisfaction, happiness, well-being, health status and living conditions, all of which are sometimes used interchangeably with QoL (Galloway et al. 2005).

In the absence of any agreed formal definition, most investigators circumvent the

issue by describing, what they mean by QoL, and then letting the items in their instrument speak for themselves (Fayers and Machin 2000).

Regarding application of HRQoL in the health care mentioned above, clarity in HRQoL meaning is critically important, because confusion hinders progress in research and applications in clinical practice. This misuse of terminology coupled with the wealth of measures that have been misinterpreted as measures of QoL make it almost impossible to compare studies and to determine the relative effects of one intervention against another (Speight and Shaw 2007).

### Definitions of HRQoL

Speight and Shaw (2007) note that although many of the studies reviewed the purpose to assess QoL, they use a variety of measures which differ substantially in their content. Very few of these can be said to accurately measure the impact of disease or its treatment regimens on overall QoL. Many clinical trials in recent years have included some measure of QoL, most of these measures have been derived from various narrow conceptualisations of HRQoL. Others appear to have no conceptual framework at all.

There is no uniform definition of HRQoL. The debate around the definition of HRQoL centres upon the following issues:

- the relationship and distinction between “health-related quality of life” and “quality of life”;
- the relationship and distinction between “health” and “quality of life”;
- distinction between indicators and HRQoL predictors, or between indicator and causal variables of QoL.

These fundamental questions remain unresolved, resulting in contradictory definitions of the HRQoL concept. There is a general consensus in the conceptualisation of HRQoL as a multidimensional construct built up by three main domains. Physical, emotional and social aspects of health are commonly considered as the core domains of HRQoL. These three domains follow the WHO definition of health as a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity. In addition to these domains, economic and

spiritual domains are commonly included (Ferrans 2005).

Despite conceptual inconsistencies, there is a general consensus that HRQoL include the following defining attributes:

- HRQoL is *multidimensional* (e.g. The WHOQOL Group 1995, Testa and Simonson 1996, Haas 1999, Ferrans 2005, Speight and Shaw 2007 etc.). It means that each person thinks about different aspects of their life when attempting to evaluate their own QoL. This suggests that QoL has several dimensions, e.g. physical, social and psychological, spiritual, and that respondents should be given the opportunity to rate each one subjectively (Speight and Shaw 2007).
- HRQoL is *subjective and value based* (e.g. The WHOQOL Group 1995, Testa and Simonson 1996, Haas 1999, Ferrans 2005, Speight and Shaw 2007 etc.). It means that each person rates their own QoL from their unique perspective based upon their own feelings, experiences and priorities. People use their personal standards for what they consider a desirable or undesirable QoL. This suggests that respondents should be given the opportunity to indicate whether or not a given domain (e.g. working life) is applicable to them (and to exclude irrelevant domains from their QoL score) and then to rate the relative importance of relevant domains for their overall QoL (Speight and Shaw 2007). Personal evaluation provides an understanding of the impact of illness from the viewpoint of the patient, which is different from their health status.
- HRQoL is *dynamic*. It means that each person's assessment of their own QoL will change over time, dependent upon his or her priorities, experiences and circumstances at the given time. This suggests that at one time, for instance, an individual might give greater weight to their 'working life' than at another time, such that QoL priorities vary within as well as between people (Speight and Shaw 2007).
- HRQoL is defined in terms of *perceived status* (e.g. WHO 1995) or subjective evaluation (Ferrans 2005). Both kinds of definitions provide subjective information about a person's life. In HRQoL instru-

ments, the wording of items "I suffer from pain because of diabetes"; or "I have the impression that I am less attractive to others because of diabetes" would elicit perceived pain or social status, whereas the question "How satisfied are you with the amount of pain relief you have or how satisfied are you with your social relationships" would elicit an evaluation (Ferrans 2005).

- HRQoL involves the individual's perceptions of both *positive and negative dimensions* (WHOQOL GROUP 1995). QoL measures are designed to capture the totality of life experiences, both positive and negative (Hagerty et al. 2001). The ultimate objective for assessment of HRQoL is enhanced well-being. Focusing on health problems, loss of abilities, or deficits in comparison to a normative ideal do not promote the positive objective of enhanced well-being (Ferrans 2005). On the other hand, some authors are sceptical of notions such as HRQoL and the use of generic or disease-specific quality of life measures. For example, Cummins and Lau (2006) argue that "HRQoL scales represent a mish-mash of medical ill-health, functional limitations and psychopathology". Several studies included in the structured reviews of HRQoL instruments for diabetes (Garratt et al. 2002, Watkins and Connell 2004) form an implicit assumption that having diabetes results in compromised QoL. In fact, there is much to be learned by focusing on the possible positive aspects of chronic disease-self-management. For example, improved QoL may occur not only as a result of minimising perceptions of diabetes self-management as a burden, but as a result of maximising other possible perceptions: meeting and overcoming self-management challenges, opportunities for self-development, role-modelling for others and in addressing the spiritual aspects of health (Watkins and Connell 2004).

### QoL versus HRQoL

QoL is a general concept that implies an evaluation of the impact of all aspects of life on general well-being. Because this term implies the evaluation of non health-related aspects of life, it is too broad to be considered appropriate for a health care claim (Bradley 2006).

Health-related QoL is concerned with QoL within the specific context of health (Galloway et al. 2005). Several authors (Spilker and Revicki 1996, Padilla and Frank-Stromborg 2004, Ferrans 2005) identified some issues surrounding the HRQoL construct. One issue concerns the distinction between QoL and HRQoL. Fundamental questions are associated with this issue – What aspects of life distinguish between QoL and HRQoL constructs? What attributes of QoL are most salient to ill and to healthy people? How do these characteristics differ between people with a differing culture, functional status etc.? Ferrans (2005) argues that HRQoL is used to distinguish these aspects of life from those that are beyond the realm of health care, such as standard of living, education, public safety etc. Thus, QoL has a more generalised meaning than HRQoL. HRQoL draws a line between those facets of life that are primarily health related and those that are not (Ferrans 2005). Spilker and Revicki (1996) developed taxonomy for non-HRQoL, composed of four domains:

- personal-internal (facets within the individual that influence perceptions and interactions with the environment);
- personal-social (the individual's social network and immediate social environment);
- external-natural environment (geographical and natural environment);
- external-societal environment (organisations and institutions created by society).

However, Spilker and Revicki (1996) note that the distinction between HRQoL and non-HRQoL is fluid, in that each component can become health related. In addition, when an individual becomes ill, almost all areas of life can become health related (Guyatt et al. 1989).

HRQoL means that the summary of attributes that characterise one's life is made at a point in time when health, illness, and treatment conditions are relevant. The relevant characteristics of a healthy person's QoL may not include physical, emotional or biomedically defined health, but rather social relationships, financial success, and a satisfying job. On the other hand, a person whose health is threatened by acute or chronic illness will likely attribute certain dimensions of life quality to the influence of

health problems, health status, and health care and health-promoting activities (Padilla and Frank-Stromborg 2004).

### **Health versus HRQoL**

QoL was used as an umbrella term to cover a wide range of PRO measures including measures of health status which are actually measuring the quality of health and not quality of life (Bradley 2006).

Singh and Bradley (2006) present that "... literature is full of reports, claiming to measure QoL using questionnaires, which in fact are actually measures of health status and measure quality of health rather than QoL. It is likely that health status will have some correlation with how good or bad a person feels their life to be, but quality of health and QoL are not the same thing. Efforts to achieve excellent health may damage QoL". For clinicians, optimal health may be perceived as the ultimate outcome and the one thing that they can aim to influence (Singh and Bradley 2006). Thus, health status becomes confused with QoL and is often referred to as HRQoL, perpetuating the confusion (Speight and Shaw 2007). Therefore, results can be highly misleading if we interpret health status measures as if they are measures of QoL (Singh and Bradley 2006). Bradley (2006) gave the example of the influential UK Prospective Diabetes Study (UKPDS) as one which used health status measures but interpreted their findings as if they were measuring quality of life. Sawatzky (2007) notes that despite this ambiguity in the conceptualisation of quality of life, some researchers have developed conceptual models in an attempt to describe the relationships between quality of life and health (Vallerand and Payne 2003, Ferrans 2005). These models generally imply that the presence of disease results in symptoms that affect various so-called dimensions of quality of life, such as physical, psychological, and social functioning, which in turn contribute to the overall quality of life (e.g. Wilson and Cleary 1985). Most models also account for the presence of a variety of psychological processes (e.g., coping, adaptation and personality) and social, cultural and environmental factors (Sawatzky 2007).

Based on a meta-analysis of studies that used instruments measuring various health status indicators, Smith et al. 1999 (cited in:

Sawatzky 2007) showed that "... variation in quality of life was explained by variables pertaining to various life domains, which were affected by differences in physiological health status (e.g., the presence of disease) and symptom severity. Examples of life domains in their meta-analysis include variables that reflected psychological, social, or physical functioning". Quality of life was represented by measures of life satisfaction, wellbeing and single-item quality of life indicators. Thus, their model of the determinants of quality of life is based on the proposition that the life domains mediate the degree to which quality of life is explained by differences in symptom severity and physiological health status. Although mental health status and physical function were both fairly strongly correlated with life satisfaction, a regressive quality of life on mental health, physical function, and social function reveal that mental health status was by far the most important explanatory variable. The authors concluded that health status is conceptually distinct from quality of life (Sawatzky 2007).

In the study of people who underwent coronary artery bypass graft surgery, Beckie and Hayduk (2004) found that "quality of life can be considered as a global personal assessment of a single dimension, which may be causally responsive to a variety of other distinct dimensions including dimensions such as health" (Beckie and Hayduk 2004). The conceptual models by Smith et al. (1999) and Beckie and Hayduk (2004) are based on the premise that health and quality of life constitute distinct concepts, and that quality of life can be viewed as a one-dimensional concept that is to some degree influenced by health (Sawatzky 2007).

### **Determinants versus dimensions of HRQoL**

A number of conceptual models of HRQoL have been proposed. The majority of conceptual models of HRQoL (e.g. Ferrell et al. 1991, WHOQOL GROUP 1995, Spilker and Revicki 1996, Ferrans 2005) focus on the identification of domains and their components. However, relationships among domains in these models are usually not specified, other than to say there are mutual simultaneous interactions among them. The current challenge is to develop causal models

that identify relationships among critical elements (attributes) of HRQoL and the variables that are determinants (or predictors) of them (Padilla and Frank-Stromborg 2004, Ferrans 2005). This is important because it will allow for distinction between process and outcome variables.

The following models are an illustration of different ways of viewing the relationships between determinants and domains of HRQoL. Padilla and Frank-Stromborg (2004) present that "the model proposed by Ware (1984) suggest that disease has its most immediate impact on personal functioning, then psychological well-being, followed by general health perceptions and social/role functioning. In contrast, the model proposed by Ferrell et al. (1991) conceptualises pain from cancer and its treatment as having an independent impact on the HRQoL domains". Wilson and Cleary (1985) described a model wherein physiological and psychological symptoms affect functional status, which affects general health perceptions and quality of life. Padilla and Grant (1985) proposed the nursing model of QoL that depicted the dimensions of QoL as dependent outcome variables and nursing process activities manipulated by the investigator as independent variables. Mediating variables affecting QoL are cognitive-emotional changes in the client that enhance self-perceptions and can be affected by nursing care. As the mediating variable is regarded as a necessary antecedent to QoL, the nursing process is viewed as having an indirect impact on QoL. Extraneous variables are those not being manipulated by the investigator but potentially affecting the outcomes, such as treatment characteristics, either in a statistical or direct way (Padilla and Grant 1985). Ferrell et al. (1991) then used the Padilla model as a conceptual framework for the development and testing of an instrument to measure QoL as an outcome variable in the management of cancer pain. The lack of a distinction between determinants and attributes of HRQoL in definitions of the construct leads to conceptual and operational confusion (Padilla and Frank-Stromborg 2004). This distinction is important for future understanding of interventions that can maintain or improve HRQoL. Padilla and Frank-Stromborg (2004) gave the following example – "Pain

is identified as a symptom of cancer or side effect of treatment that has an impact on HRQoL. At the same time, evaluation of pain distress, intensity, and frequency are used as a basis for QoL scores. Generally, pain should not be treated as both the cause and effect.”

## CONCLUSION

The term QoL has been inappropriately used to refer to a variety of patient-reported outcomes,

including treatment satisfaction, health status and well-being. While each of these outcomes may be important for QoL, they are not QoL *per se*. The future debate around the HRQoL should focus from HRQoL instruments to issues in HRQoL conceptualisation – the relationship and distinction between “health-related quality of life” and “quality of life”; the relationship and distinction between “health” and “quality of life”; distinction between HRQoL indicators and predictors, or between indicator and causal variables of QoL.

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