Methods and problems in measuring quality of life

Abstract  The US health-care transition demands increased accountability for medical care. This has contributed to increased interest in documenting valued medical outcomes, including improvements in health-related quality of life and treatment satisfaction. These data can only be obtained validly by asking patients directly about their current health state, perception of well-being, and satisfaction with care. A core set of well-validated instruments have been developed to measure health-related quality of life in patients with cancer. As these are employed with increasing frequency, rigorous quality assurance of data collection is critical. Because of the necessity of quality control, patient-reported data collection can be labor-intensive and prohibitively costly. However, time and cost-saving methods, such as centralized telephone survey methods or on-site direct data entry via interactive computer, can guarantee high-quality data while minimizing costs. Justification of the need for these methods and a brief description are provided.

Key words  Data collection methods · Quality of life Health-related quality of life Quality assurance

Introduction

The term quality of life, or health-related quality of life (HQL), has emerged to organize and galvanize a collection of outcome-evaluation activities over the past two decades in cancer treatment research. Prior to this, length of survival, regardless of its quality, was considered to be the only primary outcome in oncology treatment research. It is now widely accepted that in most circumstances quality of survival is as important as quantity of survival. This implies that a severely toxic treatment must be evaluated for its detrimental impact as well as its survival benefit. It also raises a less obvious point: treatments can be considered efficacious if they improve the quality of life even in the absence of survival benefit. Thus, investigating the impact of cancer treatments on HQL is a two-tailed enterprise where treatment toxicity is traded not only with survival time but also with post-treatment function and well-being.

Health-related quality of life (HQL) evaluation entails a multidimensional quantification of patient functional status, usually as perceived by the patient [1, 7, 13, 14, 20, 22, 25, 37, 38, 47, 52, 58]. In the decades to come, treatment-intensification strategies that increase toxicity are likely to continue, given the advent of hematopoietic growth factors and improved antiemetic regimens. This further increases the importance of evaluating toxicity, patient function, and patient preferences for treatment. HQL evaluation differs from classical toxicity ratings in two important ways: (a) It incorporates more aspects of function (e.g., mood, affect, social well-being) than those which have typically been attributed to treatment; and (b) it focuses on the patient’s perspective.
Evaluating methods of assessment

Along with the evolution of interest in HQL, many efforts to measure the construct have been created and promoted. A number of validated quality-of-life measures have become accepted for use in oncology in particular [2, 3, 15, 16, 26, 43, 45] and chronic illness in general [4, 8, 24, 30, 34, 36, 49, 60]. The diversity of available measures is potentially valuable in that it provides the user with choices based upon specific characteristics of a given disease site, clinical trial, or quality-of-life domain of interest. This paper provides the reader with some understanding of criteria to evaluate whether an HQL measure is likely to perform well in a clinical trial. Suggestions that can be helpful in the preparation of protocol documents have been published elsewhere [29].

There are many definitions of HQL [11, 13, 28, 44, 53]. Different measures of HQL are not necessarily equivalent and one must therefore be clear on the dimensions of HQL as measured by a particular instrument. Definitions of HQL may differ across study groups and still be measured reliably and validly within the parameters of a definition [19, 31, 59]. For example, most agree that important HQL domains include physical, mental and social dimensions. Whereas virtually all currently accepted HQL measures provide some ability to separate physical and psychological dimensions, social functioning is much less evenly represented. Some measures cover social well-being and function more than others. For example, deHaes et al. [19] do not measure social functioning as a component, and yet this scale can be evaluated for reliability and validity within its range of items.

Approaches to measuring quality of life

Over time, two approaches to measuring HQL have evolved: psychometric and utility. These approaches have evolved relatively independently of one another, largely because they were developed within different scientific disciplines. Psychometric approaches derive from psychology whereas utility approaches derive from economics. Only recently have investigators considered integrating these two approaches. This remains a critical challenge in HQL measurement.

Psychometric approaches

The psychometric approach includes generic health profile measurement (e.g., short forms from the Medical Outcomes Study [30, 60]) and specific instruments intended to measure the multidimensional impact of a specific disease, treatment or condition (e.g., the Functional Living Index – Cancer [45]). The psychometric approach places heavy emphasis upon an individual's response and response variability across individuals. An important contribution of the psychometric approach is that it provides measurement of subjective or perceived well-being. Psychometric measures may or may not include a summary or total score. When available, only rarely have these summary scores been connected to patients' value for their current health status. This poses a problem, because without a rating of patient preference, one cannot appropriately make a decision about the value of a given treatment to a given patient. Very often, one of two patients with identical disease and treatment options will decline therapy while the other will accept it enthusiastically. Because psychometric measures typically do not incorporate patient-specific weights for individual domains nor anchor states of health to a common standard, evaluating trade-offs between quality and length of life, or between one dimension of HQL and another, is difficult. This presents a challenge in a clinical trial where the primary purpose for integrating HQL measurement is to incorporate data on the impact of treatment on both length and quality of life into conclusions about treatment efficacy. The collection of patient preferences in clinical trials would allow the effect of treatment on quality-adjusted survival as well as on conventional outcome measures to be evaluated. Further, the addition of patient preference assessments to clinical trial outcome evaluation can make it possible to distinguish patients who favor one treatment over another when both may have an equivalent survival outcome. A strategy for doing this has been described by Till and colleagues [54].

Utility approaches

In contrast to the psychometric approach, the utility approach is explicitly concerned with decisions about treatment, usually at a policy level. In this approach, treatments are typically evaluated for their benefit compared in some way to their cost. The utility approach to health status measurement evolved from a tradition of cost/benefit analysis, into cost/effectiveness approaches and, most recently, cost/utility approaches [21]. The cost/utility approach extends the cost/effectiveness approach conceptually by evaluating the HQL benefit produced by the clinical effects of a treatment, thereby including the (presumed) patient's perspective. To be used this way, HQL must be measured as a utility since, by definition, utilities can be multiplied by time to yield a meaningful quantity. Two general cost/utility methods are the standard gamble approach and the time trade-off approach [55]. In the standard gam-