By Howard Backer, MD, MPH

Prostate Cancer Screening: Exploring the Debate

Despite widespread use of prostate specific antigen (PSA) serologic testing to screen for prostate cancer in men, authorities disagree on the benefit of this test and its optimal use. The epidemiology of prostate cancer and the characteristics of the PSA test provide compelling arguments for its use, but no clear evidence shows that the test improves outcomes as measured by cause-specific mortality—the only measure without bias. Further, the cost-effectiveness of using PSA for population screening and the policy issues related to prostate cancer screening and treatment create an apparent conflict between the public health perspective and the interests of individual patients and practitioners.

Introduction

Prostate cancer screening offers a vivid contemporary example of how the divergent perspectives of public health and clinical practitioners can lead to a rancorous debate. The conflict originated from a recent shift in medical practice toward prevention and evidence-based practice. Preventive medical practice is becoming standard practice because of its ability to improve health outcomes and because of its presumed long-term potential to decrease the cost of medical care.[1,2] To minimize variation in practice and to achieve the best health outcomes, preventive care attempts to consistently follow practices that are based on valid scientific evidence.[3] To support these goals, the US Public Health Service and the Canadian Task Force on the Periodic Health Examination jointly developed an explicit process for formulating evidence-based guidelines and used these guidelines to review preventive practices.[4] This process did not produce adequate evidence to recommend routine screening for prostate cancer; instead, routine screening was given a "D" rating, indicating that the practice is potentially harmful. Using different assumptions, methods, and level of required evidence, other groups[5] disagreed with these recommendations for prostate cancer screening[6-12] (Table 1). Recommendations from the various Kaiser Permanente Regions mirror this spectrum of opinion.[13] While the medical community debates the available evidence and most appropriate threshold for screening, patients and community health groups remain confused; in this scenario, health care agencies and health plans are caught in the middle, attempting to diplomatically maintain their credibility with all sides.

This discussion elucidates the various expert opinions in this controversy and explores the basis for their divergence. Other references[14-24] provide more extensive and explicit reviews of the voluminous literature.

Prostate Cancer: Epidemiology and Risk Factors

Few would dispute the serious personal consequences and substantial public health impact of prostate cancer, which is the second leading cause of death from cancer among men in the United States and accounts for 14% of all cancer-related deaths in US males. Prostate cancer will affect one in five American men during their lifetimes, and about 3% of these men will die from it. A total of 209,000 new cases of prostate cancer and 41,800 deaths from the disease were predicted for 1997.[23] The prevalence, incidence, and mortality rate increase exponentially for men aged 50 years and older, guaranteeing that the problem of prostate cancer will grow as our population ages.[24] The age-adjusted incidence rate is 21 cases per 100,000 person-years for US white men under age 65 years and is 819 per 100,000 person-years for US white men aged 65 years and older.

One-third to one-fourth of men who have clinically significant prostate cancer will die from it; however, due to its association with older age, prostate cancer causes the least loss of mean life-years of all cancers: eight years. In 1992, 61% of prostate cancer patients were aged 75 years or older; median age at death was 77 years.[25] Survival depends on stage and histologic grade of tumor and whether or not it is confined to the prostate. On average, only 58% of tumors are discovered while still localized. Patients with localized disease (stage A1) have a 12% chance of dying from it if they remain untreated for 10 years. The 10-year survival rate for patients with regional extension of prostate cancer is 55%; for patients with distant metastases, 15%.

These survival statistics and the 3% lifetime risk of death from prostate cancer must be reconciled with the incidence of histologic cancer shown by autopsy studies: 22% of men aged 50-59 years, 36% of men aged 60-69 years, 38% of men aged 70-79 years, and 54% of men aged 80 years and older. These

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Table 1. Recommendations of major authorities for prostate cancer screening

Organization	Recommendation	Endorsement
American Cancer Society (1997)[6]	PSA test and digital rectal examination should be offered annually, beginning at age 50 years, to men who have life expectancy ≥ 10 years and to younger men who are at high risk. Information should be provided to patients regarding potential risks and benefits of intervention.	Endorsed by the American Urological Association (AUA). Similar statement by the American College of Surgeons (ACS).
American College of Radiology (1999)[7]	Annual PSA testing is recommended for all men aged ≥ 50 years with life expectancy of ≥ 10 years. Annual screening should be offered to men aged ≥ 40 years who are at high risk for prostate cancer.	
US Preventive Services Task Force (1996)[4]	Routine screening for prostate cancer with DRE, serum tumor markers, or TRUS is not recommended (evidence grade D).	Endorsed by the Centers for Disease Control and Prevention (CDCP).
National Cancer Institute (1998)[8]	Insufficient evidence exists to establish whether screening by DRE, TRUS, or serum markers (including PSA) decreases mortality from prostate cancer.	
British National Health Service, Health Technology Assessment (1997)[9]	Routine testing to detect prostate cancer should be discouraged. Purchasers of health care services should not fund screening.	
Canadian Task Force on the Periodic Health Examination (1994)[10]	Does not recommend the routine use of PSA or DRE as part of periodic health examination.	
Canadian Workshop on Screening for Prostate Cancer (1994)[11]	No PSA for screening unless for a screening trial or if patient requests test after having pretest counseling and giving informed consent.	Endorsed by the Canadian Cancer Society; National Cancer Institute of Canada; Health Canada; Canadian Urologic Association.
American Academy of Family Physicians (1998)[12]	Men aged 50-65 years should be counseled about known risks and uncertain benefits of prostate cancer screening.	
American College of Physicians (1997)[20]	Men should not be screened routinely for prostate cancer; instead, physicians should describe potential benefits and known disadvantages of screening, diagnosis, and treatment; listen to patients' concerns; and individualize the decision to screen. The College strongly recommends that physicians enroll eligible men in ongoing clinical studies.	

rates imply that nine million cases of undiscovered prostate cancer could currently exist in US men aged 50 years and older and that only 1 of 380 men with prostate cancer will die from it.[26] The possibility of undiscovered prostate cancer suggests a need for more early detection efforts.[19] Clearly, tumor properties differ: some behave aggressively, whereas others are indolent.

Marked ethnic differences in prostate cancer rates have increased the pressure on public health agencies to support screening efforts.[24] In the United States, Hispanic and Asian men have lower incidence rates than white men, whereas African-American men have both a higher incidence of prostate cancer (234 cases per 100,000 population in 1994) than white men (135 cases per 100,000 population in 1994) and higher mortality (56 cases per 100,000 population) than white men (24 cases per 100,000 population in 1994).[27,28,29] African-American men also have a higher stage of cancer at diagnosis: only 35% are first seen with localized cancer compared with 62% of white men. Data concerning racial differences in five-year survival rates conflict when stratified for tumor grade and cancer stage. Although the clinical incidence of prostate cancer is 30% to 50% higher among African-American men, autopsy data show similar prevalence of undiscovered disease. To date, no consistent data explain the observed differences in incidence, mortality, or tumor stage; and these differences are likely to be explained by multiple factors.[28-31]

In addition to age and race, family history among first-degree relatives is the only other definitive risk factor for prostate cancer. Currently, we have no good evidence that primary prevention (ie, avoidance of risk factors) can decrease incidence and mortality[19,21]; this lack of evidence leaves secondary prevention efforts (ie, early screening to detect treatable cases) as the best hope.

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Use of Screening Tests

Screening refers to testing done to detect disease in persons who are not yet symptomatic and who are apparently well. Although appealing in principle, effectiveness of screening can be difficult to prove.[32] Screening tests are usually not intended to be diagnostic; persons who screen positive must be further evaluated to determine if they have the disease. We tend to assume that earlier detection leads to intervention that decreases morbidity or mortality from the disease, but this assumption is not always true. A higher standard is needed to show the effectiveness of screening a population of apparently healthy persons. Several criteria should be used to determine whether a test can be used effectively for mass screening[33-35] (Table 2).

In addition to their ability to improve outcomes, screening tests should be judged on their accuracy as measured by sensitivity and specificity.[36] *Sensitivity* is the probability that a person affected with the disease will test positive. High test sensitivity means that few people affected with the disease test negative; low test sensitivity means that many persons who actually have the disease will test negative. These false negative results incorrectly reassure affected persons that they do not have the disease. *Specificity* is the probability that the test will yield a negative result when the disease is not present. If conditions other than the disease cause the test to be positive, these false positive results will lead to more unnecessary testing. For diseases with low prevalence (eg, cancer), screening tests generate many more false positive results than true positive results. The discretionary cutoff level that defines a positive test determines sensitivity and specificity; gains in one are made at the expense of the other.

The *positive predictive value* (PPV) of a screening test measures yield of the test when applied to a

Table 2. General criteria to justify use of mass screening test

Test criteria	Criteria met for routine PSA screening?
Disease has serious consequences and substantial public health impact	Yes
For cancer: detectable, prevalent, asymptomatic nonmetastatic phase is present	Yes
Natural history of disease is adequately understood	No
Screening test is simple to perform, available, low-cost, has adequate sensitivity and specificity, is acceptable to physician and patient, and is safe	Yes, except specificity
Test improves outcomes as measured by decrease in cause-specific mortality rate	Insufficient evidence
Improvement in prognosis justifies the cost, effort, risks, and discomfort of screening; cost is considered in context of overall medical system and health priorities	Insufficient evidence
Agreed-upon policy exists regarding whom to screen and treat	Screening: yes Treatment: no

population and indicates the probability that a person who tests positive actually has the disease. For a given sensitivity and specificity, the PPV varies directly with prevalence of the disease. Actual yield also depends on compliance with screening, follow-up diagnosis, and treatment.

Screening Tests for Prostate Cancer

Identifying prostate cancer early in the course of the disease is compelling because the cancer generally causes no symptoms until it reaches an advanced stage. Most men who have been diagnosed with prostate cancer were initially thought to have the disease on the basis of digital rectal examination (DRE) and serum prostate-specific antigen (PSA).[37,38]

Screening with DRE seems a logical approach because most prostate cancer begins in the peripheral zone adjacent to the rectum. However, for several reasons, DRE is a poor routine sequential screening test. DRE is not sufficiently sensitive, having a PPV ranging from 15% to 30%, and has a detection rate of 1% to 3% in screened populations.[19,39] Because most prostate cancer detected has already spread beyond the gland, DRE fails to improve survival. The test is relatively subjective, has poor reproducibility, and is highly dependent on the examiner's level of experience. In addition, regular DRE is unacceptable to many men.

The PSA test, which measures levels of an enzyme produced by prostatic tissue, has some of the attributes of an ideal screening test: it is reproducible, inexpensive, generates results rapidly, is easy to perform, is accessible to clinicians, and is well tolerated by patients. The availability of the PSA test has resulted in a steep increase in its use[40] and has been credited with "creating an epidemic" of prostate cancer (because it revealed many existing cases of cancer). Unfortunately, the PSA test has several disadvantages: it lacks specificity; PSA levels can be elevated not only in cancer but also in benign prostatic hypertrophy; and the test cannot reliably predict prognosis or progression of disease.[41] Results of PSA testing have varied widely between studies; however, on average, the PSA test has a sensitivity of 70% to 80%, specificity of 38% to 59%, and PPV of 20% to 30% in asymptomatic men, and the detection rate among study volunteers is about 3% to 5%.[39] Thus, at the common cutoff point of 4.0 mg/ml, the PSA test may fail to detect 10% to 30% of clinically relevant cases of cancer; and as many as three of four positive test results are falsely positive.[17]

Nonetheless, many studies have documented the validity of PSA testing as a method for assessing the risk of prostate cancer.[38,39,42,43] Moreover, most cancer detected by PSA is considered clinically significant,[44-47] and by detecting localized cancer, annual screening can reduce the frequency of metastatic cancer.[48] Some of the most convincing evidence for the usefulness of PSA testing comes from prospective studies of other illnesses where serum was frozen, tested for PSA level, and compared with serum of patients subsequently diagnosed with prostate cancer.[48] One such study of 22,000 physicians[49] found sensitivity of 73% in the first four years and a mean lead time of 5.5 years until diagnosis. A single test would have detected 80% of aggressive cancers diagnosed within five years and 50% of aggressive cancers appearing 9-10 years later. Few men in the study had a long disease-free interval followed by diagnosis of nonaggressive cancer.[50] However, the authors[40] did not state the number of men who had potentially curable disease when the blood sample was taken.

Several methods have been proposed for increasing the sensitivity and specificity of the PSA test, including measurement of age- and race-specific values, velocity (rate) of change in PSA level, ratio of bound to unbound forms of PSA, and PSA density; but none of these methods have gained widespread acceptance.[50]

Currently, the most effective method for early detection of prostate cancer is combined use of DRE and PSA testing to assess risk. PSA detects 33% of cases missed by DRE, and DRE finds 20% of cases missed by PSA. A third technique, transrectal ultrasound, has not been found to be an effective screening test when used by itself, but the technique is commonly used to guide biopsy of the prostate gland.[42,51,52] The standard for confirming the diagnosis of prostate cancer is transrectal biopsy using a spring-driven instrument, taking six specimens in a systematic pattern.

Outcomes of Screening for Prostate Cancer

To determine ultimate outcome, treatment must be considered in combination with screening. Early diagnosis leads to other invasive tests and treatments that may produce complications without improving cause-specific mortality. Three main treatments are used for prostate cancer—radical prostatectomy, external or interstitial radiation therapy, and hormonal treatment—but radical prostatectomy predominates because the prospect of surgically curing localized

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cancer is so appealing. Driven by the increased number of prostate cancer diagnoses resulting from PSA testing, rates of prostatectomy have risen steadily. This increase cannot be fully justified by results, because the rates remain high in men aged 70 years and older (who account for a third of the procedures done) despite the suggestion that less aggressive treatment is indicated when life expectancy is less than 10 years.[53-56] Whether and when early treatment effectively reduces mortality remains to be proved.

Table 3. Summary of complications of prostate cancer treatment reported by various authors[15,21,63]

Treatment	Complication	Reported range of complications (%)
Surgery	Impotence	(25-30 in nerve sparing)
	Incontinence	5-30
	Urethral stricture	10-18
	Thromboembolism	2-30
	Permanent rectal injury	1-3
	Death	0.5-1
Radiation therapy	Impotence	25-67
	Incontinence	0.5-7
	Urethral, bladder	3-17
	Acute gastrointestinal or genitourinary complications	3-67
	Chronic gastrointestinal or genitourinary complaints requiring prolonged hospital stay or surgery	1-2
	Anorectal	2-23
	Death	0.2-0.5

One argument for aggressively treating prostate cancer is the survival rate after such treatment: this rate approximates the expected survival rate among men of similar ages in the general population. Studies promoting nonintervention are criticized for their technique and conclusions,[57] yet studies of aggressive treatment are all uncontrolled.[26] Pooled data of nonrandomized studies of conservative treatment suggest that low-grade tumors could be treated conservatively with delayed hormone therapy.[56] At 15-year follow-up, a nonrandomized group of patients with low-grade tumors had 4% to 7% cause-specific mortality.[58] Although the benefit of treatment is debated, the complications are well known and may be higher than commonly reported[59-62] (Table 3).

In the absence of experimental screening trials with the end point being cause-specific mortality, decision analyses have attempted to determine screening outcomes. A structured literature review published in 1993[15] was unable to determine treatment effectiveness for localized cancer because of methodologic inadequacy in studies reported in the literature. Other analyses[17,41] show the potential for excess deaths from treatment, even given conservative assumptions. One decision analysis for localized prostate cancer screening and treatment[55] showed that in most cases, the potential benefits of therapy are small enough that the choice is sensitive to patient preference for various outcomes and discounting.[55] When this analysis was redone with assumptions favoring screening and treatment, a 50-year-old man could expect to gain, on average, 17 days of life as a result of screening. For clinically localized cancer, surgery can add 3 years of life at age 55 years and 1.5 years at age 65 years.[18]

Barry[22] analyzed a model for treating Medicare-eligible men who had been screened once and treated with radical prostatectomy; the net expected benefit shown was 1.52 additional years of life at age 65 years, 0.85 additional years of life at age 70 years, and 0.43 additional years of life at age 75 years. The study[22] showed that if aggressive treatment is ineffective, each cohort would lose 200 life-years, many biopsy procedures would be done, and a small number of surgical deaths and many new complications would result.

Uncertainty about the benefit of aggressive intervention and screening is created by the inability to predictively identify aggressive cancers.[54,63] The definition of clinically significant cancer depends on tumor size, pathologic grade of tumor, doubling time, and patient life expectancy as well as host factors[64]; however, these factors cannot all be known at initial detection. For indolent tumors detected by PSA testing, less aggressive therapy would give the same results as radical surgery or radiation therapy[65]; clinical markers can be used to predict the need for intervention.[44,45] However, using PSA density, PSA volume, and tumor grade noted at biopsy, Catalona and colleagues[39] found that only 11% of prostatic tumors were clinically insignificant. They predicted clinically significant cancer with 95% accuracy but had only 66% accuracy in predicting when to use watchful waiting in identifying clinically significant cancer. They concluded that an aggressive approach to diagnosis and treatment should be used for men who have 10- to 15-year life expectancy and apparently localized cancer.[39]

Arguments for and against routine prostate cancer screening are summarized in Table 4.[10,66-70]

Analyzing the Cost of Screening for Prostate Cancer

All routine health screening programs result in higher net costs than when no screening is done. Therefore, the cost-effectiveness of these interventions must be evaluated before monetary and personnel resources are committed to a program of routine screening. Prospective cost-effectiveness analyses of routine screening for prostate cancer are necessarily imprecise, because questions remain concerning the effects of various treatments.

Although screening may cost as little as $1500 per patient diagnosed with prostate cancer compared with $30,000 per patient diagnosed with breast cancer,[52] the main costs incurred from routine health screening are attributable to follow-up diagnostic and treatment modalities and the complications which result from use of these modalities.[22] Cost analyses of prostate cancer screening have yielded widely different values, which range from a low of $12,000-$15,000 per year of life saved (in 55-65 year-old men)[18,22] to more commonly accepted figures ($113,000-$214,000 per year of life saved)[41,65] and to an extreme value of $729,000 per life-year saved.[41] No reliable conclusions about precise costs can be made, but screening can be cost-effective. Given the scope of population screening, however, the cost may be staggeringly high. A clinical decision analysis estimate that the cost of mass screening for prostate cancer and treatment of cancers identified and complications resulting would be $12-28 billion (depending on PSA cutoff) and $3 billion per year thereafter—in other words, 5% of the total annual US expenditures for health care. High costs could continue to result if detection levels were high.[71]

Future Research on Prostate Cancer

Currently, data on treatment outcome are derived from observational cohort studies. The gold-standard study method used in medical science is the randomized controlled trial, which eliminates the biases found in uncontrolled, volunteer, early-detection studies.[72] Several large-scale trials currently in progress could provide valid data to answer the question of whether routine screening and treatment for prostate cancer reduce cause-specific morbidity and mortality in this disease. However, because these trials are prospective and because their endpoint—prostate cancer outcome—remains unknown for as long as 15 years after detection by screening, reliable results are not likely for another decade. The trials include the International Prostate Screening Trial Evaluation Group, recruiting 300,000 men from nine European countries[73]; the National Cancer Institute's Prostate, Lung, Colon, Ovarian cancer (PLCO) study,[74] which has recruited nearly 50,000 men in the United States; the Prostate Cancer Intervention versus Observation Trial (PIVOT),[75] launched by the National Cancer Institute; the Scandinavian Prostatic Cancer Group (SPCG4),[76] a randomized trial begun in the 1980s which compares results of radical prostatectomy and results of deferred treatment; and the United Kingdom Medical Research Council trial (PRO6).[77]

Critics claim these trials are unnecessary, because sufficient data already exist to justify treatment. Others argue that randomized studies are premature because the PSA test is inadequate (ie, it fails to differentiate between clinically significant and insignificant cancer).[74] Social policies that promote mass screening undermine the studies and make it difficult to recruit volunteers to be randomized. Despite the pressure for immediate screening and treatment, a more rational approach is to devote resources and time to generating convincing evidence for or against routine screening for prostate cancer; such an approach will benefit patients and the health care system in the long run.[10]

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Policy Perspectives

Population Perspective vs Perspectives Focusing on Individual Practitioners and Patients

The controversy over routine screening for prostate cancer can be framed from several different perspectives, each contributing to the vigor of the policy debate.

To justify widespread population screening for any condition, planners must identify a benefit more precisely defined than "ill people should be treated"; the benefit must be based on more than the general belief that "it is a good idea" or that it is "likely to be effective." Clinicians tend to believe that patients benefit from diagnosis itself and that after a diagnosis is made, the clinician must necessarily treat the disease; in regard to cancer, the mission is to find cancer as early as possible and to eradicate it. Under pressure to treat, however, a clinician's judgment may be impaired by presumption of benefit. Practitioner preference has traditionally determined standards of medical practice, but after new tests or treatments have gained acceptance among practitioners, changing the expectations of the public and the practice of the medical profession can be very difficult.[10,70,78] The controversy over routine PSA testing is even more confusing because it blurs the distinction between screening tests and diagnostic tests.[20]

From the perspective of the urologist, adequate tests and treatment for prostate cancer exist: because prostate cancer cannot be prevented and because meta-

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Table 4. Routine prostate cancer screening debate

Arguments for prostate cancer screening using DRE, PSA, or both	Arguments against routine use of prostate cancer screening tests
Screening increases proportion of early-stage cases of cancer, allowing increased use of curative therapy. Most patients who present with prostate cancer symptoms have metastases, but no effective treatment for prostate cancer has been advanced.[38,42,43,46,48,52,66,67]	Screening may inflate incidence due to lead time bias, length bias (preferentially finding low-risk, slow-growing tumors)[8,13,23] and serendipity (elevated PSA due to BPH leads to biopsy and random discovery of otherwise undetectable tumors).[69]
PSA test is sensitive enough to provide adequate lead time for a substantial percentage of cancers yet is insensitive enough to avoid identifying the common cases of microscopic focal disease.[49] Cancer undetectable by PSA is likely to be small, localized, low-grade, and detectable over time before the cancer becomes incurable.[44,45,51]	The PSA test has not been adequately studied as a screening test with clinical end points beyond diagnosis.[19,40,69] Effects of screening on intermediate outcomes of tumor stage and histologic grade do not prove clinical effectiveness despite their statistical association with outcome.[70] For each fatal cancer found, five other will be found that could be left untreated.[17,24,63]
Published estimates for sensitivity and specificity of PSA testing are better than those of mammography, Papanicolaou (PAP) smear, and fecal occult blood screening.[39]	Accurate calculations of sensitivity and specificity for screening with PSA are not possible because the criterion standard (biopsy) is not done in patients who test negative. Only the positive predictive value (which ranges from 8% to 33% in various studies) can be determined with confidence.[10,17,20,40]
Most cancers detected are clinically significant and have histologic features of serious cancer.[39] Long-term follow-up with watchful waiting has shown that small localized cancers may cause substantial morbidity and mortality within 15 years.[44,46,47,57]	Rate of false-positive test results is 75%, and many of the cancers found will prove to be clinically insignificant, leading to unnecessary biopsy and surgery with risk of serious morbidity, especially among low-risk men. Mortality from watchful waiting is similar to that achieved with aggressive therapy.[17,18,28,25,58,70]
New, nerve-sparing techniques for radical prostatectomy and radiation implants decrease the incidence of complications, and new therapies for impotence and incontinence can ameliorate these morbidities.	Incidence of side effects occurring after radical prostatectomy has been underestimated.[60,61] Decision analyses conclude that morbidity resulting from aggressive therapy outweigh unproven advantages for low-grade, localized cancer.[18,20,22]
A 6% decline in mortality was seen between 1991-1995, when screening began.[23]	No experimental trials exist which show that screening asymptomatic men improves quality or quantity of life; PSA testing is therefore not comparable to mammography or PAP smear.[18,20,22]

static disease cannot be cured, the best hope of decreasing mortality lies in detecting and removing organ-confined cancer in young men.[79]

The perspective of the individual patient is that every man has a right to know if he has prostate cancer when it is still at a curable stage.[80,81] Survivors of prostate cancer are convinced that PSA testing saved their lives despite decrease in quality of life. Patients dying from prostate cancer and friends and relatives of men who died from the disease are convinced that early detection saves lives.

The Public as Informed Consumer

Until consensus develops over the data, patients should be educated concerning the potential benefits and drawbacks of early detection and treatment and should be allowed to make individual decisions jointly with their medical provider.[4,18] As much as patients like to be involved in making medical decisions, they prefer a clear choice and cannot understand how studies can give conflicting information and create disagreement within the medical community.[82] Decisions require assessment of patient preferences about health outcomes, and the patient's willingness to trade current health (diagnosis of cancer and potential treatment complications) for potential future benefit (decreased cancer morbidity or mortality).[14,83] The profusion of Internet sites providing detailed medical information reflects the need for information as well as patients' suspicion that they cannot get adequate or accurate information from physicians. The proliferation of cancer support groups attests to the complexity of these decisions and the anxiety that they cause.

Group Health Cooperative of Puget Sound has trained physicians to use a process of shared decision-making in addressing patients' concerns about prostate cancer screening. In so doing, they found that PSA test ordering decreased, especially among 50- to 74-year-old men who came for routine visits; this finding suggests that patients who have been fully informed of the risks and benefits of screening by PSA testing may choose not to receive this screening.[40]

Ethical Issues

Ethical arguments can support either side of the prostate cancer screening debate: delaying screening for prostate cancer until randomized controlled trials are completed is unethical when detecting localized cancer is of some benefit; conversely, until better modes of treatment for prostate cancer are available or current modes of treatment are found to have more obvious benefits, randomized trials of screening are unethical because they result in morbidity in patients with localized cancer.[78] An opposing view is that a randomized trial is unethical only if the answer is already known. After medical opinion has accepted the value of treatment, no ethical alternative exists; at that point, objection arises to planning randomized trials of intervention and treatment.[34] To represent an intervention as effective when its efficacy is uncertain is itself unethical.[10,14,84]

Role in Medical Quality

Prostate cancer screening illustrates both the importance and the limitations of evidence-based methods in medical practice. In the past, many medical interventions based on reasonably sound pathophysiologic principles (for example, chest x-ray and sputum cytology for lung cancer screening) were championed until clinical trials proved them worthless for the given purpose.[85] The US Preventive Services Task Force based its conclusions on strict methodology so that these conclusions would be consistent and credible for a broad range of screening tests and therapeutic interventions. Circumventing this methodology could be detrimental to quality and value as evolving forces in medicine.[86] The paradigm may be shifting so that the burden of proof rests with the promoters of a particular treatment;[21,65] however, in the current debate, those who cautiously advise waiting for further proof appear to be on the defensive.[85] The traditional approach of assembling a consensus conference that includes experts and members of the public is unlikely to resolve the disagreement among the experts and is unlikely to explicitly weigh scientific and value decisions. This scenario occurred in the case of a consensus conference on breast cancer screening for 40- to 50-year-old women: the conference contributed nothing to resolution of the dispute.[87]

Health Care Policy Issues: Complicating the Debate

The question of routine prostate cancer screening is becoming increasingly distorted by financial and political interests. When federal health care agencies decided not to sponsor or fund population screening for prostate cancer, the decision was seen as discriminatory, "two-tiered" health care. Governmental refusal to pay may also seem to conflict with physicians' obligations to individual patients and may seem to ignore the desires of individual patients.[88,89]

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Resources are not unlimited, and the pursuit of unproved interventions shifts resources from known effective health services.[2,10] We can no longer provide all services to everyone without first identifying likely beneficiaries of these services; however, it is difficult to withdraw or restrict services—even to groups who receive these services inappropriately—after these services have become expected.[90]

Public debate may be inappropriate for crafting health policy. Disdainful of the slow process of scientific trials and armed with painful stories of prostate cancer deaths, an impatient public insists on routine screening. Eager to support these members of the public, elected officials have proposed numerous initiatives that mandate coverage for routine prostate screening and treatment and that require physicians to provide information on prostate cancer screening. The 105th Congress proposed at least six different bills to provide coverage for early detection of prostate cancer under part B of the Medicare program despite a comprehensive, evidence-based analysis sponsored by the Agency for Health Care Policy and Research that concluded "it is premature to offer a Medicare benefit for PSA testing for early detection of prostate cancer."[22] In California, the Grant H. Kenyon Prostate Cancer Act (SB 1) was passed in 1997 because Congressman John Burton's friend (for whom the act is named) died from prostate cancer, and Representative Burton believed that PSA screening could have saved his friend's life. The bill requires physicians to provide information about diagnostic procedures, including PSA testing, to patients having DRE of the prostate. This mandate is an ominous example of legislated health care policy-by-anecdote that leads to microregulation of medical practice. Moreover, the mandate shows the degree to which the public distrusts the medical profession to determine and provide the best care for patients. This microregulation has continued under the guise of HMO reform and as such could create two standards for medical practice: evidence-based guidelines and legislation-based mandates. Further, this microregulation threatens to deter the move toward a scientific, outcome-based approach to medicine and undermines efforts to rationally budget and control medical expenditures.

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Conclusion

Despite growing use of PSA testing to screen for prostate cancer in adult men, authorities disagree about the optimal use of this test. Lack of knowledge concerning the relative effectiveness of treatment options—and our inability to predict disease course and prognosis in individual cases of cancer detected by screening—prevent consensus over the widespread use of this screening. Physicians are faced with conflicting recommendations, patient demand, and the threat of legal mandates for PSA screening.[16] Currently, the most rational response by individual physicians is to make informed decisions jointly with the patient before testing is done. Early detection may not change the outcome for cancer patients, but in this emotionally and politically charged climate, patients may benefit from knowing the diagnosis and having the opportunity to participate in treatment decisions. Even if pending randomized controlled trials show that routine PSA testing has no benefit, we will have an uphill battle to overcome patients' and physicians' desire for early diagnosis. Ironically, widespread disagreement about the benefit of an intervention is likely to indicate that the effectiveness is minimal.[83,87] We can only hope that future advances will provide a screening test that can better predict prognosis as well as diagnosis and will provide modes of treatment that result in less morbidity than is seen currently. Meanwhile, the pressure from medical practitioners, medical societies, advocacy groups and legislators to adopt population screening using PSA undermines attempts to scientifically evaluate new health care interventions and rationally allocate scarce health care resources. ❖

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