9.6.8 Direct-to-Consumer Diagnostic Imaging Tests

Diagnostic imaging tests are sometimes marketed directly to consumers before they have been scientifically validated. This can help consumers prevent disease and promote health, but may also expose patients to risk without benefit, create conflicts of interests for physicians, and be abused for profits.

Individually, physicians who offer diagnostic imaging services that have not been scientifically validated and for which a patient has not been referred by another physician have an ethical obligation to:

(a) Perform a requested diagnostic imaging test only when, in the physician's judgment, the possible benefits of the service outweigh its risks.

(b) Recognizing that in agreeing to perform diagnostic imaging on request, the physician

(i) establishes a patient-physician relationship, with all the ethical and professional obligations such relationship entails;

(ii) assumes responsibility for relevant clinical evaluation, including pre- and post-test counseling about the test, its results, and indicated follow-up. Physicians may choose to refer the patient for post-test counseling to an appropriate physician who accepts the patient.

(c) Obtain the patient's informed consent. In addition to the usual elements of informed consent, the physician should disclose:

(i) that the diagnostic imaging test has not been validated scientifically,

(ii) the inaccuracies inherent in the proposed test,

(iii) the possibility of inconclusive results,

(iv) the likelihood of false positive and false negative results,

(v) circumstances that may require further assessments and additional cost.

(d) Ensure that the patient's interests are primary and place patient welfare above physician interests when the physician has a financial interest in the imaging facility.

(e) Ensure that any advertisements for the services are truthful and not misleading or deceptive, in keeping with ethical guidelines and applicable law.

(g) Develop suitable guidelines for specific diagnostic imaging tests when adequate scientific data become available.

AMA Principles of Medical Ethics: I, II, V, VIII

9.6.8 Direct-to-Consumer Diagnostic Imaging Tests

Diagnostic imaging tests are sometimes marketed directly to consumers before they have been scientifically validated. *This can help consumers prevent disease and promote health, but may also expose patients to risk without benefit, create conflicts of interests for physicians, and be abused for profits. [new content sets out key ethical values and concerns explicitly]*

Individually, physicians who offer diagnostic imaging services that have not been scientifically validated and for which a patient has not been referred by another physician have an ethical obligation to:

(a) Perform a requested diagnostic imaging test only when, in the physician's judgment, the possible benefits of the service outweigh its risks.

(b) Recognizing that in agreeing to perform diagnostic imaging on request, the physician

(i) establishes a patient-physician relationship, with all the ethical and professional obligations such relationship entails;

(ii) assumes responsibility for relevant clinical evaluation, including pre- and post-test counseling about the test, its results, and indicated follow-up. Physicians may choose to refer the patient for post-test counseling to an appropriate physician who accepts the patient.

(c) Obtain the patient's informed consent. In addition to the usual elements of informed consent, the physician should disclose:

(i) *that the diagnostic imaging test has not been validated scientifically,* [*new content addresses gap in current guidance*]

(ii) the inaccuracies inherent in the proposed test,

(iii) the possibility of inconclusive results,

(iv) the likelihood of false positive and false negative results,

(v) circumstances that may require further assessments and additional cost.

(d) Ensure that the patient's interests are primary and place patient welfare above physician interests when the physician has a financial interest in the imaging facility.

(e) Ensure that any advertisements for the services are truthful and not misleading or deceptive, in keeping with ethical guidelines and applicable law.

Collectively, physicians should:

(f) Advocate for the conduct of appropriate trials aimed at determining the predictive power of diagnostic imaging tests and their sensitivity and specificity for target populations.

Collectively, physicians should:

(f) Advocate for the conduct of appropriate trials aimed at determining the predictive power of diagnostic imaging tests and their sensitivity and specificity for target populations.

(g) Develop suitable guidelines for specific diagnostic imaging tests when adequate scientific data become available.

AMA Principles of Medical Ethics: I, II, V, VIII

Background report(s):

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA Report 3-A-05 Direct to consumer diagnostic imaging test

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS[*]

CEJA Report 3 - A-05

Subject: Direct-to-Consumer Diagnostic Imaging Tests

Presented by: Michael S. Goldrich, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Art L. Klawitter, MD, Chair)

Resolution 508 (I-01), "Inappropriate Medical Screening Tests" and Resolution 509 (A-02), "Commercialized Medical Screening" raised concerns regarding the emergence into the market place of "commercial medical screening," wherein tests are advertised directly to consumers. Thus, patients without referral from a physician can pay to be tested for a broad range of conditions. Together, these resolutions called for a close examination of the use of such tests, their effectiveness, and their marketing.

At the 2003 Annual Meeting, the Council on Scientific Affairs (CSA) presented its report on scientific aspects of three specific diagnostic imaging tests.[**] The CSA Report was built upon the premise that preventive services should be supported by evidence that demonstrates improved health outcomes or quality of life, as well as cost-effectiveness. It briefly discussed issues of sensitivity, specificity, and predictive value regarding screening tests, and emphasized that to be considered effective, screening tests should be capable of detecting a high proportion of disease in preclinical phase, among other criteria. Overall, the report concluded that evidence was currently lacking to support these three specific tests without referral by a physician. Finally, in its recommendations, the CSA noted "That considering the summary information in this report, the Council on Ethical and Judicial Affairs [should] further consider the ethical ramifications of commercialized medical screening."

The proliferation of direct-to-consumer diagnostic imaging tests, including full-body scans, raises not only scientific and policy questions regarding effectiveness and overall costs but also ethical questions regarding the limited clinical encounter that takes place between patient and physician. This report, therefore, focuses on the role of the physician involved in delivering direct-to-consumer diagnostic imaging tests and also considers issues related to their commercialization. This report does not address other diagnostic tests that may be available to patients without referrals, such as pregnancy tests, HIV tests, genetic screening, and other laboratory tests, nor scientifically validated screening imaging services such as mammography.

---

[*] Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

[**] Electron beam computed tomography (CT) for determining coronary artery calcification, spiral CT for lung cancer screening, and CT colonography for colon cancer screening.

MEDICAL ENCOUNTERS TO PROVIDE PREVENTIVE SERVICES

All encounters between patients and physicians need not stem from symptoms of a possible medical illness or be related to therapeutic interventions. Indeed, there has been considerable emphasis on preventive care, as physicians can play an important role in assisting patients to maintain good health. However, there also has been substantial debate in recent years regarding various preventive services and their clinical validity, particularly in relation to expanding use of imaging technology. In the face of uncertainty, large-scale studies have been undertaken to better assess the benefits and harms of various interventions. When findings from such research have failed to support common practices, there has been much confusion among the public. As much as possible, medical practice should be based on evidence; similarly, preventive services should be rigorously evaluated before they are widely adopted.[1]

Screening tests and informed consent

Whenever offering tests, whether for diagnostic workup or for screening purposes, physicians generally must obtain informed consent. Moreover, the ethical and legal principles of a patient's right to self-determination and physicians' concurrent obligation to respect patients' autonomy generally require that physicians and patients engage in a shared decision-making process. This entails physicians sharing with patients information that addresses the nature of the test, the reasons for it, and the benefits that may result (i.e. diagnostic information). In addition, any physical risks inherent in an imaging test,[2] as well as other risks such as ambiguous results that necessitate further testing, and alternatives to the test (with their respective advantages and disadvantages) must be communicated. By presenting such information in addition to their own recommendations, physicians generally seek the patient's understanding and authorization to proceed. This exchange of information is intended to help patients make choices that are aligned with their own values and preferences. When the goal of mutual understanding and agreement has been reached, the ethical and legal requirements for informed consent have been fulfilled.

When tests are performed in asymptomatic patients, it is imperative that physicians explain their nature and possible results. Overall, physicians must be able to explain to patients that some tests are more or less accurate and that results may not be definitive but may merely reveal increased probabilities that a certain condition may develop. When presenting risks of testing, physicians must discuss the possibility of false negatives: if this is not mentioned, the patient may leave with a (false) sense of well-being and later ignore symptoms of ill health. The possibility of false positives – a frequent outcome of CT screening[3] – may lead to additional tests, costs, and anxiety. Even true negative results must be explained carefully, since a patient may otherwise have the impression that unhealthy behavior can be continued – for example, continuing smoking because a lung scan was negative. On a more positive note, there may be some psychological benefit if a test accurately detects no disease. Yet, physicians must not capitalize on patients' fears and should not offer testing when, in their judgments, the risks outweigh the potential benefit (e.g. given the patient's age and medical history, the low probability of a positive finding is outweighed by the risks of the procedure). Overall, physicians must communicate in terms that patients can understand the unique aspects of diagnostic and screening tests including their specificity, sensitivity, and predictive value.[4]

Although the benefits of positive findings may appear straightforward, detection of a condition may have no effect on morbidity or mortality. Therefore, before testing, physicians also should discuss the implications of positive findings, including the likelihood of successful treatment.

Limitations of direct-to-consumer diagnostic imaging services

In the context of certain imaging tests, it has been argued that patients should be permitted to access and pay for such tests without a referral because the risk of physical harm caused by the test is minimal. This is a departure from the practice of tests being ordered within an existing patient-physician relationship, in which either the physician ordering the test or the one performing it is available to discuss the test and its results, and to offer treatment options or other follow-up advice as may be necessary. Such discussion and follow-up are necessary even though there may be few or no options for treatment.

A study of self-referred full-body CT imaging found that follow-up often is lacking. A large proportion of centers offering such tests simply mail results to the patient; a smaller proportion of centers provided results during a consultation between a physician and the patient; and only one center mailed results to the patient's primary care physician after a consultation.[5]

OFFERING NEW TECHNOLOGIES

Assessment of new technologies

The profession has certain responsibilities in the development of new medical knowledge, including helping to determine the safety, efficacy, and appropriateness of new treatments or products. Some have argued that new technologies should be tested in a controlled setting before broad clinical adoption. Moreover, "foregoing this step may jeopardize future research, place the patient at risk of unexpected health consequences due to invasive follow-up, and lead to unwarranted health care expenditures well beyond the out-of-pocket expense initially incurred."

The American College of Radiology (ACR), in a statement on CT screening examinations, has concluded that more research is necessary to evaluate whether lung scanning, coronary artery calcium scoring, and virtual colonoscopy are clinically valid or reduce the rate of mortality. The ACR has concluded that there is not sufficient evidence to justify recommending total-body CT screening to patients with no symptoms or family history suggesting disease.[6]

According to Opinion E-2.19, "Unnecessary Services," physicians should not provide medical services that they know are unnecessary. Medical services should always be based on scientific evidence, sound medical judgment, relevant professional guidelines, and due concern for economic prudence, as well as patient preferences.

Considerations of cost

At a societal level, one of the most vexing concerns about new high-technology imaging tests is the question of costs. Although at this time direct-to-consumer tests are not reimbursed by health plans and therefore are available only to patients who are able to pay for them out-of-pocket, follow-up tests generally are covered by health plans. From this perspective, some commentators have criticized the practice of some hospitals to offer such screening programs as a means of generating income through the follow-up testing that is required to validate a positive test.[7]

These commentators also have pointed out that many patients who are asymptomatic but desire high technology imaging tests, rather than self-referring and paying out-of-pocket, are seeking a referral with a false diagnosis by their physicians. The impact of pressure to "game the system"

has been analyzed elsewhere,[8] and the practice has been condemned by CEJA: Opinion E-9.132, "Health Care Fraud and Abuse," states that "Physicians should make no intentional misrepresentations… to secure non-covered health benefits for their patients."

Commercial motivations

The Council previously has noted that ownership interests in health care facilities can lead to conflicts of interest, whereby physicians' clinical judgment may be unduly influenced by the prospect of financial gains from referrals.[9] When a physician holds financial interests in a diagnostic imaging facility, every test carried out increases revenues, and every test not done represents a financial loss. In such circumstances, physicians should be guided by the warning not to provide, prescribe, or seek compensation for medical services that are unnecessary.[10] Commercial pressures are likely to be amplified when physicians who offer diagnostic imaging tests advertise their services directly to the public. Direct-to-consumer advertising can create false expectations and can compromise patient care rather than enhance it, especially when it does not appropriately convey to patients the risks involved in using a product or undergoing a treatment.[11] Direct-to-consumer advertising regarding diagnostic imaging tests is likely to create the same kind of expectations unless it is truthful, easily comprehensible, and is not intended to mislead or deceive patients.

Physicians who offer direct-to-consumer diagnostic imaging services must be mindful that patients trust physicians' medical expertise and rely on their advice to identify appropriate or necessary care. Patients' desires and ability to pay are not sufficient by themselves to justify the provision of care when risks are present; balancing of benefits and harms is necessary. Physicians can preserve the professional ethos of medicine only by placing patients' medical interests above their own financial interests.

CONCLUSION

There are many concerns regarding the medical appropriateness of patient-requested diagnostic imaging tests. Ideally, these services should be supported by evidence demonstrating improved health outcomes or quality of life, as well as cost-effectiveness.[12] At this time, scientific data is insufficient to support broad access to these tests; more needs to be known about their predictive value, sensitivity, and specificity. While consumers may believe that these tests can bring psychological and emotional benefits, this also remains to be studied. Necessary data can only be gathered through carefully developed research protocols. Diagnostic imaging services that are performed without referral and outside of research protocols run counter to the medical profession's intent to develop and use new technologies in a manner that is evidence-based and economically responsible.

RECOMMENDATIONS

The Council recommends that the following be adopted and the remainder of the report be filed:

> Diagnostic imaging services that have not been scientifically validated for screening purposes are being offered without prior referral by a personal physician. Examples include total body scanning, electron beam computed tomography (CT) for determining coronary artery calcification, spiral CT for lung cancer screening, and CT colonography for colon cancer screening. Physicians and relevant specialty societies should advocate for the conduct of

appropriate trials aimed at determining the predictive power of the tests, and their sensitivity and specificity for target abnormalities. When adequate data regarding a screening diagnostic imaging service become available, the profession has a responsibility to develop suitable guidelines, as has been done for mammography.

The following ethical guidelines apply to physicians providing screening imaging services that have not been scientifically validated, without referral from another physician:

(1) Performance of a diagnostic imaging test at the request of an individual is justifiable only if, in the judgment of the physician, the potential benefits of the service outweigh the risks.

(2) Once a physician agrees to perform the test, a patient-physician relationship is established with all the obligations such a relationship entails. (See Opinion 10.01, "Fundamental Elements of the Patient-Physician Relationship" and Opinion 10.015, "The Patient-Physician Relationship").

In the absence of a referring physician who orders the test, the testing physician assumes responsibility for relevant clinical evaluation, as well as pre-test and post-test counseling concerning the test, its results, and indicated follow-up. Post-test counseling may also be accomplished through referral to an appropriate physician who accepts the referral.

In obtaining the patient's informed consent (see Opinion 8.08, "Informed Consent"), the testing physician should discuss, in a manner the patient can understand, the usual elements of informed consent as well as (1) the inaccuracies inherent in the proposed test, (2) the possibility of inconclusive results, (3) false positives or false negatives, and (4) circumstances which may require further assessment and additional costs.

(3) Physicians who hold financial interests in imaging facilities must not place those interests above the welfare of their patients, as stated in Opinions 8.03, "Conflicts of Interest: Guidelines" and 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician." Moreover, physicians who advertise diagnostic imaging services should ensure that advertisements are truthful and not misleading or deceptive. (New HOD/CEJA Policy)

The Council gratefully acknowledges the American College of Radiology for its contributions to this Report.

Fiscal Note: Staff cost estimated at less than $500.00 to implement.

REFERENCES

[1] See U.S. Food and Drug Administration. Center for Devices and Radiological Health. Whole Body Scanning: Using Computed Tomography (CT) at www.fda.gov/cdrh/ct/index.html (last visited April 6, 2004).
[2] Brenner DJ, Elliston CD. Estimated radiation risks potentially associated with full-body CT screening. Radiology. 2004; 232:735-738.
[3] Hillman BJ. CT screening: Who benefits and who pays? Radiology. 2003;228;26-28.
[4] See U.S. Food and Drug Administration. Center for Devices and Radiological Health. Whole-Body CT Screening – Should I or Shouldn't I Get One at www.fda.gov/cdrh/ct//screening.html (last visited April 6, 2004).
[5] Iles J, Fan E, Koenig BA, Raffin TA, Kann D, Atlas SW. Self-referred whole body CT imaging: Current implications for health care consumers. Radiology. 2003;228:346-351find reference of study
[6] American College of Radiology statement on CT screening exams. Available at www.acr.org/departments/pub_rel/press_releases/total-bodyCT.htm. Accessed March 27, 2003.
[7] Lee TH, Brennan TA. Direct-to-consumer marketing of high-technology screening tests. NEJM. 2002;346:529-531.
[8] Wynia MK, Cummins DS, VanGeest JB, Wilson IB. Should physician manipulate reimbursement rules to benefit patients? JAMA. 2000; 284:1382-3.
[9] CEJA Opinion 8.032
[10] CEJA Opinion 2.19
[11] CEJA Opinion 5.015
[12] CSA Report 10-A-03 and Policy H-425.997, Preventive Services, AMA Policy Database