

SELF-REFERRED WHOLE-BODY COMPUTED TOMOGRAPHY (CT) SCREENING

Introduction

"Whole-body screening is the performance of whole-body CT examinations on otherwise healthy individuals who have no clinical symptoms indicating the need for or justification for the procedures." - Kenneth Miller, Professor of Radiology and Director of the Division of Health Physics at Penn State Hershey Medical Center, Hershey, Pennsylvania, Health Physics Society Newsletter, April, 2002.

Controversy surrounds the benefits versus the risks for whole-body CT screening for individuals who have these procedures without demonstrative clinical symptoms. Additionally, there is controversy involving the proliferation of these screening procedures, without the process of clinical trials being conducted to demonstrate the safety and efficacy of this imaging modality.

Currently whole-body CT screening is being performed, in some cases, via self-referral. Unlike other diagnostic procedures involving ionizing radiation, there does not seem to be any medical or clinical indication necessary for this procedure.

Background

Federal

Food & Drug Administration (FDA): "FDA has not approved or cleared CT systems for any application or indication that involves "screening of individuals" who do not have symptoms or other high risk factors. To my knowledge, there have been no studies that document that the benefits for such screening use of CT outweigh the risks. The approvals that FDA has made to date for CT systems have been under the assumption that the devices were to be used with patients having symptoms and thus there is an appropriate justification for the use of the CT system" (Dr. Thomas Shope, FDA, 2/8/02).

The Technical Electronic Product Radiation Safety Standards Committee has "encouraged the FDA to work with manufacturers to pursue a dose indicator on CT scanners that is appropriately formulated to be consistent with other national and international bodies and that would provide a meaningful dose readout" (minutes from 5/17/01 meeting).

"There are four themes that are involved within the current thinking about recent CT developments: 1) radiological practice, 2) rapid technological change, 3) revision of industry consensus, standards and guidance, and 4) regulations." (Stanley H. Stern, FDA).

"Digital x-ray imaging modalities such as computed tomography (CT), digital radiology (DR), and computerized radiography (CR) do not have the fundamental limitation of overexposure or black films." (Shope)

States

The radiation control programs in all 50 states and New York City were surveyed. With all 50 states and New York City responding, the survey produced the following results.

1. Whole-body screening is being performed in 16 states or 32.6%.
2. Whole-body screening has been requested in 21 states or 42.8%.
3. Whole-body screening has been denied in 9 states or 18.3%.

Rules in at least 5 states do not prohibit screening. The major concerns stated are with high doses and the risk / benefit issue. Also, because of state statute, some states do not have the authority to prevent whole-body self-referred screening.

Organizations

American College of Radiology (ACR): The American College of Radiology "does not believe there is sufficient scientific evidence to justify recommending total body computed tomographic (CT) screening for patients with no symptoms or a family history suggesting disease." The organization says there is no evidence that the procedure is either cost-effective, or effective in prolonging life. www.acr.org/department/pub

American Association of Physicists in Medicine (AAPM): CT Body Scanning Not Scientifically Justified for Asymptomatic Patients 7/18/02. The use of computed tomography (CT) for total body screening of asymptomatic patients has not currently been found to be scientifically justifiable or clinically efficacious. The greatest concerns surrounding this procedure are: (1) that the procedure will lead to the discovery of minor anomalies that have no influence on patient health,

but their identification will lead to added medical examinations with associated risks and unnecessary medical expenses, and (2) the wide-scale use of significant radiation exposures from total body screening CT for a yet unproven screening procedure. Total body CT screening should not be confused with the scientific CT studies of screening for lung cancer in high-risk patients or cardiac scoring to identify calcification in coronary vessels. Scientists in the AAPM will continuously assess the scientific literature as to the efficacy of total body CT screening and make revisions to this policy statement when appropriate.

Conference of Radiation Control Program Directors (CRCPD): CT Scanning resolution of May 8, 2002. www.crcpd.org/medicine/index.html. Additionally, CRCPD has suggested state regulations (SSR's) available for states that wish to develop, or amend, their rules regarding CT under SSR Part F, F.3 (a)(xi), the definition of healing arts screening and its appropriate documentation under appendix B. In Part F,F.3 (a)(xi), it states: "Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix B of this part. If any of the information submitted to the Agency becomes invalid or outdated, the agency shall be immediately notified." www.crcpd.org/publications.asp.

Minnesota Department of Health: "There is evidence that helical CT scanning is more sensitive than conventional chest X-ray, and can detect cancers at an earlier stage. However, there is no evidence that diagnosing and treating lung cancer at an earlier stage can increase survival time or reduce lung cancer-related deaths. Also, helical CT scanning produces more false-positive results than does chest X-ray, which may lead to unnecessary secondary testing causing anxiety, additional medical expense and potential risk to patients." www.health.state.mn.us

American Society of Radiologic Technologists (ASRT): Resolution 02-3.08: The ASRT recommends caution regarding the use of full-body CT screening for healthy clients with no symptoms or risk factors. The performance of condition-specific CT screening should be based on clinical evidence and endorsed by experts in radiation safety and radiologic diagnosis. Further information is needed to evaluate the efficacy, benefits and risks of full-body CT screening" (Advance, July 15, 2002).

American Lung Association: "The American Lung Association believes this is an important study, which may represent a significant advance, and that finding lung cancer early should increase cure rates. However, it is premature for the Lung Association to endorse screening of all at-risk patients with this method."
www.lungusa.org

Society of Thoracic Radiology: "We do not recommend mass screening for lung cancer at this time, but strongly encourage appropriate subjects to participate in trials so that the true effectiveness of lung cancer screening with low-dose helical CT can be determined at the earliest possible time."
www.thoracicrad.org

American Heart Association: "The American Heart Association does not recommend routine (CT screening) use in people without heart-related symptoms unless standard cardiac risk assessment is considered insufficient."
www.quackwtch.com

Mercola: "Food and Drug Administration officials are worried that the growing popularity of full-body scans for early health screening might be exposing thousands of Americans to unnecessary and potentially dangerous radiation." "There is little the FDA can do about it, however. After the agency has approved medical devices for any purpose, it has no authority to regulate their actual use. It cannot stop doctors from using them for full-body scans." "But for people without symptoms, many doctors believe the risks from the radiation more than offset the benefits from the unlikely detection of some type of early cancers or other diseases." "For the average Joe walking in off of the street and getting himself screened from head to toe is probably a bad idea, especially if he isn't in any risk group." - John Cardella (Chief Radiology Department at the State University of New York, Upstate Medical University in Syracuse and FDA advisor. "The scans emit far more radiation than conventional X-rays - a CT scan of the chest delivers 100 times the radiation of conventional X-ray." www.mercola.com

National Cancer Institute: "Because no such standard of care exists for spiral CT scans, participants with suspicious scans will be referred to their primary care physician and advised to consult a specialist for follow-up."
www.cancertrials.nci.nih.gov

Aetna: "These studies documented that helical CT improved the rate of detection of non-calcified and suspicious lesions compared with chest X-ray, and that cancer nodules identified by helical CT were generally at an earlier stage than those detected on chest X-ray. However, the false-positive rates were much higher with helical CT than with chest X-ray, and none of the studies was able to demonstrate a true increase in survival or a decrease in lung cancer-related mortality as a result of helical CT examination." www.aetnaushc.com

Blue Cross: "While the CT scanning improved the detection rate of suspicious lesions, the false positive rates were much higher with helical CT than with chest X-ray. No study was able to document that earlier detection with CT scanning resulted in an improved survival or decreased patient morbidity." "Screening whole body CT scan, i.e., in patients without signs or symptoms disease is considered INVESTIGATIONAL / NOT MEDICALLY NECESSARY." www.medpolicy.bluecrossca.com

Insight: "Because these scans are almost always paid for directly by the patient and rarely by commercial or government insurance, they likely will continue to be private and intimate in the immediate foreseeable future. The decision to have - or not to have - a screening whole-body scan is really a matter of freedom and patient choice," and mostly available to higher income population excluding lower income population availability. www.insightmag.com

Legal Requirements Involving Screening

The self-referred whole-body CT scan is becoming a popular method for the general population to screen for medical problems without consultation or examination of a referring physician. As a result, the industry has exploded, and screening centers are being built in every conceivable area, from shopping malls to mobile units. As this industry grows, the number of potential legal and regulatory challenges has grown, along with the ethical challenges.

The Federal and State Self-Referral Law "strictly prohibits physicians from making referrals for Medicare and Medicaid designated health services (including CT services) to an entity in which the physician, or an immediate family member, has an ownership or investment interest or with which the physician has a

compensation relationship unless an exemption applies. Physician owners in screening centers should make certain that the federal self-referral prohibition is not implicated by their business practices, as they are likely will be if either (1) diagnostic services are combined in the same entity with screening services or (2) a screening service fails to identify that a requested screening service actually involves, for instance, a covered service" (www.arentfox.com ALERT, May 31, 2002).

It may not be enough for a screening center to notify patients that they must pay out-of-pocket, and that Medicare will not be billed. The center must have in place a mechanism to detect when a screening test on a patient who is a Medicare beneficiary is, medically indicated for a purpose other than screening and is therefore a covered service. This may be an incentive for direct involvement by a referring physician.

Additionally, most states have enacted self-referral and anti-kickback prohibitions, and some states even go further in that the prohibitions are more comprehensive than the federal prohibitions. Elsewhere, a number of state prohibitions involve all players and are not confined to services that may be paid to federal health care programs.

"Many states prohibits a corporation from practicing medicine. Thus, a screening center should take care to ensure that its corporate structure complies with any applicable corporate practice of medicine restrictions. Particular concerns can occur when a business entity is used to provide both the technical and the professional (i.e., interpretation) components of the service. A few states appear to take the surprising position that the corporate practice of medicine prohibition can be implicated even when only technical component services are housed in a business entity" (www.arentfox.com ALERT, May 31, 2002).

State medical boards may look at whole-body CT screening more closely than other types of medical centers. Depending on the medical board, these centers may be investigated for engaging in the unauthorized practice of medicine. As a result, of a complaint that screening centers may be screening patients for whom whole-body CT screening scans are contraindicated, they may take the position that licensed physicians must play an active role in authorizing or clearing patients for scans. They must be involved in screening the patient, and adhering to approve

protocols. Various other medical boards may require a physician order prior to a patient undergoing a scan.

Additionally, because screening centers employ radiation producing equipment, the CT screening centers must register the equipment with state regulatory agencies that have jurisdiction over radiation protection or radiological health. Additionally, some jurisdictions require an approved "shielding" plan prior to use of the equipment to ensure that a member of the public will not receive a dose exceeding the regulatory limits of 2 mR/hr or 100 millirem in a year. In some states, criteria for screening is required to be submitted and approved by the regulated body prior to any commencement of screening operations.

Screening centers should be aware that the medical practice statutes and other statutes regulate advertising, as does the Federal Trade Commission. States prohibit advertising that is false, fraudulent, or misleading. Screening centers should be careful when using patient testimonials. In some states, use of patient testimonials is absolutely prohibited.

Some states have specific laws that specify the required content of informed consent forms. Screening centers should determine whether such laws exist in their jurisdiction and write the informed consent forms accordingly.

A number of states have laws that prohibit physicians from engaging in fee splitting. Facilities should ensure that their financial arrangements with physicians who perform professional interpretations comply with applicable state fee splitting laws.

Finally, certain states have a law that prohibits a physician from "abandoning" his or her patients. Screening centers should implement strict policies and procedures, particularly with respect to notifying patients of the results of their studies and the need for further follow-up (www.arentfox.com ALERT, May 31, 2002).

Guidelines

Patient education

Studies have not yet been performed to weigh the benefits and risks of self-referred whole-body CT screening. Currently, a certain percentage of the population present themselves as "asymptomatic," or without family history of disease to facilities who perform whole-body CT screening, and request that they have this procedure performed, without a written physician's order. The Food and Drug Administration or like organizations should aggressively pursue the acquisition and verification of the scanning results from facilities who are in the business of offering these services, and who perform whole-body CT scanning procedures on this type of patient. After adequate data has been submitted, the FDA or like organization, will be in a better position to be able to provide accurate information to members of the public regarding the efficacy of this examination.

Any state screening criteria should include: a) age of patient, b) family history, c) medical history of patient, d) informed consent of the patient and verification that they have been educated in the capabilities and radiation dose of the scanning unit and e) alternate procedures (modalities) available which may be more effective in what is attempting to be examined. Written guidelines for screening criteria for asymptomatic patients must be developed, submitted, and approved by the state or regulatory jurisdiction prior to approval for facilities to perform whole-body CT scanning. The guidelines should also include a statement that informs the patient that the facility has contracted specialists, or to what means the patient can locate a specialist if necessary.

Science uncertainty of benefits versus risks

Prior to the whole-body CT screening procedure, the patient should be provided with written, visual, and verbal information regarding the procedure. If possible, the patient education should be performed prior to the day of the procedure. The written material can be in the form of a pamphlet, the visual can be in the form of a film or tour of the facility and CT scanner, and the verbal can be a professional staff member available to answer patient questions. Patient education must include the methods employed to review the results of the examination with the patient, and should there be findings, the option available for specialist referrals, such as staffed specialists, contracted specialists, or self selected specialists.

Patient demand

The patient demand is dependent upon several factors. Among them are advertising, self-control over their own health, and economics. The only one of these factors that can be influenced is advertising, and the only aspect that can be impacted is "truth in advertising." The advertisements, written, television and radio, must be factual, and neither state or imply anything that cannot be verified. Until the efficacy of this examination has been verified, facilities offering advertised specials such as two for the price of one, should be encouraged to cease such practices.

Recommendations

If a state has no rules or regulatory authority for the oversight and regulation of self-referred whole-body CT screening, the state radiation control regulatory agency is encouraged to pursue adoption and implementation of rules governing this issue. These rules should require facilities to establish criteria for screening and a mechanism to submit the criteria and obtain approval from the radiation control agency prior to beginning screening. Consultation with other regulatory agencies, such as the state Board of Medical Examiners, Department of State, and Department of Health is advisable.

If self-referred whole-body CT screening is already being performed in a state, the state radiation control regulatory agency is encouraged to consult their legal counsel and consider the ramifications of adoption and implementation of rules governing this issue as stated in the paragraph above. The state radiation control regulatory agency should consider factors such as high dose and the need for physician involvement rather than self-referral in their pursuit of initiating rules.

While this may be difficult to require if there are no rules in place, statistics on positive findings, follow-up examinations, surgeries, and pathologies would be beneficial. The state radiation control regulatory agency is urged to consider this in conjunction with screening criteria.

State radiation control regulatory agencies should have programs to educate the general public on the pros and cons regarding screening, i.e., risk of high dose may outweigh benefit.

Considerations

"Controversy remains as to which screening procedures are justified and how proposed screening procedures should be evaluated. Failure to understand basic concepts can lead to unrealistic expectations for screening programs and sometimes to inefficient use of resources" (AAFP, 2001).

Ethical questions

We must recognize that the fundamental purpose of screening is the reduction of morbidity and mortality. And that being the case, whenever increased outcomes cannot be concluded, the justification for screening would become suspect. "Early diagnosis by itself does not justify a screening program. The only justification for a screening program is early diagnosis that leads to a measurable improvement in outcome" (Thomas J. Gates, MD, AAFP article). What then determines the validity of CT screening?

First and foremost is the issue of ethics. "Science has set before us decisions of immense consequence. We can pursue medical research with a clear sense of moral purpose, or we can travel without an ethical compass into a world we could live to regret . . . Advances in biomedical technology must never come at the expense of human conscience. As we seek what is possible, we must always ask what is right, and we must not forget that even the most noble ends do not justify any means" (President George W. Bush, April 10, 2002).

"Once technology advances, it can be difficult to limit its use" (Advance, April, 22, 2002). For all of technologies advances, there is but one thing that technology cannot promise, and that is reassurance! A CT image can discover an image of something harmful, or it may not, and in addition, it may find something that no one can be cured of. The backlash of this ethical issue may result in increased anxiety for normally healthy individuals. There is harm in pronouncing false assurance. "Only extensive research will determine the true value of CT screening." Until definitive results are available, are medical professionals doing more harm than good by screening patients who demand it (and pay for it)" (Advance, Vol. 12, No. 8, August 2002)?

In considering the question of ethics there is the matter of bias, of which there are three to take into account. These biases will confuse the situation even

further whenever the disease is diagnosed via screening within the asymptomatic period. On the surface the screening study results look positive. Yet when one begins to dig deeper into the study, the generally assumed "early diagnosis improves survival concept" can appear to bear truth, even though it is learned that the proscribed remedy is essentially worthless. Therefore, the first bias occurs whenever subjects who have volunteered for a screening (with specific screening requirements) tend to be healthier, and would therefore have a much lower mortality rate than those who do not fit the controlled study conditions. In this scenario, we must conclude that any perceived benefit may be the result of selection of the cohort, and not screening itself.

The second bias occurs when the asymptomatic period mentioned previously, is not taken into account. This is known as lead-time bias. In effect, the timing of the diagnosis is omitted. This gives the perception that screened patients are living longer, when in actuality, they are only discovering their diseases at an earlier time within the natural history of the disease. The real effect of this bias is that the patients are not blessed with extra years of life, but extra years in reverse of the disease. The only way to avoid this bias is to contrast actual mortality rates in both the screened and unscreened cohorts, in that the mortality rates will not be influenced by the timing of diagnosis.

Lastly, there is the bias known as length-time. In this situation the length of growth time of the cancer is not considered. Some cancer patients will possess a fast-growing, aggressive form of tumors within a short asymptomatic time frame and rapid succession from symptoms to death. Others may have the complete opposite with a less likely prevalence of metastasis, thereby indicating a much better prognosis. These types of tumors may possess a longer asymptomatic period, and would most likely be identified in a screening program. This form of screening program gives one the appearance of improved survival, when in actuality it has only selected the best cohort with the best prognosis.

Another ethical issue has just emerged on the radar screen in the form of "patient abandonment." This occurs whenever the physician-patient relationship has been established, whereby in this case, the reading of a patient's exam would constitute the initiation of such a relationship. "One issue is the transfer of care where there needs to be a transfer of care" (William Sarraille, Esq., *Advance*, September, 2002). In short, providers are obligated to follow up on their patients,

or at the very least, ensure that they are properly referred. The patient's exam must be forwarded to specific providers, or the physician risks a claim of malpractice.

Anxiety

As stated previously, screening revolves around the premise that it is more beneficial to discover an abnormality prior to the appearance of a symptom, thereby decreasing the development of disease and the death rate. In essence, the screening becomes a "clean bill of health," or "we caught this in time" scenario, neither of which can actually be substantiated. What "medical professionals must discern is whether earlier detection with CT screening . . . actually improves outcomes or simply turns people into patients for longer portions of their lives" (B. Kramer, MD, *Advance*, Vol. 12, No. 8, August 2002). In short, does this place the patient in the revolving door of unknown numbers of ultimately unnecessary tests and / or surgeries, along with the anxieties that accompany them?

Misdiagnosis

Next comes the issue of the risk of misdiagnosis. In typical screening tests conducted on a specific cohort of people with similar physical conditions, benefits have been proven even if only to a small few. Conversely, for those involved in a self-referred screening test within multiple cohorts with no apparent physical condition, individuals expose themselves to harmful risk in many different manners. Never mind the obvious in terms of financial cost to the patient and the possibility of discomfort (claustrophobia), what is of significant importance is the harm of a misdiagnosis in the form of a false-positive outcome, i.e., the diagnosis that a tumor is evident, when in fact one may not be present. "It's possible that screening picks up a kind of cancer that medicine has never encountered - the harmless kind." Overdiagnosis involves diagnosing tumors that under a microscope and to most pathologists will appear like a cancer, but whose behavior is not what we think of as malignant. In other words, people would die with it rather than die of it" (B. Kramer, MD, *Advance*, Vol. 12, No. 8, August 2002).

For all practical purposes, screening for diseases typically produces a low prevalence of the disease, and would therefore equate to a low positive predictive value. In turn, this would indicate that most positives would in fact be false positives. Over time, these false positives induce additional heightened anxiety and increased exposure due to additional, unnecessary tests. Now add to this the

situation involving false-negatives, whereby the reporting that a CT screening has concluded no abnormalities, wherein these results can be just as harmful as false-positives. In this situation, giving a patient a "clean bill of health," could deter the patient from seeking medical help whenever a symptom does appear. Neglecting a medical health symptom in this particular case is similar to psychologically denying the existence of the known health problem.

Unnecessary exposure

Finally, there is the ill-forgotten, oft-avoided topic of radiation exposure. "In conventional x-ray procedures, medical personnel can tell if the patient has been overexposed because the resulting film is overexposed, producing a dark image. However, with CT, there are no obvious evidences that the patient has been overexposed due to the fact that the quality of the image may not be compromised." (K.A.Jensen et.al, Applied Radiation and Isotopes 50 (1999) pages 165-172).

"While the benefits of computed tomography (CT) are well known in diagnosing diseases and trauma and in the guidance of interventional and therapeutic procedures, those benefits are not without risks." (FDA Public Health Notification: "Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients 11/01).

By exposing healthy, asymptomatic people to ionizing radiation, we increase the risks of exceeding the threshold of individual cancers, no matter how low the advertised statement may espouse. Couple that with people who have an over-protective, almost paranoiac temperament, and you end up with a segment of society who will want to get these exams on an annual or biennial basis. Over time, what occurs is exposure to a very significant amount of radiation, that in and of itself unnecessary!

Consider the following information. The relative contribution of CT to the dose per capita has increased. CT exposure accounts for about 3-4 percent fraction of all medical x-ray examinations, but more importantly, this exposure contributes to an estimated 40 percent of the total radiation dose to the population (K.A.Jensen et.al. Applied Radiation and Isotopes 50 (1999) pages 165-172).

Conclusions

- **Until large scale clinical trials have been performed and analyzed thoroughly and effectively, insufficient scientific evidence exists for the efficacy and safety of the self-referral whole-body CT process. Unnecessary radiation exposure during medical procedures should be avoided at all costs.**
- **Whole-body Computerized Tomography should only be administered when specifically ordered by a licensed practitioner of the healing arts, and in conjunction with specific symptoms and corresponding data.**
- **"The bottom line is, until we have specific evidence that these studies are beneficial to the asymptomatic population, they should not be done" (Garth A. Koniver, MD, FACR, Papastavros' Association Medical Imaging LLC, Wilmington, DE, Advance, August, 2002).**

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