Promoting an Ethical Approach to Unproven Screening Imaging Tests

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The use of screening imaging technology such as electron beam computed tomography and computed tomographic scans for the early detection of coronary artery disease, lung cancer, and other diseases is rising, even though they have not been proven to reduce disease-specific mortality. Until randomized, controlled trials assess the efficacy of these tests as screening tests, they will remain controversial. It is unclear whether the potential benefits of these screening tests outweigh the risks. In a practice environment in which public demand and enthusiasm for screening is high, radiologists can recognize the ethical issues associated with unproven screening imaging tests; understand current national policies toward professionalism and informed and shared decision making for screening; draw on the lessons learned from the proliferation of another unproven screening test, the prostate-specific antigen blood test for prostate cancer; and work with others in the health care system to promote an ethical approach to screening imaging tests.

Key Words: Screening imaging tests, ethics, informed decision making, shared decision making, informed consent

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THE RISE OF SCREENING IMAGING TESTS

The use of screening imaging technology such as electron beam computed tomography (EBCT) and computed tomography (CT) scans for the early detection of coronary artery disease, lung cancer, and other diseases is rising, even though they have not been proved to reduce disease-specific mortality [1-3]. Until randomized, controlled trials assess the efficacy of these tests as screening tests [3], they will remain controversial. It is unclear whether the potential benefits of these screening tests outweigh the risks, which include unnecessary workups for false-positive test results, side effects from unnecessary treatments, unnecessary financial costs from downstream procedures, false reassurance from false-negative test results when noncontrast studies fail to detect solid organ tumors, radiation, and patient anxiety [2-6]. Yet some physicians are ordering these screening tests, and some patients are self-referring and even paying out of pocket for them [1]. Media attention and direct-to-consumer advertising through radio, the Internet, and print media have contributed to an increased demand for these tests at a time when physicians and hospitals, feeling economic pressures from the health care environment, are willing to sell preventive health care services from which they might financially gain [1,2,7,8].

Despite professional guidelines against screening lung, heart, and whole-body scans [3], some physicians are even self-referring patients to imaging facilities that they have invested in for these services [8]. They reason [1], "If patients are willing to pay, why not offer it to them?" Others believe that screening "works." At least it gives people "peace of mind" [1]. Such reasoning and behavior have the potential to undermine a physician's ethical duty to uphold the principles of nonmaleficence and patient autonomy and can lead to situations in which physicians fail to uphold professional ethics and inadvertently create gaps in patient care.

In a practice environment in which public demand and enthusiasm for screening are high [7], what can radiologists do? They can recognize the ethical issues associated with unproven screening imaging tests; understand current national policies toward professionalism and informed decision making (IDM) and shared decision making (SDM) for screening; draw on the lessons learned from the proliferation of another unproven screening test, the prostate-specific antigen (PSA) blood test for prostate cancer; and work with others in the

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health care system to promote an ethical approach to screening imaging tests.

ETHICAL ISSUES ASSOCIATED WITH UNPROVEN SCREENING IMAGING TESTS

A fundamental ethical issue concerning unproven screening imaging tests is whether it is appropriate to offer them to the general public before their net benefit or efficacy at reducing disease-specific mortality has been proven through clinical trials. People in favor of offering them argue that screening imaging tests are another commodity in the marketplace that consumers can choose to purchase from providers [1]. In this less paternalistic model [5] of a patient-physician relationship, patients have the right to new screening technology as long as they can pay for it.

People against offering unproven screening imaging tests say that the practice of medicine is not a marketplace commodity to be sold but rather a profession with physician responsibilities that include an altruistic commitment to patients [1]. Physicians have a responsibility to uphold the principle of nonmaleficence, expressed as "*Primum non nocere*," or "Above all [or first], do no harm" [9]. Offering unproven screening imaging tests that lack specificity can lead to high rates of false-positive test results, undue worry about disease, and unnecessary follow-up testing [1].

Others argue that physicians who recommend screening tests that lack evidence for a net benefit tend to focus more on what screening and early detection could do for "sick" people than on what screening and potential risks do to "healthy" people. This focus runs counter to the principle of nonmaleficence [10,11]. There are several potential harms of screening. The early detection of diseases for which there is no, or only rarely successful, treatment may cause anxiety because patients will know for a longer period of time that they have diseases for which little can be done [10,11]. A patient may receive unnecessary treatment or overtreatment, which is defined as a treatment that the patient would have never received had he or she not been screened and from which there was no net benefit [10,11]. A patient may undergo a procedure for the removal of a lesion or cancer that was the preferred method of treatment at the time of diagnosis but later was shown to be a more aggressive or more damaging procedure than was needed [10,11]. Early detection does not necessarily mean "better care."

Physicians ought to be concerned about social justice, about the whole class of patients, not just the ones who are potential candidates for screening, and as such, they ought to consider the impact of recommending unproven screening imaging tests on the limited resources of the health care system. Unproven screening imaging tests can boost health care costs because follow-up testing and care are often paid for by public or private health insurance, even though a patient may have paid out of pocket for the initial screening [2]. Expending health care dollars on patients who are potential candidates for unproven screening imaging tests diverts resources from proven screening tests and patients who lack care [1].

On a societal level, a premature recommendation for screening can reduce the chance that a randomized, controlled trial of a screening test can be completed to determine whether there is a net benefit on a population level. If people come to believe that a test is beneficial, they may be less willing to be assigned to the control group [10,11]. This concern has already been raised with clinical trials for some screening tests [10,11].

For characterizing screening tests, there is the issue of how proven is "proven" and how unproven is "unproven." Independent organizations such as the U.S. Preventive Services Task Force (USPSTF) follow an explicit process that considers the quality of the evidence and the magnitude of the net benefit for a screening test to make a recommendation about it [12-14]. Radiologists and professional societies can provide screening guidelines to the general public after considering the recommendations of such independent organizations. They can also develop a process of their own to weigh the quality of the evidence for each screening imaging test and assign a point value indicating the level of evidence in support of each test.

Regardless of whether screening imaging tests ought to be offered, many are already widely available. This gives rise to another ethical issue: whether radiologists have an ethical obligation to promote informing patients about the potential risks, benefits, and limitations of a test, particularly in cases of patient self-referrals. In short, the response is "yes." As physicians, radiologists have a duty to uphold the principle of patient autonomy. It is not sufficient to assume that just because a patient has shown up and asks for a screening imaging test that the patient is exercising autonomy. Many patients may not understand the unproven nature and potential risks associated with testing.

In a study involving 1,057 audiotaped encounters containing 3,552 clinical decisions between patients and physicians in outpatient practice, Braddock *et al.* [15] found that 9% of the decisions met criteria for complete IDM, and only 0.5% of complex decisions such as those involving unproven screening tests were completely informed. Given this dismal state of IDM in outpatient clinical practice, patients are unlikely to be informed about the potential risks, benefits, and limitations of an unproven screening imaging examination by the time they show up at imaging centers.