SHARED MEDICAL DECISION-MAKING: A NEW PARADIGM FOR BEHAVIORAL MEDICINE—1997 PRESIDENTIAL ADDRESS[1,2]

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ABSTRACT

Different conceptual models lead to different health care choices. The traditional biomedical model emphasizes identification of pathology (diagnosis) and remediation of these biological deficits (treatment). An alternative approach, known as the outcomes model, focuses attention on the outcomes of health care. Specifically, health care is regarded as effective only if it extends life or if it improves quality of life. Indices that combine life expectancy and life quality can be used to monitor the benefits of health care. According to the traditional model, medical care is effective if it improves a clinical indicator (i.e. reduces blood pressure, decreases tumor size, etc.). According to the outcomes model, treatments are not advocated unless they improve general outcomes. There are circumstances in which clinical indicators improve but general outcomes remain the same or get worse. Data on the detection and treatment of prostate cancer are used to illustrate how these models might lead to different treatment decisions. According to the traditional model, aggressive screening and treatment of prostate cancer should be advocated because more cases are detected early and more tumors are removed. According to the outcomes model, net quality-adjusted life may be reduced rather than enhanced with screening. Shared medical decision-making is an outgrowth of the outcomes model. Using these methods, patients and providers integrate the best scientific evidence on treatment efficacy with patient preferences for outcomes. Often shared decision-making leads to reductions in the use of medical procedures.

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INTRODUCTION

Health care has been dominated by linear thinking. According to the traditional biomedical model, the purpose of medicine is to find disease pathology and to fix it. We sometimes refer to this as "find it–fix it medicine." For problems such as high blood pressure, for example, the physician's task is to diagnose the problem and to administer a treatment that will make blood pressure normal. The measure of success is a blood pressure reading that falls within a defined range of normality. Unfortunately, many medical procedures may affect biological processes but may not affect life expectancy or life quality. It has been estimated that 30% to 50% of all medical procedures have little effect on long-term outcomes (1). Further, some procedures may have a negative effect on survival and quality of life.

An alternative model, known as the outcomes model, is similar to the traditional biomedical model. However, the ultimate outcome is not a measure of disease process. The goals of health care are to extend the duration of life and/or to improve the quality of life. Disease processes are of interest because pathology may either shorten life expectancy or make life less desirable. However, in contrast to the traditional biomedical model, behaviors or biological events may affect life expectancy independently of disease process. Further, the measures of success in the outcomes model are different than those in the traditional biomedical model. The outcomes model emphasizes quality of life and life duration instead of clinical measures of disease process. As similar as these two models appear, they lead to substantially different approaches to the organization, financing, and delivery of health care (2). These distinctions are addressed in the following sections.

PATIENT ROLES

The traditional model of health care is designed to respond to acute disease. Nearly everything about health care has an acute disease focus. For example, modern medicine promotes diagnostic tests for single diseases. These diagnostic tests lead to the specific remedies to those problems. Patient reports are of little value because diagnostic tests can accurately pinpoint the nature of the problem. Test results inform the specific action that will be taken.

Despite the impressive successes of the acute disease model, most expenses in the health care system are directed toward the management of chronic diseases. Although chronic diseases might be detected with diagnostic tests, they cannot be cured with modern therapies. Further, most adults have multiple chronic disease diagnoses. For example, in the Medical Outcomes Study, nearly 95% of adults who entered the study with one chronic disease diagnosis had other diagnoses as well (3). Further, psychological and social adaptation are important factors in chronic illness. Patient interpretation and behavior play important roles in determining the impact of chronic illnesses. Thus, how patients relate to their illness is of central importance (4).

FOCUS OF ATTENTION

The biomedical and outcomes models focus attention on different measures of success. A central component of the acute disease model is that treatment must be based on the understanding of the disease mechanism. Diagnostic tests are required to find disease, and treatment is based on understanding of pathophysiology. Taken to the extreme, this would argue that treatments should not be used unless the basic mechanism of disease is understood and the treatment addresses a well-known aspect of pathophysiology. I once heard it argued that research on the effects of tobacco use is only important if it identifies the mechanisms relating

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tobacco use to disease. According to the traditional model, we must understand how tobacco use changes observable levels of cotinine and how this, in turn, relates to physical changes and measurable differences in blood nicotine and other biological measures (5). Further, research must identify the basic mechanisms by which tobacco use causes low birth weight, changes in lung tissue, and pathologic changes resulting in cancer of the lung, bladder, throat, and other organs (6). Clearly, this model is remarkably complex and might even lead to the conclusion that the consequences of tobacco use are poorly understood (7).

In contrast to this very complex disease model of smoking, the outcomes model is remarkably simple. Substantial evidence suggests that tobacco use shortens life expectancy and causes reductions in health-related quality of life prior to death (8). A variety of analyses argue that the traditional model that requires disease diagnoses in understanding the disease mechanism has retarded our appreciation of the impact of tobacco use. The outcomes model simply relates tobacco use to total deaths without attempting to break down deaths by diagnosis. Considered this way, the impact of tobacco use has been underestimated. For example, McGinnis and Feoge (9) use national data sets to estimate the impact of various risk factors on actual deaths in the United States in 1990. Their analysis suggests that tobacco use is associated with approximately 400,000 deaths each year or about 19% of all premature cases of mortality. Diet and activity patterns are associated with an additional 300,000 deaths, while alcohol abuse accounts for about 100,000 deaths. Each of these risk factors is associated with a variety of different diagnoses. The traditional route of estimating the impact of a risk factor by adding together deaths attributable to different diagnoses makes the process more complex and leads to inaccurate estimates of the impact of these modifiable risk factors.

The second problem with the traditional diagnosis-based model is the assumption that diagnoses are accurate. We assume, for example, that if a physician diagnoses a problem, the diagnosis would be the same if another competent person considered the same case. However, a substantial literature suggests that physicians are highly variable in their evaluation of cases (10). They disagree with their peers who have reviewed the same patient. Further, they disagree with themselves when presented with the same patient at two points in time. Consider these examples. In one case, four cardiologists were given very high quality angiograms and asked to say if the stenosis in the proximal or distal left anterior descending artery was greater than 50%. This is an important threshold because it serves as the criterion for a revascularization of the coronary arteries. When presented with these films, cardiologists disagreed among themselves in 60% of the cases (11). In another study, cardiologists looking at the same angiograms at two points in time disagreed with themselves between 8% and 37% of the time (12). Another study evaluated the reliability of pathologist-assessed ductile carcinoma in situ (DCIS). The six pathologist subjects were given written guidelines and examples of each of the problems they were looking for. 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. For example, 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 pathologist saw cancer in 8 of the 10 cases, while another saw DCIS in only 3. One case was diagnosed by only one pathologist, and only two cases were seen by all six (13). These variations in diagnostic patterns imply that patients with the same problem going to different doctors may get different diagnoses.

One of the consequences of this variation is that health care expenditures can be very different in different geographic areas. *The Dartmouth Atlas of Health Care* (14) has documented remarkable variation of Medicare expenditures for Medicare recipients in various regions of the United States. For example, health care expenditures for Medicare recipients in southern California, southern Texas, and Florida are about twice as high per recipient as they are in other regions such as New Mexico and parts of the Pacific Northwest (14). The Medicare program spends almost twice as much per recipient in Boston, Massachusetts as it does in New Haven, Connecticut. Yet, systematic investigations show that people in Boston enjoy at least the same level of health outcome as those in New Haven (15). In fact, some evidence suggests that patients are more likely to be rehospitalized for the same conditions in Boston than in New Haven (16).

DEFINING THE OBJECTIVES OF HEALTH CARE

Many of these problems arise because we have not clearly defined the objectives of health care. The traditional biomedical model is directed toward diagnosing and treating conditions. Success might be indicated when diseases are accurately diagnosed and specific pathologies are eliminated. In contrast, the outcomes model argues that success is achieved through the extension of life expectancy and through improvements in life quality. We have attempted to develop measures that reflect these general objectives (17,18). Traditional outcome measures include life expectancy, infant mortality, and disability days. Life expectancy is a good measure because it is generic and can be used to compare different interventions in health care. However, life expectancy is not sensitive to most investments in health care. For example, the treatment of osteoarthritis may significantly improve quality of life but may have no impact on life expectancy. The infant mortality rate, defined as the number of babies born alive who die within one year, is very sensitive to socioeconomic variations in health. However, the infant mortality rate fails to capture the benefits of treatment given to people who live beyond their first year.

A sensitive generic expression of health benefit must combine measures of life expectancy and life quality into the same index. We have proposed a generic measure which combines survival and quality of life. In traditional survival analysis, a person is scored 1.0 for each year he or she is alive. Death is scored as zero. Thus, a person with a life expectancy assumed to be 80 years, who dies at age 50, would be scored as 1.0 for each of the first 50 years and zero thereafter. Their early death caused a loss of 30 life years. The difficulty with traditional analysis is that it fails to distinguish between levels of wellness. Thus, a person in a vegetative coma is scored as 1.0 because he or she is alive. However, a person engaged in athletic competition is also scored as 1.0 because they too are alive. The fault of traditional survival analysis is that it fails to distinguish between wellness and disability.

We have proposed quality-adjusted survival analysis as a method that summarizes the life expectancy with adjustments for quality of life. In adjusted survival analysis, quality of life is measured on a scale ranging from 0 (for dead) to 1.0 for perfect health without symptoms. The core component of this analysis is the quality-adjusted life year (QALY). The QALY combines morbidity and mortality into a single index and represents the life expectancy with adjustments for quality of life. The QALY is defined as a year of life free of all disabilities and symptoms.

Detailed descriptions of the QALY and quality-adjusted survival analysis are available in our publications (17–22) and those of others (23–26). Although space does not allow a full description of this model here, suffice it to say that maximizing QALYs is the basis for an outcomes oriented health care system (2).

When QALYs become the focus of health care, different priorities sometimes emerge. For example, some treatments may be successful at curing a particular disease while, at the same time, reducing QALYs. For example, some cancer treatments may have significant benefits in terms of reduced tumor size. However, these treatments may also have serious consequences that may reduce quality-adjusted survival even after consideration of their positive impact on cancer. QALYs and similar measures such as the disability-adjusted life year (DALY) are now commonly advocated for public policy studies (25,26). The World Bank and The World Health Organization use DALYs to estimate world health priorities. In their analysis, it was reported that high-profile infectious diseases, such as the E-Bola virus, will have relatively little impact on DALYs worldwide. In contrast, tobacco use, motor vehicle accidents, and undiagnosed mental illness are expected to have huge effects by the year 2020 (27).

IS MORE BETTER?

The traditional model argues that the solutions to many of our public health problems are more money, more health care, and more procedures. The outcomes model evaluates investments in relation to the outcomes they produce. It is clear that advancing medical technology has led to more diagnoses. Between 1987 and 1993, the rate of coronary angiography went up by 75%. The number of computer tomography (CT) or magnetic resonance images (MRI) of the lumbar spine doubled (28,29). One analysis systematically demonstrated that simple improvements in diagnostic tests can lead to increased diagnostic rates between a few hundred and 6000%. For example, new technology to diagnose deep venous thrombosis using duplex ultrasound leads to over a 6000% increase in the number of cases diagnosed. Using new technologies, about one in four young adults has a knee abnormality as diagnosed by MRI (30) and half have abnormalities of lumbar discs (31).

In addition to improving technology, changing definitions of disease also lead to greater numbers of diagnoses. For example, about one in five U.S. adults has an abnormal cholesterol level if the current threshold of 240 mg/dl is used. However, hypercholesterolemia is now being redefined as 200 mg/dl. As a result, one in two adults will now qualify for the hypercholesterolemia diagnosis (32). As more people are diagnosed, more and more individuals with "pseudodisease" will be found. These people carry the diagnosis but would never have experienced shortened life expectancy or reduced quality of life if their condition had not been detected. Further, increased diagnoses also suggest that some people will be harmed by treatment (32). We explore this in greater detail in the following sections.

WAR ON CANCER

In 1971, Congress passed the National Cancer Act which was also described as President Nixon's War on Cancer (33). The purpose of the National Cancer Act was to deploy significant resources toward the eradication of cancer. Most of those resources have been directed toward treatment, with relatively few resources devoted to cancer cause and prevention. Progress in the War on Cancer was recently evaluated by Bailar and Gornik (34). Mortality from cancer appeared to peak in about 1991 and has gone down slightly since then. Overall, there have been slight increases in cancer mortality since the War on Cancer began in 1971. However, changes in cancer death rates have been relatively modest. The American Cancer Society provides data on cancer mortality trends over the past 60 years. For both men and women, there have been significant declines in cancers of the stomach and significant increases in cancers of the lung. For women, there have also been significant declines in cancers of the uterus and small declines in cancers of the colon and rectum. However, for most sites, the proportions of people dying of cancers have been relatively unaffected by major changes in medical care. The rapid increase in deaths from cancers of the lung can be attributed almost exclusively to the use of cigarettes. It is encouraging that deaths from lung cancer appear to have peaked for males by 1990 and are now declining as cigarette use has decreased. Rates of lung cancer for women, however, are continuing to increase. Overall, the war on cancer which focused on the find it–fix it approach has had very modest effects. Changes in cancer death rates can be attributed to behaviors rather than developments in diagnosis and treatment (34).

LOOKING INTO ARTERIES

Other examples come from the treatment of cardiovascular disease. Acute myocardial infarction is the most common cause of morbidity and mortality in both the United States and Canada. However, the two countries approach the treatment of cardiovascular disease differently. Invasive cardiac procedures, such as coronary angiography, are performed considerably more often in the United States than in Canada. Some years ago, we noted that about eight of every ten well-insured patients treated in private San Diego hospitals received angiography following a heart attack (35). However, only 40% of patients at the San Diego Veterans Affairs Health Center received the procedure following a heart attack. In Vancouver, only 20% of postmyocardial infarction patients got angiography and only 10% of patients in Sweden received the procedure. This variation would be acceptable to U.S. citizens if we knew that more care led to better health. However, there was little evidence that more aggressive care produced better results. Controlling for the seriousness of the heart attack (measured by the ejection fraction) the probability of surviving a heart attack in San Diego, Vancouver, and Sweden was comparable.

More recently, the use of invasive cardiac procedures in the United States and Canada was evaluated for 224,258 elderly Medicare recipients in the U.S. and 9,444 older patients in Ontario, Canada. Each of these patients had been the victim of a heart attack after 1991. Among U.S. patients, 34.9% underwent coronary angiography, while only 6.7% of the Canadian patients received this procedure. Having coronary angiography increases the likelihood that other invasive procedures will be performed. Among the American patients, 11.7% underwent percutaneous transluminal coronary angioplasty (PTCA) in comparison to 1.5% of the Canadian patients. Further, 10.6% of the American patients versus only 1.4% of the Canadian patients underwent coronary artery bypass grafting (CABG) surgery. Figure 1 summarizes both the procedure rates and the mortality rates for these patients. It might be presumed that American patients are better off because they are more likely to obtain the latest procedures. However, mortality rates 30 days following the attack were comparable in the two countries (21.4% versus 22.3%). Further, the mortality rates one year later were virtually identical (34.3% for U.S. versus 34.4% in Canada). These data suggest that the use of high-technology medical procedures is much more likely in the American system

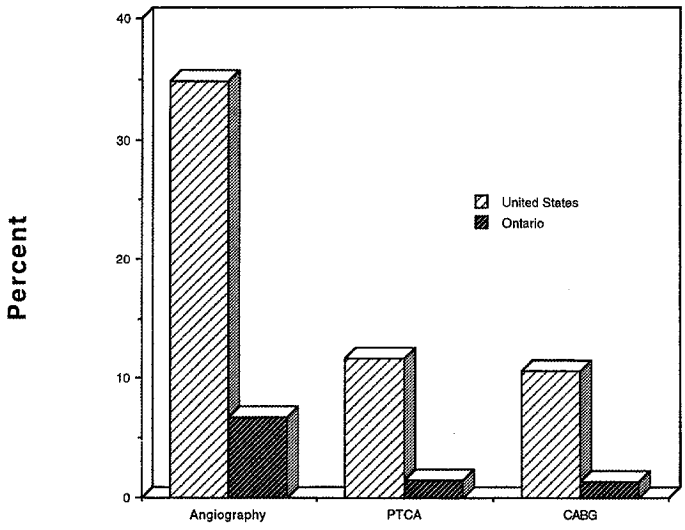

FIGURE 1: Percentage of MI patients receiving angiography, percutaneous transluminal coronary angioplasty (PTCA), and coronary artery bypass grafting (CABG) within 30 days of the event (36).

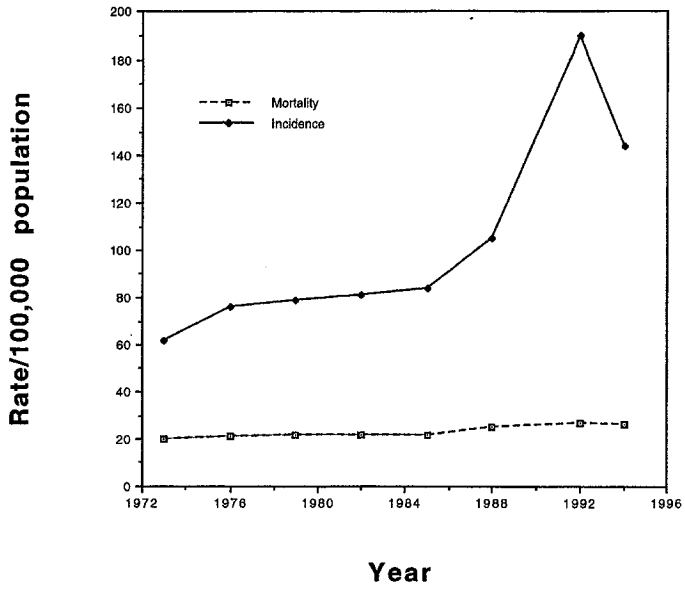

FIGURE 2: Prostate cancer incidents and mortality per 100,000 men in the U.S. population from 1973 to 1994. Data from Surveillance, Epidemiology, and End Results (SEER), *Cancer Statistics Review, 1973–1994* (NIH Publication No. 97-2789).

than in the Canadian health care system. However, there is no clear evidence that patients benefit, at least in terms of survival (36).

These findings suggest that the find it–fix it approach to established coronary heart disease (CHD) may have limited benefits. The procedures are expensive but may not extend life. An alternative might be to invest in programs that attempt to enhance outcomes by promoting health in entire communities. For heart disease, this might be accomplished by changing behaviors to reduce cholesterol. Programs to lower cholesterol might have only a small benefit for individuals but might have a substantial benefit for communities. As many as 40% of men and 20% of women have serum cholesterol levels >240 mg/dl. One analysis considered the benefits of population-wide heart disease prevention programs in California and Finland. Some of these programs have been criticized because they reduce serum cholesterol by only 1% to 4%. However, these slight reductions in average serum cholesterol may have contributed to as much as one-third of the decline in coronary heart disease in the United States since the mid-1960s. The education programs in Finland and California use media campaigns and face-to-face instruction. The programs cost about $4.95 per person per year and, on average, produce a reduction of about 2% in serum cholesterol. The programs produce a quality-adjusted year of life at about $3,200 for individuals at risk for coronary heart disease. A more intensive program that reduces serum cholesterol by about 3% might cost $16.55 for the first year and $8.28 per year thereafter and could produce a year of life at about $6,100. Even though advances in medical care may have cut CHD mortality, the evidence suggests that population-based efforts to reduce serum cholesterol should become part of U.S. health policy (37).

HEALTH CARE DECISIONS

The outcomes model shifts the focus of health care from finding and fixing disease to maximizing quality-adjusted life years. Although the outcomes model and the traditional biomedical model are similar in many ways, they lead to very different approaches to care. According to the traditional biomedical model, medicine is about diagnosis and treatment (finding and fixing). According to the outcomes model, medicine is about making decisions that will maximize the quality-adjusted life expectancy.

Perhaps the best example of contrast between the two models concerns the diagnosis and treatment of prostate cancer. Prostate cancer is an important health problem. The epidemiology is interesting because there may be a large reservoir of undetected cases (38). The National Center for Health Statistics reports that there were 132,000 new cases in 1992 (39). However, the American Cancer Society (ACS) reported that there were 334,500 new cases in 1997 (40). National data suggest that there were 34,000 deaths from prostate cancer in 1996 while the American Cancer Society projected 41,000 expected deaths in 1997. Prostate cancer is the second leading cause of cancer death among men (behind lung cancer). There are significant differences of opinion about whether the public should invest in screening programs for prostate cancer. The American Urological Association and the American Cancer Society have promoted large-scale screening of all men older than age fifty (41). These organizations suggest yearly screening using digital-rectal exams or prostate specific antigen (PSA). The State of California enacted legislation in 1998 requiring physicians to advise men about the benefits of prostate cancer screening. Other organizations, including the American College of Physicians (ACP), argue that such screening programs may be of limited benefit (42,43) and that they may be costly, accounting for about 5% of all health care costs (44).

One of the challenges is in determining whether there really is an epidemic of prostate cancer. Figure 2 shows changes in prostate cancer incidence and mortality between 1976 and 1994. The number of reported prostate cancer cases doubled over this interval. Following concern about the value of screening, there has been a recent downturn in incidence. However, mortality from prostate cancer has remained relatively constant. One explanation for this apparent discrepancy is that there is a reservoir of undetected prostate cancer. Many of the undetected cases are unlikely to lead to ill health or death (45).

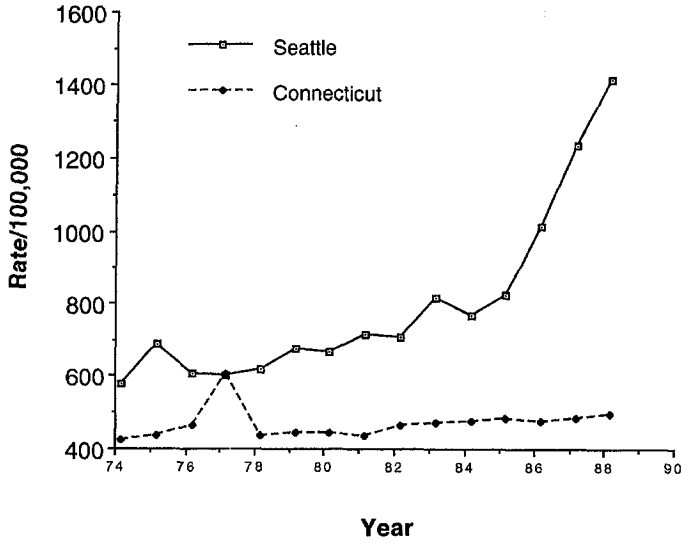

FIGURE 3: Incidence of prostate cancer in Seattle and Connecticut between 1974 and 1989. Adapted from Wennberg et al. (14), data from SEER, National Cancer Institute.

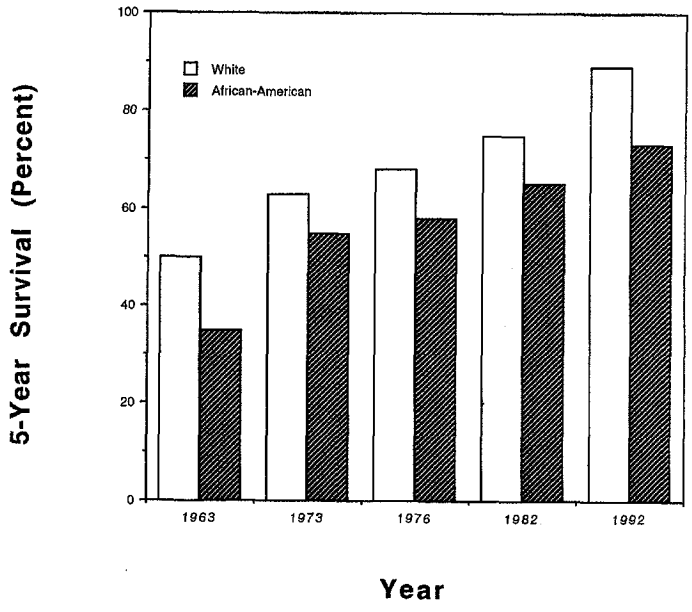

FIGURE 4: Relative 5-year survival for European–American and African–American men following the diagnosis of prostate cancer between 1963 and 1992. Data from SEER, 1960–1973 and SEER *Cancer Statistics Review, 1973–1994* (NIH Publication No. 97-2789).

One of the most intriguing comparisons is between Seattle, Washington and the state of Connecticut. Each of these areas has a National Cancer Institute SEER registry. Between 1974 and 1994, there was a substantial increase in the number of cases of prostate cancer reported to the Seattle registry. In contrast, cases of prostate cancer remained relatively constant in the state of Connecticut (see Figure 3). This reflects different approaches in these two areas. In Seattle, led by the local urological surgeons, there was an intense effort to make men aware of the need to be screened for prostate cancer. Physicians in Connecticut, on the other hand, took a much more conservative position and did not encourage screening. Death rates attributable to prostate cancer have remained the same in the two regions. This suggests that intensive screening for prostate cancer identifies new cases, but knowledge of these new cases is unrelated to increased survival. The observations are consistent with the hypothesis that screening taps a reservoir of indolent disease. In other words, screening produces little public health benefit because it detects cases that may have been harmless if left undiscovered.

In contrast, the American Cancer Society continues to argue that there have been major improvements in survival from prostate cancer. This is best summarized in Figure 4, which shows prostate cancer survival in White and African–American men between 1970 and 1992. For both African–American and White men, survival has significantly increased over the course of time. How might we explain these findings?

EPIDEMIOLOGICAL BIASES AND RESEARCH METHODOLOGY

How could reasonable groups such as the ACS and the ACP come to such different conclusions of the basis of the same data? In order to understand this controversy, it is necessary to consider two biases: lead time bias and length bias.

Lead Time Bias

Cancer screening may result in early detection of disease. Survival is typically calculated from the date that disease is documented until death. Since screening is associated with earlier disease detection, the interval between detection and death is longer for screened cases than for unscreened cases. Epidemiologists refer to this as lead time bias. Figure 5 illustrates this bias.

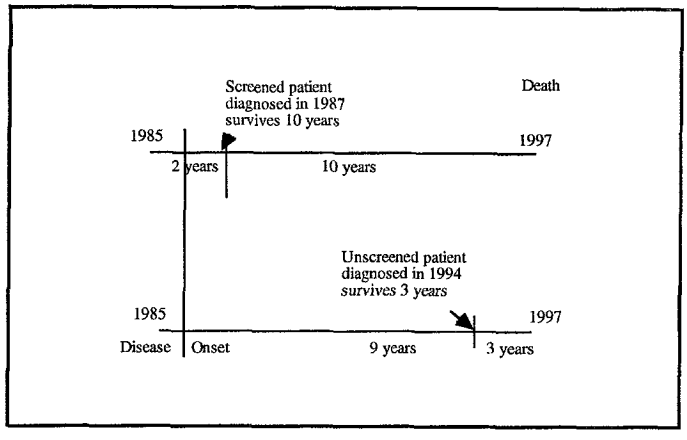

FIGURE 5: Example of lead time bias. The two lines show two different patients; each patient develops prostate cancer in 1985 and dies 12 years later in 1997. However, it appears that the patient shown on the top line survives longer because the disease was detected earlier.

Imagine that two men each develop prostate cancer in 1985 and die in 1997. Hypothetically, the progression of the cancer is identical in these two men. The man illustrated on the top line of Figure 5 was screened in 1987 and the cancer was detected. After this diagnosis, he lived 10 additional years before his death in 1997. The man shown on the lower line did not receive screening and developed symptoms of urinary retention in 1994. After this, he lived 3 additional years. Survival for the man on the top appears to be much longer than that for the man on the bottom, even though the interval between developing cancer and dying is exactly the same. Referring back to Figure 4 which showed changes in survival among those diagnosed with prostate cancer according to

the ACS, these data prompted the conclusion, "Over the past 30 years, the survival rate for all stages combined has increased from 50% to 87%" (46). The ACS attributes these changes to advances in cancer diagnosis and treatment.

Observational (nonrandomized) studies are often unable to separate lead time bias from treatment effect. It has been suggested that increased survival associated with screening can be attributed to lead time and not to early detection and treatment (47–49). The only way to eliminate lead time bias is to perform clinical trials in which men are randomly assigned to either treatment or control groups and followed for many years. To date, there has been no randomized clinical trial evaluating the benefits of screening for prostate cancer. As a result, the ACS statement on increased survival cannot be confirmed nor refuted.

Length Bias

Tumors progress at different rates. Some cancers are very slow growing, while other tumors progress very rapidly. Some cases may regress, remain stable, or progress so slowly that they never produce a clinical problem during an ordinary lifetime. These cases might be described as pseudodisease because they are not clinically important (45). The probability that disease is detected through screening is inversely proportional to the rate of progression. For example, with rapidly progressing disease, early detection may not produce a clinical benefit because cases are detected too late. On the other hand, diseases with very long preclinical phases are more likely to be detected by screening. However, diseases that are progressing extremely slowly may never cause clinical problems. Ironically, advances in screening technology have a greater likelihood of detecting cases for which a clinical manifestation will never materialize (38).

It is possible that some of the apparent benefits of screening and treatment for cancer are actually attributable to lead time and length bias. If this were true, then the greater incidence of detected disease would not be reflected in reduced mortality rates. This appears to be the case for prostate cancer. Current data suggest that, despite increases in screening, mortality rates of prostate cancer have remained relatively constant over the last two decades (50). The same holds for ovarian cancer, breast cancer, colon cancer, and most other malignancies (except lung cancer).

Technology will improve disease detection rates. Newer approaches adjust raw PSA level by gland density (51) or use ratios of free to complexed PSA (52). These approaches are still under evaluation, but it is likely that they will identify more cases at an earlier stage. Although they may identify some men who will benefit from early treatment, they will also find a larger number of men who would have died never knowing they had prostate cancer.

In summary, we typically assume that the more sensitive the test, the more it will contribute to population health status. However, tests can also do harm because false–positive tests can lead to other investigations that might be physically or psychologically harmful (53).

DECISION ANALYSIS

The outcomes model recognizes the significant ambiguity surrounding many treatment choices. Although we may be able to find and attempt to fix prostate cancer, the real challenge is in deciding if diagnosis and treatment are valuable.

There have been several simulations of the benefits of screening and treatment. There are at least three methods available to screen for prostate cancer: digital-rectal exams, transrectal ultrasound, and prostate specific antigen. About 3% of all men will die of prostate cancer. However, autopsy studies show that for men in their mid 70s, about 40% have prostate cancer (54). Better diagnostic procedures will identify more men who have the condition. For those who do have disease, there are three options: radical prostatectomy (surgical removal of the prostate gland), external beam radiation, and watchful waiting.

For men who choose radical prostatectomy, it is unclear whether there is a survival benefit (42). They may gain some relief knowing that they have chosen the most aggressive option. However, there are consequences. Among men receiving radical prostatectomy, about 40% will become incontinent, and 30% of these will have incontinence that requires the use of pads or clamps. Sixty percent of the men who will undergo prostatectomy will become impotent, and only about 11% will have had sexual intercourse in the 30 days prior to the interview (55).

The traditional model encourages treatment for those with a diagnosis (find it–fix it). The outcomes model recognizes another option: watchful waiting. Watchful waiting involves monitoring the condition without treatment. Treatment can be initiated if the disease changes. Understanding the value of watchful waiting requires an understanding of the natural history of disease. Computer simulations of cohorts of 68-year-old men suggest that the risk of distant metastasis is about 5 per 100 patient years. The median time to metastasis is about 14 years. During the 14-year interval, 58% of the men will die of other causes prior to the development of metastatic problems from their prostate cancer. For those who do develop metastases, hormonal therapy can provide control of symptoms and delay disease progression long enough that many of the men will die of other causes prior to serious complications from their prostate cancer (56).

Using QALYs as an outcome measure, simulations suggest there are few benefits of screening. For example, Krahn and colleagues (57) estimated the population benefit for programs to screen 70-year-old men for prostate cancer. They found that the benefits, on average, were improvements in the life expectancy between a few hours and two days. However, when they adjusted the life expectancy for quality of life, they discovered that screening programs reduced quality-adjusted life days. The reason for this negative impact is that screening identifies many men who would have died of other causes. These men, once identified with prostate cancer, are then likely to engage in a series of treatments that would significantly reduce their quality of life. For these men, the treatment causes harm without producing substantial benefits.

ASSISTING THE DECISION PROCESS

The outcomes model requires active patient participation in the decision process. Within the last few years, several organizations have suggested greater patient involvement in medical decisions. For example, a controversial consensus council at the National Cancer Institute reviewed the evidence that women between the ages of 40 and 50 years should be screened for breast cancer. They concluded the data were ambiguous and that women should be informed of the risks and benefits and encouraged to make their own decisions (58). A similar census statement urged patient involvement in decisions about hormone replacement (59). The Agency for Health Care Policy and Research (AHCPR) convened a panel of experts to review screening for colorectal cancer. The panel encouraged screening for adults older than age 50, but argued that there was considerable uncertainty about which screening method was most appropriate. They concluded that patients should be informed about the advantages and disadvantages of each and should participate in decisions about their own

care (60). Finally, the American College of Physicians reviewed the evidence on the benefits of screening and treatment for prostate cancer. They concluded that the benefits of both screening and treatment were uncertain and that men should be informed of the risks and benefits and participate in decisions about whether or not they should be screened (61).

All of these reviews suggest a new paradigm known as shared medical decision-making. Important decisions affecting patients' lives go beyond finding and fixing disease. Treatments have benefits, but they also have consequences. Focusing on a general outcome, such as the QALY, argues that many decisions cannot be made exclusively by providers. Patients must contribute information that only they fully understand. For example, prostate cancer surgery carries a significant risk of impotence. This may be a major concern for some older men. Other older men may not have partners and may be unconcerned. If the patient asks the doctor, "What would you do?," the response may be irrelevant because impotence may have different meaning in the lives of the doctor and the patient. The decision depends on very personal information and can only be provided by the patient.

There are many challenges in determining how information should be presented and solicited in shared decision-making. In a classic study by McNiel, Pauker, Sox, and Tversky, patients with lung cancer were asked to choose between radiation therapy or surgery. Patients were presented with the best data available at the time suggesting that surgery led to a greater chance of immediate death, but those who survived surgery would have a better long-term chance of survival. In contrast, radiation would be safer in the short run, but in the long run may be associated with a lower chance of survival. Overall, short-term chances of living were better with radiation, while long-term chances were better with surgery. If patients were given only information about long-term life expectancy, they favored surgery. On the other hand, if they were given information that focused on the short-term chances of survival, they favored radiation (62).

Most patients are risk-averse or reluctant to accept treatment that causes death in the short term (63). Further, most people want certain benefit. For example, patients tend to choose a drug that is described as extending life for 1 year over another drug described as having a two-thirds chance of extending life by 1.5 years (64). To date, few patient decision-making studies have actually studied patient preferences. In many cases, the studies are based on simulations involving college students or patients who do not face these decisions. The cognitive science literature is rich in methodology and theory. However, few studies have addressed real life decision problems. For example, few patients make a decision about whether or not to accept a radical surgery on the basis of a single source of information. Most people gain input from friends and family and may seek other sources of information. We need to learn considerably more about these decisions and the factors that influence them.

SUMMARY

Health care is changing. The traditional biomedical model suggested that if there was any chance of benefit, treatment should be offered. Often the entire effort might be justified because a single patient could benefit. The traditional model emphasized that treatment and diagnosis were valuable in their own right and should be encouraged whenever possible (65).

In contrast, an outcomes model considers the impact of care from the patient's perspective. According to the outcomes model, the goals of health care are to increase the life expectancy and to improve quality of life. Decisions about treatment are not the sole province of the provider. Instead, the model encourages shared decision-making involving an informed patient and a respectful provider. As we shift toward this patient-oriented model of care, it will be important to recognize that we know little about how complex decisions are made. The new frontier for behavioral medicine will require applications of cognitive science to improve health care decisions.

Shared decision-making requires a strong provider–patient relationship. The health care provider is more than simply a broker of information. In shared decision-making, we must communicate medical uncertainty and solicit patient preferences for outcomes. We must also understand uncertainty and communicate the probabilities of particular benefits and consequences of treatment. Communicating probabilities is difficult. At present, many of the most important issues relevant to patient decision-making are poorly understood. There will be many opportunities for behavioral medicine to contribute new ideas, methods, and applications.

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