Radiation From Imaging a Growing Concern

BY KERRI WACHTER

Medical imaging exposes a significant portion of patients to various doses of ionizing radiation, and in some cases, to substantial doses, potentially increasing the associated risk of cancer, according to findings of a retrospective cohort study.

The results are based on an analysis of 952,420 nonelderly adults who were enrolled in United Healthcare's database between Jan. 1, 2005 and Dec. 31, 2007, and living in Arizona, Dallas, Orlando, South Florida, and Wisconsin.

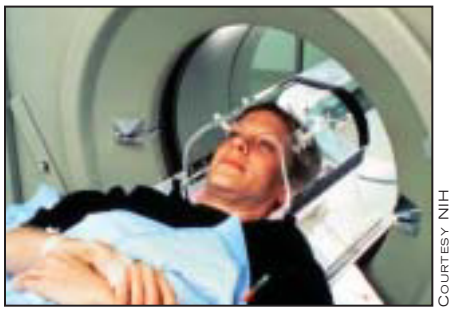
Roughly 70% of the study population underwent at least one imaging exam during the 3-year study period, "resulting in mean effective doses that almost doubled what would be expected from natural sources alone," wrote Dr. Reza Fazel of Emory University, Atlanta, and her coinvestigators.

While most patients received less than 3 millisievert (mSv) per year—which was considered low exposure—there was a sizable minority of patients who received moderate, high, or very high radiation doses, they wrote.

CPT codes for imaging procedures involving radiation were used to identify claims from hospitals, outpatient facilities, and physicians' offices. They excluded procedures in which radiation was specifically delivered for therapeutic purposes, such as high-dose radiation for cancer. Procedures were categorized by technique: plain radiography, CT, fluoroscopy (including angiography), and nuclear imaging. They also categorized the procedures by area of focus: chest (including cardiac imaging), abdomen, pelvis, arm or leg, head and neck (including brain), multiple areas (including whole-body scanning), and unspecified.

To account for the possibility of procedure overlap—for example, coronary stent placement and catheterization of the left heart performed at the same time—subjects were limited to one procedure per day that involved the same type of technique and the same anatomical area, selecting the highest dose.

Estimates of typical effective doses from published literature were used to approximate radiation exposure for each imaging procedure. The effective dose is an inexact measure of the overall detrimental biologic effect from radiation exposure.



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Almost 80% of women had at least one imaging procedure in a 3-year period.

Patients were stratified by gender and age: 18-34, 35-39, 40-44, 45-49, 50-54, 55-59, and 60-64; 52% were women. The researchers calculated effective doses for the population overall and for each age-based and sex-based group and categorized them by dose: low (no more than 3 mSv/yr, the background level of radiation from natural sources in the United States); moderate (3-20 mSv/yr, the upper annual limit for occupational exposure for at-risk workers, averaged over 5 years); high (20-50 mSv/yr, the upper annual limit for occupational exposure for at-risk workers in any given year); and very high (greater than 50 mSv/yr).

A total of 3,442,111 imaging procedures associated with 655,613 patients were identified in the 3-year period. The average number of procedures per person per year was 1.2 and median number was 0.7/person per year. The mean effective dose was 2.4 mSv/person per year with a median effective dose of 0.1 mSv/year.

The proportion of patients undergoing at least one procedure during the study period increased with age—from 50% in those aged 18-34 years to 86% in those aged 60-64 years. A total of 79% of women underwent at least one procedure during the study period, compared with 60% for men (N. Engl. J. Med. 2009;361:849-57).

Moderate doses occurred at an annual rate of 199 per 1,000 patients. High and very high doses occurred at annual rates of 19 and 2 per 1,000 patients, respectively. "Each of these rates rose with advancing age," noted Dr. Fazel.

"Generalization of our findings to the United States suggests that these procedures lead to cumulative effective doses that exceed 20 mSv per year in approximately 4 million Americans," the researchers wrote.

Myocardial perfusion imaging accounted for almost a quarter of the total effective dose (22%). CT of the abdomen, pelvis, and chest accounted for 38% of the total effective dose.

"CT and nuclear imaging accounted for 21% of the total number of procedures and 71.4% of the total effective dose," the researchers reported. By anatomical site, chest procedures accounted for 45% of the total effective dose. Lastly, the bulk of the total effective dose—82%—was delivered in outpatient settings, primarily physicians' offices.

The findings are concerning, particularly for patients who undergo several imaging tests in a short time, Dr. Michael S. Lauer wrote in an accompanying editorial (N. Engl. J. Med. 2009;361;841-3).

"Though the danger may be small, it is cumulative and hence of particular relevance to the small but substantial minority of patients, who … undergo clusters of tests."

Despite the cumulative risk associated with radiation exposure, it's generally not something that is discussed with patients undergoing an imaging procedure, noted Dr. Lauer, who is director of the prevention and population sciences division of the National Heart, Lung and Blood Institute in Bethesda, Md. "The issue of radiation exposure is unlikely to come up because each procedure is considered in isolation [and] the risks posed by each procedure are low and seemingly unmeasurable. …

"We have to think and talk explicitly about the elements of danger in exposing our patients to radiation," wrote Dr. Lauer. Physicians will need to take a careful history to assess the cumulative dose of radiation that a specific patient has already received. This specific risk should be conveyed to the patient.

The study authors acknowledged the long-term risk, but noted that restricting patient dose—as is done for nuclear workers—is not feasible. "The exposure of patients cannot be restricted, largely because of the inherent difficulty in balancing the immediate clinical need for these procedures, which is frequently substantial, against stochastic risks of cancer that would not be evident for years, if at all."

Dr. Fazel reported that she has no relevant conflicts of interest, though several of her coauthors reported significant relationships with pharmaceutical and medical imaging companies. Dr. Lauer reported that he has no relevant conflicts of interest. ■

NIH to Track Imaging Device Radiation

The National Institutes of Health will require new CT and PET equipment purchased by the agency's clinical center to routinely record the patient's radiation dose in their hospital-based electronic medical record.

"The [NIH] Clinical Center's approach is an important first step in making it possible to more easily document and track information about a patient's exposure to radiation," Dr. John I. Gallin, director of the center, said in a statement.

The risks associated with exposure to low doses of radiation from medical imaging tests are unknown. However, the effects of radiation exposure are cumulative over a lifetime. The ability to track a person's radiation exposure will help researchers evaluate the health risks of these procedures.

The center plans to work with its vendors to develop software tools to extract the type of examination, the date, and the radiation dose for uploading to an electronic health record.

Both the American College of Radiology and the Radiological Society of North America recommend that patients keep a record of their x-ray history, according to the NIH statement.

FDA Chief Announces Six Steps to Speed Enforcement

BY MARY ELLEN SCHNEIDER

The Food and Drug Administration is vowing to get tougher and act faster when it comes to protecting public health.

Over the past several years, the FDA's enforcement activities have declined significantly, and those enforcement actions taken have been hamstrung by delays, mostly due to internal red tape, said Dr. Margaret A. Hamburg, the agency's new commissioner.

"The pathways to enforcement action can be too long and arduous when the public's health is in jeopardy," Dr. Hamburg said at a Food and Drug Law Institute conference. "We're fixing these pathways to improve the effectiveness of our enforcement system," she said.

Dr. Hamburg outlined six steps to streamline the way the FDA handles enforcement across all regulated areas—drugs, devices, and food. For example, in cases where agency officials deem that public health is at risk, the FDA is prepared to take enforcement action before issuing a formal warning letter. Agency officials will also work with other regulators—state, local, and international—to figure out who can act fastest in a public health emergency.

The FDA also plans to change some of its internal processes. The agency will establish a 15-day deadline for industry to respond once a significant problem is identified during an inspection. They will also aim to get warning letters out the door more quickly by limiting review to significant legal issues.

Prompt follow-up on warning letters and other enforcement actions is another part of Dr. Hamburg's plan. The FDA will move more quickly in assessing corrective actions taken by industry after a warning letter is issued or a major product recall occurs. And in an effort to motivate industry to act quickly, the FDA is developing a formal warning letter "close-out" process. Once the FDA has confirmed that a firm has fully corrected its violations, the agency will issue a close-out notice and post the information on the FDA Web site.

"What we want to create is really a standard of practice that is a little bit different than what's been happening in recent years, where we commit to being as transparent as possible about our expectations and industry commits to working in as responsive a way as possible to address our concerns," she said. ■