BY NOW, EVERY RADIOLOGIST IN AMERICA is aware of the recent allegations that a faulty CT brain scanner at noted Cedars-Sinai (C-S) Medical Center in Los Angeles exposed as many as 260 patients to radiation levels eight times the necessary amounts during imaging procedures.

According to reports, the problem began in February 2008 when the facility re-configured the scanner and was discovered in August 2009, when a patient who had undergone a scan at C-S began experiencing hair loss. The following month, the hospital notified 206 patients of the potential problem before discovering that even more patients had undergone scans with the malfunctioning machine. Moreover, an investigation by hospital staff discovered that about one-fifth of the patients had received exposure directly to the lenses of their eyes, which could put them at a higher risk for developing cataracts later in life.

The hospital sent out a letter to each affected patient, with the signatures of the facility’s chief operating officer and chief medical officer, apologizing for the situation. In the letter, C-S also offered to pay for any medical care that would be required as a result of the inappropriate radiation levels and the opportunity to meet with a medical specialist to answer any questions they might have about the matter.

Of those patients involved in the case, 47 had already passed away by the time the hospital contacted the victims, which hospital officials maintain was the result of the severity of their illnesses, not the radiation exposure. According to a Nov. 9, 2009, update on the case in the Los Angeles Times, about 80 patients temporarily lost patches of hair as a result of the overexposure.

With the affected patients being, on average, 70 years old, experts have opined that most of them will likely die from other causes before they could develop any symptoms related to the overexposure.

Now, the celebrated facility is facing a litany of lawsuits, scrutiny, and further blows to its reputation. In fact, several class action and individual lawsuits have already been filed against the hospital, which will be the focus of intensive investigations by the state’s Department of Public Health and the U.S. Food and Drug Administration.

ARE YOU AT RISK FOR A RADIATION BLUNDER? ARE YOU PREPARED TO RESPOND?

BY CARY BOSHAMER

Analyzing the
Can It Happen in Your Facility?
Reports indicate that the scanner at the center of the firestorm was reset in February 2008, overriding the manufacturer's instructions and guidelines, to increase radiation doses and enable improved analysis of the blood flow to brain tissue. Hospital officials have said that steps have been taken to prevent future such incidents and that staff will undergo additional training and review.

But is this type of incident more common than we would like to believe? Is it simply receiving the inordinate amount of attention because of the hospital's reputation as a medical facility catering to a celebrity patient base?

“I have seen nothing in the lay or scientific literature that leads me to doubt that the Cedars incident is isolated and rare,” suggests noted radiologist and medical-legal expert Leonard Berlin, M.D., FACP, a professor of radiology at Rush University Medical Center in Chicago, chair of the Department of Radiology at NorthShore University HealthSystem in Skokie, Ill., and author of Malpractice Issues in Radiology. “I suppose it is possible that similar incidents have been reported at other facilities over past years, but, if so, they have not been publicized, and I certainly think they would have been.”

“No institution, now or ever, can be completely immune to errors, some of which may carry significant risk of harm; outstanding institutions with strong quality and safety programs, such as Cedars-Sinai, are not exempt,” contends Michael A. Bruno, M.D. Bruno, associate professor of radiology and medicine at the Penn State Hershey Medical Center in Hershey, Penn., where he also serves as director of quality management services and patient safety in the Department of Radiology, adds, “We know that errors will still occur with a small, but measurable frequency, even under ideal working conditions and despite the extreme diligence of well-trained and well-meaning professionals.”

Of course, several experts note, if your facility performs a large number of imaging procedures involving high levels of radiation, such as CT scans and nuclear medicine, your leadership and staff should conduct a close review of your equipment, as well as your policies and procedures, to minimize the likelihood that the C-S case could happen to you.
Reviewing the Technology

“How do we know if the dosing of a scan is accurate?” asks Anand P. Lalaji, M.D., chair of The Radiology Group in Atlanta, a network of subspecialty radiologists who support a national digital platform of hospitals, imaging centers, and surgery centers with imaging services. “We rely on the technicians and the technology companies to make sure the machines are performing to optimum standards, but, as a radiation specialist, I can’t tell if the dosage is in line with a manufacturer’s specifications,” he adds.

“We need more inspections and certification to ensure the technology is accurate,” he insists. “If it can happen at Cedars-Sinai, it can happen anywhere.”

The key is for designated staff members to be involved with the equipment and its settings from the moment it is installed, Lalaji recommends. Typically, when a new piece of equipment such as a CT scanner is installed in a facility, it is done by a representative of the manufacturer who is working with a radiologic technologist from the company as well. The company representative will normally program the machine with the necessary codes and guidelines for radiation dosage and imaging performance if the software isn’t already loaded into the system.

Lalaji recommends that a department-designated radiologist, perhaps the head of CT or a medical physicist, also be involved in the installation process, even if only as an observer, to ensure that the necessary protocols are entered correctly to meet the department’s needs. After it is installed, only the radiologist should have the authority to change or reconfigure the machine’s protocol. “Once a machine is in place, only a signature from the radiologist, the head of the department, or someone in hospital administration can change the designated protocols,” Lalaji maintains.

“The consumer of imaging services is at the mercy of the equipment and the imaging technology operator,” Lalaji continues. “There is very little patients can do to protect themselves in these instances. In fact, we need more oversight about the quality of the technology and the training of the imaging technicians.”

Fortunately, there are avenues for radiologic technologists to learn about various aspects of technology and potential risks of radiation, one of which includes the ARRS’ Continuing Education for Radiologic Technologists (CERT) program. With CERT, RTs can earn continuing education credits by reviewing content — from the American Journal of Roentgenology — relevant to their jobs. Plus, each CERT lesson is designed by an RT. For more information and available lessons, visit http://cert.arrs.org.

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A Quality Monitoring Program Can Help

With the recent increased emphasis on quality-management programs within medical facilities, specifically radiology departments, more and more sections are developing and implementing quality oversight programs to identify potential problem areas and take the appropriate steps to address them before they become reality. “An established quality program, which relies on evidence and quantitative analysis and which regularly analyzes potential threats and responds proactively, especially when ‘near-miss’ events are recognized and dealt with, has been shown to be extremely effective in improving the quality and safety of care,” Bruno says.

“Sadly, however, studies have proven that not all errors are preventable.”

Lalaji points out that one of the key problems is that unless you are looking for the exact exposure information, there is no way to know whether or not the amount of radiation being delivered is excessive. While any radiology department has specific safeguards, such as radiation-detection badges, they are there for the protection and safety of the doctors and the staff, and there typically is little in place to ensure the safety of the patient. And while having a detailed quality-assurance program in place is a good idea for any department or facility, Lalaji points out that most of these programs “don’t take radiation dosage into account.

“The actual delivery of radiation to patients is not addressed in these programs at a lot of facilities,” Lalaji says. “This is simply a problem across the board.”

Berlin explains that in the event such as the one that occurred at Cedars-Sinai, a department has to respond promptly to ensure that such an incident doesn’t happen again. “Obviously there [have] to be daily and weekly checks evaluating the functioning of the equipment to ensure that everything is operating as it should,” he emphasizes.

“This usually falls within the realm of the medical physicist. All daily checks should be documented and kept in a log or record book.” Additionally, Berlin adds, “technologists and radiation oncologists should be shown how to be on the lookout for any untoward reaction that may occur in the future.”

In the meantime, Berlin points out that there is no evidence of an extensive system failure or other kind of problem at C-S, “so we have to assume the occurrence is isolated.” (Editor’s Note: Since this story was originally written, other reports of excessive CT dosages have come to light. For more information, please see http://tinyurl.com/ye2b975).

Public Response

While questions have arisen about why it took C-S so long to publicly acknowledge the overexposure incidents, many radiologists suggest that the facility handled it appropriately. “Cedars seems to have responded in a fairly good manner,” Berlin
says, “acknowledging the errors, notifying the patients involved, apologizing, and offering to cover the costs of additional testing that the patients may require.

“The question has been raised as to why Cedars didn’t discover the error earlier, and thus why it took so long for them to react publicly. We don’t know the answer to that yet — was it all an innocent situation where they simply didn’t know what had happened, or did they know and try to cover it up?” Berlin asks.

“Let’s hope for Cedars’ sake that it was the former. However, if an ensuing investigation reveals the latter, then it will be a bad PR and financial situation for Cedars, as many lawsuits would be generated and, perhaps, even criminal charges could result.

“The PR for Cedars has not been particularly good,” Berlin continues, “but I don’t think they’ve been harmed — yet. I suspect that there will be no significant long-term injuries sustained by the patients and, if any of them should be litigious, settlements will be made without any publicity.

“If that is the case, things will be fine and the incident will be forgotten within several months. On the other hand,” he notes, “should there be a big lawsuit alleging significant injury (and I’d be surprised if that happens), then it would get on the front pages again.”

So, is there such a thing as an “ideal response” to an incident such as this one? It depends on who you ask.

Lalaji says if a mistake is recognized, then it should be handled as discretely as possible while the facility notifies those involved.

“You should identify the patients affected and take the necessary steps to settle the matter quietly and effectively as soon as possible. Of course,” he adds, “the more patients involved, the more likely word will get out to the press and public about what has happened, and then you’re dealing with an entirely different PR ballgame.”

“Only open disclosure and unblinking scrutiny of all errors, done in a nonpunitive way, can allow any needed corrective or ameliorative action to be put into place rapidly,” Bruno maintains. At Hershey, he explains, the department convenes a ‘root-causes analysis [RCA]’ team to address the matter. “RCA is an established methodology to essentially dissect every aspect of an error once it is brought to light, including all of the factors that led to it, as well as those elements of the underlying system that might have served as safeguards but failed.

“At Hershey Medical Center, we wholeheartedly embrace the concept of the ‘blameless culture,’ originally championed by the aviation industry. This concept presupposes the competence and best intentions of all involved professionals and emphasizes that all errors must quickly be brought to light. And that is done without fear or recrimination.”

Bruno continues, “Errors and ‘near-misses’ must be analyzed at multiple levels. This would include their ‘systems’ component, which can be corrected only by fully understanding the involved systems flaw, such as an equipment malfunction or workflow maldesign, as well as at the individual or interpersonal level, such as a failure of communications, memory lapse, or flawed performance by an individual.”

In the end, Bruno maintains that mistakes of any magnitude can happen anywhere, even at the best and most highly regarded medical centers in the country. However, he insists, “it is important not to become fatalistic about the inevitability of mistakes but to face them honestly and openly, and with the optimism and belief that the fundamental quality-improvement process — error analysis, corrective action, and remeasurement/verification — will lead to future performance improvement.”

REDDUCING RADIATION

While mistakes can and do happen in radiology, there are steps you can take to improve your practice and examine your current protocols, beginning with ACR accreditation.

The College offers facility accreditation in a variety of modalities, from CT to breast ultrasound. The process includes a rigorous review process to be sure your facility meets nationally accepted standards. It also ensures that your personnel are well-qualified, through education and certification, to perform and interpret patients’ medical images and administer radiation therapy treatments.

Perhaps more importantly, especially in an effort to avoid a case like the one at the Cedars-Sinai Medical Center, accreditation tells your patients that your equipment is appropriate for the test or treatment they are to receive, and that your facility meets or exceeds quality-assurance and safety guidelines. To learn more about the value ACR accreditation can add to your facility, visit www.acr.org/accred.

Safety is also notably important for the younger patient population, who are extra sensitive to radiation dose. Image Gently™, a campaign to increase the awareness of opportunities to lower radiation dose in children’s imaging, offers many ways to address this issue. The Image Gently Web site (www.imagetgently.org) includes protocol recommendations, worksheets, and resources for radiologists, technologists, medical physicists, and even parents. Pledging to Image Gently is easy — visit the Web site and click “take the image gently pledge” on the left navigation bar.