Federal Oversight of Medical Radiation Is on Horizon as Experts Face Off

By Renee Twombly

Recent scientific articles on the cancer risk of computed tomography (CT) imaging, combined with a series of New York Times articles, seem to have led to a tipping point in a field that has been largely self-regulated up to now. A hearing in the House Committee on Energy and Commerce February 26 opened the door to federal oversight of medical radiation.

At the House hearing, witness after witness made the point that most people who operate such machines—technicians, physicists, dosimetrists, and others—do not need to be licensed in most states and that accreditation of facilities is currently voluntary. What’s more, they said, training is lax even as machines become more and more complex.

“In some states, hairdressers are better regulated than people who perform medical radiation technologies,” testified Sandra Hayden, a member of the Board of the American Society of Radiologic Technologists. She said that in 17 states, technicians do not have to be licensed and that no state licenses medical dosimetrists, who design radiation therapy plans. Michael Herman, Ph.D., representing the American Association of Physicists in Medicine, said that only four states license medical physicists, the specialists responsible for delivering safe and accurate imaging and radiation therapy. Most states don’t require reporting of either human or machine errors in medical radiation procedures.

“Even in states where there are licensing requirements, the requirements to report errors and the penalties for making errors are basically nonexistent or not enforced,” said Rep. Frank Pallone Jr. (D-N.J.), chairman of the Health Subcommittee, which held the hearing. “As a result, we have no idea how often these errors occur and have no good data on where the weaknesses in the system truly are.”

Saying that the committee’s job is to lower the risks associated with medical radiation, Pallone asked for a show of hands among the 10 expert witnesses, who represented radiologists, technicians, radiation oncologists, equipment manufacturers, and others. He asked how many believe that federal oversight isn’t called for. No one responded.

But outside the hearing, some in the field worried about the shape that oversight could take, suggesting that strict regulation might stymie innovation while adding bureaucracy and cost. The American College of Radiology (ACR) and two other groups, the Medical Imaging and Technology Alliance and the American Society for Radiation Oncology, have recently unveiled new patient safety programs, or called attention to existing ones, which some say make the federal rules unnecessary.

Rising Exposure . . .

The two sides to the debate—federal regulation versus private-sector training and quality programs—are sharply divided, but all agree that medical radiation exposure in the U.S. is growing rapidly. Since the Mayo Clinic purchased the first CT scanner in the U.S. in 1973, exposure has dramatically increased, much of it from CT imaging (see Stat Bite). A March 2009 report by the National Council on Radiation Protection and Measurements estimated that 67 million CT scans occurred in the U.S. in 2006, along with 18 million nuclear medicine procedures, such as positron emission tomography, and 17 million interventional fluoroscopy scans. The increase in the U.S. has been much greater than anywhere else in the world. Currently, one in five people in the U.S. undergoes a CT scan each year, according to a 2008 study by the Government Accountability Office.

Given this increase, scientists have attempted to quantify the health risks, including studies on whether radiologic procedures—one or repeated tests—might spur cancer development. These studies have centered on CT scanning, which, because it takes a series of cross-sectional X-rays to compile a three-dimensional picture, delivers a relatively large dose of radiation.

In 2006, the National Academy of Sciences’ National Research Council concluded that even the smallest dose could cause a small increase in risk to humans. However, the report also said that below a certain threshold (about 10 CT scans), the exact risk is difficult to determine from existing data. The report’s lifetime risk model estimated that approximately one person in 100 would be expected to develop cancer (solid or leukemia) from one relatively low dose of medical radiation, whereas approximately 42 of the 100 individuals would be expected to develop these cancers from other causes. The researchers add, however, that because of data limitations, risk estimates could be a factor or two larger or smaller.

Also, a 2007 study in the New England Journal of Medicine (NEJM) estimated that up to 2% of all cancers in the U.S. may be attributable to radiation from CT studies. Another NEJM study in August 2009 sought to estimate the number of people who might receive radiation doses from diagnostic imaging at a level that would cause concern in an occupational-health setting. The authors, led by cardiologist Reza Fazel, M.D., of Emory University in Atlanta estimated that about 4 million Americans each year receive radiation doses higher than moderate.

In an editorial in the same NEJM issue, Michael Lauer, M.D., at the National Institutes of Health said that large-scale, randomized trials should be conducted to figure out which imaging procedures yield net benefits. “Overall, we must conclude that with a few exceptions, such as mammography, most radiologic imaging tests offer net negative results,” he wrote.

. . . and Overdoses

Then, in December 2009, the Archives of Internal Medicine published two studies look-
ing at dosage variations as well as estimates of cancer risk. One study, led by Rebecca Smith-Bindman, M.D., a professor at the University of California, San Francisco, and a visiting scientist with the National Cancer Institute’s Radiation Epidemiology Branch, looked at radiation dose from CT scanning on more than 1,000 patients at four hospitals, which used equipment from the same manufacturer.

She found that dose varied dramatically between patients who received the same kind of scan, whether or not it was at the same institution. “For example, we found that one patient had 20 times the radiation dose as another patient for a routine heart CT when both studies were done at the same institution,” she testified at the House hearing. The mean variation between the lowest and highest radiation doses was 13-fold, she said. Some of this effect is due to patient size, but many machines also use higher doses to produce clearer images than what is really needed. “Most of the machines can be ‘programmed’ to give [a] much lower dose and unfortunately it takes a lot of work, as well as guidelines regarding what are appropriate, to make it happen,” Smith-Bindman said. “We could lower the dose tomorrow by 30%–50% if we have the will or motivation to do so.”

The researchers also found that for some patients, the risk of developing cancer from one test could be as high as one in 80.

In the same issue of *Archives*, Amy Berrington de González, D.Phil., also of NCI, used National Research Council data, among other sources, to estimate that approximately 29,000 future cancers and 14,500 cancer deaths could be expected to be caused by the 72 million CT scans
performed in the U.S. in 2007. “There are so many scans now that even a small individual risk can result in . . . a reasonable risk at the population level,” she said.

“Things have gotten out of hand,” said Archives editor Rita Redberg, M.D., a cardiologist at UCSF, who wrote an accompanying editorial. She said the fact that every day, more than 19,500 CT scans are performed, subjecting each patient to the equivalent of 30–442 chest radiographs per scan, is creating “a public health time bomb.”

Just as these studies were emerging in late 2009, the New York Times was publishing a series of stories that documented the fragmented oversight that exists over both diagnostic and therapeutic medical radiation. Reporters told the stories of two patients who died after receiving extremely high doses of radiation from linear accelerators, deaths that might not have occurred if technologists and others responsible for the operation of the devices had been paying attention. They also documented other cases of overdose.

Oversight Options

Now, the question before the House subcommittee is how involved Congress should be in regulating medical radiation. A spectrum of options exists. At one extreme, federal control could supersede state rules. For example, Congress could task the U.S. Food and Drug Administration with regulating the practice of medical radiation, a decision that has some precedence. In 1992, Congress passed the Mammography Quality Standards Act, which required the FDA to inspect and certify mammography facilities to ensure safety and reliability. The ACR carries out that accreditation.

At the other end, Congress could decide to rely on improved educational and quality programs that the professional groups are developing. For instance, ACR is addressing safety issues and will start credentialing more radiology facilities, said James Thrall, M.D., chair of the ACR Board of Chancellors. And recently, the Medical Imaging and Technology Alliance has promised to safeguard radiation doses, and the American Society for Radiation Oncology has issued a “six-point patient protection plan” to improve safety and quality and reduce the chance of medical errors.

Middle-of-the-road options are also possible. One is passage of the CARE (Consumer Assurance of Radiologic Excellence) bill, requiring that technicians be licensed, which has been before Congress in one form or another since 2000. Another is to see how things might change under the Medicare Improvements for Patients and Providers Act of 2008, which requires that, beginning in 2012, advanced diagnostic imaging services be accredited if they are to receive Medicare reimbursement. The law, however, applies only to nonhospital facilities, and although the units would be subject to accreditation, licensing of personnel who work there would depend on state rules.

Another option is to see what emerges from an FDA initiative, issued several weeks before the House hearing, to reduce radiation exposure from three types of imaging procedures, including CT (but not therapeutic radiation). The FDA said it will quickly convene meetings to figure out how to use its “regulatory authority judiciously” while also collaborating with the health care professional community to promote safe use of medical imaging devices. The first such meeting, held in late March, explored steps that device manufacturers could take to reduce unnecessary exposure. Later the FDA said it would no longer use a streamlined approval process for new devices.

Simon Choi, Ph.D., at the FDA’s Center for Devices and Radiological Health, said that one option would be requiring manufacturers of CT scanners and fluoroscopic devices to build safeguards into their machines as well as provide better training to users of their equipment, steps that the Medical Imaging and Technology Alliance promised it would pursue shortly after the FDA’s announcement of its initiative and just before the House hearing. The Alliance also endorsed other steps, such as a dose checks for machines, warnings when doses are exceeded, and recording of doses.

Choi pointed out that several programs that ACR and other professional associations have developed could help reduce dosage overall. Among them are the Image Gently (pediatric) and Step Lightly (adult) campaigns, designed to increase awareness of ways to reduce radiation dose.

The debate will certainly intensify. On one side are those who are adamantly in favor of regulation. “There is no question now that radiation causes cancer in humans,” said Fred Mettler Jr., M.D., a professor of radiology at the University of New Mexico and the U.S. representative to the United Nations Scientific Committee on the Effects of Atomic Radiation. “And if the FDA approves toxic drugs, it makes sense they should look at carcinogens from medical radiation.”

And from the other side: “Passing laws doesn’t do anything; the real issue is education: when radiographic studies are appropriate and how to do them correctly,” argues Elliot Fishman, M.D., a professor at Johns Hopkins who also heads diagnostic imaging and body CT at Johns Hopkins Hospital.

Cynthia McCollough, Ph.D., from the Mayo Clinic in Rochester, Minn., took a more moderate position at the House hearing, speaking about the need for “nationally prescribed, minimum levels of training and competency,” regardless of who formulated the standards.

Still, McCollough said in an interview, although she has devoted her career to acting like a “dose cop”—finding ways to reduce radiation doses—she now feels the need to defend the technology from what she describes as a “feeding frenzy.” “It’s not science anymore but a religion: whatever nuances and complexities there were before to medical imaging have been lost,” she said.

© Oxford University Press 2010. DOI: 10.1093/jnci/djq148