

Radiation Exposure From Medical Imaging

Time to Regulate?

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THE AVERAGE RADIATION DOSE TO WHICH PERSONS IN the United States are exposed has doubled over the past 30 years.^{1,2} Although the average dose from natural background sources has not changed, the average radiation dose from medical imaging has increased more than 6-fold.^{1,2} Medical imaging now contributes about 50% of the overall radiation dose to the US population, compared with about 15% in 1980.²

The largest contributor to this dramatic increase in population radiation exposure is the computed tomography (CT) scan. In 1980 fewer than 3 million CT scans were performed, but the annual number now approaches 80 million and is increasing by approximately 10% per year.² Because CT scanning involves acquiring multiple images, CT scans result in a far larger radiation dose to the patient than most other common radiographic procedures such as chest x-rays or mammograms. Although CT is responsible for most of the rapid increase in population exposure from medical imaging, other radiographic imaging and nuclear medicine procedures are also increasing rapidly, particularly in cardiology.² Newer radiographic imaging modalities such as positron-emission tomography CT (PET/CT), single-photon emission CT (SPECT/CT), and, potentially, CT screening of asymptomatic patients are likely to increase the population radiation exposure still further.

This increase in radiological imaging and nuclear medicine certainly has revolutionized medical practice in a fundamental and highly beneficial manner. However, like almost all medical procedures, medical imaging has benefits and risks, and the goal is to provide the public with the optimal benefit/risk balance.

The risks associated with radiation doses typical of CT scans are not yet fully quantified, but there is persuasive evidence, at the doses relevant to CT, that the risks of radiation carcinogenesis are real, although small for any individual.³ The concern arises when an increasingly large population is exposed to small individual risks.¹ Regardless of the actual magnitude, these population risks would undoubtedly be reduced if radiation doses were optimized for each procedure and if medically unnecessary imaging were minimized.

Although it is impossible to imagine contemporary medicine without modern medical imaging, there are serious issues of quality control, training, and, particularly of overutilization that can best be addressed through national legislation. In fact, radiation exposure from medical radiographic imaging is comparatively unregulated; this is in striking contrast to radiation exposure in occupational settings, which is stringently regulated despite it contributing a far smaller population exposure.

The current US situation is that quality control and quality assurance for x-ray machines and facilities are the responsibility of individual states, and a variety of different standards and rules are in place; accreditation programs, through the American College of Radiology, are currently voluntary. With a single exception, US federal agencies have no legislative authority to regulate usage of x-ray devices. The exception is the 1992 Mammography Quality Standards Act (MQSA), which regulates quality standards at all US mammography facilities. While mammography is an important component of the radiological imaging armory, it contributes much less than 1% to the overall population dose from medical imaging.

This patchwork of regulations in the United States stands in contrast to the situation in Europe, where a uniform European medical exposure directive was introduced in 1997, providing wide-ranging requirements that each member state must implement. Should the United States move in this direction or is the current status quo adequate?

There are several issues that need to be addressed to optimize the benefit-risk balance for medical imaging. The first is quality control and assurance. Recent incidents in which several hundred patients received radiation overdoses from CT scans⁴ suggest that quality control is, at the least, uneven in US medical imaging facilities. Moreover, radiation doses from identical CT procedures can vary by as much as 10-fold from facility to facility.⁵ Some recent initiatives by the US Food and Drug Administration,⁴ as well as by the American College of Radiology and the Radiological Society of North America, are designed to improve medical imaging quality control. However these initiatives are largely

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voluntary, and we can learn here from our experience with mammography in the 1990s; specifically, the MQSA legislation was designed to require regulatory compliance with what previously were voluntary quality control and accreditation standards. Mammography quality control has significantly improved since the MQSA was mandated,⁶ and it therefore represents a regulatory paradigm that should be seriously considered for all medical imaging facilities.

A second issue is training. In the United States, no special training is required for any physician to prescribe any diagnostic radiographic examination. Yet the amount of radiological training in medical school curricula is very limited. Moreover, as new imaging modalities are introduced, there is no mechanism for ensuring that practitioners are trained in their use. Analogous to provisions in the mammography legislation, it should be mandatory that practitioners associated with radiological imaging, from the prescribing physician, to the interpreting physician, to the physicist, to the technologist, should receive continuous education specifically on modern imaging techniques.⁷

The third and potentially most problematic issue is overutilization of medical imaging. This is a particular concern for CT, and because CT is the largest contributor to the population dose from medical imaging, overutilization is a major contributor to unnecessary population radiation exposure. Clinically appropriate CT scanning has particularly benefited diagnosis and management of trauma and of cancer, and has a major role in cardiology and neurology. But there is convincing evidence that a substantial fraction of the approximately 80 million CT scans currently performed each year in the United States are performed without good medical justification. The quantitative evidence comes largely from comparing actual CT use patterns with those that would be expected if appropriate clinical decision guidelines were followed. Several previous studies (eg, references^{8,9}) suggest that 20% to 40% of CT scans could be avoided if clinical decision guidelines were followed.

Reducing the number of CT scans that are not clinically justified is difficult because a variety of pressures are pushing in the other direction including legal and economic considerations, as well as patient preference. One approach that successfully increased use of CT decision guidelines has been to incorporate them into the computerized systems used by physicians to order CT scans.¹⁰ Although more quantitative studies on computerized decision support in the context of imaging are needed, the available evidence suggests that if decision guidelines are universally provided to physicians at the time of ordering a CT, and CT ordering pat-

terns are regularly audited, the frequency of clinically unnecessary CT scans can be significantly reduced. Of course, specific guidelines, which will change with time as clinical evidence accrues, cannot and should not have the status of law, nor must the profession start down the road toward cookbook medicine with mandatory protocols. However, access to and consideration of current imaging guidelines as support for the physician's imaging decisions could be and should be mandatory.

Introducing legislative fiats into clinical medicine should not be undertaken lightly and other alternatives such as tort reform and payment system reform should be considered in parallel⁷; however, the compelling and continuing issues of quality control and overprescribing in medical imaging do need to be addressed. Voluntary standards have not been ineffective, but the positive mammography experience in transitioning from voluntary to mandatory standards demonstrates that legislation can be much more effective in improving quality control. It follows that legislation would also be effective in reducing the current high level of medically unwarranted imaging studies.

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REFERENCES

1. Brenner DJ, Hall EJ. Computed tomography: an increasing source of radiation exposure. *N Engl J Med*. 2007;357(22):2277-2284.
2. Mettler FA Jr, Bhargavan M, Faulkner K, et al. Radiologic and nuclear medicine studies in the United States and worldwide: frequency, radiation dose, and comparison with other radiation sources—1950-2007. *Radiology*. 2009;253(2):520-531.
3. Brenner DJ, Doll R, Goodhead DT, et al. Cancer risks attributable to low doses of ionizing radiation: assessing what we really know. *Proc Natl Acad Sci U S A*. 2003;100(24):13761-13766.
4. US Food and Drug Administration. White paper: initiative to reduce unnecessary radiation exposure from medical imaging. <http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199994.htm>. Accessed June 20, 2010.
5. Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Arch Intern Med*. 2009;169(22):2078-2086.
6. Destouet JM, Bassett LW, Yaffe MJ, Butler PF, Wilcox PA. The ACR's mammography accreditation program: ten years of experience since MQSA. *J Am Coll Radiol*. 2005;2(7):585-594.
7. Amis ES Jr, Butler PF, Applegate KE, et al; American College of Radiology. American College of Radiology white paper on radiation dose in medicine. *J Am Coll Radiol*. 2007;4(5):272-284.
8. Lehnert BE, Bree RL. Analysis of appropriateness of outpatient CT and MRI referred from primary care clinics at an academic medical center: how critical is the need for improved decision support? *J Am Coll Radiol*. 2010;7(3):192-197.
9. Kuppermann N, Holmes JF, Dayan PS, et al; Pediatric Emergency Care Applied Research Network (PECARN). Identification of children at very low risk of clinically important brain injuries after head trauma: a prospective cohort study. *Lancet*. 2009;374(9696):1160-1170.
10. Sistrom CL, Dang PA, Weilburg JB, Dreyer KJ, Rosenthal DI, Thrall JH. Effect of computerized order entry with integrated decision support on the growth of outpatient procedure volumes: seven-year time series analysis. *Radiology*. 2009;251(1):147-155.