

# DECISION MAKING IN MEDICINE AND HEALTH CARE

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Robert M. Kaplan

*Department of Health Services, School of Public Health, University of California,  
Los Angeles, California 90095-1772; email: rmkaplan@ucla.edu*

Dominick L. Frosch

*Robert Wood Johnson Health & Society Scholars Program, University of Pennsylvania,  
Philadelphia, Pennsylvania 19104; email: frosch@wharton.upenn.edu*

**Key Words** medical decision making, quality of life, shared decision making,  
patient-provider interaction, decision aids

■ **Abstract** Decision making is central to health policy and medical practice. Because health outcomes are probabilistic, most decisions are made under conditions of uncertainty. This review considers two classes of decisions in health care: decisions made by providers on behalf of patients, and shared decisions between patients and providers. Considerable evidence suggests wide regional variation exists in services received by patients. Evidence-based guidelines that incorporate quality of life and patient preferences may help address this problem. Systematic cost-effectiveness analysis can be used to improve resource allocation decisions. Shared medical decision making seeks to engage patients and providers in a collaborative process to choose clinical options that reflect patient preferences. Although some evidence indicates patients want an active role in making decisions, other evidence suggests that some patients prefer a passive role. Decision aids hold promise for improving individual decisions, but there are still few systematic evaluations of these aids. Several directions for future research are offered.

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## UNCERTAINTY IN MEDICINE

Considerable uncertainty surrounds many medical decisions (Gillett 2004, Kaplan et al. 2004, Kemm 2004, Scheidt et al. 2004). Often, patients come to treatment expecting benefit. However, experienced clinicians are aware that not all patients benefit from each episode of treatment. Instead of being certain, most health outcomes are probabilistic (Lurie & Sox 1999, Ratliff et al. 1999). This chapter considers the process of medical decision making. We pay particular attention to the role of uncertainty in the decision process. Part of our mission is to gain a better understanding of the patient's role in medical decision making.

Most patients expect their physicians to make a perfectly reliable diagnosis for each of their medical problems. In an ideal world, a patient could approach a physician with a list of symptoms and problems. The physician would identify the problem and administer a remedy. The service would be inexpensive, effective, and painless. However, a substantial literature suggests that medical decisions rarely meet these ideals (Eddy 1996). Further, there is substantial variability in the treatment options used by physicians (Wennberg 1998, Wennberg et al. 2004). Until recently, medical decisions were left in the hands of the physician. Patients were advised, but rarely consulted, about the alternatives. Over the past decades, patients have been gaining an increasing role in the medical decision process (Frosch & Kaplan 1999a).

A new paradigm in health care is emerging. Shared decision making is a process by which patients and physicians join together in a partnership to evaluate the alternatives for a particular medical decision (Elwyn et al. 1999b, Frosch & Kaplan 1999b, Woolf 1997). Patients and physicians have multiple options when confronted with most medical problems. In shared decision making, the dyad begins with the recognition that there is uncertainty about diagnostic and treatment pathways for many conditions. Patients learn of the risks and benefits associated with each option and often participate in guided exercises to help them understand the consequences of different alternatives. Information can be presented using a variety of formats (O'Connor et al. 2003). Many components of health care decisions involve factors that cannot be known by the health care provider. For example, many decisions involve concerns about sexual side effects or cosmetic features. Shared decision making involves elicitation of these preferences and their integration into the formal decision process. We discuss the emerging field of shared decision making in the last sections of this chapter. First, we develop the rationale for new approaches to medical decision making.

## The Reliability and Consistency of Clinical Decisions

The traditional Biomedical Model treats disease as a binary variable. People are sick or they are not. However, most chronic diseases are gradual processes and cannot be classified as binary. The threshold for deciding whether someone has the disease can be ambiguous. Many biological variables, such as cholesterol, blood pressure, and blood glucose, are normally distributed in the population. For most of these variables, an expert panel decides that a certain point along the continuum separates disease from nondisease. For several conditions, values now considered risk factors for disease were considered completely normal only a few years ago (Kaplan et al. 2004). Within the past year, for example, lower diagnostics thresholds have been set for blood pressure (Chobanian et al. 2003), blood glucose (Genuth et al. 2003), and cholesterol (Grundy et al. 2004). Setting diagnostic thresholds has a substantial impact upon health care costs. Pharmaceutical companies, for example, benefit significantly from lowering diagnostic thresholds. Each time the threshold is lowered, a significantly larger portion of the population is eligible to use particular pharmaceutical products.

In the definition of the disease, judgment also enters in the interpretation of clinical data. Using their experience, clinicians examine and interpret clinical information. Like any judgment, these perceptions are not always reliable. It is known that physicians are highly variable in their interpretation of clinical data. They disagree with one another when examining the same clinical information (Eddy 1994). Further, they disagree with themselves when presented with the same information at two points in time. Many examples support this claim. For instance, one study gave cardiologists high-quality angiograms and asked them to say if the stenosis in the left anterior descending artery was greater than 50%. This judgment is important because it is usually the threshold for revascularization of the coronary arteries. The study showed that the clinicians disagreed with one another in about 60% of the cases (Zir et al. 1976). In another study, cardiologists were given the same angiograms at two different times. At the second assessment, they disagreed with their own first judgment in 8% to 37% of the cases (Detre et al. 1975).

Another study evaluated the reliability of pathologist-assessed ductile carcinoma in situ (DCIS). Six pathologist subjects were given written guidelines and examples of each of the problems for which they were looking. Following this training, these experienced pathologists were given 24 high-quality slides of breast tissue. There was considerable variability in the propensity to see DCIS. One pathologist saw cancer in 12% of the slides while another saw DCIS in 33% of the same slides. Among 10 slides where at least one pathologist saw DCIS, no two pathologists had the same pattern of identification. One case was diagnosed by only one pathologist, and only two cases were seen by all six (Schnitt et al. 1992, Welch 2004). These variations in diagnostic patterns imply that patients with the same problem, going to different doctors, may get different diagnoses. Table 1 summarizes studies from health status assessment, radiology, and pathology suggesting poor reliability of diagnostic judgment.

**TABLE 1** Examples of studies on clinician agreement for studies in health status, radiology, and pathology

Reference	Problem	Comparison	Reliability	Comments
(Rothwell et al. 1997)	Which domains of the SF-36 are important for patients with multiple sclerosis	Patients versus clinicians	Poor agreement on which dimensions are important	Measures of disability were poorly correlated with patient-rated quality of life
(Shiels et al. 1996)	Evaluation of intervention to improve reliability for severity-of-illness judgments	25 clinicians reviewed 14 patient records before and after training	Interclass correlations low before intervention and improved little with intervention	Reliability problems are not easily remedied through training
(Unsworth et al. 1995)	Discharge decisions for stroke patients	13 multidisciplinary teams (74 clinicians) rated 50 hypothetical cases	Poor correspondence of recommendations across teams	Recommendations may depend on characteristics of teams as much as on characteristics of patients
Pathology				
(Kendall et al. 1998)	Endometrial cancer diagnosis	Five pathologists rated 100 endometrial biopsies	Kappas ranged from 0.67 to 0.89. For atypical hyperplasia, kappa = 0.47	Individual pathologists attend to different features
(Sylvester et al. 1998)	Site variability in postmortem blood alcohol determination	Blood alcohol was measured from six sites in nine subjects (after death)	Taking samples from different sites produced different estimates of blood alcohol	Choice of site for sample can affect results
(Frierson et al. 1995)	Histological grading of infiltrating ductal breast cancer	Six surgical pathologists rated 75 infiltrating ductal tumors	Kappas ranged from 0.43 to 0.74 for histological grade	Normalizing mitotic counts resulted in only slight improvement

Radiology					
(Drapé et al. 1998)	Agreement on MRIs for articular cartilage abnormalities in osteoarthritis	Multiple observers rated images from 43 patients	Interobserver reliability = 0.80	Ratings were significantly correlated with anatomic findings	
(Naitoh et al. 1998)	Use of intraoral radiography to detect dental caries	Six observers rates 93 tooth surfaces	Kappa for interobserver agreement = 0.43	Agreement for diagnosis of caries modest using two different methods	
(Bright et al. 1997)	Evaluation of rotator cuff disease	Six reviewers with different levels of training rated radiographs of 40 patients twice (separated by four months)	Kappa for interobserver reliability ranged from 0.01 to 0.75. For intraobserver, kappas ranged from 0.26 to 0.80	Reliability was higher for those with more training	
(Mussurakis et al. 1996)	Detection and differentiation of breast cancer using contrast-enhanced MRI	Three radiologists reviewed MRIs from 57 women	Agreement between radiologists was only moderate	Agreement better for detection than for differentiation	
(Dahlström & Lindvall 1996)	Panoramic radiography to assess TMD	Two oral radiologists reviewed 50 TMD and 20 non-TMD cases on multiple occasions	Interobserver agreement varied between 0.22 and 0.65	Agreement improved some after calibration training	
(Jarvik et al. 1996)	MRI for lumbar disk disease	Three radiologists reviewed 34 consecutive patients with back pain	Kappas for extrusion present ranged from 0 to 0.78	Agreement for presence or absence of extrusion was only modest	

From (Kaplan 2003). Abbreviations: MRI, magnetic resonance imaging; SF-36, Medical Outcomes Study 36-Item Short Form; TMD, temporomandibular joint disease.

## How Much Health Care Do We Need? The Geographic Distribution of Health Services

Epidemiology is the study of the distribution and determinants of disease. Using epidemiologic methods, investigators have revealed that diseases, such as multiple sclerosis and coronary heart disease, are more common in some areas than others. Heart disease and stroke, for example, are more common in the Deep South in comparison to the North or Far West regions of the United States (Obisesan et al. 2000, Pickle & Gillum 1999). However, disease prevalence explains only part of the differences in the use of health care in different regions. After controlling for the prevalence of disease in different communities, we would expect rates of health care use to be roughly equivalent. However, physicians vary markedly in the rates of illness they detect and the services they recommend. Wennberg and his colleagues have devoted the past quarter century to the description of this problem (Wennberg 1996, Wennberg & Gittelsohn 1982). They report that a major factor in the use of medical services is supplier-induced demand; providers create demand for their services by diagnosing illnesses. When new diagnostic technologies gain acceptance from physician groups, new epidemics of "disease" appear. One of the earliest documented cases of supplier-induced demand was described by Glover in the United Kingdom. Glover recorded the rates of tonsillectomy in the Hornse Burrough school district. In 1928, 186 children in the district had their tonsils surgically removed. The next year, the doctor who enthusiastically supported tonsillectomy was replaced by another physician who was less attracted to the procedure. In 1929, the number of tonsillectomies had been reduced to only 12 (Wennberg 1990).

Often, surgeons agree on the need to perform surgery. For example, there are high-consensus diagnoses, such as resection of the colon for colon cancer and surgery for appendicitis. Other areas of high agreement might include amputation of a toe with gangrene, removal of some well-defined tumors, or intervention to repair a compound fracture. However, for most surgical procedures, there is substantial discretion and rates for surgery vary (Birkmeyer et al. 2003, Finlayson et al. 2003, Pope et al. 2002).

**BOSTON VERSUS NEW HAVEN, A CASE EXAMPLE** Boston, Massachusetts, and New Haven, Connecticut, are similar in many ways. Both are traditional New England cities that have multiethnic populations. The two cities have approximately the same climate and both cities are home to prestigious Ivy League universities. Since the cities are near one another, we would expect that the costs of medical care would be approximately the same. Using data from the mid 1970s, Wennberg and colleagues (Wennberg et al. 1987) demonstrated that, in fact, medical care costs in Boston were nearly twice as high as they were in New Haven.

In 1975, Medicare was paying \$324 per recipient per month for people in Boston and only \$155 per month for residents of New Haven. The situation has not changed much. In 1989, per capita hospital expenditures for acute care were

\$1524 for residents of Boston and \$777 for those living in New Haven. By 2000, medical care in the United States had changed, but most differences between practice in Boston and practice in New Haven remained.

Further study by Wennberg and his colleagues showed that Boston has more hospital capacity than does New Haven. In Boston, there are 4.3 hospital beds for every 1000 residents, whereas in New Haven there are fewer than 2.3 beds per 1000 residents. Residents of Boston are more likely to be hospitalized for a wide variety of acute medical conditions than are residents of New Haven. For medical conditions such as pneumonia or congestive heart failure, Bostonians were more likely to be cared for as hospital inpatients while residents of New Haven were treated outside the hospital.

Boston is rich with medical institutions. Boston has three medical schools (Harvard, Tufts, and Boston University); New Haven has only one major medical school (Yale). Further, the Harvard Medical School is associated with a variety of teaching hospitals. Boston has four hospitals associated with different religious establishments while there is only one religious-affiliated hospital in New Haven.

The Boston-New Haven comparison is particularly interesting from a public policy perspective. U.S. Medicare is a federal program that hopes to provide equal benefit to all of its recipients. Yet, on average, Medicare now spends about \$1.64 in Boston for each \$1.00 it spends in New Haven (Wennberg et al. 2002). Are New Haven residents getting a bad deal? Since the government is spending less on New Haven residents, it might be argued that the health of New Haven residents will suffer because they receive insufficient medical attention. However, evidence does not show that residents of Boston are any healthier than are residents of New Haven. In fact, some evidence implies that Boston residents may be worse off. For example, people in Boston are more likely to be rehospitalized for the same condition in comparison to people in New Haven (Fisher et al. 1994). Residents of Boston appear to have more complications from medical treatment.

It seems plausible that communities with greater hospital resources are better able to care for their populations. More health care should lead to more health. However, several analyses have shown that people are slightly more likely to die in communities where more acute hospital care is used. An obvious explanation is that these communities have people who are older, sicker, or poorer. However, in a careful analysis that controlled for age, sex, race, income, and other variables related to illness and the need for care, none of these variables was able to explain the relationship (Fisher et al. 2003). In other words, the analysis suggests that more is not better. In fact, it implies that more may be worse.

Studies of end-of-life care offer another compelling example of the uncertainty in medical decision making. There is remarkable variation in the quantity of services patients receive during the final stages of life (Wennberg 1998). It does not appear that this reflects differences in disease burden or patient preferences (Fisher et al. 2003). In one evaluation, Wennberg and colleagues examined end-of-life care among hospitals listed by *U.S. News and World Report* as America's best hospitals. Using Medicare claims data, they were able to get data on 100% of hospital

admissions. The analysis of more than 100,000 patient records demonstrated that the intensity of care during the last six months of life and at the time of death vary dramatically across geographic areas in the United States. Using hospitals as the unit of analysis, the average stays ranged from 9.4 to 27 days. The number of days in the ICU varied from 1.6 to 9.5 days per person. The variation was not explained by common indicators such as teaching hospital versus community hospital. For example, at the University of California, San Francisco Medical Center, patients had on average 27 physician visits, with about 30% seeing 10 or more physicians. At New York University Hospital, patients on average had 76 physician visits. In New York, 57% of the patients saw 10 or more physicians and the number of hospital days was more than 2.5 times greater than the rate in San Francisco. Despite these variations, there was no evidence that patients in New York had better outcomes.

The selection of hospitals from the *U.S. News and World Report* list is of interest. All of these hospitals are believed to be the very best in the nation. However, the care delivered within these hospitals varies dramatically. If the high-quality hospitals are treating patients in very different ways, can they all be offering the highest quality care? If different doctors are making different decisions, can they all be making the right decisions?

**IMPLICATIONS OF PROVIDER DECISION VARIATIONS** If there is variation in the use of medical services, might it be better to live in an area where you could get the most care? Why is there so much variation in the first place? Could it be that some doctors are missing important diagnoses and others are overdiagnosing nonexistent medical problems? Studies in small area variation do not allow us to answer these questions. However, we do know that patients who receive a diagnosis are likely to get treatment. Sometimes the treatment they receive will not offer benefit.

The connection between diagnosis and treatment raises several important issues. Because diagnoses typically lead to treatment, people living in areas with high use of diagnostic tests are more likely to get further workup for health conditions. Kaplan & Saltzstein (2005) recently considered the issue of declining cancer rates among the oldest members of society. The rate of diagnoses of breast cancer increases with age until about age 75. Thereafter, identification of new breast cancer systematically declines with age. Similarly, the use of mammography increases until about age 75 and systematically declines in a manner parallel to the rate of known new breast cancer cases (see Figure 1). One of the problems is that many cases of identified disease may never affect patients during their lifetime. We refer to this as "pseudodisease" rather than real disease. Pseudodisease is defined as disease that, although identifiable by a pathologist, will never have an impact on life expectancy or quality of life. Identification of pseudodisease increases anxiety, cost, and the strain upon the health care system. However, because pseudodisease is clinically unimportant, its identification has no impact on population health outcomes (Kaplan et al. 2004).

In summary, there is reason to question the conclusions of even the most trusted health care providers. Different clinicians, considering the same patients, will



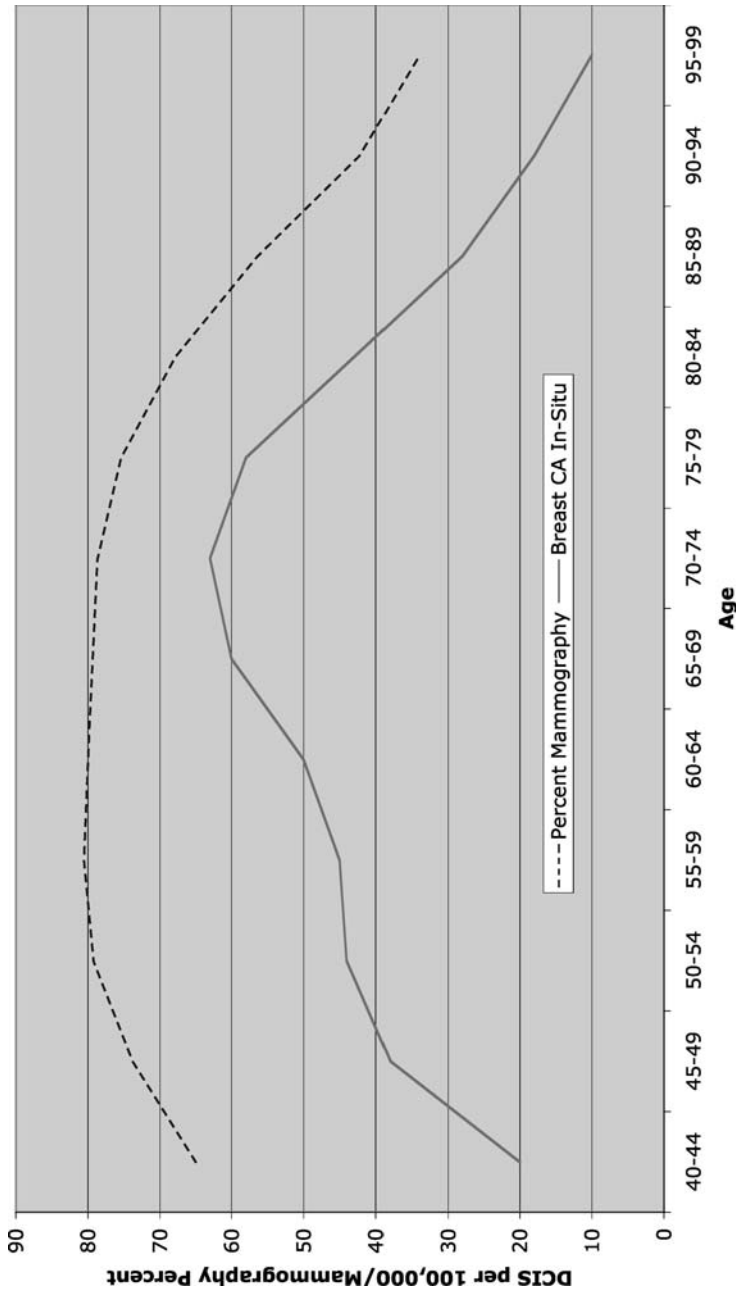


Figure 1 Mammography and breast ductile carcinoma in situ by age.

make very different diagnoses and will recommend different treatment pathways. These decisions are usually made with minimal patient consultation. Frequently, important aspects of the patient's preferences are unknown to the clinician. In the following sections, we consider two different approaches to the variation problem. The first approach uses health policy options. Evidence-based reviews are used to set clinical policy by applying policy decision models to identify the best use of limited health care resources.

## POLICY MODELS

How might patient preferences be integrated into the process? The remainder of this chapter introduces decision models that might contribute to this goal. Before reviewing applications of the models, two conceptual issues are introduced. The first is a conceptualization of health outcomes and the second is a "disease reservoir model" that probes our understanding of the need for health services.

### Evidence-Based Medicine

In order to address the problem of variation, medicine has embraced the approach of evidence-based medicine. Evidence-based medicine is defined as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (Eddy 2001, p. 271). Evidence-based medicine, which was introduced at McMaster University in Canada, has gained significant international attention. The approach involves systematic reviews of the literature and evaluation of studies using formal rules of evidence. Although most health care practitioners often believe that they practice evidence-based medicine, the rules of evidence rarely have been applied formally. Thus, individual practitioners exercise their own opinion as to what treatments worked or did not work (Davidson et al. 2003).

In the development of evidence-based guidelines, peer groups assemble the published literature. More credit is given to randomized, clinical trials than to studies with other research designs. Quality of evidence is assessed based on length of follow-up, quality of outcome measures, and characteristics of the experimental design.

Evidence-based medicine is important in resolving problems of uncertainty in medicine. Those who practice evidence-based medicine might use common synthesis of the literature to make judgments about the efficacy of treatment. Formal evidence-based medicine centers provide systematic guidance, accessible over the Internet, for the management of a large number of medical conditions.

### Clinical Guidelines

The purpose of clinical guidelines is to provide direction to clinicians so that different providers practice from a common protocol. Ultimately, this should result

in reduced practice variation. Practice guidelines are now used commonly in clinical medicine. Guidelines developed by professional associations may be given less credibility than those developed through government agencies or through respected organizations such as the American Heart Association or the American Diabetes Association. Nevertheless, there are concerns about bias, particularly since it has been documented that participants in expert review panels often have consultant relationships with the industries that produce the products they are reviewing. For example, one study found that 81% of clinical practice guidelines authors had financial relationships with the pharmaceutical industry and 59% had relationships with companies whose drugs were evaluated in the guidelines they authored (Choudhry et al. 2002, Kassirer 2004).

Despite the controversy, evidence-based medicine guidelines have become a boom industry. Adherence to guidelines has become the gold standard for quality. For example, in one recent study by McGlynn and colleagues, four 9-member multidisciplinary panels from different geographic regions estimated the best approach to the management of a variety of health conditions. In a telephone survey, adults living in 12 metropolitan areas were asked about their health care experiences and written consent was obtained to review their medical records. The investigators evaluated performance on 439 indicators for 30 acute and chronic medical conditions and for preventive care. The study suggested that just more than half of the participants received the recommended care for their health conditions. For some conditions, such as alcohol dependence, adherence to recommended care was only about 10%. The authors concluded that the health of Americans is compromised because physicians do not adhere to treatment guidelines (McGlynn et al. 2003).

Despite the appeal of this analysis, we do not have clear evidence that aggressive adherence to clinical guidelines actually results in patient benefit. Problems with the analysis include the disease-focused instead of person-focused approach of most guidelines and the lack of explicit flexibility guidance (i.e., when the rules can be bent). Another problem is that it is difficult to do evidence-based reviews for mild spectrum conditions because there is no systematic evidence base of randomized trials. Once a program is shown to be effective in the severe spectrum of a disease, there is a tendency to extend the findings to those with mild-spectrum disease despite the lack of supporting evidence and a possible shift in the risk-benefit ratio.

## Defining Health Outcomes

The clinical guidelines model identifies approaches that represent provider consensus, but does not always consider patient perspective. In order to quantify the benefits of health care, it is necessary to build a comprehensive model of health benefit. Traditional measures of health outcomes are very general. They include life expectancy, infant mortality, and disability days. The difficulty with these indicators is that they do not reflect most of the benefits of health care. For example, life expectancy and infant mortality are good measures because they allow for comparisons between programs with different specific objectives. The difficulty

is that neither is sensitive to minor variations in health status. Treatment of most common illnesses may have relatively little effect on life expectancy. Infant mortality, although sensitive to socioeconomic variations, does not register the effect of health services delivered to people who are older than one year.

Survival analysis is an attractive generic measure of health status. Survival analysis gives a unit of credit for each year of survival. Suppose, for example, that a person has a life expectancy of 80 years and dies prematurely at age 50. In survival analysis, they are scored as 1.0 for each of the first 50 years and zero each year thereafter. The problem is that years with disability are scored the same as those years in perfect health. For example, a person with severe arthritis who is alive is scored the same as someone in perfect health. To address this problem, we have proposed adjusted survival analysis. Using this method, we can summarize outcomes in terms of quality-adjusted life years (QALYs). In quality-adjusted survival analysis, years of wellness are scored on a continuum ranging from zero for death to 1.0 for optimum function (Kaplan 1994).

QALYs are measures of life expectancy with adjustments for quality of life (Gold 1996a; Kaplan 1990, 1994; Weinstein et al. 1996). QALYs integrate mortality and morbidity to express health status in terms of equivalents of well years of life. If a woman dies of breast cancer at age 50 and one would have expected her to live to age 75, the disease was associated with 25 lost life years. If 100 women died at age 50 (and also had life expectancies of 75 years), 2500 life years ( $100 \times 25$  years) would be lost.

Death is not the only outcome of concern in cancer. The disease leaves many adults somewhat disabled over long periods. Although still alive, the quality of their lives has diminished. QALYs 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 0.5 QALYs over the course of one year. If it affects two people, it will take away one year ( $2 \times 0.5$ ) over a one-year period. A pharmaceutical treatment that improves quality of life by 0.2 for each of five individuals will result in the equivalent of one QALY if the benefit is maintained over a one-year period. The basic assumption is that two years scored as 0.5 add up to the equivalent of one year of complete wellness. Similarly, four years scored as 0.25 are equivalent to one completely well year of life. A treatment that boosts a patient's health from 0.5 to 0.75 produces the equivalent of 0.25 QALYs. If applied to four individuals, and the duration of the treatment effect is one year, the effect of the treatment would be equivalent to one completely well year of life. This system has the advantage of considering both benefits and side effects of programs in terms of the common QALY units. Although QALYs typically are assessed for patients, they can also be measured for others, including caregivers who are placed at risk because they experience stressful life events. The Institute of Medicine recommended that such metrics of population health be used to evaluate public programs and to assist the decision-making process (Field 1998).

In addition to health benefits, programs also have costs. Resources are limited, and good policy requires allocation to maximize life expectancy and health-related

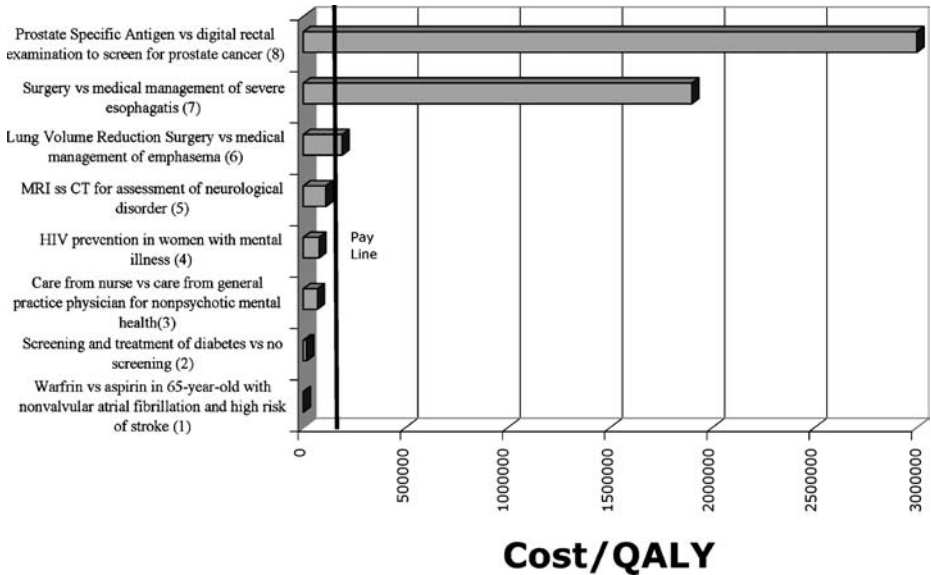
quality of life. Thus, in addition to measuring health outcomes, costs also must be considered. Methodologies for estimating costs have become standardized (Gold 1996a; Kaplan 1990, 1994; Weinstein et al. 1996). From an administrative perspective, cost estimates include all costs of treatment and costs associated with caring for any side effects of treatment. Typically, economic discounting is applied to adjust for using current assets to achieve a future benefit. From a social perspective, costs are broader and may include costs of family members taking time off from work to provide care. Comparing programs for a given population with a given medical condition, cost-effectiveness is measured as the change in costs of care for the program compared with the existing therapy or program, relative to the change in health measured in a standardized unit such as the QALY. The difference in costs over the difference in effectiveness is termed the "incremental cost-effectiveness" and is usually expressed as the cost/QALY. Since the objective of all programs is to produce QALYs, the cost/QALY ratio can be used to show the relative efficiency of different programs (Kaplan 2002).

## Cost-Effectiveness Decisions

Figure 2 compares different programs that have been analyzed using cost per quality adjusted life year (QALY). Screening for prostate cancer using the prostate-specific antigen test may offer no health benefits over the digital rectal examination, so it may be infinitely more expensive to produce a QALY. Lung volume reduction surgery may offer some benefits over medical care for the management of emphysema, but the cost per QALY is about \$190,000. Using a trained mental health nurse to manage nonpsychotic mental health patients offers significant benefits over using primary care physicians and produces a QALY for about \$69,000. Screening for type 2 diabetes and management with behavior modification and medicines produces a QALY for only about \$16,000. The figure shows a hypothetical pay line. It might be argued that programs to the left of the pay line should be funded, but those with cost/QALY ratios to the right of the line should be examined more carefully.

Contrary to the portrayal of cost/effectiveness analysis in the popular media, the purpose of the analysis is not to cut costs; rather, cost/effectiveness analysis attempts to identify which interventions produce the greatest amount of health using the available resources. Because of the confusion about cost/effectiveness analysis, the Office of Disease Prevention and Health Promotion in the Public Health Service appointed a panel to develop standards for these analyses (Gold 1996b, Weinstein et al. 1996).

In summary, policy approaches help identify the best treatment alternatives for the average patient. They address the variation problem by suggesting uniform approaches to care. The methods help reduce uncertainty by offering formal evaluations of complex literatures. However, policy approaches do not take into consideration unique preferences at the individual-patient level. An alternative approach that is oriented to individual patients is offered in the next sections.



**Figure 2** Cost/quality-adjusted life years (QALYs) for selected interventions. [Note: Prostate-specific antigen (PSA) analysis was dominated, indicating there was no benefit of PSA screening.] MRI, magnetic resonance imaging; CT, computerized tomography. Sources: CDC Diabetes Cost-Effectiveness Study Group 1998, Gage et al. 1995, Gournay & Brooking 1995, Heudebert et al. 1997, Krahn et al. 1994, Mushlin et al. 1997, Pinkerton et al. 2001, and Ramsey et al. 2003.

## SHARED MEDICAL DECISION MAKING

Historically, clinical decisions have been made by physicians (Brody 1980). This model, in which the physician is dominant and autonomous, is increasingly being questioned, and in its place shared decision-making is advocated (Frosch & Kaplan 1999b). This alternative approach, known as shared decision making, consists of multiple stages that begin with a two-way exchange of medical and personal information between patient and physician, including an explicit discussion of preferences for health states, clinical options, and outcomes (Charles et al. 1999). Following the information exchange and the completion of problem-solving tasks (i.e., diagnosis), the physician, patient, and potential others (e.g., family members) engage in a shared deliberation to arrive at a mutually agreed upon decision (Charles et al. 1999, Deber 1994). There is debate about which clinical decisions should be shared. Some have argued that shared decision making is best suited to decisions in which no single best alternative can be identified and physicians are in a state of equipoise (Elwyn et al. 2000, Woolf 1997). Such decisions have also been termed “preference sensitive” (Wennberg et al. 2002, Whitney 2003).

Others have argued that shared decision making should be applied more broadly because patients often decide not to follow physicians' recommendations, in effect deciding that "doing nothing" is an option (Steven 2001).

## Are Patients Interested in Sharing Decisions?

The increasing emphasis on shared clinical decision making is driven in part by patient demand for more involvement in selecting pathways to health outcomes (Frosch & Kaplan 1999b). Nevertheless, patient interest in shared decision making is not universal. Numerous studies have examined patient interest across a variety of health conditions with varying results. Clinical domains have ranged from preventive and chronic disease care to life-threatening conditions including cancer and coronary artery disease. Sample sizes and instruments used to assess interest in participating in decision making have varied substantially, as have the settings in which these questions were examined, thus complicating interpretation of this body of literature.

The first studies that investigated patient interest predate the broader interest in promoting shared decision making in health care but coincided with a growing focus on patient autonomy in medical ethics (Brody 1980; see also Katz 1984). The earliest such study, focused on cancer patients, found that an overall majority (62.5%) preferred participating in clinical decisions (Cassileth et al. 1980). However, younger patients were significantly more likely to desire participation than were patients over 60. Another study with cancer patients found very similar attitudes. The majority (69%) preferred to participate in clinical decisions, but preferences for participation were lower among older men with more advanced disease (Blanchard et al. 1988). Other studies examining decision-making preferences in the context of cancer show some variability across samples. Several studies found that a majority of cancer patients preferred their physician to make treatment decisions on their behalf (Beaver et al. 1996, Degner & Sloan 1992, Sutherland et al. 1989). A Dutch study assessed decision-making preferences in response to hypothetical cancer treatment scenarios among cancer patients, surgery patients, and nonpatient companions (Stiggelbout & Kiebert 1997). Whereas a majority of patients indicated a preference for participation in treatment decision making, preferences for participation were significantly greater among patients' companions. Another more recent study with a large sample of breast cancer patients found that two thirds preferred autonomous or collaborative treatment decision making (Degner et al. 1997).

Early studies among primary care outpatients showed generally lower preferences for participation in clinical decisions. In an older (mean age = 59) sample of patients with hypertension, only 19% indicated a preference for shared decision making (Strull et al. 1984). Among a small sample of inner-city patients with diabetes, preferences for participation were also low (Pendleton & House 1984). Similarly, a study of primary care patients with a variety of diagnoses found limited desire to participate in clinical decisions (Ende et al. 1989). The same authors found

comparable attitudes among physicians indicating their preferences for themselves as patients (Ende et al. 1990). A more recent study that analyzed data from the Medical Outcomes Study, collected between 1986 and 1990, also found that a majority of patients preferred a passive role (Arora & McHorney 2000). In contrast, among a sample of general practice outpatients at a Veteran's Administration hospital judging hypothetical treatment scenarios, the majority indicated a preference for shared authority in making a treatment decision (Mazur & Hickam 1997). Newer data from a large study conducted in Sweden found that most primary care outpatients preferred a shared approach to clinical decision making (Rosen et al. 2001), although more patients preferred leaving the "deciding vote" on choices of treatment with their physicians.

Comparison or aggregation of findings across studies is difficult because of variability in measures used. Several studies have found greater preferences for participation in clinical decision making among younger patients (Arora & McHorney 2000, Blanchard et al. 1988, Cassileth et al. 1980, Degner & Sloan 1992, Ende et al. 1989, Krupat et al. 2001, Rosen et al. 2001). Increasing severity of illness also has been associated with weaker preferences for shared decision making (Arora & McHorney 2000, Blanchard et al. 1988, Catalan et al. 1994, Stiggelbout & Kiebert 1997), as have lower levels of education (Cassileth et al. 1980, Ende et al. 1989, Krupat et al. 2001). Despite the consistency, we add the cautionary note that these factors explain only a small portion of the variance in preference (Benbassat et al. 1998).

Several additional factors may account for some of the variability observed in studies examining patient interest in shared decision making. Deber et al. (1996) argued that many studies fail to distinguish between problem-solving skills, including diagnosis and determining treatment options, and decision making. Problem solving is clearly the purview of physicians in addressing clinical problems, but using a measurement instrument that clearly separated problem solving and decision making, Deber et al. (1996) found that a substantial majority of patients preferred to participate.

Another explanation for the observed variability may be that many lay individuals are unaware that numerous health problems can be treated in different ways and a "best" treatment doesn't necessarily exist (Frosch & Kaplan 1999b). As a result, patients may not realize that there is a decision to be made (Sepucha & Mulley 2003). Studies with cancer patients on average found greater preferences for shared decision making, which may reflect greater awareness of uncertainties inherent in treatment choices and outcomes. Uncertainty isn't unique to oncology, though, and some have argued that patients need to be educated about the role of their personal preferences in making clinical decisions (Barry et al. 1995). The role of media may also be important in shaping beliefs about medical decision making. A content analysis of mammography messages in popular magazines found that magazines targeted at women with lower levels of education featured persuasive prescriptive messages urging mammography screening, whereas magazines aimed at women with higher levels of education provided more balanced and informative



messages (Dobias et al. 2001). Regardless of how much they are educated about uncertainty in medicine, there are clearly individuals who prefer to take a passive role and leave clinical decision making to their physician, perhaps reflecting a desire to avoid responsibility in the case of a negative outcome (Charles et al. 1998). Rather than applying one approach to all patients, physicians have to assess their patients' desire to participate in clinical decisions and modify their role and approach accordingly.

## Will Physicians Engage in Shared Decision Making?

Several studies have examined physician and physician-patient relationship characteristics associated with participatory decision-making styles. Factors associated with more participatory approaches among physicians include lower practice volume and longer office visits, training in a primary care specialty or interviewing skills, a greater satisfaction with professional autonomy, and Caucasian ethnicity (Gotler et al. 2000; Kaplan et al. 1995, 1996). Longer physician-patient relationships have been associated with more participatory decision making (Kaplan et al. 1995). Less participatory decision making occurred when male patients saw a male physician rather than a female physician, and female patients experienced more participatory decision making than did male patients regardless of physician gender (Kaplan et al. 1995). An observational study of family practice physicians found that physicians who took a more participatory approach to decision making were more likely to do this with patients who had greater medical needs and faced more complex decision making (Gotler et al. 2000). These findings are consistent with those of a study that analyzed audiotapes of 1057 patient-physician encounters that were recorded in 1993 (Braddock et al. 1999). As decisions became more complex, physicians engaged in more extensive discussions with patients. The authors defined informed decision making as consisting of discussion of seven elements: the patient role in the decision, nature of the decision, alternatives, pros and cons of options, uncertainties, patient understanding of information, and patient preferences for the decision. The overall findings were discouraging. Among primary care physicians only 7.7% of decisions met criteria for fully informed decision making.

Among encounters with surgeons, patients were fully informed in 1 of 10 decisions (Braddock et al. 1999). The authors also applied a less stringent definition of informed decision making to their data, defined as the "lowest level of acceptable dialogue for any clinical decision; a moral minimum for informed decision-making" (Braddock et al. 1999). To meet this criterion a physician had to request basic agreement or consent from a patient for a clinical decision. Among primary care physicians 18.9% of decisions met this threshold; among surgeons this was the case in 21.8% of decisions (Braddock et al. 1999). A qualitative study from the United Kingdom focused on physician-patient discussions of prescription drugs similarly found that the elements necessary for shared decision making to occur were seldom present (Stevenson et al. 2000).

Broader implementation of shared decision making faces substantial challenges in the contemporary medical care environment. In a typical encounter, the physician must greet the patient and do routine evaluations such as blood pressure, medical history, and a review of current medications. In addition, the provider must address the presenting complaint, perform a physical examination, make a diagnosis, write a prescription, discuss treatment plans, and chronicle the encounter in the medical record. Typically, the provider must be on to the next exam room within 15 minutes. Often, patients ask difficult questions at the end of the 15-minute encounter. For example, patients might ask if they should be on hormone replacement therapy, get a prostate-specific antigen test, or get a mammogram. In each of these cases, the literature is complex. Attention to discuss the problem in detail would certainly lengthen the visit. Many physicians simply bypass the discussion and make a strong recommendation for a test or a treatment. Shared decision aids are one potential solution to allow the patient to gain more information without directly using physician time.

Physicians cite lack of time as a barrier to engaging their patients in shared decision making (Elwyn et al. 1999a, Stevenson 2003, Weston 2001). One recent study confirms this barrier, finding that more time than is generally available in clinical encounters may be necessary for shared decision making to occur (Elwyn et al. 2001). The authors suggested that the information transfer necessary for shared decision making may need to occur before or after the consultation with the physician (Elwyn et al. 2001). The need for more clinical time to enable shared decision making remains subject to debate, with some authors suggesting that a more participatory style does not necessarily require more time (Greenfield et al. 1988, Towle & Godolphin 1999). It is unclear if the characteristics of the encounters examined by the different studies were comparable. However, even when decision aids are available to enable information transfer outside of the clinical encounter, time is still viewed as a barrier to shared decision making (Graham et al. 2003, Holmes-Rovner et al. 2000). Providing patients with the time to view a decision aid prior to making a clinical decision may conflict with pressure felt by physicians to reduce the time spent making decisions and performing procedures (Holmes-Rovner et al. 2000).

The shared decision-making model has been criticized philosophically for merely being an alternative name for the informative model of the physician-patient relationship (Emanuel & Emanuel 1992). In the informative model, the physician merely provides the patient with information, leaving clinical decisions solely in the hand of the patient. Physicians lose their caring characteristics and the practice of medicine is commoditized. A recent study (Charles et al. 2003) suggests this critique is misguided. Surgeons and oncologists rated descriptions of clinical encounters that were intended to depict a paternalistic approach; an approach in which the patient was given information but the physician made the decisions; an approach in which the patient was given information and left to make the decision (representing the informative model); and a shared approach to decision making. Findings indicated that most physicians correctly identified the

shared approach and distinguished it from the informative model, which suggests that the conceptualization of shared decision making is meaningful to physicians.

Concerns have been raised that physicians may lack the communication skills necessary to engage patients in shared decision making (Elwyn et al. 2000, Frosch & Kaplan 1999b, Towle & Godolphin 1999, Weston 2001). Towle & Godolphin (1999) have proposed a set of competencies necessary to engage in shared decision making. These include developing a partnership with the patient; establishing or reviewing patient preferences for information; establishing or reviewing preferences for participation in decision making; understanding and responding to patient ideas, concerns, and expectations; identifying clinical choices and evaluating evidence pertaining to the patient; presenting evidence in an unbiased manner; making or negotiating a shared decision; and agreeing on an action and follow-up plan. The authors note that the necessary competencies are concentrated in communication skills that go beyond what is typically taught in medical schools.

## How is Shared Decision Making Implemented and What is the Evidence for Benefits?

The basic preconditions for shared decision making consist of a mutual willingness on the part of patients and physicians to work together collaboratively to reach a decision that fits with the patient's preferences and the available options for a given clinical issue. The paternalistic model of medical decision making that has long predominated in medical practice has left many patients unprepared to actively participate in the process of making decisions (Frosch & Kaplan 1999b). On the other hand, sharing decisions often requires a significant transfer of information that exceeds the amount of time available in a clinical consultation.

Interventions to increase patient participation in clinical decision making can be broadly divided into two areas that have both been subject to systematic scientific review (Harrington et al. 2004, O'Connor et al. 2003). One approach focuses on activating patients during a consultation with a physician. The other approach uses decision aids to facilitate informed or shared decision making. Although interventions that have focused on increasing patient participation during a consultation have often been evaluated in the context of a particular condition, the goals of the intervention are arguably broader in that they attempt to increase patients' question asking, information seeking, and concern raising (Harrington et al. 2004). By contrast, decision aids have the goal of assisting patients in making a specific decision by choosing from a set of well-defined options (O'Connor et al. 2003). Literature in both areas has increased substantially in recent years. Two thirds of intervention studies aimed at increasing patient participation during consultations were published in the last decade (Harrington et al. 2004). The number of available decision aids increased from 87 to 221 between 2002 and 2003, although most of these have not been systematically evaluated (O'Connor et al. 2003).

A variety of methods have been used to activate patients and increase participation during a consultation with a physician. The majority of interventions have

been delivered to patients immediately prior to an appointment with a physician (Harrington et al. 2004). Modes of the interventions have varied, as have the corresponding levels of intensity. Of 20 studies included in a recent systematic review, 10 delivered the intervention to patients in written format (Harrington et al. 2004). Written interventions included advice on how to verify information provided by physicians, booklets and prompt sheets assisting patients in identifying problem areas and providing space to record their personal concerns prior to entering the physicians' office, checklists and help cards for common areas of clinical attention, and detailed workbooks with examples and room for personal notes (Butow et al. 1994, Cegala et al. 2000, Fleissig et al. 1999, Hornberger et al. 1997, Martinali et al. 2001, McCann & Weinman 1996, Robinson & Whitfield 1985, Thompson et al. 1990).

Face-to-face interventions have typically focused on training patients to ask general and disease-specific questions and to seek information, but sometimes also have included modeling and role-playing exercises (Brown et al. 1999; Greenfield et al. 1985, 1988; Kaplan et al. 1989; Roter 1977; Tennstedt 2000). Other studies have used video interventions to model active participation in medical consultation, and one study provided participants an audiotape of their last consultation with their physician, to listen to prior to the next appointment (Anderson et al. 1987, Ford et al. 1995, Lewis et al. 1991). Most interventions succeeded in increasing patient participation in medical consultations (Harrington et al. 2004). Participants generally asked more questions and were more likely to request clarification of information or instructions from their physicians. Seven of twenty studies recorded consultation length. Five of these found no increase in the length of consultations, and only one found a substantial (six minutes) increase in length (Harrington et al. 2004, Hornberger et al. 1997). Each of four studies that examined participant perceptions of control over their illness or preferences for an active role in managing the illness found significant increases for these variables (Harrington et al. 2004, Roter 1977).

Studies of patients with chronic diseases found increases in clinic attendance and adherence to treatment recommendations (Harrington et al. 2004). A small minority of studies investigated the effects of the interventions on physiological measures of disease control. In one study, increased participation in the medical encounter was associated with improved glycemic control among patients with diabetes, as indicated through lower glycosylated hemoglobin values (Greenfield et al. 1988). Another study found lower diastolic blood pressure readings among patients who were more active during consultations with their physicians (Kaplan et al. 1989). The paucity of data on "harder" disease outcomes is a significant weakness of this body of literature (Harrington et al. 2004). The studies that demonstrated improvements on physiologic measures of disease activity have been widely cited in the scientific literature. Given the impact of these studies, it is surprising that other investigators have not replicated them. Part of the reason these interventions have not been replicated is that they require labor-intensive face-to-face encounters (Greenfield et al. 1988, Kaplan et al. 1989). Efforts are

under way to attempt to deliver patient activation interventions using automated computerized platforms. However, the efficacy of this delivery mode remains to be demonstrated.

The purpose of a decision aid is to assist individuals in making a specific and deliberate choice among different options to address an issue of clinical attention (O'Connor et al. 2003). Decision aids are intended to facilitate shared decision making between patient and physician (Barry 2002, O'Connor et al. 1999). They are not supposed to replace a consultation between a physician and patient, but rather serve as an adjunct by providing, at minimum, detailed information about different clinical options and their likely outcomes (Barry 2002; O'Connor et al. 1999, 2003). The design and content of decision aids varies widely and may include information about the disease or condition, costs related to different options, exercises to help users clarify their preferences and values, descriptions of others' experiences making the decision (often in the form of personal testimony), and advice or training in making decisions or communicating with health-care professionals (Barry 2002, O'Connor et al. 2003). Design templates for different types of decision aids have been proposed and a consensus process is under way to determine criteria by which to judge the quality of a decision aid (see <http://decisionaid.ohri.ca/IPDAS/index.html>) (Holmes-Rovner et al. 2001).

Decision aids have taken a variety of different forms, including scripted personal counseling, handouts, pamphlets, audio-guided workbooks, videotapes, interactive videodisc, computerized analytic hierarchy processing, and interactive websites (O'Connor et al. 2003). Most are designed to be viewed by patients prior to a consultation with a physician. A diverse range of topics has been addressed, including prostate and colon cancer screening, prenatal screening, genetic testing, hepatitis B vaccination and screening, prostate and breast cancer treatment, benign prostate disease treatment, hormone replacement therapy, ischemic heart disease treatment, back surgery, male newborn circumcision, atrial fibrillation treatment, dental surgery, infant vaccination schedules, menorrhagia treatment, and midwifery and obstetrical decisions (O'Connor et al. 2003).

A systematic review has aggregated the findings of 34 randomized trials of decision aids published before 2003 (O'Connor et al. 2003). Unlike studies of interventions aimed to increase patient participation in medical consultations, measures have focused on outcomes of using the decision aid rather than process measures of the physician consultation. In all studies where exposure to a decision aid was compared with a usual care control group, knowledge about relevant issues increased significantly (O'Connor et al. 2003). Exposure to a decision aid made it significantly more likely that individuals had realistic expectations about what an option could accomplish (O'Connor et al. 2003). Decisional conflict was lower on average following exposure to a decision aid, with the strongest effects in patients' sense of feeling informed (O'Connor et al. 2003). Several studies found greater satisfaction with the clinical decision-making process and its outcomes. Individuals who viewed a decision aid were less likely to remain undecided and often changed their preferences after reviewing the materials. Exposure to these

interventions increased the likelihood that individuals preferred an active to a passive role in clinical decision making (O'Connor et al. 2003). Exposure also increased the likelihood that individuals declined major elective surgery and instead chose more conservative options (O'Connor et al. 2003). Studies that examined general health outcomes, assessed with generic health-related quality-of-life measures, either found no differences compared with usual care groups or improvements in the decision aid group.

Disease-specific outcome measures showed similar results. To date, there are no data suggesting that exposure to a decision aid results in choices that lead to worse health outcomes (O'Connor et al. 2003). However, more long-term assessment of health outcomes several years after making decisions is necessary to provide more definitive answers than are currently available. Few studies have evaluated the effect of using decision aids on health-care costs, and those that have examined questions of cost were conducted in the United Kingdom (Kennedy et al. 2002; Murray et al. 2001a,b). One trial compared a control group with a decision aid alone to a group with a decision aid plus interview for women considering hysterectomy for menorrhagia (Kennedy et al. 2002). The lowest costs were found in the group that received the combined intervention of decision aid plus interview. This group had the lowest rates of hysterectomy, but at a two-year follow-up, it showed no differences in health outcomes compared with the control or decision-aid-alone groups (Kennedy et al. 2002). Two studies found no differences in cost comparing the decision aid group to the control group, as long as the decision aid was delivered through the Internet (Murray et al. 2001a,b). It is important to note that these were hypothetical cost analyses, since the investigators delivered the decision aid to patients using an interactive videodisc rather than using the Internet. When the cost of interactive videodisc equipment was added into the analysis, costs were higher in the decision aid group.

An increasing number of decision aids are being developed for the Internet (O'Connor et al. 2003). The Internet has the potential to make decision aids widely available at relatively low cost (Frosch et al. 2003; Murray et al. 2001a,b). However, only two studies have so far evaluated facilitation of shared decision making through the Internet, and only study was a randomized trial (Frosch et al. 2003, Lenert & Cher 1999). Lenert & Cher (1999) conducted an observational study in which a decision support tool for men with benign prostatic hyperplasia was made available on the Internet. The interactive site was designed to help men decide whether they wanted to use alpha-blocking medication to manage benign prostatic hyperplasia symptoms by comparing their desired level of symptom reduction with results from meta-analyses. Ninety-three percent of men who used the site over a six-month period felt that the information was useful and 71% felt that the type of information provided should be part of the decision-making process for alpha-blocker medications (Lenert & Cher 1999). The study did not include a comparison group, and data on men's subsequent treatment decisions were not collected. The only published randomized Internet trial compared showing a video in a medical clinic with accessing the same information online prior to visiting the

clinic among men considering the prostate-specific antigen test for prostate cancer screening (Frosch et al. 2003). Although men who reviewed the entire website showed similar outcomes to men viewing the video, many of those assigned to access the materials online did not review the materials. By comparison, almost all of the men assigned to view the video in the clinic arrived on time and saw the entire program. The authors concluded that the Internet was less effective than providing the same information in the clinic, leaving open the question of whether providing access to decision aids online will lead to lower health-care costs than providing decision aids in a clinic (Frosch et al. 2003).

## Will Patient Mood Influence Decisions?

Shared decision making is designed to help patients make clinical choices that reflect their preferences. A dilemma arises in attempting to determine whether patients do reach, in fact, the “right” decision. In part, this problem is inherent in clinical decisions that are preference sensitive. The rationale for engaging patients in the process is that scientific evidence does not support a gold-standard choice (Elwyn et al. 2000, Wennberg et al. 2002, Woolf 1997). On the other hand, there is growing body of research that has examined the role of affect or emotional states in decision making. Traditionally, decision-making research has assumed that people make choices to maximize their expected utility (Loewenstein et al. 2001).

An increasing number of studies suggest emotions that are experienced when a person faces a choice may lead to decisions that do not necessarily reflect what the person would otherwise consider the best course of action (Loewenstein et al. 2001). When in a good or positive mood, people tend to be more optimistic in their judgments and choices and correspondingly tend to be more pessimistic when in a bad or negative mood (Loewenstein et al. 2001). An alternative view of the role of affect and emotions in decision making is that affect is an important component of decision making when combined with cognitive evaluations of probabilities and trade-offs in a given set of choices (Slovic et al. 2004). The challenge lies in identifying when emotions may be overwhelming cognitive components of a decision-making process and how to temper affect to allow optimal decision making to occur (Slovic et al. 2004).

Research examining the role of affect and emotions in decision making is highly relevant to the goals of shared decision making, but is limited by the fact that these studies have thus far not focused on medical decision making. One recent study examined the role of patient testimonials about clinical choices in decision aids (Ubel et al. 2001). Patient testimonials are often used in decision aids to help patients better understand the consequences of clinical choices on subjective quality of life (Kasper et al. 1992). Patient testimonials are more vivid than purely statistical information describing health outcomes of a choice and may evoke more powerful affective responses (Ubel et al. 2001). In a simple decision aid intended to assist individuals in choosing between bypass surgery and angioplasty, the inclusion of patient testimonials in addition to statistical information led more

individuals to make conservative treatment choices of angioplasty, despite the fact that testimonials did not intend to add information not already provided (Ubel et al. 2001). Hence, testimonials appeared to significantly sway patient decisions. These findings are limited because the subjects were not patients and the choices were hypothetical. However, the study raises important concerns about optimal ways of engaging patients in shared decision making. Few studies of decision aids have examined patients' decision persistence over time (O'Connor et al. 2003). More research is needed that examines the role of patient affect and emotions when facing and participating in a clinical decision to ensure that shared decision making does indeed lead to subjectively "right" decisions.

## DIRECTIONS FOR FUTURE RESEARCH

Uncertainty is an expected nuisance in medical decision making. A rich literature now documents uncertainty, places it in the context of medical practice, and suggests methodologies for quantifying probabilities of various outcomes. Formal decision models are now available for both public policy and for clinical decision making. We believe that shared medical decision making will play an important role in the future of medical care. However, in order for this field to advance, considerably more research will be necessary. Briefly, we consider several important directions for future studies.

Patients often expect more from medical interventions than they can deliver. The pervasive role of uncertainty in medicine is not fully appreciated by the public. Although a majority of individuals would prefer to participate in medical decision making, much of the variance in preferences for participation remains unexplained. It is unclear to what degree awareness of medical uncertainty plays a role in decision making preferences. Moreover, when people are surveyed about their preferences, they may not be aware of tools that can be used to facilitate participation and reduce the anxiety that results from being presented with complex information. Older individuals tend to show less interest in participating in medical decisions, but we do not know whether this is a cohort effect or a consequence of aging.

If we accept that a paradigm shift is under way in the practice of clinical medicine, it is important to acknowledge that such shifts take time. In addition to patients' willingness to participate in medical decisions, physicians play a critical role in permitting this shift to occur. Empirical data suggest that high-quality shared decision making rarely happens in clinical encounters between physicians and patients. More research is needed to identify factors that may hinder or accelerate this shift.

A variety of outcomes measures are available for the assessment of shared decision making. Some studies use patient satisfaction while others use measures of patient knowledge. Ultimately, the goal of shared decision making is to improve health outcomes. In this review, we have described two approaches to incorporating patient preferences into medical decisions. The policy approach aggregates preferences across a population to arrive at resource allocation recommendations.



The shared decision-making approach makes individualized preferences assessments to arrive at a personalized medical decision. To date, no studies that have evaluated interventions to facilitate shared decision making have quantified outcomes in terms of QALYs. Research that combines individualized approaches to medical decision making with policy models is urgently needed.

## Policy Analysis

Shared decision making may require greater use of health-care resources. Clinicians are very busy and often do not have time to engage in these exercises. An alternative is to create decision centers so that patients can gain information away from the clinical encounter. Internet sites are also attractive but rarely have been evaluated. Some advocates believe that new health-care professionals will be required to enact shared decision making. Yet, these new professionals will create additional expense to the health-care system. Formal cost-effectiveness analysis is necessary to determine whether the use of additional resources is a good investment in terms of improved patient satisfaction and health outcomes.

## SUMMARY

Patients often assume that their health-care providers know exactly how to handle their clinical case. However, a growing literature documents uncertainty surrounding most health-care decisions (Fisher et al. 2003, Gillett 2004, Kaplan et al. 2004). Further, clinicians often disagree with one another about the appropriate course of action (Eddy 1996). There is large regional variation in the use of health-care services, suggesting that physician preference rather than patient need plays an important role in health-care usage and the expense of medical care (Wennberg et al. 2002, Wennberg et al. 2004). Evidence does not support the belief that more health care results in better patient outcomes (Fisher et al. 2003).

In order to understand this problem, it is necessary to define patient outcomes from the patient's perspective (Kaplan et al 2004). The purpose of health care is to extend the life expectancy and to improve quality of life (Kaplan 1994). Some interventions may result in changes in a biological process but may have little or no effect on outcomes relevant to patients (Kaplan et al. 2004). Emerging methodologies, such as the QALY, allow broad comparisons between different interventions in health care and can be used to develop mathematical models of the health-care decision process (Gold 1996b). These models are gaining greater acceptance in health policy research. Further, there has been a growing emphasis on systematic reviews of the literature using the principles of evidence-based medicine (Davidson et al. 2003). Based on these reviews, clinical guidelines have been developed.

Shared medical decision making involves a two-way exchange between medical professionals and the patients they serve. Although there is some inconsistency in the literature, it appears that patients are interested in participating in the shared

decision-making process. It is less clear whether physicians are willing to participate. Most studies indicate that physicians rarely offer the elements of shared decision making in clinical practice. Although there is considerable enthusiasm for using the Internet or other decision tools to enhance shared decision making, very little research supports the efficacy of these tools.

In conclusion, the study of shared medical decision making is a promising new direction in clinical health care. In order for the field to advance, we need to develop new methodologies and to conduct research on measurement, outcomes, and policy.

## ACKNOWLEDGMENTS

Supported in part by the Robert Wood Johnson Health and Society Scholars Program.

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