Ethical Considerations in the Provision of Controversial Screening Tests

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Although preventive services are a cornerstone of primary care medicine, few currently used screening tests have been demonstrated to be beneficial. Insurance organizations, the media, public advocacy groups, and patient concerns often pressure physicians to provide screening tests of controversial value. Ethical analysis provides the basis for responding to screening requests in a responsible way. Physicians may use an evidence-based medicine strategy to approach controversial screening tests. When physicians educate patients on the relative benefits and harms of controversial screening tests, it is prudent to emphasize that a screening test can assure neither a disease-free nor a risk-free state. Such preventive ethics efforts could discourage against the use of controversial screening tests. Physicians may articulate the boundaries of their own professional integrity in this process, for patients cannot compel physicians to render services that run counter to their best professional and ethical judgment.

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The provision of preventive services is a cornerstone of primary care medical practice. An important part of preventive service provided in a primary care setting is screening for asymptomatic disease states. Despite widespread screening practices, there has been little systematic examination of the ethical assumptions and issues relevant to screening for disease in asymptomatic individuals. For some diseases such as cervical cancer, there is wide acceptance that screening for diseases in their early stages is appropriate. For other diseases such as lung cancer, there is broad acceptance that a screening chest radiograph of asymptomatic individuals is not beneficial. For most diseases for which there is a potential screening test, the effectiveness of screening is controversial. For the purpose of discussion, controversial screening tests include those for which there is conflicting research or conflicting interpretations of research, as well as tests that are commonly available and implemented despite the lack of research on their effectiveness.

Patients may place their physicians in a quandary when requesting screening tests with controversial benefits, particularly when patients claim that they are entitled to such testing as part of their insurance plan. Insurers have traditionally entrusted physicians to be conscientious providers of screening interventions. With the rising demands for clinical services, but limited societal resources, there are increasing pressures on physicians to make rigorous, scientific choices about what medical interventions ought to be implemented. Unfortunately, screening guidelines intended to help guide clinical decision making often result in recommendations that vary dramatically from one professional group to another. Physicians may be pressured to provide tests of unknown effectiveness because of heightened media attention about the most recent screening breakthroughs and claims of effectiveness by health advocacy groups.

In this article, we first argue that a preventive service should meet the minimal criteria of effectiveness based on frameworks that use an evidence-based medicine approach. We examine the perspectives and potential biases of evidence-based medicine authorities, public advocacy groups, insurers, and the media. Finally, we examine moral arguments for providing sound, beneficial medical care in the provision of screening tests. This approach will help clinicians make conscientious decisions about their own approaches to the provision of preventive services. We then articulate ethical approaches for managing the difficult circumstance of a patient-initiated request for screening tests with controversial benefits.

AN EVIDENCE-BASED APPROACH TO EARLY DETECTION

The US Preventive Services Task Force (USPSTF),[1,2(ppxxxix-lv)] the Canadian Task Force

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on the Periodic Health Examination (CTFPHE),[3] and Frame and Carlson[4] advocate minimum criteria for assessing screening effectiveness. These groups articulate an evidence-based medicine approach that helps provide the minimal criteria for determining what is an effective screening intervention. For example, the widely disseminated report of the USPSTF queries the following of any screening test: (1) What is the burden of suffering? (ie, What is the prevalence and severity of the disease?) (2) What is the accuracy? (ie, How early in the disease will the test be helpful? Will the test be accurate in its detection?) (3) What is the effectiveness of early detection? (ie, Is there improvement in morbidity and mortality when screening asymptomatic individuals?)[1] The work of these groups is important as it asks, "Is there rigorous scientific evidence to support the provision of various screening interventions?" Because the USPSTF criteria essentially reflect the approaches also elaborated by the CTFPHE and Frame and Carlson, and because the USPSTF book is widely disseminated and broadly accepted, in this article we use these criteria (ie, screening accuracy and effectiveness of early detection) as the minimal criteria for a screening test to be considered beneficial.[2(ppxxxix-lv)]

Surprisingly, there are few tests that meet these minimal criteria. In a summary of available screening tests, Sox[5] compares the recommendations of the American College of Physicians, the CTFPHE, and the first edition of the USPSTF. There was agreement for offering only 5 screening examinations for asymptomatic, non–high-risk patients: a blood pressure measurement every other year, an annual breast examination by a physician for women older than 40 years, a serum cholesterol measurement every 5 years from early adulthood, annual mammography in women starting at age 50 years, and cervical cytologic screening for sexually active women every 1 to 3 years.

However, many commonly used screening tests do not meet the criteria of demonstrated screening accuracy and effectiveness to be considered beneficial. For example, screening for a disease with a low prevalence such as vaginal cancer after total hysterectomy for benign disease will result in a high ratio of false positives to true positives.[6] The consequences of a false-positive test are to falsely label as diseased persons without disease. False negatives may be similarly problematic because diseased persons will not reap the benefits of early intervention.[4,5,7]

As many screening tests do not meet the criteria to be considered beneficial, a common dilemma facing physicians is the patient-initiated request for such services. It has been argued and widely accepted that physicians are not obliged to provide nonbeneficial treatments or therapy.[8-11] Physicians have no obligation to provide treatment unless there is a reasonable expectation of benefit.[12] The grounds of this argument are primarily beneficence based. The ethical principle of beneficence obligates the physician to seek for the patient the greater balance of goods compared with harms—as those goods and harms are defined and balanced in a well-formed, rigorous clinical judgment.[13,14] An important question for those in primary care medicine is how a beneficence-based argument applies to screening tests that have not been demonstrated to be beneficial but are nevertheless requested by patients.

POTENTIAL BIASES AND SCREENING

Unfortunately, the demand for screening tests is often not driven by a rational assessment of accuracy and effectiveness. For example, the recommendations of public advocacy groups often differ dramatically from those of groups such as the USPSTF and CTFPHE, which use an evidence-based medicine approach. The CTFPHE recommends against mammography in women younger than 50 years, and the USPSTF concludes that there is insufficient evidence to recommend for or against mammography in women younger than 50 years.[2(pp73-87)] In contrast, the American Cancer Society, the American College of Radiology, the American Medical Association, the American College of Obstetricians and Gynecologists, and other organizations recommend mammography in women every 1 to 2 years and an annual clinical breast examination beginning at age 40 years.[2(pp73-87)] The USPSTF recommends against routine screening with prostate-specific antigen (PSA), a digital rectal examination, and transrectal ultrasonography in men. Similarly, the CTFPHE recommends against PSA or transrectal ultrasonography, while concluding there is inadequate evidence to recommend against a digital rectal examination in men aged 50 to 70 years. In contrast, the American Cancer Society, the American Urological Association, and the American College of Radiology support screening.[2(pp119-134)] What follows is an accounting for such external factors that have bearing on patients who request screening tests with controversial benefits.

Information about screening tests may be communicated through recommendations or guidelines of various professional groups (eg, the American Academy of Family Physicians and the American College of Physicians) or advocacy groups (eg, the American Cancer Society). Frequently, these organizations rely on consensus panels to develop the recommendations. Guidelines developed by the traditional consensus process may reflect the personal biases of the assembled participants and may conflict with, or not be supported by, the available empirical data.

Public advocacy groups may be seen as having a somewhat different focus than medical practitioners. Their goals may be more vested in enhancing public awareness about a specific disease, while not also embracing the other criteria of screening accuracy and effectiveness. These efforts may also stem from a desire to do something about a disease causing so much suffering. Therefore, their stands toward screening are more aggressive, attempting to reach zero risk of disease; these stands are widely publicized. Such positions can potentially mislead the public regarding the nature of risk and disease and may complicate the provision of effective preventive services by heightening patient expectations. The physician needs to be sensitive to these agendas, while still acting as an advocate for beneficial clinical management. When patients make requests for such testing, physicians can inform them why advocacy groups take aggressive screening stands. Physicians can then explain why such tests have not been shown to be beneficial so that their patients will not perceive the physician

as less of an advocate than the advocacy group.

Like public advocacy groups, the media play a powerful role in communicating announcements of anecdotal evidence or new, uncorroborated studies. Through announcements about such clinical trials, the media may generate hope and optimism disproportionate to the stated findings and draw premature conclusions about screening effectiveness. Unfortunately, these data may be a snapshot of the ever-evolving picture in the evaluation of a screening test and may not reflect the context, cost-effectiveness, or risks for assessing the test's propriety. The consequences of such public disclosure may be a surge of patients going to their physicians, requesting such testing, as well as having physicians follow these patient-initiated requests. One consequence may be the premature use of preventive tests before adequate research corroborates effectiveness. Once a test becomes widely used, it also becomes difficult to conduct well-designed research assessing the intervention's effectiveness (eg, external fetal monitoring). Communications from the lay press, radio, and television may be devoid of data, may be based only on a portion or a biased selection of the data, or may stem from personal experience. Physicians can educate their patients about the nature of the newest study on a screening test when there is no preponderance of evidence demonstrating benefit.

ANALYSIS: MORAL ARGUMENTS IN THE PROVISION OF SCREENING TESTS

In the following section, the moral arguments supporting preventive services are outlined; a taxonomy of moral claims for screening tests that are of demonstrated benefit, disproved benefit, and controversial benefit is highlighted; and a response to patient-initiated requests for screening tests with controversial benefits is proposed.

Assessing Risk in Beneficence-Based Clinical Judgment

Patients' requests for screening tests with controversial benefits reflect the aim of achieving zero risk. These requests may assume a willingness to accept considerable risk in attaining this goal. Patients may operate on the false assumption that all disease is eradicable. It is important to appreciate that beneficence-based clinical judgment cannot realistically aim for an end point of zero risk. On this basis, physicians and patients can more realistically work together to accept the concept of managing disease processes well, rather than eradicating them. Physicians who propagate beliefs in achieving zero risk are inhibiting patients from making informed decisions. Physicians responding with an evidence-based approach reflect a more sophisticated appreciation for uncertainty. With the use of a preventive ethics response, the physician can avert conflict regarding requests for screening tests with controversial benefits, while educating patients on the essential nature of risk in medicine.

Exploring the motivation behind a patient's request for a screening test can yield valuable information about the patient's health care fears, concerns, and expectations. The physician may discover symptoms that warrant diagnostic testing or a medical or family history that substantially increases the patient's pretest probability of disease and thereby warrants a screening test. However, screening requests may be driven by misinformation about screening test effectiveness, combined with an unfounded hope of eliminating all risk. Many patients are not aware that screening of asymptomatic individuals is not 100% accurate because of the inherent risks of false-positive and false-negative test results.

The benefit that patients often seek is the peace of mind that there is no chance that cancer is present. The physician can play a critical role as patient educator. The physician can counsel the patient that the scientific evidence does not demonstrate the test to be beneficial. In particular, education on the fallacy of zero risk is valuable—no test, even those with demonstrated benefits, can meet such an exacting standard. The essential issues to discuss with the patient are the patient's perspective of benefit (eg, quality of life and health maintenance issues), as well as the notion of ever-present uncertainty and risk in screening tests. Educating the patient that risk cannot be entirely eliminated may help physicians explain why agreeing to a patient's request for a controversial test may be inappropriate. Agreeing to such testing may convey to patients the false belief that reducing risk to zero can be achieved. Patients who understand that risk is a manageable, but not eradicable, constant in clinical practice and that controversial screening tests are not entirely benign in their sequelae can best make an informed decision about whether they prefer to proceed with screening and are willing to accept the consequences of possibly suboptimal interventions. The informed consent process aims for the development of this understanding of risk by the patient.

Physicians can also educate patients that avoiding screening tests with controversial benefits may be beneficial to them by articulating how screening could lead to avoidable, unnecessary injury. Patients may believe that a test that reduces their risk of disease to zero, or even close to it, is helpful yet may overlook the risk-laden consequences of screening. False-positive or ambiguous results could require further workup, including progressively more invasive testing or treatment that is unnecessary or costly—with potential financial, physical, and emotional costs. Such burdensome implications of results that will be difficult to interpret accurately, along with the possibility of generating patient fear or anxiety, is best prospectively addressed with the patient.

Patients may request screening tests with controversial benefits by stating that because their insurance will pay for it, or because they are willing to pay for it out-of-pocket, they are entitled to it. Patients can be informed that there is no demonstrated benefit for a test with controversial benefits (even when the health care plan pays for the test) and that no test can assure zero risk that disease is present. Physicians may want to note that it is not cost-effective for the individual patient to request such testing, as it will result in higher costs and no clinically significant return for all persons within the entire plan (including the patient requesting the test). While the costs of such discussion are not insignifi-

cant, the potential savings to the patient (in cost and avoiding harm), to the physician (in pursuing false-positive tests), and to society (in health expenditures) are noteworthy. Otherwise, requesting screening tests that have little evidence of benefit can drain health care system resources. In this way, the argument for the benefit of reducing risk is bolstered.

Physician concerns for patient benefit are best expressed as the primary rationale for not ordering such testing, with any justice-based claims made as a secondary line of reasoning. It is important not to phrase such discussions solely as saving money for the insurance plan. A rationale of not testing due to economic reasons will be rapidly lost to patients who believe that their health is being jeopardized to preserve the finances of a health care plan. This line of argument threatens to harm the trusting relationship that primary care practitioners hope to cultivate with their patients.

Just as patient education about the risks of screening tests is important, physicians also will have occasion to counsel patients regarding screening tests with controversial benefits (eg, mammography for woman younger than 50 years and PSA screening for men). We maintain that a screening test is beneficial when it adheres to the criteria of screening accuracy and effectiveness—and this assertion can be helpful in educating patients about screening tests. We offer a taxonomy of ethical considerations for screening tests with demonstrated benefits, controversial benefits, and disproved benefits.

A Taxonomy of Ethical Considerations for Screening Tests

For screening tests with demonstrated benefits, patients have a strong autonomy claim (ie, a positive right under the standard account of informed consent to have these tests offered to them). Beneficence considerations obligate physicians to offer screening to all eligible patients and actively encourage patients' participation in screening programs. Justice concerns suggest society provide availability for testing for all who qualify regardless of individual ability to bear the cost of testing. In other words, screening tests with demonstrated benefits should be routinely provided as the standard of care.

On the other hand, if a patient requests (or if a physician offers) a screening test with disproved benefits (eg, a chest radiograph for lung cancer in asymptomatic patients), no autonomy, beneficence, or justice claims exist. The lack of an autonomy claim is due to the absence of the positive right to access a test that is known to be nonbeneficial. Such testing could generate false beliefs by patients that they have zero risk for disease. Patients may mistakenly believe that by using technology, they have control over their future health. Agreeing to such requests would be likely to undermine, not support, autonomy, by promoting interventions that have no basis in medical practice, thus confounding the free choice of patients; agreeing to these requests cannot be condoned. No benefit claim exists, as there is no rigorous scientific basis to support such testing. Further, patients have no autonomy claim to a disproved test, as any claims of benefit from the patient's perspective are scientifically without foundation of benefit. Similarly, no justice claim for such services exists when such benefit is absent because such services fall below the standard of care in beneficence-based clinical judgment.

Between these 2 extremes on the spectrum of screening tests lay those interventions that have controversial benefit (ie, tests for which there is conflicting research demonstrating benefit or tests for which an adequate body of well-designed research is lacking). Mammography in women younger than 50 years and PSA screening in men are examples of tests with controversial benefits. Patients may (and do) request these screening tests. Physicians can help patients appreciate that reports of reductions in population-based mortality or morbidity that are not statistically or clinically significant do not demonstrate benefit from such tests; anecdotal cases of effectiveness also do not demonstrate benefit.

A Response to Requests for Controversial Screening Tests

While physicians may not be obliged to divulge to patients information about controversial tests, it may be prudent to discuss those tests that have wide public visibility. Such disclosure about controversial tests is best accomplished through a preventive ethics approach.[15-17] The preventive ethics approach attempts to proactively work with patients in areas of potential future ethical conflict to avert disputes. This approach proactively identifies areas of ethical conflict and works with the relevant parties to facilitate resolution.

The physician may disclose to the patient that information about a controversial screening test is part of contemporary scientific knowledge but that there is no clear evidence of the test's benefit. This dialogue shows patients that their physician knows about such controversial tests and desires to help them make an informed decision. The physician can then educate the patient on the test's lack of demonstrated benefit and discourage such testing when the patient's request is driven by misinformation or unfounded, inappropriate expectations. If using such testing is undesirable in the physician's professional judgment, the physician would articulate how such testing runs counter to the physician's medical judgment and ethical belief system. This negotiation would attempt to dissuade the patient from controversial screening tests, while encouraging beneficial screening tests. Through dialogue, physicians can articulate the boundaries of their professional integrity regarding which circumstances are reasonable for providing the controversial test. This negotiation and discussion may permit the patient and physician to reach consensus on the appropriateness of screening for that particular patient. If the patient still wants the test, and the physician believes the patient is making an informed choice, the physician has 3 choices: to provide the requested test, to refer the patient to another physician willing to perform the test, or to refuse the patient's request. If the patient persists when the physician refuses, the physician may need to ask the patient to transfer his or her care to another physician or health care plan. While such an approach may result in patients seeking care elsewhere, it allows physicians to adhere to their

integrity rather than succumb to pressure to provide these services.

The ethical basis for this response is derived from the concept of professional integrity. Professional integrity places limits on patient autonomy, because physicians cannot be forced to violate their personal and professional moral beliefs.[18] Physicians are under no obligation to violate what they view as sound medical and ethical judgment. Allowing for professional integrity prohibits physicians from being forced into violating their moral assessment of what they medically can do in good conscience—such as when they believe the requested test lacks benefit by the criteria of screening accuracy and effectiveness.

The question of whether physicians are obliged to discuss controversial tests with patients will depend on whether the physician believes there is enough evidence that benefit exists. Hence, the physician's values toward the test's benefit will dictate how such information is conveyed. Patient expectations for disclosure may be high, as controversial tests have a notable amount of lay press visibility. As any justice-based claim to tests with controversial benefits is likely to be lacking for third-party payers, the physician is prudent to advise patients that they may likely bear the economic risk.

The physician's ordering of the test is defensible when presented with scientific evidence that a controversial test may confer benefit (eg, the biological plausibility of checking stool for occult blood). Such action would be based on the concept that "at least a modicum of potential benefit [exists], as seen from the medical perspective."[17] Patients could participate in the decision to use tests with controversial benefits when evidence of their plausible benefit(s) is provided. When the patient precipitates such discussions, the physician's obligations in the informed consent process include discussion of the controversial nature of the proposed screening test and lack of encouragement of such testing.

Some physicians may feel compelled to provide controversial screening tests according to the most aggressive screening guidelines. Such action may be driven, in part, by fear of litigation if disease subsequently develops in a patient who was not screened. Yet, a litigation-based aggressive screening stand is less a posture of patient benefit than it is self-serving. The physician may believe that screening behaviors will be compared with the most aggressive screening guideline. Some physicians may argue that because the nature of knowledge is always evolving, a liberal use of screening tests is justified. While the legal and ethical implications of such a stance are debatable, the physician who chooses to use an aggressive screening policy still has an obligation to inform patients that the individual physician's policy follows the most aggressive guidelines, informing the patient that the value of such testing is controversial. This discussion includes the risks regarding the accuracy of such testing and subsequent diagnostic evaluation. Physicians with a practice policy that routinely offers screening tests with controversial benefits, such as mammography in women younger than 50 years and the PSA test in men, have as much an obligation to conduct a dialogue about the risks and benefits of screening as the physicians with a practice policy of not routinely offering tests with controversial benefits.

CONCLUSIONS

Screening tests with a demonstrated benefit are clear in connoting a positive obligation to physicians, whereas tests with disproved benefits convey no obligation to physicians. Screening tests with controversial benefits pose a greater challenge. Explaining the concepts of uncertainty and risk reduction as a foundation of testing, rather than attempting to reach zero risk, can help patients understand why these tests may not be beneficial. Physicians can use a preventive ethics approach to explain that tests with controversial benefits are unlikely to be useful. Exploring each person's concept of benefit may help in reaching a negotiated settlement. Approaching each patient who makes such requests with compassion may help the physician learn much about the fears and concerns that brought the patient to the office. At the same time, the physician can promote patient education toward screening tests with demonstrated benefits, while educating patients about the uncertainty inherent in testing generally. In this way, the relationship of trust between these parties can be nurtured through a better recognition of realistic expectations.

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