

HEALTH-RELATED QUALITY OF LIFE IS A PATIENT-REPORTED OUTCOME THAT WILL BE A CRUCIAL ELEMENT IN THE EVALUATION OF EXISTING AND EMERGING HEALTH CARE TECHNOLOGIES AND MEDICAL PRACTICES

Quality of life assessment: Understanding its use as an outcome measure

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ABSTRACT The limited available evidence of the effectiveness of many existing and emerging medical practices has led to the realization that health outcome data should be used in the evaluation of health care interventions. Interest in improving health outcome evaluation is increasing as a result of the need to balance the costs and benefits of medical technologies. Measures of health-related quality of life are receiving greater use in clinical studies. Quality of life measurement provides additional data for making clinical and health care policy decisions. In addition, there is growing awareness that in certain diseases, quality of life may be the most important health outcome to consider in assessing treatment efficacy. There are a number of methodological issues that must be considered in conducting or evaluating quality of life research.

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Our society has reached a point at which we no longer can afford to assume that medical interventions are producing the desired results. The lack of introspection and unthinking allegiance to assumptions within the health care delivery system are now exacting a heavy price. The price includes runaway medical care cost inflation with minimal evidence of the true effectiveness of many current and emerging health care practices.¹ In addition, measures of the

overall quality of the US health care system, such as access to primary health care, health indicators (eg, infant mortality and life expectancy), and public satisfaction in relation to costs, provide evidence that we trail other countries that spend significantly less than the US does on medical care.²

What are the outcomes produced by the enormous amount of resources being expended on health care? The answer to this question is crucial to understanding

and improving the quality and cost effectiveness of specific medical interventions and the US health care system as a whole. Until relatively recently, that question was not posed, and therefore not answered, in a substantive manner. However, it has become quite clear that the prevailing modes of health care evaluation are inadequate.³ Different information is needed.

One way of obtaining a more complete and satisfactory answer is through the assessment of health care outcomes. Outcomes research considers more than survival and the biomedical parameters that have traditionally been measured.⁴ In the past, effects of health care interventions have been measured, especially at the national level, by condition-specific mortality and morbidity rates.⁵ With certain chronic conditions, such as arthritis, the generally non-life-threatening nature of the disease has made it difficult to assess outcomes using traditional measures.⁶ Interest in improving health outcome assessment is increasing as a result of the need to balance the costs and benefits of existing and emerging health care technologies. Health-related quality of life is a concept that is receiving a great deal of attention as a health care outcome measure. The purpose of this paper is to briefly review outcomes assessment and to explore the concept of quality of life as a health outcome measure.

OUTCOMES ASSESSMENT

Relman suggested that the United States is entering the third era in

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modern medical care: the era of assessment and accountability.⁷ This era follows the era of expansion (ie, the late 1940s through the 1960s) and the era of cost containment (ie, the 1970s and 1980s). The excesses or failures of earlier eras led to the next. An essential element of the new era is a growing consensus that health outcome data should be used in the evaluation of health care interventions.^{8,9} Many groups (eg, the federal government, third-party payers, accrediting bodies) with influence over health care provision traditionally have emphasized the structure and process of health care delivery rather than the outcomes. The actual outcomes of health care often have been assumed to be the desired results or have been evaluated superficially based on less than optimal measures.

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However, the health care environment is changing dramatically. For a number of reasons (primarily economic), all the major stakeholders—payers, providers, regulators, manufacturers, and patients—are focusing increasingly on the out-

comes that medical care products and services produce.¹⁰ The specific questions being asked include: Are patients actually benefiting from the treatments they are receiving? Of all the alternatives available, what treatments work best for patients? Are patients getting the most value for the health care dollars spent? Outcomes research is an effort to answer those questions and is "designed to help patients, payers, and providers make rational medical care-related choices based on better insight into the effect of these choices on the patient's life."⁸

The outcomes of medical care can be characterized in a number of ways. One way is to divide them into three outcome areas: clinical, patient-reported, and economic. Clinical outcomes are the more objective biological parameters that have traditionally been used to evaluate the results of therapeutic interventions, such as blood pressure and cholesterol level. It must be pointed out that clinical outcomes are intermediate outcome measures and are not necessarily predictive of the actual impact a disease or its treatments has on a patient's life. Whereas patient-reported outcomes are the effects of medical care from the patient's perspective, such as functional status and well-being, or health-related quality of life. The use of health-related quality of life as a patient-reported outcome measure has resulted from the need to describe the overall effect of medical interventions in a way that makes sense to both patients and health care providers.¹¹

Economic outcomes refer to the resources consumed to produce a given outcome. Measures of economic outcome usually incorporate the clinical and patient-reported outcomes in the evaluation of economic efficiency. For example, cost-effectiveness analysis can be used to compare the costs associ-

ated with achieving a specific clinical outcome, such as a 10% decrease in cholesterol level, through alternative therapies. Likewise, cost-utility analysis is an evaluative technique used to examine the economic efficiency associated with achieving a patient-reported out-

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come. It uses treatment costs as the numerator and a preference- or utility-weighted outcome measure as the denominator, eg, cost per quality-adjusted life year (QALY). The QALY is an outcome measure that combines both quantity and quality of patients' lives. (For more information on pharmacoeconomic evaluation tool definitions, see part 1 of this series in the April issue (1993;28:365-78)).

QUALITY OF LIFE

One of the essential elements of outcomes research is the assessment of patient health-related quality of life. However, there is no consensus on the definition of quality of life or its overall conceptual framework.¹² In the literature, the term quality of life has been used in a variety of ways. Kaplan and Bush proposed that studies of

TABLE 1 COMMONLY MEASURED DIMENSIONS IN QUALITY OF LIFE ASSESSMENT

- Physical status and functioning
- Social/role functioning
- Emotional/psychological status
- Disease- and/or treatment-related symptomatology

health outcomes use the term health-related quality of life to distinguish health effects from the effects of job satisfaction, environment, and other factors that influence perceived life quality.¹³ Only health outcomes are discussed in this paper so the terms quality of life and health-related quality of life are used interchangeably. In addition, for the purpose of this paper, no distinction is made between the concepts of quality of life and self-reported health status.

Quality of life, like other aspects of the human experience, is hard to define. In much of the medical research literature, explicit definitions of quality of life are rare. However, some authors have provided definitions. For example, Schron and Shumaker define quality of life as "a multidimensional concept referring to a person's total well-being including his or her psychological, social, and physical health status."¹⁴ Patrick and Erickson propose that quality of life is "the value assigned to duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy."¹⁵

Although the two definitions differ in certain respects, a conceptual characteristic that they share is the multidimensionality of quality of life. Quality of life is commonly viewed as having several dimensions or domains. These are listed

in table 1. Since therapeutic interventions can enhance as well as decrease quality of life, health care providers should strive to achieve enhanced quality of life as an outcome of therapy. Although we must assume that quality of life has always played an implicit role in the provision of health care, it has not been viewed as equal in importance to the more clinical or biological outcome parameters (eg, blood pressure, cholesterol level).¹⁶ The subjective nature of quality of life assessment has made many people uneasy with it as a measure of the patient outcomes produced by medical treatment.¹¹ However, there is growing awareness that in certain diseases, quality of life may be the most important health outcome to consider in assessing treatment efficacy.¹⁶

QUALITY OF LIFE AND PHARMACOTHERAPY

As with health care interventions in general, quality of life is being viewed increasingly as a therapeutic end point of pharmacotherapy. An overriding factor leading to this has been the gradual shift in the pattern of illness in our society from a predominance of acute disease to one in which chronic conditions predominate. Although there are many diseases that can shorten life expectancy, it is more likely that a disease will have adverse health consequences lead-

ing to dysfunction and decreased well-being. Therefore, managing symptoms and maintaining function is often the primary objective of a medical intervention. Medications are used extensively as a means of maintaining and/or enhancing patients' quality of life.

Another, more specific, reason for the increased interest in the impact of pharmaceuticals on quality of life is that its measurement provides additional data for making clinical and health care policy decisions. For example, alternative treatments may have equal efficacy based on traditional clinical parameters (eg, blood pressure reduction) but produce very different patient-reported outcomes. Thus, a prescriber's selection among competing alternatives may hinge upon documented differential effect on quality of life. A perceived decrease in quality of life attributed by the patient to an adverse effect of the drug may lead to a decrease in adherence to the medication regimen. In addition, public and private health care policy makers at all levels are concerned about the costs of medical care. They are demanding more information to facilitate policy decisions (eg, formulary additions, level of reimbursement) and to assist in measuring the outcomes achieved for the health care dollars expended.

The inclusion of quality of life data in economic analyses of alternative therapies is becoming increasingly prevalent and involves the comparison of the costs and the outcomes of the interventions. It is no longer acceptable to make a selection between two medications of equal clinical efficacy based on the acquisition prices alone. One of the medications may be more appropriate because it produces better outcomes relative to its cost than does the alternative. Quality of life assessment can assist by providing documentation of differential patient outcomes.

ASSESSING QUALITY OF LIFE

However defined, measurement of health-related quality of life should focus on health outcomes that are traditionally regarded as within the domain of medical care. The use of established assessment instruments provides a basis for comparison to the existing literature and a higher degree of confidence in the results. Although there are a number of well-established quality of life instruments available, many investigators have developed their own instruments. Many of these measures have unknown scale properties, unknown psychometric characteristics, and do not provide a basis of comparison with other studies in the literature.¹⁷

In addition, there are a number of other methodological issues that must be considered in quality of life research. These issues include: the use of general or disease-specific instruments; the use of index or profile outcome measures; the quality of life dimensions measured; the relative importance of the dimensions; and the reliability and validity of the assessment instruments.

General or disease-specific instruments. A general or generic measure of quality of life is designed to be applicable across all diseases or conditions, across different medical interventions, and across a wide variety of populations.¹⁸ Disease-specific measures are designed to be used in populations with specific conditions or diagnoses. The disease-specific approach assumes that each medical condition has very specific outcomes and, therefore, greater detail concerning specific functions affected by the condition or its treatment should be included. However, some investigators believe that all conditions have a general effect on quality of life and that the purpose of quality of life assessment is not to identify clinical information relevant to a specific disease, but to

TABLE 2 EXAMPLES OF QUALITY OF LIFE ASSESSMENT INSTRUMENTS

Generic or general

Medical Outcomes Study (MOS) Short Form 36 (SF-36)
Nottingham Health Profile (NHP)
Quality of Well-Being (QWB) Scale
Sickness Impact Profile (SIP)

Disease-specific

Arthritis

■ Arthritis Impact Measurement Scale (AIMS)
■ Health Assessment Questionnaire (HAQ)

Cancer

■ Functional Living Index - Cancer (FLIC)
■ European Organization for Research on Treatment of Cancer Quality of Life Questionnaire (EORTC-QLC)
■ Linear Analogue Self-Assessment (LASA)

Chronic lung disease

■ Chronic Respiratory Disease Questionnaire (CRQ)

determine the effect of the condition on general function and well-being.¹⁹ The concern is that by focusing too specifically on clinical correlates of a disease or condition, the general or overall effect is overlooked.

In studies involving pharmacotherapy, the use of both generic and disease-specific assessment instruments may be the best approach.²⁰ The generic instrument will provide a more holistic outcome score and allow comparability across other disease states in which it has been used. An appropriately selected disease-specific instrument will provide more detailed clinical information regarding expected changes in the particular patient population.

Table 2 provides examples of some of the many generic and disease-specific instruments in use. For a much more comprehensive list, see the work of Spilker and

colleagues.^{21,22} They have compiled a bibliography of the English language health-related quality of life literature.

Index or profile outcome measures. Quality of life is a multidimensional construct; however, its general measurement can result in a single outcome score (ie, health index) or an array of scores for individual quality of life dimensions (ie, health profile). The index and the profile represent the two major approaches to quality of life assessment: the decision theory or utility approach and the psychometric approach, respectively.¹⁹ An advantage of an index, such as the Quality of Well-being (QWB) scale, is that social preferences for various health states have been empirically measured.²³ Index scores range from 0.0 to 1.0, representing death and perfect health, respectively. This makes the health index scores useful in pharmacoeconomic

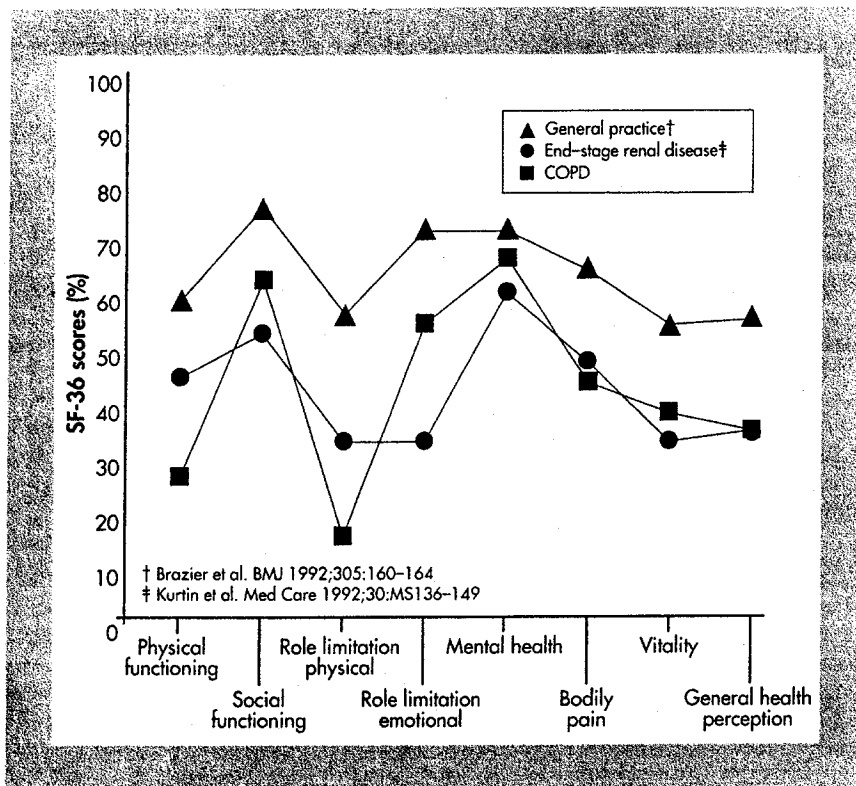


FIGURE. Mean baseline SF-36 scores compared with scores of other patient populations.

research, particularly cost-utility analysis.²⁴

As previously discussed, cost-utility analysis involves comparing the costs of an intervention (eg, a medication) to its outcomes, with outcomes expressed in units such as QALYs. For example, recent findings from an ongoing study indicated that 62 patients with chronic obstructive pulmonary disease (COPD) had a mean health index score (as measured by the QWB) of 0.58.²⁵ An earlier study using the QWB found that individuals reporting no chronic conditions (n=320) had a mean health index score of approximately 0.88.²⁶ If a therapeutic intervention were able to increase the mean index score for the 62 COPD patients from 0.58 to 0.70 and maintain it for a year, 7.44 (ie, 62 X 0.12 [the difference

between the two index score means]) QALYs would be gained. To complete the cost-utility analysis, the cost of the intervention would be divided by the 7.44 QALYs to derive the cost/QALY. This hypothetical example demonstrates the use and usefulness of health index outcome measures.

An advantage of a health profile, such as the Medical Outcomes Study (MOS) 36-item short form health survey (SF-36),²⁶ is that it provides an outcome score for specific dimensions. The SF-36 has eight health dimensions and the scores can range from 0 to 100% on each of the dimensions. Higher scores represent higher quality of life. The information obtained from administration of the SF-36 may be useful to a clinician and/or researcher who is attempting to mea-

sure differential treatment effects on the various quality of life dimensions. The figure shows a comparison of the mean SF-36 scores from two previous studies with the mean scores for the 62 COPD patients discussed above.²⁵

Dimensions measured. Although most health-related quality of life measures have multiple dimensions, there is considerable debate in the field about which dimensions need to be included. Table 3 lists the dimensions measured in four commonly used instruments. Although an instrument includes several different dimensions, there may be a great deal of overlap in the constructs actually being tapped. In addition, the fact that an instrument has fewer explicit dimensions does not mean that it is overlooking important constructs. For example, a measure without a mental health component does not necessarily neglect mental health. Mental health symptoms may be reflected in the responses to questions regarding role or social functioning. It is not clear that increasing the number of dimensions measured on an instrument make it more capable of detecting clinical differences.

Relative importance of dimensions. Although often not addressed in the existing health-related quality of life literature, a consideration of the relative importance of dimensions should be a part of the overall approach to quality of life assessment.^{27,28} For example, are physical function, social function, and treatment-related symptomatology equal in importance? Most medical interventions have risks and benefits that can negatively or positively affect quality of life. If a balance of risks and benefits is being sought, how are decisions made regarding which quality of life dimensions are allowed to be negatively affected for the sake of positively influencing others? As an illustration, a medication to control

the pain and inflammation of arthritis might be associated with slight dizziness or dyspepsia. However, the improvements in social and role functioning that are attributed to the use of the medication may make it worth tolerating the adverse effects. Often the issue is not whether the treatment has risks, but how the risks should be placed within the context of overall quality of life. How is the net benefit (or net deficit) measured? Many measures of health-related quality of life simply tabulate frequencies for different symptoms or represent quality of life or health status using profiles of outcomes. This leads to difficulty in determining the net effect. The Health Utilities Index,²⁹ the Sickness Impact Profile,³⁰ and the Quality of Well-being scale³¹ are examples of quality of life assessment tools that take the relative importance of dimensions into consideration.

Reliability of the instrument.

Reliability refers to the consistency, stability, or reproducibility of scores obtained on different administrations of a measurement instrument when all pertinent conditions remain relatively unchanged. Theoretically, reliability is defined as the ratio of true score variance to observed variance. There are a variety of different sources of error that inflate observed score variance. These include item sampling, situational factors, and time sampling. The two reliability assessment methods most often discussed in the health status literature are test-retest and internal consistency. However, as opposed to a measure of a trait that is assumed to be constant over the course of time, there can be a problem in attempting to use test-retest methods to assess the reliability of quality of life measures. Quality of life is not assumed to be constant over the course of time. In fact, most clinical studies attempt to assess how health status and/or quality of life changes. Test-

TABLE 3 DIMENSIONS INCLUDED IN VARIOUS QUALITY OF LIFE INSTRUMENTS

NHP - Nottingham Health Profile

Part I - Distress within the following domains:

| | |
|------------------|----------|
| Emotions | Energy |
| Sleep | Pain |
| Social isolation | Mobility |

Part II - Health-related problems within the following domains:

| | |
|-------------|----------|
| Occupation | Sex life |
| Housework | Hobbies |
| Social life | Holidays |
| Home life | |

QWB - Quality of Well-being Scale

Symptoms/problems
Mobility
Physical activity
Social activity

SIP - Sickness Impact Profile

| | |
|----------------|-------------------------|
| Sleep and rest | Home management |
| Eating | Recreation and pastimes |
| Work | Body care and movement |
| Ambulation | Alertness behavior |
| Mobility | Emotional behavior |
| Communication | Social interaction |

Medical Outcomes Study (MOS) short-form-36 (SF-36)

General health perception
Physical function
Social function
Role function (Physical)
Role function (Emotional)
Mental health
Energy/fatigue
Pain

retest reliability estimates may have little value in evaluating measures that are designed to assess a dynamic process.

Internal consistency, which indicates the extent to which an instrument is free of random error, is an aspect of reliability assessment that can be very important to quality of life measures. For internal consistency, it has been proposed that values above 0.90 are needed for making comparisons between individuals and above 0.50 for comparisons between groups.³¹ Inter-rater reliability, although not as critical with self-administered instruments, is a consideration when obtaining data through interviews or direct observation.

Validity of the measurement instrument. Validity defines the range of inferences that are justifiable on the basis of a score or measure. Validity is not absolute, but is relative to the domain under study. Three basic types of validity com-

monly considered are criterion, content, and construct. Criterion validity is achieved when a new measure corresponds to an established measure or observation that accurately reflects the phenomenon of interest. By definition, the criterion must be a superior measure of the phenomenon if it is to serve as a comparative norm.³² However, in quality of life assessment, a gold standard or criterion measure rarely exists against which the new measure can be compared. Content validity, which is infrequently tested statistically, refers to how adequately the sampling of questions reflects the aims of the measurement instrument. Construct validity refers to the relationship between instruments purporting to measure the same underlying theoretical construct (ie, convergent evidence) or purporting to measure a different construct (ie, discriminant evidence). For example, convergent evidence for the validity of role

performance items is established by showing associations between the responses to the items and observed verifiable functioning. Evidence for the construct validity of other aspects of the measurement instrument might be established through comparisons with physiologic measures, organ pathology, or clinical signs. Construct validity is not absolute. We do not say that an instrument is "valid," but rather support its validity through research findings.

Another aspect of a measurement instrument that supports its validity is responsiveness or sensitivity to change. Responsiveness is the ability or power of the instrument to detect clinically important change when it occurs.³³ Although some authors have suggested that responsiveness is a psychometric property of a measure that is distinct from validity,³⁴ others argue that responsiveness is an aspect of validity rather than a separate prop-

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erty.³⁵ We consider it an indication of an instrument's validity.

SUMMARY AND CONCLUSIONS

Due to the continued upward spiral of health care expenditures, it is imperative that more effective evaluation be conducted on existing and emerging health care technologies and medical practices. Very little is known regarding the actual effect on health produced by the enormous amounts of funds being expended. Effective evaluation of the outcomes that follow health care interventions will provide information that is essential to making appropriate clinical and health care resource allocation decisions. Health-related quality of life is a patient-reported outcome that will be a crucial element of the evaluation process. ■

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