ASSESSMENT OF QUALITY OF LIFE FOR SETTING PRIORITIES IN HEALTH POLICY

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INTRODUCTION

Utility is a condition or quality of usefulness. High-utility items are the most useful, and those with lower utility are less useful. States of being are also associated with utilities. Health is often identified as the highest utility asset. When Rokeach (1973) asked subjects to prioritize their values, he found no variability for the rank of health. It was always ranked first and, for this reason, was eventually removed from the Rokeach Value Scale. This chapter defines health and offers a quantitative expression of health status.

Because health is so highly valued, people will spend their energy and assets attempting to achieve it. In 1988, Americans spent $544 billion on health care services and a much larger amount on other products and services related to health. Although there is tremendous incentive to promote products and services as health-enhancing, we typically are left with little information about the extent to which health outcome is affected by these investments. Thus, another purpose of this chapter is to explore changes in a quantitative expression of health in relation to investments. First, let us consider variations in the use of expensive health care services across cultures and within the United States.

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Small Area Variation Studies

It is typically assumed that the amount of health service consumed is a reflection of the need for the service. Thus, it would be expected that in demographically equivalent communities, the use of specific health care services would be approximately equal. However, Wennberg, Freeman, and Culp (1987) have shown that this is not the case. Within New England communities with demographically equivalent populations, the variation in the use of some services is substantial. For example, women in some communities are 9 times more likely to have a hysterectomy than are women with their same characteristics in a bordering community. Men with the same symptoms are 13 times more likely to have prostate operations in some communities than in others (Roos, 1984; Wennberg, 1990).

Is More Better?

One of the basic objectives in the area of health care is to deliver service. Indeed, many policy options are justified because they provide more services. We assume that expenditure is equivalent to accomplishment. The more money allocated to a program, the better the expected outcomes. It is often assumed that the states or countries that are achieving the best health outcomes are those spending the most money. Thus, it might be argued, Americans should have the world’s best health profile because they spend the most per capita on health care.

Recently, substantial evidence has emerged suggesting that many unnecessary services are delivered by our health care system. Consider coronary artery bypass surgery. In 1979, the United States Congress Office of Technology Assessment reported that in France there are 19 such operations per million members of the population. In Austria, there are 150 such operations per million in the population. In the United States, there are nearly 800 of these operations per million (Rimm, 1985). Approximately 200,000 bypass procedures were performed in the United States in 1985—nearly twice as many as had been performed in 1980 (National Center for Health Statistics, 1986). There are also large differences in the use of other expensive interventions. For example, the number of people with end-stage renal disease is believed to be approximately equal in Western countries. Yet in the United Kingdom, less than 1 case per 1,000 was on renal dialysis, in comparison with 39 cases per 1,000 in the United States (Schroeder, 1987). As argued by a variety of analysts, there is no evidence that these regional variations in use of procedures have substantial effects on health outcomes. They do have systematic effects upon health care costs.

Policy analysts are faced with difficult choices because they hope to maximize health outcomes while maintaining control over costs. Western countries
differ in the rate at which health care costs have escalated. The United States now spends nearly 11% of its gross national product (GNP) on health care, while other countries with high technology medicine, such as Japan, spend only about 8%, and Great Britain spends about 6%. It is not clear that escalating expenditure has been associated with equal returns in health status. Among countries reporting data to the Organization for Economic Cooperation and Development, the shortest life expectancies for men are in Ireland and the longest are in Greece. Among the reporting nations, Greece paradoxically spends the smallest percentage of its GNP on health care, while Ireland spends the most. In fact, there is a rough negative relationship among the reporting nations between expenditures and life expectancy (Sick Health Services, 1988). Studies (reviewed by Voulgaropolous, Schneiderman, & Kaplan, 1989) have shown that many widely used and expensive procedures have essentially no health benefit.

In order to gain a better understanding of the alternatives in health care, we have proposed a General Health Policy Model that attempts to provide a comprehensive expression of the costs, risks, and benefits of competing alternatives in health care. Some of these choices are difficult without a model because comparing programs might be considered analogous to comparing apples to oranges.

Apples Versus Oranges

There are many alternative ways to spend money on health care. These range from complex, high technology interventions such as liver transplantation to rehabilitation to primary prevention. Comparing these alternatives might be analogous to comparing apples to oranges. Further complicating the comparison is the fact that the benefits of each intervention are measured in quite different units. Liver transplantation might be evaluated in terms of extended life expectancy. The successful procedure might be one in which the patient survives for one year. These procedures might require large expenditures for a single patient. The same amount of money might be spent to provide a different smaller benefit for a large number of people. Recently, for example, the state of Oregon was faced with a complex dilemma. They had a limited number of health care dollars and had to choose between high technology transplantation surgery and other alternatives, including prenatal care. Each liver transplant, for example, costs about $325,000. After deliberation, Oregon administrators decided to rank funding of prenatal care higher than some organ transplantation programs. Many people argued that this was a foolish decision. Yet, the systematic comparison between the benefits was not possible because the outcomes of the services were measured in quite different units. In the next sections, I will discuss models for thinking about these comparison problems. Ultimately, I will suggest that there are methods for quantifying health benefits and that the use of these models may serve to challenge many of our assumptions about health.
care. One of these assumptions is that we benefit from greater expenditures in health care.

Public policy makers are faced with complex decisions that often involve comparisons between very different alternatives. When these alternatives are measured or described using different scales, decisions can be difficult, if not impossible. Often, the confused decision-maker gives in to the most emotional appeal. In this chapter, I argue that general measurement models, based on behavioral measurement, can provide important new insights for policy makers. These models depend on general conceptualizations of the expected benefits or consequences of health care decisions. We have developed a General Health Policy Model (Kaplan & Anderson, 1988a) that quantitatively expresses the ultimate objectives of health care: to extend life expectancy and improve quality of life.

MEASUREMENT OF HEALTH STATUS

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. Shortly after, John Kenneth Galbraith, in The Affluent Society (1958), described the need to measure the effect of the health care system on quality of life. Recent years have seen many attempts to define and measure health state (Bergner, 1985; Walker & Rosser, 1988; Wenger, Mattson, Furbeg, & Elinson, 1984). Before considering any specific approach, it is worth noting that traditional indictors of health have well identified problems.

Mortality

Mortality remains the major outcome measure in most epidemiologic studies and clinical trials. Typically, mortality is expressed as a unit of time. For mortality data to be meaningful, they must be expressed as a rate, that is, the proportion of deaths from a particular cause occurring in some defined time interval (usually a year). Mortality 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). Reporting mortality rates has its advantages. They are "hard" data, despite some misclassification bias (National Institutes of Health, 1979) 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 some important illnesses (e.g., arthritis) have relatively little impact upon mortality.
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 (Bergner, Bobbitt, Carter, & Gilson, 1981), which represents the effect of disease or disability upon 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 upon physical function, social function, and mental function. These measures 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 be included in any expression of health status. For example, suppose we were evaluating the effect of Program A, integrated support and treatment, against that of Program B, no support or treatment, for randomly assigned groups of very ill, elderly, nursing home residents. Let us suppose that Program A maintained 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 follow-up, one finds Program B patients to be healthier, since the sickest had 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 combined morbidity and mortality the outcome would be very different, because mortality effects would reduce the overall health of Program B to a very low level.

Health-Related Quality of Life

The objectives of health care are two-fold. 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 (Rice, 1984).

Numerous quality of life measurement systems have evolved during the last 20 years. 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) (Bergner, Bobbitt, Carter, & Gilson, 1981), the Quality of Well-being Scale (Kaplan & Bush, 1982), and the General Health Rating Index. The latter measure, originally developed at Southern Illinois University, was adapted by the RAND Corporation under ASPE grants and has become known as the RAND Health Status Measure (Stewart, Ware, Brook, & Davies-Avery, 1978). These efforts usually involved extensive multidisciplinary collaboration between behavioral scientists and physicians and, perhaps not surprisingly, most 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 (WHO) definition of health status: "Health is a complete state of physical, mental, and social well-being and not merely absence of disease" (World Health Organization, 1948).

The second conceptual approach is based upon 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, Gorkin, Smith, Capone, and Stabein (1988) suggest that quality of life represents psychological status in addition to symptoms and mortality. In fact, most investigators believe that symptoms and mortality do represent quality of life (Bush, 1984). Croog et al. (1986) 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. Other investigators, including Hunt and colleagues (Hunt & McEwen, 1983) 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 methodological literature can assist in the evaluation of existing instruments.

Unidimensional Versus Multidimensional Constructs

Although all experts agree that quality of life is a multidimensional construct, they debate whether outcome measures must necessarily represent this multidimensional structure. Quality of life assessment can take essentially one of two major approaches: a psychometric approach or a decision theory approach. The psychometric or profile approach attempts to provide separate measures for the many different dimensions of quality of life. Perhaps the best known example of the psychometric tradition is the SIP, which is a 136-item measure that yields
12 different scores. The scores are displayed as a profile similar to a Minnesota Multiphasic Personality Inventory (MMPI).

The decision theory approach attempts to weight the different dimensions of health to gain a single unitary expression of health status. Supporters of this approach argue that psychometric approaches fail to consider that different health problems are not of equal concern: one hundred runny noses are not the same as 100 severe abdominal pains (Bush, 1984). Not uncommonly, experimental trials using the psychometric approach will find that some aspects of quality of life improve while others get worse. For example, a medication might reduce high blood pressure but also be associated with headaches and impotence. The decision theory approach attempts to place an overall value on health status by weighting the different dimensions and combining them into an aggregate quality score on the grounds that the "quality" notion is the subjective evaluation of observable or objective health states. It thus aims to provide an overall summary measure of quality of life that integrates subjective function states, preferences for these states, morbidity, and mortality.

Cost/Utility Versus Cost/Benefit

The terms cost/utility, cost/effectiveness, and cost/benefit are used inconsistently in the medical literature (Doubelet, Weinstein, & McNeil, 1986). 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, economic productivity, etc. 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 (1986) argued, there is relatively little strong empirical evidence that patient education or behavioral treatments are actually cost/beneficial. In addition, as suggested by Russell (1986), 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, such as those advocated by Yates (1978), emphasize simple, treatment-specific outcomes. For example, Yates considers the cost per pound lost as a measure of cost/effectiveness of weight loss programs (e.g., public competitions achieve a lower cost-per-pound loss ratio than 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 (WHO, 1984), 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 their 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 zero for death to 1.0 for optimum function (Kaplan, 1985a, 1985b; Kaplan & Anderson, 1988a, 1988b; Kaplan & Bush, 1982). In recent years, cost/utility approaches have gained increasing acceptance as methods for comparing many diverse options in health care (Russell, 1986; Weinstein & Stason, 1977; Williams, 1988). The purpose of the General Health Policy Model, to be described in the next section, is to evaluate different health care alternatives using common outcome units.

A General Health Policy Model

Cost studies have gained in popularity because health care costs have grown rapidly in recent years. Not all health care interventions are equally efficient in returning benefit for the expended dollar. Objective cost studies might guide policy makers toward an optimal and equitable distribution of scarce resources. Cost/utility analysis typically quantifies the benefits of a health care intervention in terms of years of life, or Quality Adjusted Life Years (QALYs). Cost/utility is a special use of cost/effectiveness that weights observable health states by preferences or utility judgments of quality (Kaplan & Bush, 1982). In cost/utility analysis, the benefits of medical care, behavioral interventions, or preventive programs are expressed in terms of well-years. These outcomes have also been described as QALYs (Weinstein & Stason, 1977), discounted life years (Kaplan, Bush, & Berry, 1976), or health years of life (Russell, 1986). Since the term quality adjusted life years has become most popular, we will use it in this presentation. QALYs integrate mortality and morbidity to express health status in terms of equivalents of well-years of life.

If a man dies of heart disease at age 50 and we would have expected him to live to age 75, it might be concluded that the disease was associated with 25 lost life years. If 100 men died at age 50 (and also had a life expectancy of 75 years)
we might conclude that 2,500 (100 men × 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 long periods of time. Although they are still alive, the quality of their lives has diminished. Quality adjusted life years take into consideration the quality of life consequences of these illnesses. For example, a disease that reduces quality of life by one half will take away .5 QALYs over the course of each year. If it affects two people, it will take away 1.0 year (equal 2 × .5) over each year period. A medical treatment that improves quality of life by .2 for each of five individuals will result in the equivalent of one QALY if the benefit is maintained over a one-year period. This system has the advantage of considering both benefits and side-effects of programs in terms of the common QALY units.

The need to integrate mortality and quality of life information is clearly apparent in studies of heart disease. Consider the case of high cholesterol. People with high cholesterol may live shorter lives if they are untreated. Thus, one benefit of treatment is to add years to life. However, for most patients, high cholesterol is not associated with symptoms for many years. Conversely, the treatment for high cholesterol may cause a variety of symptoms. In other words, in the short run, patients taking medication may experience more symptoms than those who avoid it. If a treatment is evaluated only in terms of changes in life expectancy, the benefits of the program will be overestimated because side-effects are not taken into consideration. On the other hand, considering only current quality of life will underestimate the treatment benefits because information on mortality is excluded. In fact, considering only current function might make the treatment look harmful because the side-effects of the treatment might be worse than the symptoms of elevated cholesterol. A comprehensive measurement system may take into consideration side-effects and benefits and provide an overall estimate of the benefit of treatment (Russell, 1986).

Although there are several different approaches for obtaining quality adjusted life years, most of them are similar (Kaplan, 1985b). The approach that our group prefers involves several steps. First, patients are classified according to objective levels of functioning. These levels are represented by scales of mobility, physical activity, and social activity. The dimensions and steps for these levels of functioning are shown in Table 1. Note that these steps are not actually the scale, only listings of labels representing the scale steps. Standardized questionnaires have been developed to classify individuals into one of each of these scale steps (Anderson, Bush, & Berry, 1986). In addition to classification into these observable levels of function, individuals are also classified by the one symptom or problem that bothered them most (see Table 2). About half of the population reports at least one symptom on any day. Symptoms may be severe, such as serious chest pain, or minor, such as the inconvenience of taking medication or a prescribed diet for health reasons. The functional classification (Table 1) and the accompanying list of symptoms or problems (Table 2)
were created after extensive reviews of the medical and public health literature (Kaplan, Bush, & Berry, 1976). Over the last decade, the function classification system and symptom list were repeatedly shortened until we arrived at the current versions. With structured questionnaires, an interviewer can obtain classifications on these dimensions in 11 to 16 minutes.

Once observable behavioral levels of functioning have been classified, a second step is required to place each individual on the 0 to 1.0 scale of well-

**TABLE 1** Quality of well-being general health policy model and sample calculation

<table>
<thead>
<tr>
<th>Step no.</th>
<th>Step definition</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility scale (MOB)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>No limitations for health reasons</td>
<td>-0.000</td>
</tr>
<tr>
<td>4</td>
<td>Did not drive a car, health related: did not ride in a car as usual for age (15 yr) (health related), and/or did not use public transportation (health related), or had or would have used more help than usual for age to use public transportation (health related)</td>
<td>-0.062</td>
</tr>
<tr>
<td>2</td>
<td>In hospital, health related</td>
<td>-0.090</td>
</tr>
<tr>
<td>Physical activity scale (PAC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>No limitations for health reasons</td>
<td>-0.000</td>
</tr>
<tr>
<td>3</td>
<td>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)</td>
<td>-0.060</td>
</tr>
<tr>
<td>1</td>
<td>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)</td>
<td>-0.077</td>
</tr>
<tr>
<td>Social activity scale (SAC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>No limitations for health reasons</td>
<td>-0.000</td>
</tr>
<tr>
<td>4</td>
<td>Limited in other (e.g., recreational) role activity (health related)</td>
<td>-0.061</td>
</tr>
<tr>
<td>3</td>
<td>Limited in major (primary) role activity (health related)</td>
<td>-0.061</td>
</tr>
<tr>
<td>2</td>
<td>Performed no major role activity (health related) but did perform self-care activities</td>
<td>-0.061</td>
</tr>
<tr>
<td>1</td>
<td>Performed no major role (health related) and did not perform or had more trouble than usual in performance of one or more self-care activities (health related)</td>
<td>-0.106</td>
</tr>
</tbody>
</table>

**Calculating formulas**

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

\[ W = 1 + (CPXwt + MOBwt) + PACwt + SAC wt \]

where wt is the preference-weighted measure for each factor and CPX is the symptom/problem complex. For example, the W score for a person with the following description profile may be calculated for one day as follows:
TABLE 1 Quality of well-being general health policy model and sample calculation (Continued)

<table>
<thead>
<tr>
<th>Quality of well-being element</th>
<th>Step definition</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPX-11</td>
<td>Cough, wheezing, or shortness of breath, with or without fever, chills, or aching all over</td>
<td>-0.257</td>
</tr>
<tr>
<td>MOB-5</td>
<td>No limitations</td>
<td>-0.000</td>
</tr>
<tr>
<td>PAC-1</td>
<td>In bed, chair, or couch for most or all of day (health related)</td>
<td>-0.077</td>
</tr>
<tr>
<td>SAC-2</td>
<td>Performed no major role activity (health related) but did perform self-care</td>
<td>-0.061</td>
</tr>
</tbody>
</table>

\[ W = 1 + (-0.257) + (-0.000) + (-0.007) + (-0.061) = 0.605 \]

Formula 2: Well years (WY) as an output measure:

\[ WY = [\text{No. of persons} \times (\text{CPXwt} + \text{MOBwt} + \text{PACwt} + \text{SACwt})] \times \text{time} \]


ness. To accomplish this, the observable health states are weighted by "quality" ratings for the desirability of these conditions. Human value studies have been conducted to place the observable states onto a preference continuum, with an anchor of 0 for death and 1.0 for completely well. In several studies, random samples of citizens from a metropolitan community evaluated the desirability of over 400 case descriptions. Using these ratings, a preference structure that assigns weights to each combination of an observable state and a symptom/problem has been developed (Kaplan et al., 1976). Cross validation studies have shown that the model can be used to assign weights to other states of functioning with a high degree of accuracy \( R^2 = .96 \). The regression weights obtained in these studies are given in Tables 1 and 2. Studies have shown that the weights are highly stable over a 1-year period and that they are consistent across diverse groups of raters (Kaplan, Bush, & Berry, 1978). Finally, it is necessary to consider the duration of stay in various health states. For example, one year in a state that has been assigned the weight of .5 is equivalent to .5 of a QALY. Table 1 provides an illustrative example of calculation.

The well life expectancy is the current life expectancy adjusted for diminished quality of life associated with dysfunctional states and duration of stay in each state. Using the system, it is possible to simultaneously consider mortality, morbidity, and the preference weights for these observable behavioral states of function. When the proper steps have been followed, the model quantifies the health activity or treatment program in terms of the QALYs that it produces or saves. A QALY is defined conceptually as the equivalent of a completely well year of life, or a year of life free of any symptoms, problems, or health-related disabilities.

More detailed descriptions of this system are available in other publications.
<table>
<thead>
<tr>
<th>CPX no.</th>
<th>CPX description</th>
<th>Weights</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Death (not on respondent's card)</td>
<td>-0.727</td>
</tr>
<tr>
<td>2</td>
<td>Loss of consciousness such as seizure (fits), fainting, or coma (&quot;out cold&quot; or &quot;knocked out&quot;)</td>
<td>-0.407</td>
</tr>
<tr>
<td>3</td>
<td>Burn over large areas of face, body, arms or legs</td>
<td>-0.387</td>
</tr>
<tr>
<td>4</td>
<td>Pain, bleeding, itching, or discharge (drainage) from sexual organs—does not include normal menstrual bleeding</td>
<td>-0.349</td>
</tr>
<tr>
<td>5</td>
<td>Trouble learning, remembering, or thinking clearly</td>
<td>-0.340</td>
</tr>
<tr>
<td>6</td>
<td>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</td>
<td>-0.333</td>
</tr>
<tr>
<td>7</td>
<td>Pain, stiffness, weakness, numbness, or other discomfort in chest, stomach (including hernia or rupture), side, neck, back, hips, or any joints or hands, feet, arms, or legs</td>
<td>-0.299</td>
</tr>
<tr>
<td>8</td>
<td>Pain, burning, bleeding, itching, or other difficulty with rectum, bowel movements, or urination (passing water)</td>
<td>-0.292</td>
</tr>
<tr>
<td>9</td>
<td>Sick or upset stomach, vomiting, or loose bowel movement, with or without fever, chills, or aching all over</td>
<td>-0.290</td>
</tr>
<tr>
<td>10</td>
<td>General tiredness, weakness, or weight loss</td>
<td>-0.259</td>
</tr>
<tr>
<td>11</td>
<td>Cough, wheezing, or shortness of breath with or without fever, chills, or aching all over</td>
<td>-0.257</td>
</tr>
<tr>
<td>12</td>
<td>Spells of feeling upset, being depressed, or crying</td>
<td>-0.257</td>
</tr>
<tr>
<td>13</td>
<td>Headache, dizziness, ringing in ears, or spells of feeling hot, nervous, or shaky</td>
<td>-0.244</td>
</tr>
<tr>
<td>14</td>
<td>Burning or itching rash on large areas of face, body, arms, or legs</td>
<td>-0.240</td>
</tr>
<tr>
<td>15</td>
<td>Trouble talking such as lisp, stuttering, hoarseness, or being unable to speak</td>
<td>-0.227</td>
</tr>
<tr>
<td>16</td>
<td>Pain or discomfort in one or both eyes (such as burning or itching) or any trouble seeing after correction</td>
<td>-0.230</td>
</tr>
<tr>
<td>17</td>
<td>Overweight for age and height or skin defect of face, body, arms, or legs such as scars, pimples, warts, bruises, or changes in color</td>
<td>-0.188</td>
</tr>
<tr>
<td>18</td>
<td>Pain in ear, tooth, jaw, throat, lips, tongue: several missing or crooked permanent teeth—includes wearing bridges or false teeth; stuffy, runny nose; or any trouble hearing—includes wearing a hearing aid</td>
<td>-0.170</td>
</tr>
<tr>
<td>19</td>
<td>Taking medication or staying on a prescribed diet for health reasons</td>
<td>-0.144</td>
</tr>
<tr>
<td>20</td>
<td>Wore eyeglasses or contact lenses</td>
<td>-0.101</td>
</tr>
<tr>
<td>21</td>
<td>Breathing smog or unpleasant air</td>
<td>-0.101</td>
</tr>
<tr>
<td>22</td>
<td>No symptoms or problem (not on respondent's card)</td>
<td>-0.000</td>
</tr>
<tr>
<td>23</td>
<td>Standard symptom/problem</td>
<td>-0.257</td>
</tr>
</tbody>
</table>

(Kaplan, 1985a, 1985b; Kaplan & Bush, 1982). In the following sections, we will illustrate applications of the QALY concept.

Health Promotion

Health promotion is the effort to ensure a healthy population through disease prevention and the promotion of health lifestyles. Health promotion has now become a major growth industry. Weight control alone may be a billion dollar industry. Health promotion involves not only the use of behavioral interventions, but also the use of food and drug interventions. In 1986, three of the ten most widely used drugs in the world (Tenormin, Inderal, and Aldomet) were products to lower blood pressure (Rukeyser & Cooney, 1988). One of the most important justifications for health promotion programs is that they reduce health care costs. Yet several authors have begun to challenge the cost/effectiveness of prevention or health promotion programs. In an intriguing book, Russell (1986) posed the challenging question, Is Prevention Better Than Cure? Weinstein (1986) suggested that the belief in health promotion as a money saving venture was “naive assumption number one.” More recently Warner, Wickizer, Wolfe, Schildroth, and Samuelson (1988) examined the conventional wisdom that workplace health promotion programs yield financial dividends for companies. After reviewing the literature, they concluded that most studies published prior to 1986 did conclude that health promotion programs increased profitability. However, these studies tended to use anecdotal evidence for analyses that were seriously flawed in terms of their assumptions or methodology. In fact, they found very little evidence that health promotion programs save money for companies. However, they also found little evidence against this assertion. The difficulty was that few studies had systematically examined the issue. Thus, they recommended healthy skepticism for readers of the literature. In the next sections we will review the evidence for the cost/effectiveness of interventions to lower cholesterol and to reduce cigarette smoking. The economic incentives for achieving these changes varies. In each case, the outcomes will be conceptualized in terms of years of life or well-years gained.

Industry and Health Outcomes

There is considerable commercial interest in promoting health. Indeed, many products and services are offered because they can enhance health status. Food is one of the most interesting of these commercial interests. Each year, Americans spend about $513 billion on food and beverages (about the same as they spend on health care). About $10 billion is spent on health enhancing activities, such as diet food, health clubs, diet drugs, and weight reduction programs. We spend about $800 million on frozen dinners that may not be nutritious and then devote about $350 million to diet pills and diet powders. Weight Watchers
International, one of many weight reduction programs, has had 25 million participants with 700,000 currently enrolled. The value of the company is estimated to be about $400 million in gross receipts (Rukeyser & Cooney, 1988).

An example of the commercialization of health promotion is provided by the February 13, 1989 issue of Newsweek. Each year, Newsweek magazine provides a supplement, typically written by physicians, on health promotion. This particular supplement focused on heart health. The supplement included five articles. Adjacent to each page of the supplement was a full-page ad for a commercial product. The table of contents faced an ad for Bayer aspirin. Recent evidence has suggested that regular use of aspirin may reduce the probability of a fatal myocardial infarction. However, these same studies show no advantage of aspirin for increasing survival because reductions in heart attacks are associated with increases in other types of cardiovascular death (Kaplan, 1989). The first article on heart attack prevention was followed by a two-page advertisement for Kellogg’s Oat Bran. The two-page article on exercise included two one-page advertisements, one for Schwinn Fitness Machines (stationary bicycles) and another for Nordic track stationary cross-country machines. The third article was on healthy eating. It was two pages long and was accompanied by two full-page advertisements, one for Metamucil, a bulk laxative that was promoted as a good source of wheat and oat bran, and an advertisement for Miracle Whip, which was promoted as a healthier product than mayonnaise. There was then an article on exercise, followed by another full page ad for Kellogg’s Oat Bran. Then, there was an article on what to do about a heart attack accompanied by a full page ad for Tylenol. The Tylenol ad acknowledged that many people are now taking aspirin to prevent a heart attack. The ad read, “If you are taking aspirin for your heart, you probably shouldn’t take aspirin for your headache.” The section ended with a full-page advertisement for Searle Pharmaceuticals. In total, the 20-page supplement included 10 full pages of advertising. Remarkably, the 20-page supplement on prevention of heart attacks devotes only two paragraphs to cigarette smoking, even though cigarette smoking is clearly the most important modifiable risk factor for coronary heart disease. On the back cover of that particular issue of Newsweek, somewhat far away from the healthy heart supplement, was a full-page, full-color advertisement for Marlboro cigarettes.

In the next sections, we will review the rationale for two different approaches to health promotion. One approach involves lowering cholesterol and the other requires reducing the use of cigarettes. The two approaches will be compared using concepts relevant to cost/utility analysis.

Cholesterol

Coronary heart disease remains the major cause of death in the United States. In fact, heart disease still accounts for nearly half of fatalities. Upon review of the
evidence, a National Institutes of Health (1985) Consensus Conference concluded that lowering cholesterol levels will significantly reduce deaths from cardiovascular diseases. Thus, major efforts toward cholesterol reduction have been stimulated. In previous papers, I have challenged the notion that reductions in mortality can be easily achieved through health promotion programs designed to reduce dietary cholesterol (Kaplan, 1984, 1985a).

Evidence that serum cholesterol is related to mortality has been provided in several studies. For example, Stamler, Wentworth, and Neaton (1986) presented mortality data from over 350,000 men whose cholesterol had been measured as part of the Multiple Risk Factors Intervention Trial (MRFIT). When these men were followed prospectively, there was a systematic relationship between level of elevation and blood cholesterol and likelihood of dying from heart disease.

Many health promotion programs emphasize change in dietary habits. Since cholesterol builds up in the arteries, many people assume that avoiding foods with cholesterol will reduce the chances of developing heart problems. Thus, many advertisements emphasize that particular foods have no cholesterol. However, the direct relationship between serum cholesterol and dietary cholesterol has been difficult to demonstrate. Some studies have shown that the mean serum cholesterol level is higher in countries where, on the average, high levels of fat are consumed, and the mean level of cholesterol is lower in countries where lower levels of cholesterol are consumed. Yet, correlational studies within each of these cultures often fail to show significant associations between cholesterol consumption and serum cholesterol. There are many different explanations for this failure to find an association between dietary cholesterol and serum cholesterol. For example, some authors have suggested that serum cholesterol is primarily influenced by genetic factors (Steinberg, 1979). Others suggest that a significant true correlation may be disguised because of measurement error in the assessment of dietary habits (Jacobs, Anderson, & Blackburn, 1979). Attenuation caused by this measurement error obscures potential true correlation. However, this possible explanation for a nonsignificant correlation does not mean that the significant correlation exists.

Perhaps the most pessimistic view of the cholesterol evidence has been presented by Stallones (1983). Using data from six prospective American epidemiologic studies and one British study, Stallones reported that those who die of heart disease do not consume more calories, more fat, or more cholesterol than those who remain well. Indeed, the evidence on dietary cholesterol is difficult to interpret. Studies conducted in metabolic wards clearly do demonstrate that reductions in the consumption of dietary cholesterol and dietary saturated fat result in reductions in serum cholesterol. In addition, animal studies also demonstrate the cholesterol-lowering benefits of dietary manipulation. Yet, there is very little evidence showing the long-term benefits of dietary manipulation in humans.
In previous papers, we have reviewed the experimental trials on cholesterol reduction. This is a complex literature and one that is difficult to interpret. Recently, for example, six cholesterol-lowering studies were critically evaluated (Kaplan, 1988). Several of these studies have demonstrated that lowering blood cholesterol results in reductions in coronary heart disease deaths. However, in each of these studies there is an unexpected finding for total deaths. Mortality averaged over all causes of death is typically not affected by the dietary interventions. Reductions in deaths from heart disease are usually associated with increases in deaths from other causes.

Perhaps the most influential study on cholesterol lowering was the National Heart, Lung, and Blood Institute Coronary Primary Prevention Trial (Lipid Research Clinics Program, 1984). This randomized experimental trial assigned high-risk men to either a placebo or cholestyramine, a drug that is known to reduce serum cholesterol levels significantly. Long-term follow-up was conducted over a 10-year period to determine differential mortalities from heart disease in the two groups. Cholestyramine was successful in lowering cholesterol by an average of 8.5% in the treatment group. Those in the treatment group experienced 24% fewer heart disease deaths and 19% fewer heart attacks than the placebo group. As in other studies, differences between the groups for total mortality were not statistically significant.

Although the results of the coronary primary prevention trial are very important, it is not clear that they are directly relevant to most health promotion efforts. Many authors assume that the results apply directly to diet. In fact, the subjects in the experimental all have failed to respond to dietary intervention prior to assignment into cholestyramine or placebo groups. Preliminary analysis in the CPPT trial failed to reveal any significant benefits of dietary intervention. Another feature of the CPPT trial was that it was directed to those at the extreme of the cholesterol distribution. In order to be included as a subject, a male participant had to be above the 95th percentile in serum cholesterol. The results tell us very little about diet or cholestyramine for those who did not have significantly elevated cholesterol. Even for those at high risk, the results may be difficult to understand. Although there was a 24% reduction in mortality in the treated group, the actual percentage of patients who died was similar in the two groups. In the placebo group, there were 38 deaths among 1,900 participants (2%). In the cholestyramine group, there were 30 deaths among 1,906 participants (1.6%). Thus, over a 7- to 10-year period, the medication reduced the chances of dying from 2% to 1.6%. Again, it is important to emphasize that this difference (0.4%) refers to the chances of dying from heart disease. The cholestyramine group actually had higher chances of dying from other diseases. Thus, there was no difference whatsoever in total deaths. At the end of the study, 3.7% of those in the placebo group had died, while 3.6% of those in the cholestyramine group had died. The successful intervention changed the cause of death but not the total number of people who died or survived.
Despite some of the confusion about cholesterol reduction, it has become apparent that cholesterol management is a national objective. This has been recommended by the National Institutes of Health (1985) Consensus Panel and has stimulated a growth industry of cholesterol lowering products.

One of the issues in the attempt to find methods to lower cholesterol has been the cost to achieve significant changes in health outcome. Several policy analyses have warned that cholesterol reduction will be a valuable but expensive way to promote health outcomes (Oster & Epstein, 1987; Weinstein & Stason, 1985; Himmelstein & Woolhandler, 1984). However, the high cost estimates may have resulted because the method for lowering cholesterol was an expensive cholesterol lowering drug such as cholestyramine resin. There are several alternative treatments for high cholesterol that might produce effective cholesterol lowering at a fraction of the cost. These methods have recently been compared by Kinosian and Eisenberg (1988).

In the Kinosian and Eisenberg simulation, three different approaches to cholesterol lowering were considered. The first approach involved the use of cholestyramine resin. Cholestyramine binds bile acids and blocks the endogenous production of cholesterol. A similar product, cholestrol, has equivalent effects but is offered at a lower cost. These two products were used in the analysis and were considered in two different ways. Since the products are often offered by prescription only, there is a considerable difference between retail price and bulk price. Both of these are considered in the analysis. For comparison, oat bran was also considered. There is growing evidence that oat bran, taken in substantial doses (60 to 90 g/day, or the equivalent 1 to 1.5 cups/day) can reduce serum cholesterol by 13% to 19% (Anderson, Story, Sieling, et al., 1984).

The results of the Kinosian and Eisenberg analyses are summarized in Figure 1. As the figure suggests, there are savings in cost/year of life saved for buying either cholestyramine or cholestrol in bulk. However, the most striking aspect of the figure is that oat bran produces years of life saved at a cost much less than either of the prescription medications. On a population basis, non-prescription oat bran may be the most cost-effective alternative.

We must now tackle the difficult question of whether or not investing in cholesterol lowering has advantages relative to other investments in prevention. Investments in programs to reduce cigarette smoking or to prevent cigarette smoking will be considered to illustrate this point.

Cigarette Smoking

It has now been one quarter of a century since the publication of the surgeon general's first report, Smoking and health: Report of the advisory committee to the surgeon general of the United States (U.S. Public Health Service, 1964). Twenty-five years ago there was strong evidence for the detrimental effects of
current evidence on the health consequences of cigarette smoking leaves no doubt that cigarettes cause premature deaths. According to the American Cancer Society, 390,000 people in the United States died of cigarette smoking in 1985. That is one fifth of all deaths in the United States! (American Cancer Society, 1988). Many of our public health programs are directed toward preventing the most feared types of death. Enormous amounts of public attention are devoted to AIDS, cocaine, heroin, homicide, and suicide. However, it is important to emphasize that the impact of cigarette smoking far exceeds that for any of these other causes of death. In fact, cigarette smoking causes more premature deaths than the combination of AIDS, cocaine, heroin, alcohol, fire, automobile accidents, homicide, and suicide (Warner, 1987). Thirty percent of all cancer deaths are caused by cigarette smoking, as are 21% of all cases of coronary heart disease death. Stroke, a disabling disease, is also closely linked to the use of cigarettes. An overwhelming 82% of deaths from chronic obstructive pulmonary disease (chronic bronchitis and emphysema) are attributable to cigarette smoking (American Cancer Society, 1988).

The epidemic of deaths associated with cigarette use is directly traceable to investments by tobacco companies in advertising. Groups are targeted and advertising material is directed toward them. There is substantial evidence that cigarette smoking rates increase in these targeted groups. Women, for example, are a major new target of cigarette advertising and lung cancer is now a major cause of death for women. Twenty-five years ago, lung cancer was a relatively
uncommon disease in women. Over the last twenty-five years, lung cancer rates for nonsmoking women have remained constant at about 12/100,000 women. For smoking women, lung cancer death rates rose from 23.9/100,000 to 130.4/100,000 (USDHHS, 1989). Lung cancer alone is the major factor affecting the increasing rate of deaths from cancer. In fact, age-adjusted non-lung cancer death rates have actually been falling, and we would have a declining rate of cancer death if it were not for cigarette smoking.

In addition to targeting women, the tobacco industry is also focusing on young children, minorities, and third world countries. As Warner argued in a recent editorial (Warner, 1989) we are rapidly exporting our epidemic to third world countries. It is ironic that the U.S. government is outraged that some countries have been involved in the export of cocaine to the United States. Yet at the same time, federal policies actually encourage American companies to export deadly tobacco products. Indeed, the toll in death and suffering from tobacco availability exceed that for the availability of cocaine.

Although the tobacco industry argues that they do not market cigarettes to children and adolescents, substantial evidence demonstrates the opposite. Ads for tobacco products are consistently placed in publications that are distributed primarily to the young. Indeed, the tobacco habit typically starts in youth. Ninety percent of all cigarette smokers began before the age of 19 years and 60% started by the age of 14 years. Tobacco is highly addictive, and once "hooked," cigarette smokers have great difficulty breaking the habit (US-DHHS, 1989).

Several investigators have attempted to simulate the impact of smoking cessation and smoking prevention. In one analysis, Oster, Huse, Delea, and Colditz (1986) examined the cost-effectiveness of using Nicotine gum in addition to a physician's advice against cigarette smoking. They estimated that the cost to save a year of life with smoking cessation was about $4,000 dollars. This was considerably below a wide variety of other popular prevention efforts. In another analysis, Taylor, Pass, Shepard, and Komaroff (1987) compared three different approaches to prevention. Cholesterol reduction, blood pressure reduction, and smoking prevention. They assumed that cholesterol could be lowered 6.7% with a dietary intervention because that was what was achieved in the Multiple Risk Factors Intervention Trial (MRFIT, 1982). They also assumed that blood pressure could be reduced 15%, because that was the level achieved in the Hypertension and Detection Follow-up Program (HDFP, 1979). Then, they estimated the years of life added by smoking cessation for smokers or total prevention of cigarette use. The analysis was done separately for men and women, assuming that the treatment began at age 20, 40, or 60. Figure 2 summarizes the Taylor analysis. As the figure suggests, cholesterol reduction has very little impact on life expectancy, particularly if it begins at age 60. In fact, cholesterol reduction programs may add only about 2 months of life for 60-year-old men. The benefits of blood pressure reduction are intermediate and
have the most dramatic effects if the program for men begins early in life. Most striking is the impact of programs for cigarette smoking. As the figure demonstrates, prevention of cigarette use adds a full five years of life if smoking is prevented before age 20. Clearly, not all health promotion programs yield the same benefits.

Figure 3 is adapted from the Kinosian and Eisenberg (1988) analysis. The figure compares the cost per year of life gained for a variety of treatments and preventive efforts relevant to coronary heart disease. As the figure demonstrates, the cost per year of life saved with cigarette smoking is much less than it is for cholesterol lowering or for surgery. For the cholesterol lowering options, the nontraditional, nondiagnosis related approach using oat bran is more cost-effective than the other alternatives.

CONCLUSION

In this chapter, we have considered several different approaches to prevention. Preventing heart attack deaths through cholesterol lowering is an important
approach, and one that has traditional economic advocates. There are strong financial incentives to use the traditional health care system to diagnose problems and to treat those problems using medications. Using a general health policy model, it is suggested that nontraditional approaches in which all citizens make dietary changes may be a more cost-effective approach to this problem. The most expensive approach may not necessarily be the most effective approach and is usually not the most cost-effective approach.

Not all approaches to prevention are equally useful. As this analysis has shown, investing in smoking cessation and smoking prevention yields many more benefits than do interventions to change cholesterol. Yet it is more difficult to make money preventing smoking or changing smoking habits than it is to diagnose diseases and treat them using medications. Thus, smoking cessation has fewer economic advocates than does treatment of blood pressure or cholesterol. Further, there is a strong lobby actively promoting the use of cigarettes and other tobacco products.

A general health policy model may contribute to the assessment of these policy problems. The development of the model is in a relatively early stage, and many measurement issues still need to be resolved. Nevertheless, I believe that this approach has promise for clarifying policy alternatives.
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