

# Patient Self-Referral for Radiologic Screening Tests: Clinical and Ethical Concerns

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Retail marketing of radiologic screening tests is increasingly common in the United States. Without a physician referral, patients can now directly purchase screening computed tomography (CT) or ultrasound scans. In this article, we consider the clinical and ethical ramifications of widespread screening of low-risk populations with 4 commonly marketed tests: whole-body CT, CT-based heart scans, heel ultrasound for osteoporosis, and carotid duplex sonography for carotid stenosis. All the tests are too inaccurate for screening in low-risk populations, and none has been proven to lead to early, beneficial intervention. Screening could be harmful if false-positive tests lead to extensive or invasive diagnostic evaluation. Finally, widespread testing could increase health care costs with little public health benefit. Patients should probably avoid radiologic screening tests until the tests have been appropriately evaluated in controlled studies and recommended by unbiased national panels, such as the United States Preventive Services Task Force. Primary care physicians and their professional societies should emphasize the uncertain benefits and potential hazards of indiscriminate imaging among healthy, asymptomatic consumers. (*J Am Board Fam Pract* 2003;16:494–501.)

Entrepreneurs have recently recognized a market for radiologic screening tests. For a price, many Americans—without a physician referral—can now conveniently purchase a computed tomography (CT) scan or an ultrasound examination from private, stand-alone radiology corporations. Currently, CT screening exams, including whole-body scans and coronary heart scans, are available at more than 100 centers nationwide, and the popularity of screening scans has begun to attract traditional medical centers into the market. One company is reaching rural markets by trucking scanners from town to town, and another provides ultrasound exams in mobile vans in 43 states, including heel ultrasound for osteoporosis and carotid duplex sonography. With the growth of this cottage industry, family physicians may encounter patients presenting for help interpreting their results. Other

patients may ask their physicians if they should purchase one of these tests.

Many clinicians may feel uncomfortable counseling such patients, because radiologic screening tests, other than mammography, have not been recommended by physicians' organizations and are not part of usual clinical practice. Physicians may wonder: Is screening general populations with such tests likely to be effective in reducing morbidity and mortality? How should primary care physicians interpret the results if asked? How might such testing affect the health care system as a whole?

In this article, we aim to address these questions as they pertain to the population served by most family physicians. Our goal is not to present a systematic review of the literature relevant to each test. Rather, we seek to elucidate the potential clinical and ethical implications of marketing radiologic screening tests directly to consumers.

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## Interpretation of Consumer-Purchased Screening Tests

Interpreting a screening test requires knowledge of the pretest probability of the target disorder (the prevalence of disease in the population) and the sensitivity and specificity of the test. When the prevalence of a disease is low, as is common in primary care, the predictive value of a positive

**Table 1. Selected Marketed Tests and Their Performance Characteristics among Low-Risk Populations**

Test, References	Target Condition(s)	Prevalence (%) <sup>*</sup>	Sensitivity (%)	Specificity (%)	PPV (%)	Cost (US \$)
Whole-body CT <sup>1,3-6</sup>	Lung cancer <sup>†</sup>	0.5	55-86	49-95	1.2-8	500 to 1300
Heart scan (electron beam computed tomography) <sup>9</sup>	Obstructive coronary artery disease	10	80 <sup>‡</sup>	40 <sup>‡</sup>	13	200 to 500
Quantitative ultrasound of the heel <sup>8,13-16</sup>	Osteoporosis of the hip	6-25	71 <sup>‡</sup>	73 <sup>‡</sup>	14-47	15 to 110
Carotid artery duplex sonography <sup>8,17</sup>	Carotid stenosis	0.5-10	83-86	89-94	7-61	30 to 150

\* Estimated prevalence range of target condition in US adults of age 40 to 70. Point prevalences are the highest likely prevalence in a general screening population.

† For most other plausible target conditions of whole-body CT, insufficient data exist to calculate performance characteristics.

‡ For these tests, sensitivities and specificities shown in the Table are the maximum simultaneous values based on receiver-operating characteristics.

PPV, positive predictive value.

screening test will be low even if the test is highly sensitive and specific.

### **Whole-Body CT**

“Whole-body” CT looks for disease throughout the chest, abdomen, and pelvis, so it has not one target condition but many. Whole-body CT is widely advertised as a screening test for cancer, so we considered its interpretation as a screening test for the most common cause of cancer mortality in the United States: lung cancer.

The prevalence of subclinical lung cancer is unknown in the general population, but 0.5% would be a conservatively high estimate.<sup>1</sup> Randomized trials will determine whether screening CT can improve lung cancer mortality among high-risk patients,<sup>2</sup> but nonrandomized trials suggest that CT screening may be insufficiently specific for screening low-risk populations.<sup>3-7</sup> If a low-risk population were screened using the protocol of the Early Lung Cancer Action Project (ELCAP), the predictive value of a positive CT scan (demonstrating a noncalcified pulmonary nodule) would be only 2% (Table 1). Thus, in an unselected population, 98% of people with a screen suspicious for lung cancer will not have cancer. The false-positive rate would be even higher if the prevalence of subclinical cancer is lower than our conservative estimate or if consumer-purchased scans have lower specificity than scans performed in the ELCAP trial.

For other cancers, the sensitivity and specificity of noncontrast CT is unknown. Yet, even if it were surprisingly accurate, noncontrast CT would be associated with a low positive predictive value because of the very low prevalence of each type of

cancer in asymptomatic general populations. Although noncontrast CT can accurately diagnose abdominal aortic aneurysm and nephrolithiasis, the benefit of screening for such conditions in low-risk populations is uncertain.<sup>8</sup>

### **Coronary Heart Scans**

Coronary heart scans generate a calcium score that is associated with coronary artery disease (Table 1). The sensitivity and specificity of heart scans in detecting obstructive coronary artery disease (>50% stenosis in at least one major coronary artery on angiography) depend on the calcium score that one defines as “abnormal.” Higher calcium scores are more specific and less sensitive, and the opposite is true for lower calcium scores. Based on meta-analysis of 16 studies, an American College of Cardiology/American Heart Association expert panel reported that the finding of “any detectable calcium” is approximately 80% sensitive and 40% specific for obstructive coronary disease.<sup>9</sup> Although the prevalence of obstructive coronary disease in asymptomatic populations is unknown, we will assume for illustration a high prevalence of 10%. If such a population were screened with electron-beam or helical CT of the coronary arteries, the positive predictive value of any detectable calcium would be only 13%. Thus, in a low risk population, the presence of coronary calcium increases the likelihood of obstructive coronary disease by only 3%.

Even if it poorly predicts obstructive coronary disease, might a positive heart scan give valuable prognostic data regarding a person’s risk of developing symptomatic coronary disease? Wald et al<sup>10</sup>

argue that screening for a risk factor, such as coronary calcium, is worthwhile only if it powerfully predicts poor outcomes. A recent meta-analysis of data from cohort studies of asymptomatic populations screened with heart scans suggests that an abnormal heart scan is not a powerful predictor of major coronary events, such as myocardial infarction or sudden death.<sup>11</sup> The large majority of patients with high calcium scores remain asymptomatic, and some with low calcium scores develop myocardial infarction. Current research has not proven that the calcium score adds predictive value beyond the Framingham Risk Index, which is derived from readily identified clinical data.<sup>12</sup>

### ***Heel Ultrasound***

Quantitative heel ultrasound is marketed as a screening test for osteoporosis, although it seems too inaccurate for screening in low-risk populations (Table 1). Compared with dual-energy x-ray absorptiometry (DEXA) of skeletal sites vulnerable to fracture, heel ultrasound has a sensitivity of 62% to 81% and a specificity of 60% to 82% in diagnosing osteoporosis.<sup>13-16</sup> Using receiver-operating characteristics, Dubois et al<sup>13</sup> found that the sensitivity and specificity of heel ultrasound in predicting osteoporosis of the femoral neck were simultaneously maximized at 71% and 73%, respectively. Consequently, in premenopausal women, for whom the prevalence of osteoporosis is 6%, the positive predictive value of heel ultrasound would be only 14%. Even in postmenopausal women with an osteoporosis prevalence of 25%, the positive predictive value of heel ultrasound is less than 50%. Furthermore, the low sensitivity of heel ultrasound means that many women with osteoporosis could be falsely reassured of normal bone density.

### ***Carotid Ultrasound***

Carotid duplex sonography screens for carotid stenosis. Although fairly sensitive and specific for important carotid stenosis,<sup>17</sup> carotid duplex would have a positive predictive value of less than 10% in unselected persons  $\leq 60$  years, assuming a 0.5% prevalence of greater than 50% stenosis. More than 90% of positive results would be false-positives. Even in octogenarians, the positive predictive value in asymptomatic persons would be unlikely to exceed 62%, also leading to many false-positives. Largely because of its marginal positive predictive value, the United States Preventive Services Task

Force recommended considering carotid duplex screening only for patients with multiple cardiovascular risk factors, for whom the false-positive rate would be acceptably low.<sup>8</sup>

### ***Plausible Benefits and Harms of Screening***

Screening tests should, of course, lead to interventions or treatments that alter the course of the disease. Because screening is performed on asymptomatic people, the treatment of screen-detected disease should lead to better long-term outcomes than treatment when the disease becomes symptomatic. Moreover, the benefits of screening must outweigh its harms, which frequently stem from the evaluation of false-positive test results. Is there evidence that early detection with marketed screening tests leads to beneficial intervention?

### ***Whole-Body CT***

To date, no controlled studies have proven that CT screening of the chest, abdomen, or pelvis leads to early, effective intervention. Uncontrolled trials of chest CT screening for lung cancer in high-risk patients have shown that CT detects smaller tumors at an earlier stage than chest radiography.<sup>3</sup> These findings give reason to hope that screening high-risk individuals with chest CT will reduce mortality from lung cancer.

Yet the results of prior lung cancer screening trials should give pause. In the Mayo Lung Project, screening chest radiography and sputum cytology also detected smaller, earlier stage tumors, and investigators initially reported increased lung cancer survival among the screened group.<sup>18</sup> After extended follow-up, however, screening had no effect on lung cancer mortality; the seeming benefit of early detection proved to be largely attributable to a combination of lead time, length, and overdiagnosis biases.<sup>19</sup>

Likewise, screening CT of the chest, abdomen, or pelvis may advance the time of cancer diagnosis without affecting prognosis (lead-time bias) or preferentially detect indolent, less invasive disease and miss faster growing, more lethal tumors (length bias). CT screening may also uncover tumors or aneurysms that are destined to remain clinically silent. Yet, when found, these anomalies cannot be ignored and frequently prompt definitive, often invasive treatment. Although we acknowledge the plausibility of beneficial early detection with CT

screening, controlled trials are needed to distinguish the benefit of early diagnosis from the harm of overdiagnosis and invasive treatment of "pseudo-disease."<sup>20,21</sup>

Any benefit of early detection must also outweigh the harms stemming from false-positive test results. Without question, whole-body CT screening will be associated with a considerable false-positive rate. Many false positives will result from the chest portion alone. Assuming screening companies could replicate the test characteristics of the ELCAP trial, CT screening for lung cancer in 1000 low-risk patients would result in about 213 positive scans, with 98% false-positives. All would require follow-up high-resolution scans, and some would require multiple scans over a 2-year span.<sup>22</sup> When serial scans could not exclude cancer, some patients could be referred for lung biopsy, which has frequently revealed benign histology in screening trials for high-risk patients.<sup>4,5,23</sup>

False-positive tests could also result from screening with noncontrast abdominal CT. In a large series of emergency department patients receiving helical abdominal CT to evaluate for renal stones, nearly one quarter demonstrated an incidental finding for which follow-up tests seemed prudent.<sup>24</sup> In a trial of CT screening for lung cancer, approximately 10% of patients had an indeterminate renal, adrenal, or breast finding that required further evaluation.<sup>23</sup> Although some of these findings may occasionally lead to beneficial treatments, most have no clinical significance but require follow-up testing to prove they are harmless. Again, controlled studies are needed to assure that the harms suffered by many who would receive false-positive tests are outweighed by the benefits of far fewer whose tests would be truly positive.

A recent decision and cost-effectiveness analysis suggests that lung cancer screening with CT should await the results of clinical trials.<sup>25</sup> In the base-case analysis, the investigators found that screening older smokers with chest CT would be quite costly but could reduce lung cancer mortality by 13%. However, when the investigators assessed the potential effect of greater length and overdiagnosis biases, the harms of screening outweighed its benefits.

### **Coronary Heart Scans**

By detecting coronary atherosclerosis early, heart scans could lead to beneficial modification of risk factors for coronary disease. However, current

guidelines already advocate screening for these risk factors and aggressive intervention if present.<sup>26,27</sup> No studies have proven an incremental benefit of heart scan screening beyond accepted practice of screening for risk factors for coronary disease.

Some patients could be reassured by a normal heart scan. Alternatively, others may be motivated by an abnormal heart scan to adopt a more salubrious lifestyle. Others with abnormal heart scans, however, might be harmed by the "label" of a new diagnosis of coronary artery disease. Negative psychological impacts of new diagnoses have been noted in other cardiovascular screening endeavors,<sup>28</sup> sometimes with worrisome social or physical ramifications.<sup>29,30</sup> Because the prevalence of coronary calcium is high in men >50 years old and women >60 years old,<sup>31</sup> heart scan screening will frequently diagnose subclinical coronary disease in older adults. Although evidence of the psychological effects of heart scan screening is preliminary, abnormal heart scans could have deleterious "labeling" effects in some that outweigh any plausible beneficial effects in others.<sup>32</sup>

When heart scans reveal coronary calcium, diagnostic testing for coronary artery disease will frequently ensue.<sup>33</sup> Patients may undergo stress testing or coronary angiography, with associated risks of local vascular complications, arrhythmias, renal failure, and, in rare cases, death.<sup>34</sup> In one cohort of asymptomatic subjects undergoing heart scan screening, 0.4% of patients had revascularization procedures based solely on the results of their heart scan.<sup>35</sup> Thus, widespread heart scan screening could lead to coronary revascularization in many asymptomatic subjects, despite no evidence that revascularization is beneficial in patients with asymptomatic coronary disease. Finally, like other CT scans, heart scans will frequently demonstrate incidental noncardiac findings, such as pulmonary nodules or indeterminate liver lesions, which may lead to unnecessary follow-up tests or treatments.<sup>36</sup>

### **Quantitative Ultrasound of the Heel**

The US Preventive Services Task Force recently recommended DEXA screening in women at increased risk of osteoporosis.<sup>37</sup> The recommendation was based in part on recent randomized trials demonstrating reduced risk of clinically important fractures in women with low bone density of the femoral neck who were treated with bisphosphonates.<sup>38</sup> Would widespread screening with heel ul-

trasound identify a similar group of women? Not necessarily. In populations with a low prevalence of osteoporosis, many women with abnormal heel ultrasound would have normal bone mineral density of the femoral neck. Such women may be subjected to drug therapy of no benefit and the diagnostic "label" of osteoporosis.<sup>39</sup> Alternatively, women may assume incorrectly that their bone density is normal based on a normal heel ultrasound, when in fact a hip DEXA would diagnose osteoporosis.

Screening with heel ultrasound is appealing because it is less expensive and more convenient than DEXA. In addition, cohort studies of older women have shown that abnormal heel ultrasound predicts hip fractures, even when hip DEXA does not show osteoporosis.<sup>40</sup> Thus, it is possible that heel ultrasound could identify a subgroup of women who could benefit from antiresorptive therapy despite normal hip DEXA. This hypothesis, however, has not been tested in clinical trials. Heel ultrasound screening in general populations should await evidence that such screening reduces the risk of clinically important fracture, particularly when undertaken without appropriate pretest clinical evaluation.

### ***Carotid Artery Duplex Sonography***

The United States Preventive Services Task Force suggests that carotid duplex may have a role in screening patients at high-risk for carotid stenosis. In low-risk patients, however, the false-positive rate of carotid duplex is too high. Although the positive predictive value of carotid duplex in low-risk patients would be less than 10%, patients with abnormal results would predictably seek further evaluation. Many of these would be referred for magnetic resonance angiography of the carotids, but some would conceivably be referred for carotid angiography, which poses a 1% risk of stroke.<sup>8</sup>

### **Ethical Concerns**

#### ***Retail Screening and Distributive Justice***

The bioethical principle of distributive justice holds that health care resources should be distributed as equitably as possible. Given finite resources for health services, it is unethical to provide expensive nonessential health services to one sector of society when another lacks essential services. Despite persistent inequity in the distribution of health resources in the United States, we should ask

of new medical interventions, "Does this test or treatment undermine the fair distribution of health resources?"

The private purchase of a screening test could exacerbate the misdistribution of resources, because nonspecific screening tests predictably lead to further diagnostic testing, the costs of which are likely to be insured and therefore shared by the community. Most would think it is fair for someone to pay out-of-pocket for a screening test of unproven benefit. Yet, in 3 series of patients receiving screening CT of the lungs and abdomen, radiologists recommended follow-up diagnostic testing in 50% to 80% of patients.<sup>23,41</sup> Thus, for every person who chooses to undergo CT screening, the probability seems high that their decision will result in further use of shared health resources.

If CT screening were to become widespread, the cost of follow-up diagnostic evaluation and treatment could significantly increase national health expenditures. If more funds were not allocated to cover these costs, widespread self-referral for radiologic screening tests could lead to more services for some and fewer for others, without necessarily improving the population's health as a whole.

### ***Informed Consent***

Physicians are ethically obligated to obtain informed consent from patients before tests or treatments. In the routine delivery of care, providers may obtain informed consent informally,<sup>42</sup> but the principle still holds: the patient should understand a test or treatment's indications, benefits, risks, and limitations and make the ultimate decision regarding whether to obtain a test or treatment.

As we have reviewed, the indications, benefits, and risks of CT and ultrasound screening tests have not been elucidated by clinical research in low-risk populations. Without acknowledging plausible harms or limitations, however, many companies confidently assert the benefits of screening in advertisements. Companies can elicit credible informed consent only by acknowledging the uncertain clinical benefits and possible harms of radiologic screening tests.

### ***Responding to the Trend***

Rapid growth in the screening test industry requires a reasoned response from physicians and policy-makers. National and regional medical asso-

ciations should discourage the marketing of screening tests of unproven benefit and alert patients to the potential hazards of indiscriminate testing among low-risk populations. A statement opposing whole-body CT screening from the American College of Radiology received substantial media coverage.<sup>43</sup> Similar statements from other physicians' groups could engender healthy skepticism among consumers and rebut industry advertisements, which emphasize only the positive outcomes of testing.

Individual physicians should warn about the risks of indiscriminate screening tests among low-risk populations. Some patients may be dissuaded from testing if their physicians advise against it. Before physicians will advise against a test, however, they must understand its potential harms. Many physicians may assume that advanced imaging tests are accurate, informative, and better than no screening at all. Professional societies may therefore have a crucial role in disseminating information about the limitations of marketed tests. The American Academy of Family Physicians and the American College of Physicians-American Society of Internal Medicine both issue recommendations regarding preventive health services. As the professional academies representing most primary care physicians serving adults, both should alert members about the potential hazards of radiologic screening without appropriate pretest clinical evaluation.

Although regulatory oversight could protect consumers from the hazards of indiscriminate testing, no federal agency currently has a mandate to regulate use of radiologic machinery once the United States Food and Drug Administration (FDA) has certified it for marketing and distribution. Any expansion of the FDA's mandate would require new federal legislation, which currently seems improbable. Some states require a physicians' prescription before radiologic testing.<sup>44</sup> Other states may consider legislation requiring physician referral for radiologic testing if growth in the screening industry results in substantially increased health care costs. At the federal level, the Federal Trade Commission should closely monitor company advertisements and discourage misrepresentation of the benefits of screening.

One might suggest that health insurers refuse to pay for tests and treatments stemming from an enrollee's purchase of a radiologic screening test.

Such a policy, however, could be difficult to enforce, because once abnormalities are uncovered at screening, clinicians may find them impossible to ignore. When confronted by a patient with an abnormal screening test, most physicians will feel obligated to fully evaluate the abnormality. If a physician orders further tests, the insurance company may be unable to prove that the physician ordered follow-up tests solely based on the screening test, rather than other clinical indications. Such a policy could also pose legal risks. If a single patient believes that administrative barriers erected by the insurer forestalled timely diagnosis and treatment, he or she could sue the insurer for damages that far exceed the costs of follow-up tests for many abnormal screening exams.

In summary, current evidence does not support widespread screening with most of the radiologic tests now marketed to consumers. Although advertisements dramatize the benefits of testing, these tests have the potential to cause harm, especially when falsely positive. Patients should generally avoid radiologic screening tests until the tests have been appropriately evaluated in controlled studies and recommended by unbiased national panels. Although regulatory measures could protect consumers from the hazards of screening, federal or state legislation restricting the marketing of radiologic screening tests is unlikely to be passed in the near term. Physicians and their professional organizations, therefore, have a crucial role in publicizing the uncertain benefits and potential hazards of radiologic screening tests.

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