Quality of Life Assessments in Clinical Trials, edited by B. Spilker. Raven Press, Ltd. New York © 1990.

## 11

## The General Health Policy Model:

### An Integrated Approach

### Robert M. Kaplan and John P. Anderson

Division of Health Care Sciences, Department of Community and Family Medicine, University of California, San Diego, La Jolla, California 92093

#### **QUALITY OF LIFE MEASUREMENT**

Quality of life data are becoming increasingly important for evaluating the cost-utility and cost-effectiveness of health care programs. Such analyses require the evaluation of very different types of health care interventions using the same outcome unit. This chapter highlights some of the strengths and weaknesses of general health outcome measures. The value of general versus disease-specific measures within clinical populations is also addressed. In addition, we consider the boundaries of the quality of life concept.

#### Why Measure Quality of Life?

The conceptualization and measurement of health status has interested scholars for many decades. Following the Eisenhower administration, a President's Commission on National Goals identified health status measurement as an important objective. In *The Affluent Society*, Galbraith described the need to measure the effect of the health care system on "quality of life." Within the last decade, many groups have attempted to define and measure health status (1-3). Before considering any specific approach, it is worth noting that traditional indicators of "health" have wellidentified problems that need to be addressed before they can be considered part of an adequate measure of "quality of life."

#### Mortality

Mortality remains the major outcome measure in many epidemiologic studies and some clinical trials. Typically, mortality is expressed in a unit of time and the rates are often age-adjusted. Case fatality rates express the proportion of persons who died of a particular disease divided by the total number with the disease (including those who die and those who live). Mortality rates have many benefits as health outcome measures. They are "hard" data (despite some misclassification bias [4]), and the meaning of the outcome is not difficult to comprehend. Despite their many advantages, mortality outcomes have some obvious limitations. Mortality rates consider only the dead and ignore the living. Many important treatments or programs might have little or no impact on mortality rates and many frequently occurring illnesses, such as arthritis, have relatively little impact on mortality. Thus, there has been an incentive to define and measure nonfatal outcomes.

#### Morbidity

The most common approach to health status assessment is to measure morbidity in terms of function or role performance. For example, morbidity estimates often include work days missed or bed disability days. Many different approaches to health status assessment using morbidity indicators have been introduced. These include, for example, the Sickness Impact Profile (5), which represents the effect of disease or disability on a variety of categories of behavioral function, and the RAND Health Status measures, which have separate categories for the effects of disease or health states on physical function, social function, and mental function. These measures are important quantitative expressions of health outcome. However, they do not integrate morbidity and mortality, although as each birth cohort ages, mortality cases accrue.

Death is a health outcome, and it is important that this outcome not be excluded from any expression of health status. For example, suppose we are evaluating the effect of program A, which integrates support and treatment, for randomly assigned groups of very ill, elderly, nursing home residents against the effect of program B, which offers no support or treatment. Let us suppose that program A maintains patients at a very low level of function throughout the year, but that in the comparison group (program B), the sickest 10% died. Looking just at the living in the followup, one finds program B patients to be healthier, since the sickest have been removed by death. By this standard, the program of no supportive treatment might be put forth as the better alternative. With a measure that combines morbidity and mortality the outcome will be very different, because mortality effects will reduce the overall health of program B to a very low level.

#### **Behavioral** Dysfunction

When Sullivan (6) reviewed the literature on health measurement more than 20 years ago, he emphasized the importance of behavioral outcomes. Behavioral indicators such as absenteeism, bed-disability days, and institutional confinement were identified as the most important consequences of disease and disability. Ability to perform activities at different ages could be compared to societal standards for these behaviors. Restrictions in usual activity were seen as *prima facie* evidence of deviation from well-being. Many other investigators have focused on point-in-time measures of dysfunction as measures of health (3,7,8).

#### **Prognosis**

The problem with measures of behavioral dysfunction is that they often neglect what will happen in the future. The spectrum of medical care ranges from public health, preventive medicine, and environmental control through diagnosis, to therapeutic intervention, convalescence, and rehabilitation. Many programs affect the probability of occurrence of future dysfunction (e.g., vaccines), rather than alter present functional status. In many aspects of preventive care, for example, the benefit of the treatment cannot be seen until many years after the intervention. A supportive family that instills proper health habits in its children, for example, may also promote better "health" in the future, yet the benefit may not be realized for years. The concept of health must consider not only the present ability to function, but also the probability of future changes in function. A person who is very functional and asymptomatic today may harbor a disease with a poor prognosis. Thus, many individuals are at high risk of dying from heart disease even though they are perfectly functional today. Should we call them "healthy"? We hold that the term "severity of illness" should take into consideration both dysfunction and prognosis (or probability of future dysfunction and mortality).

Many medical treatments may cause near-term dysfunction to prevent future dysfunction. For example, coronary artery bypass surgery causes severe dysfunction for a short period of time, yet the surgery is presumed to enhance function or decrease mortality at a later time. Patients may be incapacitated and restricted to coronary care units following myocardial infarction. Yet the treatment is designed to help them achieve better future outcomes. Pap smears and hysterectomies are performed in order to decrease the probability of future deaths due to cancer. Much of health care involves looking into the future to enhance outcomes over the life span. Therefore, it is essential to divide health into current and future components. We prefer the term "prognosis" to describe the probability of transition among health states over the course of time (9).

#### IS QUALITY OF LIFE DIFFERENT FROM HEALTH STATUS?

In the preceding sections, we have described some common elements in existing measures of health status. However, there is considerable variability in the definition of quality of life. Some authors define quality of life as health outcomes that are different from traditional health outcomes. Using these definitions, quality of life measures are typically limited to psychological and social attributes (10). By contrast, our definition of health-related quality of life focuses on the qualitative dimension of functioning. It also incorporates duration of stay in various health states. We will return to this definition later in the chapter; in the next section, however, we will review the value dimension, which is an important aspect of quality of life.

#### The Value Dimension

Scholars have debated the components of "health" for many centuries (11). Most concepts of morbidity involve three types of evidence: *clinical, subjective*, and *behavioral* (6). *Clinical* outcomes include clinical judgment, physical findings, laboratory tests, or results of invasive procedures. Clinical evidence is valuable if, and only if, it is clearly related to well-defined behavioral health outcomes. For example, significant abnormalities in certain blood proteins are of concern only if these deviations correlate with morbidity or early mortality. The burden of proof is on the scientist to demonstrate these associations.

Subjective evidence includes symptoms and complaints that are also very important in health care. Symptoms are a major correlate of health care utilization, but not all symptoms should be given equal weight because neither the type nor the number of symptoms necessarily depicts the severity of disease. For example, an adult with an acute 24-hour flu may have an enormous number of symptoms. Although these can include nausea, headache, cough, sneezing, aches and pains, vomiting, and diarrhea, it is not clear that this condition is more severe than the single symptom of a very severe headache.

Several factors need to be considered. First, we must determine the degree to which the symptoms limit functioning. Consider an individual with five symptoms an itchy eye, runny nose, coughing, fatigue, and headache—but who still feels well enough to work and to perform all usual activities. Another person with the single symptom of a severe headache may be limited to bed and not move around. Would we want to call the person with five symptoms less well? Another dimension is the duration of the symptoms. A year in pain is certainly worse than a day in pain. The final, and perhaps the most often neglected, factor is the value or preference associated with different types of dysfunction.

Biomedical investigators often avoid reference to values or preferences because these constructs are considered not "scientific." However, the value dimension in health status is inescapable. Fishburn defined value as the quantification of the concept of worth, importance, or desirability (11). Ultimately, our judgments of the value of health states, and whether one level of functioning is "better" than another level of functioning, depend on subjective evaluations. If we advise individuals to change their diet to avoid heart disease, we inherently assume that the reduced probability of heart disease later in life is valued more than the immediate but enduring mild displeasure of dietary change. The phrase "quality of life" necessarily presumes a qualitative judgment.

As noted earlier, Sullivan emphasized *behavioral dysfunction* as the third type of evidence for morbidity. Behavioral dysfunction includes disruption in role performance, confinement to hospitals, or work loss.

# SHOULD QUALITY OF LIFE BE LIMITED TO PSYCHOLOGICAL AND SOCIAL ATTRIBUTES?

Some authors use the term "quality of life" as a limited descriptor of psychological and social health (10). We believe that most psychological and social dimensions can be incorporated into a general health status measure. However, some concepts of social health are correlates of health outcomes rather than outcomes themselves. We have addressed these issues elsewhere (12-14) but will summarize them in the following sections.

#### Social Health

For nearly 35 years, physicians, psychologists, sociologists, and epidemiologists have been attempting to include social support and social function in a definition of health status. Despite relentless efforts, it has been difficult to meaningfully define social support as a component of health. The term "social health" was included in the World Health Organization definition of health that accompanied their charter document in 1948 (15). They defined health as, "a state of complete physical, mental, and social well-being and not merely the absence of infirmity." In identifying the dimensions of health, the World Health Organization neglected to provide any operational definitions. Thus, different investigators have taken different approaches in their attempts to capture physical, mental, and social dimensions. Since the publication of the World Health Organization statement, many investigators have tried to develop measures to operationalize the three components of health status. With surprising consistency, authors quote the World Health Organization definition and then present their methods for measuring the three components. So prevalent is the notion that health status must include these three components that many reviews now negatively evaluate any measure that does not conform to the World Health Organization definition. For example, Meenan (16) disapproved of several health measures because, "these approaches fall short of conceptualizing or measuring health in the World Health Organization sense of a physical, psychological, and social state" (p. 785).

With the command of the World Health Organization so plainly set forth, many investigators have struggled to develop their measures of social health. Yet there have been consistent problems. For example, Kane and Kane (17) devoted a substantial section of their monograph to describing problems in the quantification of social health. These problems included vague concepts, lack of norms, the interactive nature of variables, difficulty in construction of a continuum, and the subjective nature of social health.

Only Ware and colleagues have begun to question the meaning of social health (18,19). In one paper, Donald, Ware, and colleagues (19) reviewed 70 studies relevant to social health. From these they selected 11 studies for more detailed analysis. The great majority of these studies focused on what we now call social support. Yet, there were at least two separate components being assessed by the many investigators contributing to this literature. One component, was social contacts, or the performance of social role. The other component is social resources, which is more analogous to the concept of social support. This distinction is very important. Social contacts might include participation in work, attendance at school, and other aspects of functioning. Social resources are relevant to social life, friendships, and family relationships.

In a series of analyses, it has been demonstrated that social support may be a predictor for health outcomes (13,19), but the direction is not always clear. For example, Heitzmann and Kaplan (20) have demonstrated that social support may predict positive outcomes for women but negative outcomes for men. Social support is not an outcome that can serve as the target of health care. On the other hand, social functioning is a component of health status. Diseases and disabilities affect social function. Social function is a central component in the concept of quality of life.

Optimizing social health raises issues of social control and public policy. Considering the example of function, there is strong consensus that function is desirable. Thus, it seems reasonable to devote public resources to maximize the level of function and quality of life within a community. Optimized health status might be considered a common goal, as is national defense, a strong educational system, etc. Many current methods of health measurement do include a social functioning component. On the other hand, including social support in the definition of health status would imply that community resources should be used to obtain some defined level of social support. We might expect considerable public disagreement about what the social support objective might be. For example, would we want to develop a public policy that requires people to have friends?

Excluding social support from the definition of health makes policy analysis relatively straightforward. There is little disagreement about what levels of functioning are desirable (21,22). When people agree on what is desirable, the objective of health care can be directed toward achieving the desired states. A major issue is in defining a mix of programs that most efficiently and effectively achieve these objectives. Programs that enhance social support might be considered in this mix, but we believe that including social support in the definition of health only confuses the definition of these objectives.

#### **Mental Health**

The separate category for mental health in the World Health Organization definition prompted many investigators to develop separate measures of mental health functioning. Perhaps the best known effort in this area is the work by Ware and his associates (23). These investigators adapted Dupuy's (24) General Well-Being Index and administered it to large numbers of people as part of the RAND Health Insurance Experiment. Ware et al. (25) argue that the correlation between psychological distress and physical functioning is only .25 and suggested that this confirmed that mental health was a separate dimension. In addition, they offered comparisons between those with no physical limitations but with differences on items about psychological distress. For this high physically functioning group, those with higher scores on mental distress used three times as many mental health services as those low in distress.

The separate measurement of mental health remains a major issue in the conceptualization of general health status. Although our position is against the norm, we believe mental health can be conceptualized as a portion of general health status and that there is considerable disadvantage to attempting separate measurement and specification of mental function. We do understand that some investigators are interested in specific subcomponents of mental health, such as cognitive functioning. In these cases, more detailed measures might be considered additions to (but not replacements for) the general measures.

We argue that the World Health Organization conceptualization of health status promotes an artificial dichotomy between mental and physical function. In order to understand this argument, it is important to think about the impact of mental illness. anxiety, or poor social adjustment on functioning. Mental health affects longevity (26) and quality of life. In other words, the impact of mental health on general health status is expressed through its impact on life expectancy, functioning, and symptoms. However, many individuals with perfect physical functioning experience symptoms. For example, an individual experiencing anxiety at work might check a symptom describing anxiety. This anxiety might effect quality of life in a manner similar to a physical symptom such as shortness of breath. Severe anxieties, such as phobias, may disrupt role performance. Thus, individuals may be limited to their homes because they are afraid to go outside. Many individuals experience symptomatic depression that does not disrupt their activities of daily living. At the other extreme, anxiety and depression can be so severe that they result in hospitalization. Thus, the impact of the condition on functioning is very much the same as the impact of a physical malady.

As in physical health, the duration of mental health conditions must also be considered. For example, depression may last 3 days, 3 weeks, or 1 year. The total impact needs to be expressed as a function of its duration. More importantly, mental health status may effect differential transition among functional states over the course of time. The term "positive health" is used typically to describe some aspect of lifestyle or mental outlook that is associated with better future health. Or, people with positive health have lower probabilities of transition to poor health over the course of time. An individual who can cope with stress may seem no different from individuals without such coping skills. However, given certain epidemiologic linkages, they may have a higher probability of better functioning at future points in time.

Much of the confusion about mental health has been generated by a very refined technology for assessing mental states. Often, detailed questionnaire methods have been factor analyzed to describe different dimensions of mental health. Nevertheless, these very different levels of functioning may ultimately impact the general wellbeing. This may be analogous to the many available measures of blood chemistry. For example, indicators of kidney function (creatinine, BUN, etc.) may be identified as separate factors, yet the importance of these measures is their relationship to longevity and to function at particular points in time. We might not be concerned about elevated creatinine, for example, if these blood levels were not correlated with death or dysfunction due to kidney disease.

There are some justifications for not separating mental and physical function. The growing literature on psychoneuroimmunology (27) clearly demonstrates the intertwining nature of physical and mental health outcomes. In addition, experiments have demonstrated that general health status can be improved in medical patients even though physical functioning is unaffected. For example, patients with chronic obstructive pulmonary disease do not achieve changes in lung function following rehabilitation. However, they may reach higher levels of activity and reduced symptoms (28). The rehabilitation programs are not necessarily medical and may depend on physical or respiratory therapists. Indeed, the changes in outcome may result from improved attitude or from the enhanced ability to cope with symptoms. Ultimately, we are interested in patient function and quality of life. It may not matter if this is achieved through enhanced lung function or improved coping skills. The most important point is that all providers in health care are attempting to improve quality of life and extend the duration of life. It is valuable to allow mental health providers and physical health providers to compare the benefits of their services using a common unit.

#### Health-Related Quality of Life

The objectives of health care are twofold. First, health care and health policy should increase life expectancy. Second, the health care system should improve the quality of life during the years that people are alive. It is instructive to consider various measures in health care in light of these two objectives. Traditional biomedical indicators and diagnoses are important to us because they may be related to mortality or to quality of life. We prefer the term "health-related quality of life" to refer to the impact of health conditions on function. Thus, health-related quality of life may be independent of quality of life relevant to work setting, housing, air pollution, or similar factors (29).

Numerous quality of life measurement systems have evolved during the last 20 vears. These systems are based primarily on two different conceptual approaches. The first approach grows out of the tradition of health status measurement. In the late 1960s and early 1970s, the National Center for Health Services Research funded several major projects to develop general measures of health status. Those projects resulted in the Sickness Impact Profile (SIP) (5), the Quality of Well-Being Scale (30.31), and the General Health Rating Index. The latter measure, originally developed at Southern Illinois University, was adapted by the RAND Corporation under Health and Human Service grants and has become known as the RAND Health Status Measure (8). These efforts usually involved extensive multidisciplinary collaboration between behavioral scientists and physicians. Most of the measures are focused on the impact of disease and disability on function and observable behaviors, such as performance of social role, ability to get around the community, and physical functioning. Some systems include separate components for the measurement of social and mental health. All were guided by the World Health Organization's definition of health status: "Health is a complete state of physical, mental, and social well-being and not merely absence of disease" (5).

The second conceptual approach is based on quality of life as something independent of health status. Some investigators now use traditional psychological measures and call them quality of life outcomes. For instance, Follick et al. (10) suggest that quality of life represents psychological status in addition to symptoms and mortality. Croog et al. (32) used a wide variety of outcome measures and collectively referred to them as "quality of life." These measures included the patients' subjective evaluation of well-being, physical symptoms, sexual function, work performance and satisfaction, emotional status, cognitive function, social participation. and life satisfaction. Yet mortality is not part of the concept. Other investigators. including Hunt and colleagues (33) regard quality of life as subjective appraisals of life satisfaction. In summary, a wide variety of different dimensions have all been described as quality of life. Although agreement is lacking on which dimensions should be considered the standard for assessing quality of life in research studies, recurrent themes in the methodologic literature can assist in the evaluation of existing instruments. As will be shown, our approach to quality of life measurement focuses on health-related outcomes of mortality, morbidity, symptoms, and prognosis. We believe that many definitions of quality of life are poorly operationalized. Before addressing our definition of health-related quality of life, it will also be important to clarify some economic terms that are often used in the same literature.

#### **Cost-Utility Versus Cost-Benefit**

The terms "cost-utility," "cost-effectiveness," and "cost-benefit" are used inconsistently in the medical literature (34). Some economists have favored the assessment of cost-benefit. These approaches measure both program costs and treatment outcomes in dollar units. For example, treatment outcomes are evaluated in relation to changes in use of medical services and economic productivity. Treatments are cost-beneficial if the economic return exceeds treatment costs. Diabetic patients who are aggressively treated, for example, may need fewer medical services. The savings associated with decreased services might exceed treatment costs. As Kaplan and Davis (35) have argued, there is relatively little strong empirical evidence that patient education or behavioral treatments are actually cost-beneficial. In addition, as suggested by Russell (36), the requirement that health care treatments reduce costs may be unrealistic. Patients are willing to pay for improvements in health status just as they are willing to pay for other desirable goods and services. We do not treat cancer in order to save money. Instead, treatments are given in order to achieve better health outcomes.

*Cost-effectiveness* is an alternative approach in which the unit of outcome is a reflection of treatment effect. In recent years, cost-effectiveness has gained considerable attention. Some approaches emphasize simple, treatment-specific outcomes. For example, the cost per pound lost has been used as a measure of cost-effectiveness of weight loss programs (37). Public competitions, for example, achieve a lower cost-per-pound loss ratio than do traditional clinical interventions. The major difficulty with cost-effectiveness methodologies is that they do not allow for comparison across very different treatment interventions. For example, health care administrators often need to choose between investments in very different alternatives. They may need to decide between supporting liver transplantation for a few patients versus prenatal counseling for a large number of patients. For the same cost, they may achieve a large effect for a few people or a small effect for a large number of people. The treatment-specific outcomes used in cost-effectiveness studies do not permit these comparisons.

*Cost-utility* approaches use the expressed preference or utility of a treatment effect as the unit of outcome. As noted in World Health Organization documents (38), the goals of health care are to add years to life and to add life to years. In other words, health care is designed to make people live longer (increase the life expectancy) and to live a higher quality of life in the years prior to death. Cost-utility studies use outcome measures that combine mortality outcomes with quality of life measurements. The utilities are the expressed preferences for observable states of function on a continuum bounded by 0 for death to 1.0 for optimum function (39–41). In the next section, we outline a model that combines utilities with measures of mortality, morbidity, symptoms, and prognosis. The system can be used as either a healthrelated quality of life measure or an instrument in cost-utility analysis.

#### A COMPREHENSIVE SYSTEM—THE GENERAL HEALTH POLICY MODEL

Our approach is to express the benefits of medical care, behavioral intervention, or preventive programs in terms of well-years. Others have chosen to describe the same outcome as Quality-Adjusted Life-Years (QALY's) (42). Well-years integrate mortality and morbidity to express health status in terms of equivalents of well-years of life. If a cigarette smoker died of heart disease at age 50 and we would have expected him to live to age 75, it might be concluded that the disease cost him 25 life-years. If 100 cigarette smokers died at age 50 (and also had life expectancies of 75 years), we might conclude that 2,500 (100 men  $\times$  25 years) life-years had been lost.

Yet, death is not the only outcome of concern in heart disease. Many adults suffer myocardial infarctions that leave them somewhat disabled over a longer period of time. Although they are still alive, the quality of their lives has diminished. Our model permits all degrees of disability to be compared to one another. A disease that reduces the quality of life by one-half will take away .5 well-years over the course of 1 year. If it effects two people, it will take away 1.0 well-year (equal to  $2 \times .5$ ) over a 1-year period. A medical treatment that improves the quality of life by .2 for each of five individuals will result in a production of 1 well-year if the benefit is maintained over a 1-year period. Using this system, it is possible to express the benefits of various programs by showing how many equivalents of well-years they produce (39–41). Yet, not all programs have equivalent costs. In periods of scarce resources, it is necessary to find the most efficient use of limited funds. Our approach provides a framework within which to make policy decisions that require selection from competing alternatives. Preventive services may in this way compete with traditional medical services for the scarce health care dollar. Performing such comparisons requires the use of a general health decision model. In the next section, the general model of health status assessment and benefit–cost-utility analysis will be presented.

#### The General Model

#### **Building a Health Decision Model**

The Health Decision Model grew out of substantive theories in economics, psychology, medicine, and public health. These theoretical linkages have been presented in several previous papers (43–45). Building a health decision model requires at least five distinct steps.

Step 1: Defining a function status classification. During the early phases of our work, a set of mutally exclusive and collectively exhaustive levels of functioning were defined. After an extensive, specialty-by-specialty review of medical reference works, we listed all of the ways that disease and injuries can affect behavior and role performance. Without considering etiology, it was possible to match a finite number of conditions to items appearing on standard health surveys, such as the Health Interview Survey (National Center for Health Statistics), the Survey of the Disabled (Social Security Administration), and several rehabilitation scales and ongoing community surveys. These items fit conceptually into three scales representing related but distinct aspects of daily functioning: mobility, physical activity, and social activity. The mobility and physical activity scales have three levels, whereas social activity has five distinct levels. Table 1 shows the steps from the three scales. Several investigators have used this function status classification (or a modified version of it) as an outcome measure for health program evaluation (46,47). However, the development of a truly comprehensive health status indicator requires several more steps.

Step 2: Classifying symptoms and problems. There are many reasons a person may not be functioning at the optimum level. Subjective complaints are an important component of a general health measure because they relate dysfunction to a specific problem. Thus, in addition to function level classifications, an exhaustive list of symptoms and problems has been generated. Included in the list are 25 complexes of symptoms and problems representing all of the possible symptomatic complaints that might inhibit function. These symptoms and problems are shown in Table 2.

Step 3: Preference weights to integrate the Quality of Well-Being Scale. We now have described the three scales of function and 25 symptom/problem complexes.

TABLE 1.	Quality of	Well-Beina	Scale	elements and	d calculating	formulas
IADEE I.	Quanty Of	Wen-Denig	Juaie	elenienis and	i caiculating	ionnuia

Step no.	Step definition	Weight
	Mobility Scale (MOB)	
5	No limitations for health reasons	000
4	Did not drive a car, health related (younger than 16); did not ride in a car as usual for age, and/or did not use public transportation, health related; or had or would have used more help than usual for age to	062
•	use public transportation, health related	
2	in hospital, health related	090
	Physical Activity Scale (PAC)	
4	No limitations for health reasons	000
3	In wheelchair, moved or controlled movement of wheelchair without help from someone else; or had trouble or did not try to lift, stoop, bend over, or use stairs or inclines, health related, and/or limped, used a cane, crutches or walker, health related; and/or had any other physical limitation in walking, or did not try to walk as far or as fast as others the same age are able, health related	060
1	In wheelchair, did not move or control the movement of wheelchair without help from someone else, or in bed, chair, or couch for most or all of the day, health related	<b>077</b>
	Social Activity Scale (SAC)	
5	No limitations for health reasons	000
4	Limited in other role activity, health related	061
3	Limited in major (primary) role activity, health related	061
2	Performed no major role activity, health related, but did perform self- care activities	061
1	Performed no major role activity, health related, and did not perform or had more help than usual in performance of one or more self-care activities, health related	106
	_	

Calculating Formulas:

Formula 1: Point-in-time Well-being score for an individual (W):

W = 1 + (CPXwt) + (MOBwt) + (PACwt) + (SACwt)

where wt is the preference-weighted measure for each factor and CPX is symptom/problem complex. For example, the W score for a person with the following description profile may be calculated for one day as follows:

QWB Elemer	nt Description	Weight	
CPX-11	Cough, wheezing, or shortness of breath, with or without fever, chill, or aching all over	257	
MOB-5	No limitations	000	
PAC-1	In bed, chair, or couch for most or all of the day, health related	077	
SAC-2	Performed no major role activity, health related, but did perform self-care activities	061	
	W = 1 + (257) + (000) + (077) + (061) = .605		

Formula 2: General Health Policy Model Formula for Well-Years (WY) as an output measure:

WY = [No. of persons × (CPXwt + MOBwt + PACwt + SACwt)] × time

CPX no.	CPX description	Weights
1	Death (not on respondent's card)	727
2	Loss of consciousness such as seizure (fits), fainting, or coma (out cold or knocked out)	407
3	Burn over large areas of face, body, arms, or legs	367
4	Pain, bleeding, itching, or discharge (drainage) from sexual organs—does not include normal menstrual (monthly) bleeding	349
5	Trouble learning, remembering, or thinking clearly	340
6	Any combination of one or more hands, feet, arms, or legs either missing, deformed (crooked), paralyzed (unable to move) or broken —includes wearing artificial limbs or braces	333
7	Pain, stiffness, weakness, numbness, or other discomfort in chest, stom- ach (including hernia or rupture), side, neck, back, hips, or any joints of hands, feet, arms or legs	299
8	Pain, burning, bleeding, itching, or other difficulty with rectum, bowel movements, or urination (passing water)	292
9	Sick or upset stomach, vomiting or loose bowel movements, with or with- out fever, chills, or aching all over	290
10	General tiredness, weakness, or weight loss	259
11	Cough, wheezing, or shortness of breath with or without fever, chills, or aching all over	257
12	Spells of feeling upset, being depressed, or of crying	257
13	Headache, or dizziness, or ringing in ears, or spells of feeling hot, or ner- vous, or shaky	244
14	Burning or itching rash on large areas of face, body, arms, or legs	240
15	Trouble talking, such as lisp, stuttering, hoarseness, or inability to speak	237
16	Pain or discomfort in one or both eyes (such as burning or itching) or any trouble seeing after correction	230
17	Overweight or underweight for age and height of skin defect of face, body, arms or legs, such as scars, pimples, warts, bruises, or changes in color	186
18	Pain in ear, tooth, jaw, throat, lips, tongue; missing or crooked permanent teeth—includes wearing bridges or false teeth; stuffy, runny nose; any trouble hearing—includes wearing a hearing aid	170
19	Taking medication or staying on a prescribed diet for health reasons	144
20	Wore eyeglasses or contact lenses	101
21	Breathing smog or unpleasant air	101
22	No symptoms or problem (not on respondent's card)	000
23	Standard symptom/problem (not on respondent's card)	257
24	Trouble sleeping	257
25	Intoxication	257
26	Problems with sexual interest or performance	257
27	Excessive worry or anxiety	257

**TABLE 2.** List of Quality of Well-Being Scale symptom/problem complexes (CPX) with calculating weights for QWB scale, version 6B

\* CPX 24-27 are assigned standard weights until empirical weights can be derived in new studies.

With these, all we can do is compare populations in terms of frequencies of each scale step (and, if necessary, symptom/problem complex). Although comparisons of frequencies are common in health services research, our system offers a strategy for integrating the frequencies into a single comprehensive expression. If our intent is to say which of these distributions is "better off" and which "worse," simple frequency distributions may not be able to help much. For example, is a group with 80 people able to travel and limited in their mobility and 5 restricted to their homes worse off than a group in which 85 can travel freely, but 10 are restricted to their homes? Obviously comparing frequency distributions is complex. Further, the example involves frequencies for only one scale. How can one make decisions when there are three scales and symptom/problem complexes to consider?

Another step is necessary to integrate the three scales and the symptom/problem complexes in a manner that will allow a single numerical expression to represent each combination of steps on the scales and symptom/problem complexes. The empirical means of accomplishing this is measured preferences for the health states. These might be regarded as "quality" judgments. As we noted earlier, the General Health Policy Model includes the impact of health conditions on the quality of life. This requires that the desirability of health situations be evaluated on a continuum from death to completely well. An evaluation such as this is a matter of utility or preference, thus combinations of behavioral dysfunction and symptom/problem complexes are scaled to represent degrees of relative importance.

Human judgment studies are used to determine weights for the different states. We have asked random samples of citizens from the community to evaluate the relative desirability of a good number of health conditions. Random sample surveys were conducted in the San Diego community during 2 consecutive years. The probability sample included 866 respondents ethnically representative of the population. When necessary, interviews were conducted in Spanish. From a listing of all possible combinations of the scale (mobility, physical activity, social activity, and symptom/ problem complexes), we drew a stratified random sample of 343 case descriptions (items) and divided them into eight sets of computer-generated booklets. All respondents were assigned randomly to one of the eight booklets, creating eight subgroups of approximately 100 respondents each. In a series of studies, a mathematical model was developed to describe the consumer decision process. The validity of the model has been cross validated with an R of .94 (10). These weights, then, describe the relative desirability of all of the function states on a scale from 0 (for death) to 1.0 (for asymptomatic optimum function). Thus, a state with a weight of .50 is viewed by the members of the community as being about one-half as desirable as optimum function or about halfway between optimum function and death.

Some critics have expressed concern that community, rather than specific population weights are used. The advantage of community weights is that they are general (like the model) and do not bias policy analysis toward any interest group. More important, however, is that empirical studies consistently fail to show systematic differences between demographic groups (21), providers, students and administrators (20), and Americans versus British (48). Relevant to the general versus disease-specific issue, Balaban and colleagues (49) found that weights provided by rheumatoid arthritis patients are remarkably similar to those we obtained from members of the general population.

Using preference weights, one component of the general model of health is defined. This is the Quality of Well-Being Scale, which is the point-in-time component of the General Health Policy Model (50,51). The quality of well-being score for any individual can be obtained from preferences or "quality" judgments associated with his/ her function level, adjusted for symptom or problem.

The example in Table 1 describes a person classified on the three scales of observable function and on a symptom/problem. The table shows the adjustments for each of these components. Using these, a weight of .605 is obtained. By including symptom/problem adjustments, the index becomes very sensitive to minor "top end" variations in health status. The adjustments for particular symptom/problems are shown in Table 2. For example, there are symptom/problem complexes for wearing eyeglasses, having a runny nose, or breathing polluted air. These symptom adjustments apply even if a person is in the top step in the other three scales. For example, a person with a runny nose receives a score of .83 on the Quality of Well-Being Scale when he is at the highest level of behavioral function (i.e., the top step on each scale shown in Table 1). Thus, the index can make fine as well as gross distinctions.

Mathematically, the quality of well-being score may be expressed as:

$$W = \frac{1}{N} \sum_{l=1}^{L} W_{\kappa} N_{\kappa}$$

where

- W = the symptom-standardized, time-specific quality of well-being score. *l* indexes the function levels [l = 1, ..., L].
- $W_{\kappa}$  = the quality of well-being (weight, utility, relative desirability, social preference) for each function level, standardized (adjusted) for all possible symptom/problem complexes.
- $N_{\kappa}$  = the number of persons in each function level.
- N = the total number of persons in the group, cohort, or population.

Thus, quality of well-being is simply an average of the relative desirability scores assigned to a group of persons for a particular day or a defined interval of time.

Several studies attest to the reliability (21,52) and validity (51) of the Quality of Well-Being Scale. For example, convergent evidence for validity is given by significant positive correlations with self-rated health and negative correlations with age, number of chronic illnesses, symptoms, and physician visits. However, none of these other indicators were able to make the fine discrimination between health states which characterize the Quality of Well-Being Scale. These data support the convergent and discriminant validity of the Scale (51).

Step 4: Estimate transitions among health states. The Quality of Well-Being Scale is the point-in-time component of the model. A comprehensive measure of health status also requires an expression of prognosis or the probability of moving between health states over time. People who are well now want to remain well. Those who are at suboptimal levels want to become well, or at least not get worse. A General Health Policy Model must consider both current functioning and probability of transition to other function levels over the course of time. When transition is considered and documented in empirical studies, the consideration of a particular diagnosis is no longer needed. We fear diseases because they affect our current functioning or the probability that there will be a limitation in our functioning some time in the future. A person at high risk for heart disease may be functioning very well at present, but may have a high probability of transition to a lower level (or death) in the future. Cancer would not be a concern if the disease did not affect current functioning or the probability that functioning would be affected at some future time.

When weights have been properly determined, health status can be expressed precisely as the expected value (product) of the preferences associated with the states of function at a point in time and the probabilities of transition to other states over the remainder of the life-expectancy. Quality of well-being (W) is a static or time-specific measure of function, whereas the well-life expectancy (E) also includes the dynamic or prognostic dimension. The well-life expectancy is the product of quality

State	k	Υ <sub>κ</sub>	Wx	W <sub>x</sub> Y <sub>k</sub>
Well	A	65.2	1.00	65.2
Non-bed disability	B C	4.5 1.9	.59 .34	2.7
Bed disability				.6
Current Life Expectance .	y	71.6 life-yea 68	rs .5 well-years	

 TABLE 3. Illustrative computation of the well-life expectancy

From Kaplan and Bush, ref. 51

of well-being times the expected duration of stay in each function level over a standard life period. The equation for the well-life expectancy is

$$E = \sum W_{\kappa} Y_{\kappa}$$

where E is the symptom-standardized well-life expectancy in equivalents of completely well-years, and  $Y_{\kappa}$  is the expected duration of stay in each function level or case type estimated with an appropriate statistical (preferably stochastic) model.

A sample computation of the well-life expectancy is shown in Table 3. Suppose that a group of individuals was in a well state for 65.2 years, in a state of non-bed disability for 4.5 years, and in a state of bed disability for 1.9 years before their deaths at the average age of 71.6 calendar years. In order to make adjustments for the diminished quality of life they suffered in the disability states, the duration of stay in each state is multiplied by the preference associated with the state. Thus, the 4.5 years of non-bed disability become 2.7 equivalents of well-years when we adjust for the preferences associated with inhabiting that state. Overall, the well-life expectancy for this group is 68.5 years. In other words, disability has reduced the quality of their lives by an estimated 3.1 years.

Step 5: Estimating the benefit-cost-utility ratio. The San Diego Group has shown in a variety of publications how the concept of a well or weighted life expectancy can be used to evaluate the effectiveness of programs and health interventions. The output of a program has been described in a variety of publications as quality-adjusted life-years (43,53), well-years, equivalents of well-years, or discounted well-years (20,51,54). Weinstein (55,56) calls the same output Quality-Adjusted Life-Years (QALYs), and this has been adopted by the Congressional Office of Technology Assessment (57). It is worth noting that the quality-adjusted life-years terminology was originally introduced by Bush, Patrick, and Chen (43), but later abandoned because it has surplus meaning. The term "wellness" or "well-years" implies a more direct linkage to health conditions. Whatever the term, the number shows the output of a program in years of life adjusted by the quality of life which has been lost because of diseases or disability.

#### CONCLUSIONS

The term "quality of life" has been used inconsistently in the health services research literature. The definitions range from descriptions of functioning, to qualitative judgments of functioning, to measures typically unrelated to traditional health outcomes. In this chapter, we argue that "quality of life" is often poorly defined.



**FIG. 1.** Cost per quality-adjusted life-years for various programs, 1988 U.S. dollars. CABG, coronary artery bypass surgery; COPD, chronic obstruction pulmonary disease; PKU, phenylketonuria.

Several dimensions of quality of life emerge across different discussions. These include: mortality, functioning and role performance, symptoms, prognosis, and preference weights. We have proposed a system that combines these dimensions into a single number.

The objectives of health care include the extension of the life expectancy and the maximization of quality of life during years people are alive. In other words, health care should add years to life and also add life to years. All activities in the system should be evaluated by estimating their contribution toward these goals. The General Health Policy Model attempts to quantify the contributions from various providers and interventions so that the outcomes can be compared across very different interventions. These broad comparisons require an aggregate measure of health outcome have little value for these comparisons. For example, many investigators suggest mental health outcomes cannot be evaluated using the same systems as used to measure physical health outcomes. However, we ultimately must make decisions about the comparative value of programs aimed at mental or physical health problems. Further, we must evaluate products that may have some benefits in one domain and side effects in another. A comprehensive system is required for these evaluations.

The General Health Policy Model has been used to evaluate outcomes in a variety of settings. Unfortunately, we will not have the opportunity to review each of these applications in detail. Suffice to say that different investigators have estimated the expected well-year benefits of competing interventions. Figure 1 summarizes many of these studies with adjustments to 1988 dollars. As the figure suggests, some interventions such as coronary artery bypass surgery for patients with ejection fractions less than 20% have been estimated to cost nearly one-half million dollars to produce the equivalent of a life-year. Traditional medical interventions in prevention, such as cholesterol and blood pressure reduction, may be much less expensive to produce the equivalent of a year of life. However, some nontraditional interventions including smoking cessation programs are even more cost-effective. Interestingly, our estimate suggests that the most cost-effective program has nothing to do with traditional health care: it involves passing laws that require the use of seat belts.

The use of the General Health Policy Model requires many heroic assumptions. The data for Fig. 1 come from a variety of different studies. In many of these cases, the health benefits were estimated using expert judgment. The accuracy of many of these estimates is unknown because they are based on judgments and not empirical studies. Furthermore, there are important assumptions in the application of the model that include the discount rate and the reliability of the estimate of treatment effectiveness. Despite these limitations, we believe the General Health Policy Model provides a unique new way of thinking about alternatives in health care. We hope to see more systematic experimental trials that employ structured measures such as the Quality of Well-Being Scale. As more data accumulate, we hope to provide a stronger database for comparing different alternatives in health care.

#### ACKNOWLEDGMENT

This work was supported by Grants no. RO1 HL 34732 and AR 33489 from the National Institutes of Health and Grant no. RO1 HS 05617 from the National Center for Health Services Research and Technology Assessment.

#### REFERENCES

- 1. Walker S, Rosser R, eds. Quality of life: Assessment and applications. London: WTP Press, 1988.
- 2. Wenger NK, Mattson ME, Furberg CD, Elinson J. Assessment of quality of life in clinical trials of cardiovascular therapies. New York: LaJacq, 1984.
- 3. Bergner M. Measurement of health status. Med Care, 1985;23:696-704.
- National Institutes of Health. Epidemiology of Respiratory Diseases Task Force, Washington, D.C., U.S. Government Printing Office, NIH Publication, 1979;81:2019.
- 5. Bergner M, Bobbitt RA, Carter WB, Gilson BS. The sickness impact profile: Development and final revision of a health status measure. *Med Care* 1981;19:786-787.
- 6. Sullivan DF. Conceptual problems in developing an index of health. Office of Health Statistics, National Center for Health Statistics, Monograph Series II, No. 17, 1966.
- 7. Katz ST, Downs H, Cash H, Grotz R. Progress and development of an index of EDL. Gerontologist, 1970;10:20-30.
- 8. Stewart AL, Ware JE, Brook RH, Davies-Avery A. Conceptualization and measurement of health for adults: Volume II, Physical health in terms of functioning. Santa Monica: RAND, 1978.
- 9. Fanshel S, Bush JW. A health-status index and its applications to health-services outcomes. Operations Research, 1970;18:1021-1066.
- 10. Follick MJ, Gorkin L, Smith T, et al. Quality of life post-myocardial infarction: The effects of a transtelephonic coronary intervention system. *Health Psychology*, 1988;7:169–182.
- 11. Fishburn P. Decision and value theory. New York: Wiley, 1964.
- Kaplan RM, Anderson JP. A general health policy model: Update and applications. Health Services Research, 1988;23:203-235.
- 13. Kaplan RM. Social support and social health: Is it time to rethink the WHO definition of health? In: Sarason IG, Sarason BR, eds. Social support: Theory, research, and applications. The Hague, Martinus Nijhoff, 1985c; 95-112.
- Kaplan RM. Human preference measurement for health decisions and the evaluation of long-term care. In: Kane RL, Kane RA, eds. Values and long-term care. Lexington, MA: Lexington Books, 1982;157-188.
- 15. World Health Organization. Constitution of the World Health Organization. Geneva: WHO Basic Documents, 1948.

#### CHAPTER 11

- 16. Meenan RF. AIMS approach to health status measurement: Conceptual background and measurement properties. J Rheumat 1982;9:785-788.
- 17. Kane RA, Kane RL. Assessing the Elderly. Boston: D.C. Heath, 1985.
- 18. Donald CA, Ware JE, Jr., Brook RH, Davies-Avery A. Conceptualization and measurement of health for adults in the health insurance study. *Social health (R-198714-HEW) (vol. IV)*. Santa Monica: RAND, 1980.
- 19. Ware JE, Jr, Donald CA. Social well-being: Its meaning and measurement. Santa Monica: RAND, 1980.
- Heitzmann C, Kaplan RM. Interaction between sex and social support in the control of type II diabetes mellitus. J Consult Clin Psychol 1984;52(6):1087-1089.
- Patrick DL, Bush JW, Chen MM. Methods for measuring levels of well-being for a health status index. Health Serv Res 1973b;8;228-245.
- 22. Kaplan RM, Bush JW, Berry CC. The reliability, stability, and generalizability of a health status index. American Statistical Association, Proceedings of the Social Statistics Section, 1978;704-709.
- 23. Ware JE, Jr., Johnston SA, Davies-Avery A, Brook RH. Conceptualization and measurement of health for adults. In: *The Health Insurance Study, Vol. III, Mental Health.* Santa Monica: RAND, 1979.
- 24. Dupuy H. Utility of the national center for health statistics general well-being schedule in the assessment of self-representation of subjective well-being and distress. *National Conference on Education in Alcohol, Drug Abuse, and Mental Health Programs*, Washington, D.C., 1974.
- 25. Ware JE, Jr., Manning WG, Duan N, et al. Health status and the use of outpatient mental health services. Am Psychol 1984;30:1090-1100.
- 26. Wells KB. Depression as a tracer condition for the national study of medical care outcomes. Santa Monica: RAND, 1985.
- Biondi M, Pancheri P. Stress, personality, immunity and cancer: A challenge for psychosomatic medicine. In: Kaplan RM, Criqui MH, eds. *Behavioral epidemiology and disease prevention*. New York: Plenum, 1985;271-298.
- Atkins CJ, Kaplan RM, Timms RM, Reinsch S, Lofback K. Behavioral programs for exercise compliance in chronic obstructive pulmonary disease. J Consult Clin Psychol 1984;52:591-603.
- 29. Rice RM. Organizational work and the overall quality of life. In: Oscamp S, ed. Applied social psychology annual: Applications in organizational settings., Vol. 5. Beverly Hills, CA: Sage, 1984;155-178.
- 30. Kaplan RM, Bush JW. Health-related quality of life measurement for evaluation research and policy analysis. *Health Psychol* 1982;1:61-80.
- 31. Bush JW. Relative preferences versus relative frequencies in health-related quality of life evaluations. In: Wenger NK, Mattson ME, Furberg CD, Elinson J, eds. Assessment of quality of life in clinical trials of cardiovascular therapies. New York: LaJacq 1984;118-139.
- 32. Croog SH, Levine S, Testa MA, Brown D, Bulpitt CJ, Jenkins CD, Klerman GL, Williams GH. The effects of anti-hypertensive therapy on quality of life. *New Engl J Med* 1986;314:1657-1664.
- 33. Hunt SM, McEwen J. The development of a subjective health indicator. Sociol Health Illness, 1983;2:231-245.
- Doubilet P, Weinstein MC, McNeil BJ. Use and misuse of the term "cost-effectiveness" in medicine. New Engl J Med 1986;314:253-256.
- 35. Kaplan RM, Davis WK. Evaluating the costs and benefits of outpatient diabetes education and nutritional counseling. *Diabetes Care*, 1986;9:81-86.
- 36. Russell L. Is prevention better than cure? Washington, D.C.: The Brookings Institution, 1986.
- Yates BT, DeMuth NM. Alternative funding and incentive mechanisms for health systems. In: Broskowski A, Marks E, Budman SH, eds. *Linking Health and Mental Health*. Beverly Hills, CA: Sage, 1981;77-99.
- 38. World Health Organization. Health promotion: A discussion document on the concept and principles. Copenhagen: WHO Regional Office for Europe, 1984.
- 39. Kaplan RM. Quantification of health outcomes for policy studies in behavioral epidemiology. In: Kaplan RM, Criqui MH, eds. *Behav Epidem Dis Prev.* New York: Plenum, 1985;31-54.
- 40. Kaplan RM. New health promotion indicators: The general health policy model. *Health Promotion*, 1988;3:35-49.
- Kaplan RM, Anderson JP. The quality of well-being scale: Rationale for a single quality of life index. In: Walker S, Rosser R, eds. Quality of life: Assessment and application. London: MTP Press, 1987;51-77.
- 42. Weinstein MC, Stason WB. Hypertension: A Policy Perspective. Cambridge, MA: Harvard University Press, 1976.
- 43. Bush JW, Chen MM, Patrick DL. Cost-effectiveness using a health status index: Analysis of the New York State PKU screening program. In: Berg R, ed. *Health Status Index*. Chicago: Hospital Research and Educational Trust, 1973;172–208.
- 44. Chen MM, Bush JW, Patrick DL. Social indicators for health planning and policy analysis. *Policy Sciences* 1975;6:71-89.

- Fanshel S, Bush JW. A health status index and its application to health-services outcomes. Operations Research 1970;18:1021-1066.
- 46. Reynolds WJ, Rushing WA, Miles DL. The validation of a function status index. J Health Soc Behav 1974;15:271.
- 47. Stewart AL, Ware JE, Jr., Brook RH, Davies-Avery, A. Conceptualization and measurement of health for adults: Vol. 2, Physical health in terms of functioning. Santa Monica: RAND, 1978.
- 48. Patrick D, Sittanpalam Y, Somerville S, et al. A cross-cultural comparison of health status values. Am J Public Health 1985;75(12):1402-1407.
- Balaban DJ, Fagi PC, Goldfarb NI, Nettler S. Weights for scoring the quality of well-being instrument among rheumatoid arthritic. *Med Care* 1986;24(11):973–980.
- Kaplan RM, Bush JW. Health-related quality of life measurement for evaluation research and policy analysis. *Health Psychol* 1982;1:61-80.
- 51. Kaplan RM, Bush JW, Berry CC. Health status: Types of validity for an index of well-being. *Health* Serv Res 1976;11:478-507.
- 52. Anderson JP, Kaplan RM, Berry CC, Bush JW, Rumbaut RG. Interday reliability of function assessment for a health status measure: The quality of well-being scale instrument. University of California at San Diego, (*unpublished*).
- 53. Bush JW, Fanshel S, Chen MM. Analysis of a tuberculin testing program using a health status index. Social-Economic Planning Sciences 1972;6:49-69.
- 54. Patrick DL, Bush JW, Chen MM. Toward an operational definition of health. J Health Soc Behav 1973a;14:6-23.
- 55. Weinstein MC, Feinberg H. Clinical decision analysis. Philadelphia: W.B. Saunders, 1980.
- 56. Weinstein MC, Stason WB. Cost-effectiveness of coronary artery bypass surgery. Harvard University: Center for Analysis of Health Practice, 1983.
- Office of Technology Assessment, U.S. Congress. A review of selected federal vaccine and immunization policies: Bases on case studies of pneumococcal vaccine. Washington, D.C.: U.S. Government Printing Office, 1979.