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## FDA addresses radiation safety

**The agency aims to protect patients from unnecessary exposure, with safety controls on medical devices and development of more precise dosing standards.**

By Andrew Zajac and Alan Zarembo

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Reporting from Los Angeles and Washington

The Food and Drug Administration has decided to impose new safety controls on medical imaging devices and encourage development of more precise dosing standards in a bid to reduce unnecessary exposure of patients to diagnostic radiation.

The agency also will promote a personal medical imaging history card that will enable patients to keep track of the number of images, and the amount of radiation, they receive over time, according to a medical imaging safety initiative unveiled Tuesday.

The safety push comes months after Cedars-Sinai Medical Center in Los Angeles discovered that it had accidentally exposed more than 260 patients to eight times the normal dose of radiation for CT brain scans over a period of 18 months.

Two other Los Angeles County healthcare facilities -- Providence St. Joseph Hospital in Burbank and Glendale Adventist Medical Center -- and one hospital in Huntsville, Ala., reported possible overdoses by imaging equipment to at least 104 people.

"We're aware that the exposure of the American public to [diagnostic] radiation was increasing fairly dramatically over the past 20 years," said Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health. "These tests can provide tremendous medical benefit. We're trying to optimize that benefit while lowering the risk."

The FDA will hold a public meeting March 30 and 31 to collect suggestions about new safety features and training that should be required for CT and fluoroscopic devices, Shuren said.

Equipment might be automatically calibrated to a recommended dose for a given procedure, so that any dosage increase would require an action by the operator. Equipment might also be designed to require



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identification of the operator as a way of tracking errors.

Shuren said regulators also are looking at software upgrades and other fixes to existing equipment.

In addition, the FDA is encouraging the development of a voluntary national database to determine the optimal dosages for a given procedure, fine-tuned to variables such as age and body type. Such a database also would allow individual practitioners to measure their use of radiation against that of their peers, Shuren said.

The FDA effort will build on data gathering already underway by the American College of Radiology and the National Council for Radiation Protection.

Some medical radiation experts questioned whether the FDA went far enough.

Requiring scanner manufacturers to add safeguards to their machines would have prevented the CT overdoses at Cedars-Sinai Medical Center, said David Brenner, director of the Center for Radiological Research at Columbia University Medical Center. But "it doesn't address what I see as the central issue: too many CT scans being done without medical justification," he said.

The number of CT scans performed in the U.S. each year has climbed to more than 70 million, more than triple the number in 1995.

The trend is driven by a variety of factors, including economic incentives for doctors and hospitals to order tests, and doctors' fear of being sued if they miss a problem.

CT has become standard procedure in emergency rooms for diagnosing head injuries, kidney stones and appendicitis. Scans are often repeated as part of routine follow-up or if a patient is transferred.

Shuren said the FDA was not directly addressing the question of medical justification because "it's really outside FDA's scope." But Shuren pointed out that putting imaging history cards in the hands of patients will call attention to previous exposures to diagnostic radiation.

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