Diagnostic and Treatment Decisions in US Healthcare

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Abstract

The practice of medicine links diagnosis to treatment. However, for many diagnosed conditions diagnosis and treatment may not affect health outcome. Examples include low-grade cancers that do not influence life expectancy or quality of life. Further, there is considerable uncertainty about the point along a biologic continuum where treatment should begin. Changes in diagnostic thresholds often increase healthcare costs even though the benefit of the treatment is uncertain. Although this uncertainty is understood by the healthcare providers, it often is not shared with patients. We advocate a new paradigm called shared medical decision making that makes uncertainty about diagnosis and treatment transparent to patients and engages them in the treatment decision process.

Keywords
definition of disease, quality of life, shared medical decision making, uncertainty
There is a healthcare crisis in the USA. Costs are escalating, and many question the effectiveness of common medical procedures. Perhaps no field illustrates this problem better than preventive medicine where there has been a strong move toward secondary prevention. As opposed to primary prevention that attempts to prevent disease, the goal of secondary prevention is to diagnose disease early and arrest disease progression.

At the core of the issue is a series of interrelated topics. First, there is a common assumption that medical diagnoses are ‘correct’ and that a high specificity diagnosis will lead to treatment decisions that make patients well. However, medicine is an art that is often based on ambiguous or conflicting evidence. Second, despite this uncertainty, there is an increasing reliance on technology to create a ‘health’ and ‘disease’ dichotomy, a dichotomy that fails to recognize the vast spectrum of disease. Implicit in this is an assumption that any disease is worth treating, no matter how mild it is within the disease spectrum. Even if all disease responded to treatment with the same relative effectiveness (an unproven assumption), the absolute benefit afforded by treating mild spectrum disease will usually be much less than that achieved by treating more advanced disease.

These issues have been widely discussed in the medical literature. Published studies make clear that there is uncertainty about the utility of many tests and procedures. However, the uncertainty has not been made transparent to patients and newer definitions of quality health-care require greater levels of disclosure in making treatment decisions (Institute of Medicine (US). Committee on Quality of Health Care in America, 2001). Shared decision making is a new paradigm for sharing the evidence base and engaging patients in the process of deciding which treatments and tests are appropriate for them.

In this article we review current cost issues, including the question of efficiency of some new technologies and approaches to care. We then explore reasons for this diminished efficiency and how many of these reasons may lead to poorer patient outcomes. Because of these problems, we argue that patients need to be much more active in sharing decisions about their own care. In the final section of the article, we will review some of the emerging literature on shared medical decision making.

**Uncertainty and variability**

This article focuses on uncertainty and variability. We will present evidence that there is substantial variability in the way physicians make decisions. This results in remarkable variation in the decisions to apply diagnostic tests and therapeutic interventions. Further, it will be argued that the US healthcare system has incentives to increase the number of patients. Often, people become patients by receiving chronic disease diagnoses. However, the thresholds for these diagnoses can vary over time. Changes in the definition of what we label as ‘disease’ can have substantial impacts on healthcare costs, patient anxiety and the organization and delivery of healthcare.

Preventive medicine is moving toward more aggressive screening and treatment of mild spectrum disease. There is considerable variability in the population for the values of biological variables used to define or describe many diseases. We define a mild spectrum disease as one with values close to the population norm. Scores on these variables are used to classify people as ‘normal’ or in need of medical attention. ‘Normal’ is defined differently for different diseases. For example, sometimes normal is defined as the range that includes 95 percent of the population. For other conditions there is an arbitrary cut-off often based on clinical judgment and evidence-based reviews. Both methods divide continuous distributions into disease–non-disease dichotomies (Fisher & Welch, 1999a, 1999b).

The most crucial problem facing patients diagnosed with these new, lowered definitions of ‘disease’ is whether they should take treatment. Using a theoretical framework that we call the ‘outcomes model’, we suggest that resources should be used to help people live longer (increase life expectancy) and to feel better (improve quality of life). Diagnosing and treating disease may or may not contribute to this objective. The comprehensive model of health benefit combines survival and quality of life information. A treatment is considered to produce benefit if it improves the combined index of life expectancy and quality of life.
Treatments that do not improve this index are not regarded as valuable. Black and Welch (1997) make the distinction between disease and pseudodisease. Pseudodisease is disease that will not affect life duration or quality of life at any point in a patient’s lifetime. When the disease is found, it is often ‘fixed’ with surgical treatment. However, the fix may have consequences, often leaving the patient with new symptoms or problems. The outcomes model considers the benefits of screening and treatment from the patient’s perspective (Kaplan, 2000). Often, using information provided by patients, we can estimate the quality adjusted life expectancy for a population and determine if they are better off with or without screening and treatment (Kaplan, 1997).

The cost problem

Good health is highly valued, and most adults make many choices to achieve wellness for themselves and for their families and friends. Health services are used to help achieve better health, to maintain good health and to prevent health damaging conditions. We are willing to use resources to ‘purchase’ health. But, are we using our resources wisely in the pursuit of better population health? In order to address this question, we must consider the implications of purchasing healthcare. We recognize that issues of healthcare costs and outcomes are extremely complex and that it is impossible to do justice to the arguments in a few paragraphs. So, with caution, we will offer a brief overview. Readers interested in more detailed discussion of these issues should consider several excellent references (Coffield, Maciosek, McGinnis, Harris, Caldwell, Teutsch et al. 2001; Haugh, Thrall, & Scalise, 2002; Institute for the Future, 2000; Institute of Medicine (US). Committee on Quality of Health Care in America, 2001; Kronick & California Program on Access to Care, 1999; Starfield, 2000).

A good starting point is the comparison of medical decisions and healthcare expenditures in the USA in comparison to other countries. Healthcare costs in the United States have grown exponentially since 1940. Although there was a temporary slowdown in the early 1990s, the rate of increase began to accelerate again by the turn of the century. Healthcare in the USA now consumes about 14.5 percent of the gross domestic product, while no other country in the world spends more than 10 percent. Although the rate of growth has slowed, the Institute for the Future estimates that healthcare expenditures will increase at a rate of 6.4 percent annually and will account for 15.6 percent of the GDP by 2010 (Institute for the Future, 2000).

While we assume that greater expenditure results in greater health benefit, developed countries that spend considerably less on healthcare in comparison to the USA have about equal health outcomes. The United Kingdom, for example, spends about half per capita on healthcare as the United States. However, life expectancy in the United Kingdom is slightly longer than it is in the United States and infant mortality is slightly lower. Among 13 countries in one recent comparison, the USA ranked 12th when compared on 16 health indicators (Starfield, 2000).

Within the United States, there is considerable variability in spending. For example, using data from the Medicare program, the per capita spending ranges from a low of $2736 in Oregon to a high of $6307 in Alaska. State-level data are also available on the average quality of healthcare. Quality is typically defined as adherence to defined standards of patient care. For example, it is possible to estimate the extent to which physicians adhere to defined patient guidelines. There is essentially no relationship between per capita spending and quality across the USA. Spending more does not buy better quality of care. Adjusting for socioeconomic status does not alter this finding (Fisher & Skinner, 2001).

One explanation for the failure to control healthcare cost is the belief that society has a moral obligation to provide all necessary services for those who are sick and in need of help. Yet, we have no assurance that investments in healthcare will improve population health because many services produce limited benefits. The challenge is in determining how many people are in need of help and whether services will really help them. We argue that the medical care system has expanded the number of people who are ‘sick’ and, therefore, in need of medical service. This has been accomplished, in part, through screening programs that
identify disease at very early phases. Once an individual is identified as ‘sick’ it is incumbent upon the system to treat the problem. However, in many cases, attention to early stages of disease may offer little or no benefit, though mass screening programs may produce harm. For example, while there is little evidence that they harm physiologically, they may harm by diverting resources away from programs with greater potential for population benefit.

Treatment of the newly diagnosed illness has become expensive. Pharmaceutical costs are now the strongest driver of increases in healthcare costs in the United States. The most recent evidence suggests that pharmaceutical costs rose twice as fast as other components of US healthcare expenditures during the 1990s. Currently, the costs of prescription medications for Medicare patients are rising about 20 percent each year. For most of these conditions, an expensive pharmaceutical product is available with treatment costs approaching US$3/day. For older adults with a multiple diagnoses, the costs of medications may exceed the cost of food (Liberman & Rubinstein, 2002). In order to address the policy issues, we need to understand the impact of lowering diagnostic thresholds upon population health status and healthcare costs.

**How much disease is there?**

Estimating the amount of disease that could potentially be treated is very difficult because there are large reservoirs of undiagnosed disease (Black & Welch, 1993, 1997; Welch & Black, 1997). Autopsy studies consistently show that most young adults who died from non-cardiovascular causes have fatty streaks in their coronary arteries indicating the initiation of coronary disease (Strong, Malcom, McMahan, Tracy, Newman, Herderick et al., 1999). Cancers of the breast and prostate have been identified in as many as 30 percent (breast) (Horton, 2001; Kaplan & Wingard, 2000) and 40 percent (prostate) (Fowler, Bigler, & Farabaugh, 2002; Vis, 2002) of older adults who die from other causes. As diagnostic technology improves, common problems will be identified in many individuals who would not be harmed by the disease and, therefore, would not benefit from treatment. The problem has been fiercely debated in relation to cancer screening tests such as mammography and PSA (Gelmon & Olivotto, 2002; Vis, 2002).

An important corollary involves the diagnostic thresholds for common health problems. Many biological processes are approximately normally distributed in the general population. Diagnostic thresholds are often set toward the tail of the distribution (see Fig. 1). Schwartz and Woloshin (1999) evaluated the population effect of proposed reductions of diagnostic thresholds for four conditions: hypercholesterolemia, hypertension, type 2 diabetes and overweight. Under proposed lower thresholds for ‘disease’, 75 percent of the US adult population qualified for a chronic disease diagnosis (Schwartz & Woloshin, 1999). This is important because those with the mildest disease (values closest to

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Figure 1. Proportion of the adult population with total cholesterol values >240 mg/dl and >200 mg/dl (NHANES data).

![Figure 1](image-url)
the mean) usually have the lowest risk of complications from their ‘disease’; yet they often face the same risks of treatment side-effects as those more clearly in need of therapy.

In fact, to dichotomize ‘disease’ oversimplifies the issue. Currently, we act as though biological processes are either ‘normal’ or ‘abnormal’. For example, brown hair is normal and green hair (a sign of copper excess) is abnormal. A nevus (common mole) is not ‘normal’ per se, but it is not considered pathologic. Hence, the ‘abnormal’ element of the dichotomy evolves to a second dichotomy: ‘not pathologic–pathologic’. This is not enough, however, since pathology is generally considered something that needs treatment. Thus, any cancer, all diabetes and all high blood pressure are considered the same in terms of our ‘need’ to evaluate and treat. While we act this way, we know this is not the case—we realize there is a broad range within the ‘pathology’ group, even in the more severe end of the spectrum. For example, some people with ovarian cancer die quickly, while others, with the cancer detected at the same stage, live much longer. Our tendency to lump all ‘abnormal’ into ‘pathologic’, and to consider that all pathology is created equal leads us to treat all disease with the same aggressiveness.

**Cholesterol lowering**

The definition of high serum cholesterol offers an excellent example. Total cholesterol values greater than 240 mg/dl were once used as the diagnostic thresholds for hypercholesterolemia. Recently, diagnostic thresholds have been reduced and some groups advocate treatment for individuals closer to the center of the distribution. In the total cholesterol example, the third National Health and Nutrition Examination Survey (NHANES III) showed that about 20 percent of the adult population have values above 240 mg/dl. However, over half of the adult population has total cholesterol over 200 mg/dl. If some group advocated changing the diagnostic threshold from 240 to 200, the policy change would identify an additional 30 percent of the adult population in need of treatment.

**Diabetes**

A similar example is available for type 2 diabetes (with a change in diagnostic threshold for fasting blood glucose from 140 mg/dl to 126 mg/dl). The prevalence of varying levels of blood glucose has been estimated from the NHANES III Study. It has been difficult to estimate the prevalence of type 2 diabetes because a significant number of cases go undiagnosed. The NHANES III community-based investigation obtained blood samples from a random sample of the American population. In addition, oral glucose tolerance tests (OGTTS) were performed on 66 percent of a random half sample of the adult participants. This subsample excluded people with a medical history of diabetes. The American Diabetes Association reports that there are about 15.7 million cases of diabetes in the United States (about 5.9 percent of the US population). Among these, they estimate that about 5.4 million are undiagnosed. About 90 to 95 percent of all the cases of undiagnosed diabetes are type 2 or non-insulin dependent. Engelgau, Narayan and Herman (2000) considered the receiver operating characteristic (ROC) curve associated with different diagnostic thresholds for diabetes mellitus. They considered fasting for glucose of 7.8 mmol/l (140 mg/dl) and 7.2 mmol/l (129 mg/dl). On the basis of analysis and relation to diabetic complications, they suggested that the lower diagnostic threshold has greater sensitivity and a stronger relationship to two-hour glucose challenge. On the other hand, if diabetes is defined by the complication of retinopathy, the higher threshold has greater specificity (Engelgau et al., 2000).

On the basis of this information, the American Diabetes Association changed the diagnostic threshold of blood glucose levels for type 2 diabetes from 140 mg/dl to 126 mg/dl. In doing so, they increased the number of Americans with diabetes by 1.7 million cases or by about 14 percent (Schwartz & Woloshin, 1999). Since clinical trials have not included evaluations of treatments for this new group of patients (people previously believed to be free from diabetes), it is unknown whether treatment will be of value. The benefit of medical care for people with blood glucose levels between 126 mg/dl and 140 mg/dl is uncertain and unevaluated.

**Depression**

Prevalence of subsyndromal symptomatic depression can be estimated from the National
Institute of Mental Health (NIMH) Epidemiologic Cachment Area Program (ECA). This program administered the diagnostic interview schedule to a random sample of the general population. Depressive symptoms that were below threshold for a diagnosis of depression were systematically related to household strain, social irritability and financial strain. In addition, there were limitations in physical and job functioning, restricted activity, bed days and self-rated health status (Judd, Paulus, Wells, & Rapaport, 1996). It was estimated that about 11 percent of the population had subsyndromal depressive symptoms that may benefit from pharmacologic therapy. Lifetime prevalence is estimated to be 40 percent or higher (Judd & Akiskal, 2002).

It has been suggested that patients with subsyndromal depression be treated with medication (Judd, Rapaport, Paulus, & Brown, 1994; Schwartz & Woloshin, 1999). However, as with high cholesterol and diabetes, the literature does not include systematic evaluation studies for groups of patients previously believed to be free of this diagnosis. Since the effect of the illness is believed to be very mild, the effect of treatment would also be expected to be small. As with other conditions discussed here, the adverse effect profile would likely be the same in those with this mild illness. In the absence of systematic outcome data, both patients and healthcare providers face uncertainty of balancing the potential benefits and harms.

How many people would be expected to receive treatment for each incremental reduction in diagnostic threshold?

Only a portion of people in each diagnostic category will be diagnosed. For example, it has been estimated 52 million Americans have serum cholesterol levels deserving attention, while the number in active treatment is a small fraction of potential cases (Sempos, Cleeman, Carroll, Johnson, Bachorik, Gordon et al., 1993). Further, among those who have an identified diagnosis, not all are assigned to treatment. The American Diabetes Association estimates that at least one-third of adults with diabetes have not been diagnosed. In the case of subsyndromal depression, it has been argued the great majority of cases have not been diagnosed. In the ECA study, about 4 percent of the population qualified for a diagnosis of depression, while 11 percent had symptoms of depression (Judd & Akiskal, 2002). For those given treatment, between 15 and 90 percent do not adhere to physician recommendations.

For all three clinical problems discussed above, there is considerable uncertainty about whether treatment confers benefit. An honest healthcare provider would need to explain that it is unknown whether therapy will make a condition better or whether it will prevent poor health outcomes in the future. Further, treatment may be costly and it may cause harm. Shared medical decision making may be an appropriate paradigm for this disclosure.

Shared decision making

So far, we have argued that healthcare in the USA is too expensive, and resources are often used to treat pseudodiseases. A central component of the problem is that the role of uncertainty in medical decision making is underappreciated. Although patients accept treatment with high expectations of benefit, experienced healthcare providers may recognize that the potential benefit of many treatments is probabilistic. One approach to this problem is greater patient involvement in decisions about care. This section reviews some of the literature in the emerging study of shared medical decision making, in which choices of treatment pathways are a collaborative effort between provider and patient (Frosch & Kaplan, 1999).

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 should be inexpensive and painless. However, this scenario is not common. For most medical decisions, judgments about disease are not perfectly reliable and even when an early diagnosis is available, it is not always clear that treatment is the best option (Lenert & Kaplan, 2000). Choices about what treatments should be offered have typically been left to the physician. For a variety of reasons, however, patients are becoming activated in the decision process.
These include changes in the standard of informed consent in making and implementing treatment decisions, increased access to information among patients through the Internet and a growing recognition of the importance of patient preferences in making clinical decisions (Frosch & Kaplan, 1999).

Shared decision making is the process by which the patients and physicians join in partnership to decide whether the patient should undergo diagnostic testing or which if any therapy to receive. Often, shared decision making involves formal decision aids that provide patients with detailed information about their options. The information is usually presented through interactive video disks, decision boards, descriptive consultations or through the Internet (Frosch & Kaplan, 1999; Lenert & Cher, 1999). Using these decision aids, patients complete exercises to inform them of the risks and benefits of treatment options and then evaluate these with their physician relative to their preferences for outcomes (Frosch & Kaplan, 1999).

Decision aids are valuable for both patients and physicians. One of the challenges of contemporary primary care medicine is that patient visits are short. Typically, the entire visit is limited to 15 minutes. During this time, the physician must greet the patient, do routine evaluations such as taking blood pressure, review medical history, determine the presenting complaint, perform a physical examination, make a diagnosis, write a prescription discuss treatment plans, write notes in the patient’s chart and be on to the next patient. If at the end of this interaction, the patient asks the difficult questions such as, ‘Should I be on hormone replacement therapy, should I get a PSA test or do I need a mammogram?’ the physician knows that there is not enough time to discuss the issue properly. For each of these issues, the literature is complex and conflicting. Instead of dealing with the complexity, it is much easier to simply say that the test or treatment is recommended. However, each of these decisions may have important consequences for the patient.

The decision to get a PSA test, for example, may lead to a significant chance of having a false positive result, creating unnecessary anxiety, or heading down a pathway toward further evaluation. Not getting the test might mean that a cancer would go undetected. The decision whether or not to get the test is fiercely debated among scientists and physicians and there is significant uncertainty as to whether or not the test is of value. Shared decision making allows patients to gain a better understanding of this uncertainty and to make an informed choice.

Shared decision making is not patient decision making. In other words, there are technical aspects of medical decisions for which patients are not well equipped (Deber, Kraetschmer, & Irvine, 1996). For example, patients are not expected to know what approach to surgery is best or the advantages or disadvantages of particular medications. On the other hand, patients have a perspective that only they fully understand. For instance, surgical treatment of prostate cancer may make a man impotent. For some men, this is a major concern, even at older ages. Other men may not be sexually active and impotence may not be a concern. The patient provides the perspective that is typically unknown to the physician. Use of decision aids allows these preferences to be expressed. The personal issues brought by the patient can be merged with the technical concerns and dispassionate evaluation of risks and benefits of their physicians.

One of the most interesting examples concerns the choice between mastectomy and lumpectomy for women with well-defined breast cancer. For women diagnosed with breast cancer, there is substantial variation in the treatments delivered. In 1992-3 more than 100,000 women in the Medicare program had surgery for breast cancer. For women who have breast cancer, the surgeon has at least two major options. These are lumpectomy which involves removal of the tumor or mastectomy which requires the removal of a larger portion of tissue (partial mastectomy) or complete removal of the breast through total mastectomy. Clinical trials have shown little or no difference in survival rates between women who receive lumpectomy followed by radiation or chemotherapy and women who receive total mastectomy. Since the outcomes are likely to be similar, the woman’s own preference should play an important role in the decision process. However, the Dartmouth Health Care Atlas shows that there are some regions in the country where mastectomy is typically done and other
regions where lumpectomy is typically done. For example, considering the proportion of women who had breast sparing (lumpectomy) surgery, women were 33 times more likely to have lumpectomy if they lived in Toledo, Ohio than they were if they lived in Rapid City, South Dakota (48% versus 1.4%). The proportion of women having breast sparing surgery in Patterson, New Jersey and Ridgewood, New Jersey was 37.8 percent and 34.8 percent respectively. At the other extreme, only 1.9 percent had breast sparing surgery in Ogden, Utah and 3.8 percent in Yakima, Washington. In general, breast sparing surgery is more widely used in the Northeast than anywhere else in the United States. Rates tend to be low in the South, Midwest and Northwest. Although many advisors shun the more aggressive surgical approaches, the psychological effects of treatment choice are not well understood. Investigators in the UK have studied psychosocial impact of the choice between mastectomy and lumpectomy. The UK study found that those who elected mastectomy had better psychological outcomes. A more aggressive treatment may reduce worry, even though it confers no benefit in terms of expected outcomes (Fallowfield, 1997). The study demonstrated that, as patients become better informed, they are less likely to take the PSA test. The study also obtained information on patient knowledge. As knowledge increased,

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One specific example (Frosch, Kaplan, & Felitti, 2001), considered a decision aid to help men decide whether or not they should be screened for prostate cancer using the PSA test. The men were all enrolled in a clinic that provides a wide variety of medical screening tests. In an experiment, the men were randomly assigned to one of four groups in a two-by-two factorial design. One factor was for use of a decision video. Men either watched or did not watch a video that systematically reviewed the risks and benefits of PSA screening. The video featured a debate between a urologist who favored PSA screening and an internist who opposed PSA screening. Further, the video systematically reviewed the evidence for the benefits of treatment for prostate cancer. The other factor in the experimental design was whether or not men had the opportunity to discuss the decision with others. The design resulted in four groups: usual care, discussion alone, video alone and video plus discussion. All men were asked if they wanted the PSA test and medical records were obtained to determine whether the test was completed.

The study showed that there was a systematic effect of the video and discussion groups. In the usual care control group, virtually all men (97%) got the PSA test. In other words, with no new information, men will typically take the test. In the other groups, having more information led to a conservative bias. In contrast to the usual care control, those in the other groups were more sensitive to the risks of the test in relation to its benefits. Among those participating in the discussion group, 82 percent got the PSA test. For those watching the video, 63 percent completed the test. Those watching the video and participating in those discussions had only a 50 percent PSA completion rate (see Fig. 2). The study demonstrates that, as patients become better informed, they are less likely to take the PSA test. The study also obtained information on patient knowledge.
The likelihood of getting the PSA test decreased, stressing that better-informed patients make more conservative decisions.

The Internet has significant potential advantages for shared decision making. Because medical knowledge changes so quickly, the Internet provides a great opportunity to continually update information. It may allow for more efficient delivery of information to patients since it does not require a dedicated clinic space for patients to view a videotape or interact with a decision aid. However, we do not know how effective the Internet is at delivering information. New evidence suggests that 66 percent of all US adults have Internet access of which 80 percent have looked for healthcare information online (http://cyberatlas.internet.com/markets/healthcare/article/0,10101_1151011,00.html#table2). Yet, how good of a platform is the Internet for delivering shared decision-making aids? In one study, 226 men, 50 years of age or older, who were scheduled for a complete physical exam, were randomly assigned to access a website or to view a 23-minute video tape about the risks and benefits of being screened for prostate cancer using the PSA test. Those watching the video were more likely to increase their knowledge about the PSA test and were more likely to decline the test than those assigned to the Internet group. Further, those who watched the video were more likely to express confidence that watchful waiting was the best treatment for prostate cancer. Thus, it appeared that the video may have been the best channel for delivering the information. However, using tracking data from the website, it was possible to determine how much of the online presentation each participant reviewed. The analysis indicated that only 53.5 percent of men assigned to view the Internet program reviewed it in its entirety. Among those men who reviewed the entire Internet program, the results were identical to those who watched the video. Hence, both methods of delivering the information were efficacious, but those watching the video were more likely to review the materials than those watching the Internet. In other words, the Internet and the video worked about equally as well if people exposed themselves to the entire program. This study indicates the potential of the Internet but also suggests that additional prompts may be necessary to increase patient use of an Internet decision aid. Future studies will need to evaluate the use of e-mail

![Figure 2. Percentage of men completing PSA test after participation usual care, discussion groups, video, or video plus discussion group (From Frosch et al., 2001).](image-url)
prompts or motivational strategies to increase the effectiveness of Internet decision aids (Frosch, Kaplan, & Felitti, 2002).

Most studies of decision aids have used fairly short follow-up periods and have not examined long-term effects on health outcomes and healthcare costs. One of the first studies to examine these issues, compared women with menorrhagia randomly assigned to a control group, an information only group and an information plus interview group. Participants in this study conducted in the UK completed final follow-up assessment after two years. Results showed that women in the information plus interview group were significantly less likely to choose a hysterectomy, the most aggressive option, as treatment for menorrhagia. Health outcomes at two-year follow-up, as measured by the SF-36 were similar in all three groups. The only difference was that women in the information plus interview group had better outcomes on the role-physical dimension of the SF-36. Healthcare costs were lowest in the information plus interview group and highest in the control group with a mean difference of almost $1200 (Kennedy, Sculpher, Coulter, Dwyer, Rees, Abrams et al., 2002).

The shared approach to clinical decision making also has significant benefits for the management of chronic diseases. An early study that examined the relationship between ‘Active patient orientation’ and blood pressure outcomes among hypertensive patients, found a correlation between greater patient participation in clinical decision making and lower blood pressure (Schulman, 1979). A study among patients with diabetes examined a brief intervention to increase patient participation in medical decision making (Greenfield, Kaplan, Ware, Yano, & Frank, 1988). Patients who received the intervention communicated more actively with their physicians and subsequently showed improved glycemic control. Although the recently reported UK Prospective Diabetes Study showed improved microvascular outcomes for patients receiving aggressive therapy, controversy remains since there were no significant differences in macrovascular complications, diabetes-related mortality or all cause mortality (Nathan, 1998). In light of this continued uncertainty around the relative value of aggressive therapy, incorporating patient preferences in clinical decision making is critical.

**Conclusions**

Our efforts at preventive medicine should be devoted to the prevention of disease and complications. However, the major focus of much of our preventive efforts has been toward the identification of established disease at an early phase. The tools of preventive medicine emphasize medical diagnosis and pharmacological treatment. Analyses of many large-scale screening and treatment programs indicate that the benefits have been limited (Kaplan, 2000). Nevertheless, we are currently witnessing greater emphasis on population screening and lowering of diagnostic thresholds for many disease categories. This will result in significant increases in healthcare costs with unknown population health benefits.

A major contributor to the expense of contemporary healthcare is that there is considerable uncertainty about the potential benefit of many treatments. Typically, Americans assume all minor health problems will grow into major health concerns. The favored option is to medically treat these conditions. However, the benefit of these treatments is typically uncertain and the treatments carry some risks. Further, aggressive treatment of mild spectrum conditions is costly with little evidence of benefit at the population level.

Although the uncertain benefit of many programs for screening and treatment of mild spectrum disease is well documented in the medical literature, most patients are unaware of the controversies. When there is uncertainty among providers, approaches to treatment are often highly variable. Typically the variation represents differences in physician preferences. Shared medical decision making is a new paradigm in healthcare that uses decision aids to help patients understand the risks and benefits of treatment. Early studies suggest that allowing patients a greater role in decision making usually results in more conservative decisions. The selection of less aggressive care results is reduced healthcare costs. Further shared medical decision making typically results in greater patient satisfaction. By offering a better basis for informed consent, shared medical
decision making may also protect physicians from litigation.

Shared decision making is a new paradigm in medicine and healthcare. There will be ample opportunities to develop new methodologies and to evaluate the effect of these methods on patient outcomes, patient satisfaction and medical care costs.

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