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## After Stroke Scans, Patients Face Serious Health Risks

By **WALT BOGDANICH**

When Alain Reyes's hair suddenly fell out in a freakish band circling his head, he was not the only one worried about his health. His co-workers at a shipping company avoided him, and his boss sent him home, fearing he had a contagious disease.

Only later would Mr. Reyes learn what had caused him so much physical and emotional grief: he had received a radiation overdose during a test for a [stroke](#) at a hospital in Glendale, Calif.

Other patients getting the procedure, called a CT brain perfusion scan, were being overdosed, too — 37 of them just up the freeway at Providence Saint Joseph Medical Center in Burbank, 269 more at the renowned Cedars-Sinai Medical Center in Los Angeles and dozens more at a hospital in Huntsville, Ala.

The overdoses, which began to emerge late last summer, set off an investigation by the [Food and Drug Administration](#) into why patients tested with this complex yet lightly regulated technology were bombarded with excessive radiation. After 10 months, the agency has yet to provide a final report on what it found.

But an examination by The New York Times has found that radiation overdoses were larger and more widespread than previously known, that patients have reported symptoms considerably more serious than losing their hair, and that experts say they may face long-term risks of [cancer](#) and brain damage.

The review also offers insight into the way many of the overdoses occurred. While in some cases technicians did not know how to properly administer the test, interviews with hospital officials and a review of public records raise new questions about the role of manufacturers, including how well they design their software and equipment and train those who use them.

The Times found the biggest overdoses at Huntsville Hospital — up to 13 times the amount of radiation generally used in the test.

Officials there said they intentionally used high levels of radiation to get clearer images, according to an inquiry by the company that supplied the scanners, GE Healthcare.

Experts say that is unjustified and potentially dangerous.

“It is absolutely shocking and mind-boggling that this facility would say the doses are acceptable,” said Dr. Rebecca Smith-Bindman, a radiology professor who has testified before Congress about the need for more controls over CT scans. Yet because the hospital said no mistakes were made, regulatory agencies did not investigate.

The F.D.A. was unaware of the magnitude of those overdoses until The Times brought them to the agency's attention. Now, the agency is

considering extending its investigation, according to Dr. Alberto Gutierrez, an F.D.A. official who oversees diagnostic devices.

Patients who received overdoses in Huntsville say that in addition to [hair loss](#), they experienced headaches, [memory loss](#) and confusion. But at such high doses, experts say, patients are also at higher risk of brain damage and cancer.

A spokesman for Huntsville Hospital, which now acknowledges that some patients received “elevated” radiation, said officials there would not comment.

### **Growing Number of Cases**

So far, the number of patients nationwide who got higher-than-expected radiation doses exceeds 400 at eight [hospitals](#), six in California alone, according to figures supplied by hospitals, regulators and lawyers representing overdosed patients. A health official in California who played a leading role in uncovering the cases predicts that many more will be found as states intensify their search.

“I cannot believe that this is not occurring in the rest of the country,” said Kathleen Kaufman, head of radiation management for the Los Angeles County Department of Public Health. “That’s why we are so keen on the rest of the states to go look at this.”

The Food and Drug Administration acknowledges, too, that the number does not capture all the overdoses.

The cases come at a time when Americans are receiving more medical radiation than ever before, a result of rapid technological advancements that improve diagnosis but can also do harm when safeguards and oversight fail to keep pace.

Even when done properly, CT brain perfusion scans deliver a large dose of radiation — the equivalent of about 200 X-rays of the skull. But there are no hard standards for how much radiation is too much. The overdoses highlight how little some in the medical profession understand about the operation of these scanning devices and the nature of radiation injuries, as well as the loose requirements for reporting accidents when they are detected.

For a year or more, doctors and hospitals failed to detect the overdoses even though patients continued to report distinctive patterns of hair loss that matched where they had been radiated. After the Food and Drug Administration issued a nationwide alert asking hospitals to check their radiation output on these tests, a few hospitals continued to overdose patients for weeks and in some cases months afterward, according to records and interviews.

Four of the hospitals involved were identified in recent months: the Los Angeles County and [University of Southern California](#) Medical Center, where one patient received seven and a half times the amount generally used; Bakersfield Memorial Hospital, where 16 people received up to five and a half times too much; South Lake Hospital in central Florida, where an unknown number of patients received 40 percent more than usual; and an unidentified hospital in San Francisco, government officials said.

None of the overdoses can be attributed to malfunctions of the CT scanners, government officials say.

At Glendale Adventist Medical Center, where Mr. Reyes and nine others were overdosed, employees told state investigators that they consulted with GE last year when instituting a new procedure to get quicker images of blood flow, state records show. But employees still made mistakes.

As a result, hospital officials said, a feature that technicians thought would lower radiation levels actually raised them. Cedars-Sinai gave a

similar explanation.

“There was a lot of trust in the manufacturers and trust in the technology that this type of equipment in this day and age would not allow you to get more radiation than was absolutely necessary,” said Robert Marchuck, the Glendale hospital’s vice president of ancillary services.

A GE spokesman, Arvind Gopalratnam, said the way scanners were programmed was “determined by the user and not the manufacturer.” GE, he added, has no record of Glendale seeking its help setting up the new procedure in 2009.

Most of the known overdoses, including the biggest, occurred on scanners made by GE Healthcare. At two hospitals that use Toshiba scanners — Los Angeles County-U.S.C. and South Lake in Florida — officials said the manufacturer suggested machine settings that ultimately produced too much radiation. Representatives of Toshiba agreed to be interviewed in their California office but abruptly canceled.

A dozen overdose victims in California and Alabama said in interviews that the long delay in uncovering the flawed tests had left them struggling to understand what was happening to their health. One patient suspected that the Rogaine he used to stop hair loss was actually causing it. Another patient received [steroid](#) injections to stop the hair loss.

Patients said doctors speculated that their temporary hair loss might stem from a variety of causes — stress or a ponytail tied too tight — and that redness and [rashes](#) were caused by detergent used to wash bed sheets.

“What is amazing and seems painfully obvious is if someone walks in with a band of hair missing around the entire circumference of their head, you would ask the question: Have you had a [CT scan](#)?” said Richard A. Patterson, a Los Angeles lawyer who represents some of the patients. “Not ‘What did you eat for breakfast yesterday that would cause your hair to fall out today?’ ”

The overdoses did not discriminate. Among the victims: a member of Cedars-Sinai’s own board of governors, Ruthe Feldman. Mrs. Feldman says she left the board after learning about the mistake.

The Food and Drug Administration, in trying to assess the scope and cause of the overdoses, has had to rely on state radiation control officials for information. But if Alabama is any indication, the agency is not getting a full picture.

A Huntsville Hospital spokesman, Burr Ingram, said that about 65 possible stroke patients there had been overradiated. Lawyers representing patients say the number of overdoses is closer to 100.

Nonetheless, Alabama officials say the number is actually zero since the state does not define an acceptable dosing level. “No such thing as an overdose,” said James L. McNees, director of the Alabama Office of Radiation Control.

### **A Hospital’s Low Moment**

One day last August, the radiation safety officer at Cedars-Sinai, Donna Early, decided she had to act.

It was a low moment for such an esteemed institution. Patients were being overradiated during CT brain perfusion scans, hospital officials concluded, and it was Ms. Early’s job to tell county health officials.

The genesis of Ms. Early’s alert was an event on the morning of July 4, when a 52-year-old executive producer of films, H. Michael Heuser, arrived in the emergency department with stroke symptoms.

A “code brain” was immediately called, signaling a life-or-death situation. A blood clot in the brain can be dissolved with medicine, but doctors must do it within several hours, before brain cells die from a lack of oxygen. So Mr. Heuser was rushed into a room with several CT scanners, where he underwent one brain perfusion study and at least one more later. A CT perfusion scan, which lasts about 45 seconds, can identify a stroke through a series of blood flow images.

Mr. Heuser did have a stroke, from which he would recover. But other parts of his body inexplicably began to break down.

“I had a full body rash — my whole body, legs, armpits, bottom, my back — with these red welts,” Mr. Heuser said.

It burned and itched. Then clumps of hair began to fall out. “I went completely bald in a perfectly symmetrical 4-inch-wide band that extended from ear to ear all the way around my head,” he recalled. The hospital, he said, responded by offering him a hairpiece.

Finally, a doctor was so struck by the unusual nature of Mr. Heuser’s hair loss that he took a picture. A second patient reported similar hair loss. Eventually, the hospital made the connection, and on Aug. 28, Ms. Early called county health officials, records show. From then on, as the accounting of overdoses at Cedars-Sinai reached 269 over a period of 18 months, Mr. Heuser would be known in government reports simply as “Patient 1.”

To this day, no one at Cedars-Sinai knows who programmed the scanners that delivered the overdoses, officials there say. But in written statements to The Times, hospital officials said they had figured out how they might have occurred.

Normally, the more radiation a CT scan uses, the better the image. But amid concerns that patients are getting more radiation than necessary, the medical community has embraced the idea of using only enough to obtain an image sufficient for diagnosis.

To do that, GE offers a feature on its CT scanner that can automatically adjust the dose according to a patient’s size and body part. It is, a GE manual says, “a technical innovation that significantly reduces radiation dose.”

At Cedars-Sinai and Glendale Adventist, technicians used the automatic feature — rather than a fixed, predetermined radiation level — for their brain perfusion scans.

But a surprise awaited them: when used with certain machine settings that govern image clarity, the automatic feature did not reduce the dose — it raised it.

As a result, patients at Cedars-Sinai received up to eight times as much radiation as necessary, while the 10 overradiated at Glendale received four times as much, state records show.

GE says the hospitals should have known how to safely use the automatic feature. Besides, GE said, the feature had “limited utility” for a perfusion scan because the test targets one specific area of the brain, rather than body parts of varying thickness. In addition, experts say high-clarity images are not needed to track blood flow in the brain.

GE further faulted hospital technologists for failing to notice dosing levels on their treatment screens.

But representatives of both hospitals said GE trainers never fully explained the automatic feature.

In a statement, Cedars-Sinai said that during multiple training visits, GE never mentioned the “counterintuitive” nature of a feature that

promises to lower radiation but ends up raising it. The hospital also said user manuals never pointed out that the automatic feature was of limited value for perfusion scans.

A better-designed CT scanner, safety experts say, might have prevented the overdoses by alerting operators, or simply shutting down, when doses reached dangerous levels.

To Mr. Heuser, it is unconscionable that equipment able to deliver such high radiation doses lacks stronger safety features.

“When you are in a car and it backs up, it goes beep, beep, beep,” he said. “If you fill the washing machine up too much, it won’t work. There is no red light that says you are overradiating.”

Manufacturers say they will address some of these issues in newer models.

### **Form Letter, No Apology**

Huntsville Hospital informed patients that they had been overdosed in a two-page form letter that included no apology. The word radiation was mentioned once — in the ninth sentence.

“We have identified a few patients, including you, who received a scan in which the dosage level was elevated,” stated the letter, dated Dec. 11, 2009.

The acknowledgment by hospital officials that 65 people were overradiated has come slowly.

After the California overdoses became public, Huntsville officials reviewed their testing and determined that their use of higher doses to get clearer images was not a mistake and was, in fact, appropriate, according to the GE inspection report. Therefore, they concluded, they had no overdoses.

State and federal officials said they did not investigate Huntsville, because there were no equipment malfunctions or because the dosing decisions were considered part of the practice of medicine. As a result, the only public accounting of the number of overdoses in Huntsville has come from the hospital, not government inspectors.

By contrast, California officials conducted investigations, released inspection reports and have cited at least four hospitals for failing to safely irradiate patients.

Because Huntsville Hospital officials declined to be interviewed, it is unclear how they determined who had been overradiated, when the overdoses started or why patients with sudden hair loss did not arouse more suspicion.

Melissa Faye Adams is one of a number of patients who have yet to be told they were overdosed, even though they have pictures of themselves with the distinctive band of hair loss. More than two years ago, just shy of her 40th birthday, she underwent a stroke test at Huntsville Hospital after developing a [headache](#). Fifteen days later, her hair began falling out and her life began to lurch about in disquieting ways. She still keeps a plastic bag full of her hair marked with that date, 6/15/08. “I panicked,” she said.

It would take another year and a half of worry, of unsatisfying doctor visits, before her hairdresser called one day last December telling her to pick up a copy of the local paper. In the paper, the hairdresser said, was “a picture of a lady who looks just like you.” The woman said she had

been overradiated at Huntsville Hospital.

Dr. Lon Raby, a Huntsville dermatologist, also noticed the picture. "I recognized the pattern with it," Dr. Raby said. "I've seen six or eight all in the same time frame."

Suzanne Sloan, a popular fifth-grade teacher, was one of his patients. She saw the picture, too. "We were screaming," Ms. Sloan said. "She had the same identical thing."

Ms. Sloan's fruitless search for an explanation had taken her to the University of Alabama at Birmingham Hospital, Ochsner Health System in Louisiana and [Vanderbilt University](#) in Tennessee. "They had no clue," she said. "I lost 15 pounds. I couldn't sleep."

Ms. Sloan had tried to cover her missing hair using bobby pins. But one day at school, a gust of wind blew and children saw her strip of missing hair. One got sick and vomited, she said. As word of her condition spread, former students flocked to her classroom, some crying. "We heard you were dying," one said. "Is there something we can do?"

Another patient, an aerospace engineer who says she had a [seizure](#) after her scan, said her dermatologist wrote to Huntsville Hospital out of concern for her and another patient with similar symptoms.

"Even after the dermatologist put two and two together and asked Huntsville Hospital to contact me, they never did," said the engineer, who provided a picture of her hair loss but asked that her name be withheld because of professional reasons.

She said she suffered from memory loss and confusion.

Huntsville Hospital officials said they did not routinely record radiation dose levels before 2009. Mr. Ingram, the spokesman, said the hospital did keep information needed to calculate the dose, but he declined to say whether officials had gone back to determine doses for all patients who had brain perfusion scans.

The form letter Huntsville sent to overdose patients appears to play down the damage that high doses can inflict. The hospital told patients that hair loss and skin redness might occur but would go away. "At this time, we have no recommendations for you to have any follow-up treatment," the letter said.

Health experts elsewhere have warned of possible eye damage, in addition to the higher risk of cancer and brain damage.

For Dr. Smith-Bindman, a professor at the [University of California, San Francisco](#), the larger question raised by her review of overdose cases, including one in Huntsville, is whether their symptoms actually required such a powerful test in the first place. She also noted that many of the patients were relatively young.

"These tests have really high doses," she said. "And there's no system for figuring out who is getting them and why they are getting them."

Reducing mistakes is important, but the bigger challenge, she said, is to eliminate unnecessary testing.

"Utilization has increased dramatically, and as a society we have not had the time to respond."

*Kristina Rebelo contributed reporting.*