

Health Outcome Models for Policy Analysis

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The increasing therapeutic options in health care have created new dilemmas because resources to pay for the new technologies are limited. Cost/effectiveness and cost/utility models are required in order to evaluate the return on the invested dollar for various health care technologies. The problem is that different technologies are often evaluated using very different outcome units. The alternatives may range from liver transplantation to rehabilitation to preventive care. This article presents an overview of a general health policy model that expresses the benefits of all programs in a common unit known as the well-year—defined as the equivalent of 1 completely well year of life. The model uses two data sources: life expectancy and health-related quality of life during years prior to death. The quality-of-life component considers behavioral scales for mobility, physical activity, social activity, and symptoms. These dimensions are weighted by utility or preference to create a single scale that ranges from 0 (for death) for 1.0 (for optimum health). The model also considers duration of stay in each health state. Because all providers in health care attempt to extend life expectancy and improve quality of life, very different approaches in health care can be evaluated against one another. Preliminary analyses suggest that some behavioral interventions compete favorably with traditional medical and surgical treatments in terms of cost/well-year of life production. Various applications of the model are discussed.

Key words: cost/effectiveness, quality of life, health policy, health status

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 article, I argue that general measurement models,

based on behavioral measurement, can provide important new insights for policymakers. These models depend on very general conceptualizations of the expected benefits or consequences of health care decisions. Along with other colleagues, Anderson and I (Kaplan & Anderson, 1988a) have developed a general health policy model that quantitatively expresses the ultimate objectives of health-care—to extend life expectancy and to improve quality of life.

Reductionistic approaches to health measurement have produced important new insights. The reductionistic focus on the components of health, however, often obscures the most important outcomes. Many years ago, Brunswik (1952) offered an organizing philosophy of science for psychology that extended Darwinian principles. Brunswik's model forces the observer to consider various measures in relation to some ultimate outcome. Many measures in health psychology and medicine are intermediate or predictor variables rather than health outcomes. Triglycerides, for example, although objectively measured, do not necessarily characterize health status. Other measures, such as blood pressure or blood cholesterol, are important, but only because they bear systematic probabilistic relationships to observable health outcomes. In Brunswik's model, these blood chemistry values are proximal measures that gain their meaning through their empirical relationships with distal outcomes such as mortality and health status. Further, investigators sometimes focus too narrowly on specific outcomes without consideration of the comprehensive picture. There are many examples in which the focus on specific, easily quantifiable measures obscures the most important health outcomes. The Physicians Health Study on the benefits of aspirin is one of many such examples.

The Physicians Health Study, discussed in a recent article by Young, Nightingale, and Temple (1988), is a randomized, double-blind, placebo-controlled experimental trial. The preliminary publication of its results suggested that 325 mg of aspirin taken every other day may significantly reduce cardiovascular mortality (Steering Committee of the Physicians Health Study Research Group, 1988). The report was greeted by headlines in the popular media suggesting that aspirin is a miracle drug. Indeed, Relman (1988) wrote: "Some critics maintain that the results were too important to withhold from the public—even for only the five weeks required to review and publish it" (p. 920). However, the benefits of aspirin might have been overestimated because researchers have focused on specific outcomes without regard to a comprehensive expression of patient health. The objectives of health care include reductions in total mortality. Reductions in cause-specific mortality might not necessarily support this general objective.

Figure 1 summarizes the difference in total mortality from the Physicians Health Study. The bottom section (horizontal lines) of the figure shows the difference in fatal myocardial infarction (MI). There were 5 fatal

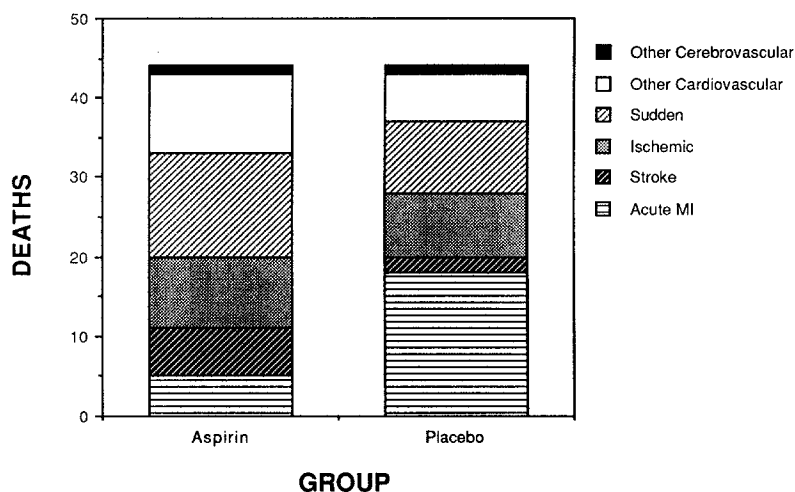


FIGURE 1 Cardiovascular deaths by treatment condition.

MI in the aspirin group and 18 fatal MIs in the placebo group. The next section in Figure 1 (dark cross-hatched) summarizes the differences for fatal stroke. There were 6 fatal strokes in the aspirin group and 2 in the placebo group. Although this yields a risk ratio of 3.00, the difference was not statistically significant ($p = .16$). The other components of the figure show death due to ischemic heart disease, sudden death, other cardiovascular diseases, and other cerebrovascular diseases. Although there were more fatal MIs in the placebo group, there were actually more deaths due to stroke, ischemic heart disease, sudden death, and other cardiovascular categories in the aspirin group. None of these differences, however, was statistically significant. The total height of the bars in Figure 1 summarizes the differences between groups for total cardiovascular mortality. There were exactly 44 deaths in the aspirin group and 44 deaths in the placebo group. In other words, the total mortality from cardiovascular and cerebrovascular deaths was identical in the two groups.

Figure 2 shows cardiovascular deaths and nonvascular deaths versus those participants in the study who were alive and healthy at the follow-up. As the figure suggests, all causes of mortality are compressed toward the bottom of the figure. The great majority of the participants (99% in each group) were alive at the time the preliminary results were published. These data hardly justify the bold claims made in the popular media about the life-extending benefits of aspirin.

Although there was a significant benefit in terms of the relative risk ratio with respect to one event—MI—the increment in survival benefit in the Physicians Health Study was less than 1%. Even for the MI variable, statistical detection of the effect was aided by an enormous sample size. A some-

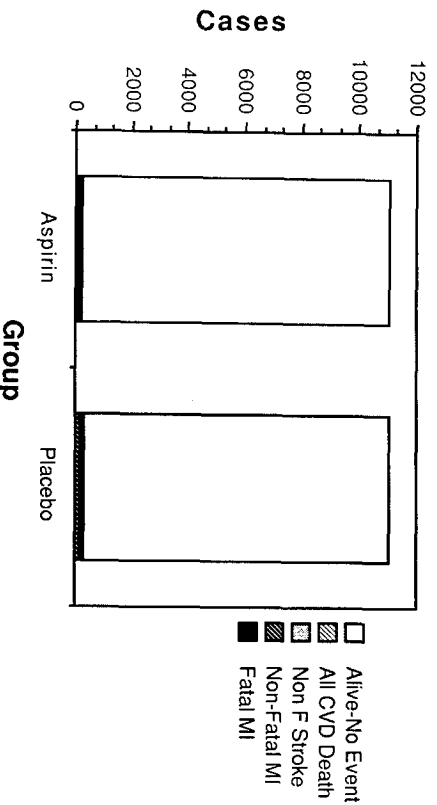


FIGURE 2 Fatal and nonfatal outcomes by treatment.

what smaller, British equivalent of the Physician Health Study, published approximately the same time, showed no benefit of aspirin (Peto et al., 1988). Neither study attempted to document the minor inconveniences or side effects associated with using aspirin. Further, the physicians in the study were male and in the age range that made them subject to MI. If the general public (including younger women) took aspirin regularly, there might be more potential risk because individuals at lower risk for MI might be subjected to the potential risk of the drug, whereas a smaller proportion would be exposed to its benefits.

The objective of treatment is to extend life expectancy and improve quality of life. Examining cause-specific mortality might produce misleading results. Exchanging categories marked on death certificates does not meet the broad objective of improved health outcome.

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 terms. Liver transplantation might be evaluated in terms of extended life expectancy. The successful procedure might be one in which the patient survives for 1 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 to each of a large number of people. Recently, for example, the state of Oregon was faced with a com-

plex dilemma. It had a limited number of health care dollars and had to choose between high-technology transplantation surgery and other alternatives including prenatal care. After deliberation, the state decided to rank funding of prenatal care higher than some organ-transplantation programs. Many people argued that this was a foolish decision. Yet, systematic comparison of benefits was not possible because the outcomes of the services were measured in quite different terms. How can we compare apples to oranges? In the next sections, I discuss models for thinking about these problems. Ultimately, I suggest that there are methods for quantifying health benefits and that the use of these models might serve to challenge many of our assumptions about health care. One of these assumptions is that we benefit from greater expenditures in health care.

IS MORE BETTER?

One of the basic objectives in health care is to deliver service. Indeed, many policy options are evaluated as to whether they provide service. We assume that expenditure is an accomplishment. The more money allocated to a program, the better we expect the outcomes to be. It is often assumed that the states or countries that are doing the most important things in health are those spending the most money.

Recently, substantial evidence has emerged suggesting that many unnecessary services are delivered by our health care system. Consider coronary artery bypass surgery. The Office of Technology Assessment (1979) reported that there are 19 such operations per million members of the French population. In Austria, there are 150 per million in the population. In the United States, there are nearly 800 operations per million (Rimm, 1985). Approximately 200,000 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, fewer than 1 case per 1,000 was on renal dialysis in comparison to 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 on 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 their rate of escalation of health care costs. The United States now spends nearly 12% of its gross national product (GNP) on health care, whereas other countries with high-technology medicine (e.g., Japan) spend only about 8%; Great Britain spends about 6%. It is not

clear that escalating expenditure is associated with an equal return of health status. Among countries reporting data to the Organization for Economic Co-operation and Development, the shortest life expectancies for men were in Ireland, and the longest were in Greece. Among the reporting nations, Greece paradoxically spends the smallest percentage of its GNP on health care, whereas 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 Voulgaropoulos, 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.

COST/UTILITY VERSUS COST/BENEFIT

The terms *cost/utility*, *cost/effectiveness*, and *cost/benefit* are used inconsistently in the medical literature (Doubilet, Weinstein, & McNeil, 1986). Some economists have favored the assessment of cost/benefit. These approaches measure 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, and so forth. Treatments are cost-beneficial if the economic return exceeds treatment costs. Diabetic patients who are aggressively treated, for example, might 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 might 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 and DeMuth (1981), have emphasized simple, treatment-specific outcomes. For example, Yates and DeMuth considered the cost per pound lost as a measure of the cost/effectiveness of weight-loss programs. 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 might need to decide between supporting liver transplantation for a few patients versus supporting 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 for a treatment effect as the unit of outcome. As noted by the World Health Organization (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 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 (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 GENERAL HEALTH POLICY MODEL

Our approach to these problems is reflected in a general health policy model.

Quality of Well-Being Scale

The Quality of Well-Being Scale outcome measure is part of a general health policy model (Kaplan & Anderson, 1988a). The purpose of the system is to express benefits and side effects of the program in terms of equivalents of completely well-years of life. The years-of-life figure is adjusted for diminished quality of life produced by disease or disability. Scores on the Quality of Well-Being Scale are obtained by classifying people into one step in each of the scales described in Table 1. In addition, subjects indicate the symptom or problem that bothered them most on a particular day (Table 2). Each of these steps is associated with a weight derived from community surveys to reflect social preference or utility for the state on a scale ranging from 0 (dead) to 1.0 (for optimum functioning). (See Tables 1 and 2.) A score of .64, for example, suggests that an individual was in an observable state for which the societal preference was 64% of the distance between optimum functioning and death. The person remaining in this state for 1 year would have lost .36 (or $1.0 - .64$) well-years. Prognoses in the model are defined by transitions among observable states over time. These are represented in all

TABLE 1
Quality of Well-Being General Health Policy Model
Elements and Calculating Formulas

Step Number	Step Definition	Weight
<i>Mobility Scale (MOB)</i>		
5	No limitations for health reasons.	-.000
4	Did not drive a car, health related; did not ride in a car as usual for age (younger than 15 years), health related, <i>and/or</i> did not use public transportation, health related; <i>or</i> had or would have used more help than usual for age to use public transportation, health related.	-.062
2	In hospital, health related.	-.090
<i>Physical Activity Scale (PAC)</i>		
4	No limitations for health reasons.	-.000
3	In wheelchair, moved or controlled movement of wheelchair without help from someone else; <i>or</i> had trouble or did not try to lift, stoop, bend over, or use stairs or inclines, health related, <i>and/or</i> limped, used a cane, crutches, or walker, health related; <i>and/or</i> 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, <i>or</i> in bed, chair, or couch for most or all of the day, health related.	-.077
<i>Social Activity Scale (SAC)</i>		
5	No limitations for health reasons.	-.000
4	Limited in other (e.g., recreational) 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, <i>and</i> 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 :

$$W = 1 + (CPX_{wt}) + (MOB_{wt}) + (PAC_{wt}) + (SAC_{wt}),$$

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 1 day as follows:

<i>Quality of Well-Being</i> CPX-11	<i>Step Definition</i>	<i>Weight</i>
	Cough, wheezing, or shortness of breath, with or without fever, chills, or aching all over.	-.257
	(Continued)	

TABLE 1 (Continued)

<i>Calculating Formulas^a</i>		
<i>Quality of Well-Being</i>	<i>Step Definition</i>	<i>Weight</i>
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.	-.061

$$W = 1 + (-.257) + (-.000) + (-.007) + (-.061) = .605.$$

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

$$WY = [\text{Number of Persons} \times (\text{CPXwt} + \text{MOBwt} + \text{PACwt} + \text{SACwt})] \times \text{Time}.$$

^aFunction scales, with step definitions and calculating weights.

calculations of well-years. Using this system, it is possible to estimate the number of well-year equivalents produced by a program. Dividing the cost of the program by the well-year production results in an estimate of the cost/utility of the program. The cost/utility ratio can be used to compare the relative value of different programs, thereby providing a common metric for comparison of programs with different specific objectives.

Applications

The general health policy model has been used to evaluate outcomes in a variety of settings. Unfortunately, I do not have the opportunity to review each of these applications in detail here. Suffice to say that different investigators have estimated the expected well-year benefits of competing interventions. Figure 3 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%, cost nearly \$500,000 to produce the equivalent of 1 well-year. Traditional medical interventions in prevention, such as cholesterol and blood pressure reduction, are much less expensive to produce the equivalent of 1 well-year. 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 Figure 3 come from a variety of different studies. In many of these cases, the health benefits were estimated using expert judgment. The accuracy of these estimates without detailed follow-up is unknown. 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, I believe that the gen-

TABLE 2
List of Quality of Well-Being General Health Policy Model
Symptom/Problem Complexes (CPX) With Calculating Weights

<i>CPX Number</i>	<i>CPX Description</i>	<i>Weight</i>
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.	-.387
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, stomach (including hernia or rupture), side, neck, back, hips, or any joints or 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 movement, with or without fever, chills, or aching all over.	-.290
10	General tiredness, weakness, or weight loss.	-.259
11	Cough, wheezing, or shortness of breath <i>with</i> or <i>without</i> 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 nervous, 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 being unable 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 for age and height or skin defect of face, body, arms, or legs, such as scars, pimples, warts, bruises, or changes in color.	-.188
18	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.	-.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.	-.257

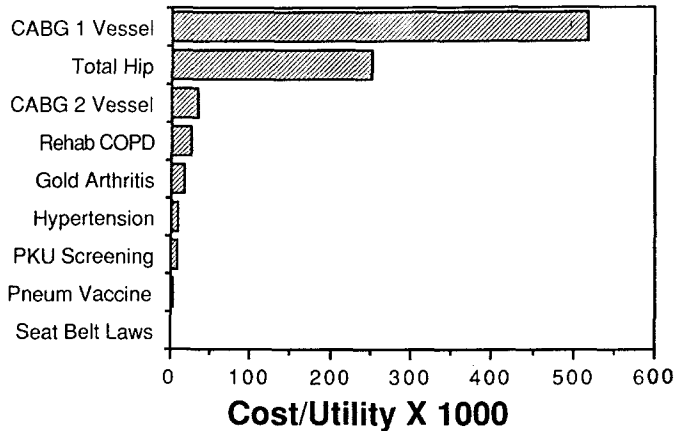


FIGURE 3 Cost per well-year for various programs, in 1988 U.S. dollars. CABG 1 Vessel = coronary artery bypass surgery (data from Weinstein & Stason, 1982), Total Hip = total hip replacement (data from Liang et al., 1986), CABG 2 Vessel (data from Weinstein & Stason, 1982), Rehab COPD = chronic obstructive pulmonary disease (data from Toevs, Kaplan, & Atkins, 1984), Gold Arthritis = oral gold medication in rheumatoid arthritis (data from Thompson, Read, Hutchins, Paterson, & Harris, 1988), Hypertension = screening and treatment for 40-year-old men with diastolic blood pressure of 90 to 100 mm Hg (data from Weinstein & Stason, 1977), PKU Screening = phenylketonuria (data from Bush, Chen, & Patrick, 1973), Pneum Vaccine = pneumococcal vaccine for older adults (data from Office of Technology Assessment, 1979), Seat Belt Laws = laws requiring mandatory seat belt use (data from Kaplan, 1988).

eral health policy model provides a new, unique way of thinking about alternatives in health care. I hope to see more systematic experimental trials that employ structured measures such as the Quality of Well-Being Scale. As more data accumulate, I hope to provide a stronger data base for comparing different alternatives in health care.

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