

*Sounding Board***DIRECT-TO-CONSUMER MARKETING OF HIGH-TECHNOLOGY SCREENING TESTS**

**I**NCREASINGLY, entrepreneurs, including physicians, are offering to the general public high-technology screening tests that are not covered by most health insurance plans. These tests are frequently being marketed directly to consumers by radio, the print media, the Internet, and other media.<sup>1,2</sup> People who undergo these tests pay fees that generally range from \$300 to \$1,000.<sup>3</sup>

The physicians who offer these services assert that screening with new testing technology can improve outcomes, particularly for people at high risk for coronary disease, lung cancer, and certain other conditions. Clinical research to explore these issues is under way but thus far has not demonstrated such benefits for these forms of technology. Two prominent examples of such screening technology are electron-beam computed tomography (CT), which is being used to screen for undetected coronary artery disease, and low-dose spiral CT, which is being used to screen for cancer in the lungs and other organs. Despite the absence of data to support the usefulness of the tests for these purposes, their advocates argue that people should have the right to undergo screening without waiting years until its effectiveness can be definitively established or refuted. Finally, some physicians believe that consumers should have the right to spend their own funds to purchase medical services — even if those services have uncertain clinical value — if the consumers believe that the tests might give them “peace of mind.”

We hope that research will eventually assess the value of these and other forms of testing technology: as clinicians, we need all the tools we can get to improve the outcomes of our patients. However, we are concerned that the use of unproven forms of technology in screening programs marketed directly to consumers raises issues of clinical, financial, and ethical concern.

**CLINICAL ISSUES**

Ideally, a screening test should have a high sensitivity for detecting previously undiagnosed disease, and earlier detection should lead to changes in management that improve patient outcomes. Negative test results should provide reassurance that the risk of disease is very low. Screening tests should also have low false positive rates, so that large numbers of healthy people are not unduly alarmed or subjected to unnecessary tests or procedures in follow-up. Do the high-technology screening tests that are being mar-

keted to the public meet these criteria? Is the “peace of mind” that many seek when they undergo these tests warranted when the results are normal?

On the basis of the currently available evidence, we believe that the answer to these questions is no — particularly when these tests are performed in asymptomatic persons with a low risk of disease. For example, electron-beam CT is performed with the promise that, by quantifying the extent of coronary-artery calcification, it can identify persons with an increased risk of coronary artery disease. An expert consensus document from the American College of Cardiology and the American Heart Association summarized published data in 2000 and concluded that the sensitivity and specificity of electron-beam CT were 80 percent and 40 percent, respectively.<sup>4</sup> The gold standard used in these studies was coronary angiography. Thus, the sensitivity of electron-beam CT appears to be similar to that of other noninvasive tests for ischemic heart disease, whereas the false positive rate is much higher, especially among the elderly. Persons without obstructive coronary disease are unlikely to get the peace of mind they seek from electron-beam CT. For these reasons, the consensus document concluded that “the majority of the members of the Writing Group would not recommend EBCT [electron-beam CT] for diagnosing obstructive CAD [coronary artery disease].”<sup>4</sup>

Electron-beam CT is also promoted as potentially useful for predicting the prognosis for asymptomatic persons, and pooled data indicate that patients with higher calcium scores on such tests have an increased risk of coronary events.<sup>5</sup> However, the ability of data from electron-beam CT to enhance the prognostic stratification that is based on routinely available clinical information is uncertain. For example, in a group of 1196 asymptomatic high-risk patients, data from electron-beam CT were no better than the Framingham Risk Index in predicting the risk of coronary events during a 41-month period.<sup>6</sup> In this study, the use of data from electron-beam CT did not improve predictions made on the basis of clinical data alone, perhaps because many acute coronary events are caused by the rupture of soft, unstable atherosclerotic plaques that have little or no calcification. Studies are under way to determine whether lipid-lowering treatment of patients with high calcium scores on electron-beam CT leads to better outcomes, but currently, the role of electron-beam CT as a screening test or a tool to guide therapy remains unclear.

Whereas the high rate of false positive results underlies reservations about electron-beam CT as a screening test for coronary disease, other problems have kept major professional societies from endorsing the use of low-dose spiral CT for the detection of asymptomatic lung cancer. There is no question that this type of technology offers better resolution than chest ra-

diography and might therefore identify small lung cancers that would otherwise be missed.<sup>7</sup> However, there is no evidence to date that earlier detection leads to better patient outcomes.

Common sense suggests that identification of lung cancers when they are smaller should improve the likelihood that resections will be curative, but thus far, available data do not provide support for that hope. For example, in a recent study of 510 patients with non-small-cell lung cancer and no known metastases, there was no correlation between tumor size at the time of diagnosis and survival.<sup>8</sup> Outcomes were similar for those with 3-cm masses and those with nodules of less than 1 cm. The reason may be that small tumors, such as 5-mm nodules, probably do not truly represent early disease; by the time tumors are visible on CT imaging, their potential to metastasize has already been realized. Research suggests that metastases may occur when lesions are just 1 to 2 mm in diameter — well before they are detectable by any current method.<sup>9</sup> As a result, CT screening for lung cancer may fail to improve outcomes just as screening with chest radiography failed in randomized trials in the 1970s.<sup>10</sup>

In addition, the rate of false positive results tends to be high when low-dose spiral CT is used in high-risk patients, particularly in regions of the country where there is a high prevalence of benign causes of lung nodules. For example, in a series of 1520 current or former smokers studied at the Mayo Clinic, 15 cases of lung cancer were diagnosed, of which 60 percent were in early stages. However, 51 percent of all patients had at least one nodule and required follow-up with either additional CT examinations or invasive procedures.<sup>9</sup>

There are no rigorous published data on the use of CT scanning of the entire body to screen for cancers. However, there is every reason to believe that both sensitivity and specificity fall far short of the perfection expected by patients seeking “peace of mind.” The most obvious weakness of these screening programs is that they do not use oral or intravenous contrast medium, thereby compromising the ability of CT scans to detect small tumors in organs such as the liver, pancreas, and kidneys. (Fortunately, none of the companies offering screening CT scanning seem to be offering studies with contrast medium, which would subject patients to the risk of reactions to the contrast agent.) False positive findings are also common, with the detection of cysts and other benign lesions that can only be evaluated through other tests or invasive procedures.

False positive tests expose patients to risks and discomfort, but false negative studies may also pose hazards. Patients who have had a negative screening could conclude that they need not worry about cancer or heart disease. The sensitivity of these forms of technology is not sufficient to justify such confidence.

## FINANCIAL ISSUES

Ideally, early detection of disease should improve patient outcomes and reduce costs by preventing complications. The ability of these high-technology screening tests to accomplish either of these goals remains unproven. Nevertheless, even if patients pay out of pocket with their own funds for such screenings, there are financial consequences that affect the rest of the health care system.

The most obvious of these consequences are the costs associated with the follow-up of false positive results and the much smaller proportion of true positive results. These costs include not only those of additional tests and procedures that are likely to be covered by the patient's health insurance, but also the costs resulting from complications of those interventions. Indeed, according to some entrepreneurs, one of the attractions for hospitals of high-technology screening programs is the ability to generate income by creating a new market of patients who need follow-up exercise testing and coronary angiography. Although such a return on investment may be attractive for the institutions and physicians who administer screening programs, there is a strong possibility that they will be consuming dollars that might be used with greater benefit elsewhere in the health care system.

These screening programs create “costs” for the health care system in another, more subtle way that is becoming increasingly apparent to primary care physicians. Patients are asking their primary care physicians whether they should have these screening tests, why insurance does not cover them, and whether a referral can be written so that the patient can have the test without having to pay out of pocket. The resulting discussions are often long and frustrating for both patient and physician. The price that is being paid by primary care physicians is their time — and, in some cases, the loss of the trust of their patients.

## ETHICAL AND PROFESSIONAL ISSUES

Physicians may have honest disagreements about whether these forms of technology are valuable, and this uncertainty may eventually be resolved through research. However, these services are being offered today, even when professional societies have expressed their reservations. Some might argue that offering screening services of unproven value is perfectly reasonable from an ethical point of view. If health care is treated simply as a part of the marketplace, and consumers can choose freely what to purchase in that marketplace, then there is nothing wrong with offering, for example, a whole-body CT scan. The patient has a right and should have the opportunity to choose which tests he or she wants to undergo.

An appeal to the concept of the marketplace, however, overlooks the fact that medicine is a profession

and, as such, carries certain responsibilities for physicians. The foundation of those responsibilities is an altruistic commitment to the individual patient. The physician's foremost concern is the patient's good. Screening tests that lack specificity are not in the patient's interest, given their high false positive rates. The likely outcome of widespread use of such tests is that a greater proportion of patients would worry unduly about disease and undergo further unnecessary testing.

Some might counter that perhaps these tests can be ethically provided so long as the risks of false positive results are carefully explained to patients. An ethical physician would take the time to explain the issues to the patient, and then, satisfied that the patient is fully informed, perform the test.

But this position misses another key element of professionalism, which is that the profession should act in a unified fashion when faced with critical choices. Not only must we act individually out of commitment to the patient's good, but as a profession, we must be concerned about the good of the entire class of patients. The proliferation of tests that lack a scientific basis is an issue that must be addressed by the profession, not left to the discretion of the individual physician.

In emerging views of professionalism now being discussed by ethicists and leaders in health care, professional responsibilities with regard to high-technology screening tests are even more salient.<sup>11</sup> Leaders in medicine have begun to recognize that issues of increasing costs of care and lack of access to health care for a large proportion of the population require our professional attention. Professional organizations have begun to integrate notions of social justice into their understanding of professionalism, explicitly recognizing that care provided to one patient will most likely affect the care available to other patients.

A good example is the recently published charter for medical professionalism, prepared by the American College of Physicians, the American Society of Internal Medicine, the American Board of Internal Medicine, and the European Federation of Internal Medicine.<sup>12</sup> These organizations, representing internists from throughout the United States, Canada, and Europe, have set forth a series of principles and key commitments to guide the judgment of physicians. In describing the necessity of a commitment to cost-effective care, the charter argues that unproven therapies lead to spiraling costs of health care. A just health care system cannot accept such developments, even if the market would allow it.

Finally, we must recognize that at least some informed members of the public will realize that a major reason for providing these unnecessary tests is that physicians profit from them. In fact, many might conclude, quite reasonably, that remuneration is the key factor. This kind of suspicion harms the profession it-

self and the perception of its commitment to patients. Therefore, a good case can be made that professional ethics prohibits providing unproven diagnostic screening tests, even if there is substantial demand from patients. Rather, physicians should be instructing patients that such tests are unnecessary and using their energy for the appropriate development of evidence regarding the efficacy of these tests.

## CONCLUSIONS

In all likelihood, physicians and the public will eventually have data to guide them in making decisions about whether and when to use these tests. Trials are under way to evaluate the ability of electron-beam CT and low-dose spiral CT to prevent death due to coronary disease and lung cancer, respectively. The researchers who are performing these studies deserve our respect and support. We hope that these forms of technology can be demonstrated to improve health by allowing earlier detection of disease or by enabling us to target more aggressive interventions at higher-risk patients. In the meantime, however, we have serious reservations about the clinical, financial, and ethical implications of offering these tests as screening interventions that are marketed directly to consumers.

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