

# Increasing Efforts to Regulate Computed Tomography Scans

By Charlie Schmidt

In 2009, Cedars–Sinai Medical Center in Los Angeles disclosed that 206 patients had been severely overdosed with radiation while receiving perfusion computed tomography (CT) scans of the brain.

That debacle catalyzed a California law that now represents the first effort to regulate U.S. CT scans. Dubbed SB-1237, with an effective date of July 1, 2012, the law directs hospitals in California to record the dose of every CT scan they give in an electronic archive for annual review by a health physicist. And as of July 1, 2013, any facility that offers CT scans will need accreditation from the Centers for Medicare and Medicaid Services (CMS), a CMS-approved body, or the state department of public health. Also, repeat CT scans that exceed certain specified dose levels will have to be reported to California health officials.

Texas, Florida, and New York are also considering similar legislation, because apart from mammography, which falls under the 1992 Mammography Quality Standards Act, radiation doses from medical imaging in the U.S. aren't subject to evidence-based guidelines or standard protocols.

But CT scans raise the most concern because they deliver 10–500 times more radiation than most other types of radiography. Although the Cedars–Sinai situation was anomalous, overdosing episodes elsewhere have since been disclosed, and experts worry that even typical CT doses can be unpredictably high. “You could get a CT scan at one facility, and the radiation dose could be a 10–100 times higher than it would be somewhere else,” said Rebecca Smith-Bindman, M.D., a radiologist and professor at the University of California's Helen Diller Family Comprehensive Cancer Center in San Francisco.

## What's the Risk?

CT scans improve medical care in many clinical situations, so any discussion of their risks must also consider their benefits. Still, the number of U.S. CT scans went from 3 million in 1980 to 80 million in 2010, costing hundreds to several thousand dollars each. Up to 30% of these scans probably aren't medically necessary, according to David J. Brenner, Ph.D., director of the Center for Radiological Research at Columbia University Medical Center in New York. Meanwhile, CT scans account for more than one-third of the U.S. population's total exposure to ionizing radiation, which can break chemical bonds in DNA and produce mutations leading to cancer.

That CT scans cause a substantial number of cancers isn't clear; prospective studies of that risk are still under way. Scientists rely on statistical modeling and estimate the risk by using dose–response models derived from other exposed groups, such as atomic bomb survivors or nuclear power plant workers. Using that approach, Amy Berrington de González, D.Phil., a senior investigator in the National Cancer Institute's Radiation Epidemiology Branch, predicted that up to 29,000 additional cancers could result from CT scans given over a single year in the U.S. The *Archives of Internal Medicine* published her results in 2009.

In that same issue, Smith-Bindman published a study of modeled risks to individuals. Women in particular—who tend to be more sensitive to radiation than men—could develop cancers at rates ranging from one for every 270 coronary angiography CT scans to one for every 8,100 routine CT scans of the head (the brain is not especially radiosensitive). Developed for

40-year-old women, those estimates double for 20-year-old women.

## Dealing With Doses

Smith-Bindman's estimates assume that cancer can occur from radiation doses as low as 10 mSv (millisieverts), and estimates of risk at these low levels are not universally accepted. The millisievert is an international dose unit that tries to account for radiation's biological effects on human tissue, as opposed to an alternate unit called the Gray, which reflects only the absorbed dose of radiation. Some experts dispute that cancer can result from doses so low, however, giving rise to a long-standing debate.

“In my view, radiation epidemiology has not convincingly demonstrated risks at organ doses below 100–150 mSv,” said John D. Boice Jr., Sc.D., a professor at Vanderbilt University School of Medicine and scientific director of the International Epidemiology Institute in Rockville, Md. The debate centers on whether a threshold dose exists, below which radiation carries no danger.

Meanwhile, organ doses are the “gold standard” for this type of research, but calculating them requires considerable effort. CT doses are more often described in other ways that don't account for the absorbed fraction of radiation. The most common metric is the

CT dose index (CTDI), which describes only the amount of radiation that machines emit during one scan, not the amount that enters the body. Another metric, the dose-length product (DLP), combines all the scans from



Michael McNitt-Gray, Ph.D.

an examination into one value. The lack of a consensus metric, combined with institutions' different imaging protocols, makes defining CT dose averages hard for particular indications, according to Michael McNitt-Gray, Ph.D., a professor of radiological

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sciences at UCLA. “If you were to ask, ‘What’s the average radiation dose for a head scan in the U.S.?’ the answer would be, ‘We don’t know,’” McNitt-Gray said.

### **Spotlighting Variation With Registries**

That variation in dosing helped drive the American College of Radiology (ACR) to create the first-ever U.S. CT registry, which launched last May after a 4-year pilot project. Known as the CT Dose Index Registry, it allows

technicians to upload anonymized patient information and dose data (expressed both as CTDI and DLP) from the CT machine to a centralized database. The database includes 850,000 scans and counting. In turn, the registry supplies reports and graphs that let hospitals compare their doses with those used elsewhere.

“That way, if a facility sees that its values are higher than what other hospitals are using, they’ll know they’re overradiating and vice versa,” explained Richard L. Morin,

Ph.D., the registry’s director and a professor at the Mayo Clinic in Jacksonville, Fla. “What we hope is that as hospitals become more aware of where they lie in this distribution, the dose ranges will decrease.”

The ACR also champions other voluntary programs to reduce doses. Its Image Gently campaign, for instance, supplies educational materials focused on reducing CT doses in children. But if the ACR programs have a limitation, it’s that they focus too much on

optimization, or the goal to get the best image at the lowest possible dose, said Donald L. Miller, acting chief of the diagnostics devices branch at the U.S. Food and Drug Administration. They don't emphasize enough the broader issue of justification, which looks at when CT scans are really needed. Both optimization and justification must be addressed to lessen radiation risks from medical imaging, Miller said. "What's more, nonradiology facilities probably won't join a registry run by the ACR," he added.

Aiming to win broader participation, the FDA recently partnered with CMS on a symposium that looked at what a national CT registry might look like. The National Academy of Sciences hosted the symposium in December 2011; a report summarizing its conclusions is expected soon. In Miller's view, a national registry should tackle optimization and justification, as well as research and individual risk assessment for specific patients. Patient-specific assessments are controversial—privacy becomes an issue, if doses must be recorded in identifiable ways, and so do scientific issues surrounding dose additivity, or the way in which cancer risks might increase with repeated CT scans.

For facilities to determine whether they're adequately minimizing radiation risks, Smith-Bindman recommended that they review

doses with all their patients, not just a select few. The National Quality Forum, which sets performance benchmarks for U.S. hospitals and clinics, recently accepted her recommendation as a formal measure. However, the FDA, the Society for Pediatric Radiology, and other groups unsuccessfully appealed against that decision, claiming that although the measure's goals are laudable, its implementation would be flawed—partly because hospitals lack the infrastructure to qualify doses by each patient's physical features. For instance, the radiation dose of a CT scan given to a morbidly obese person might be four times higher than that of the same scan for someone of healthy weight and height. And anyone who reviewed the dose data without that added information might think the higher dose had been given inappropriately.

Other issues apply for identifiable patient-specific registries—also floated at the symposium—that might empower individuals to track their own doses. (The California law does not mimic a patient-specific registry, said McNitt-Gray, in part because it doesn't compel hospitals to release dose information to patients who might request it.) The FDA explored patient-specific records during the 1970s, when it issued wallet cards into which patients could enter their exam history. But that

idea never caught on with the public, Miller said, and a centralized database would be preferable for data retrieval anyway. Such a database would require comprehensive electronic medical records that currently aren't available.

Some who attended the National Academy of Sciences meeting claimed that it ended in disarray, without consensus. "I know what's going to appear in the report," one source said. "No strong recommendations at all."

But McNitt-Gray disagreed, arguing that this conclusion implies that the meeting had some specific goal apart from fostering dialogue. "The white paper that comes out of this will reflect the current diversity in opinion," he said. Meanwhile, sources also worry that the rather alarmist media coverage on CT risks has produced some troubling consequences.

"We're hearing of patients who refuse CT scans for themselves or their children out of fears of radiation risks that are actually small for individuals," McNitt-Gray said. "On the other hand, we're examining our protocols and thinking more about how to use the least amount of radiation possible, even if we still haven't figured out exactly how. So it's a good thing we're having these conversations."

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