Radiation Safety Demands Legislation, Standards

BY MONICA HOGAN

WASHINGTON — One congressional hearing on medical radiation safety may not be enough for the Health Subcommittee of the House Energy and Commerce Committee. "We probably will need an additional hearing because I just have so many questions that came out of this today," chairman Frank Pallone Jr. (D-N.J.) observed during a recent hearing.

Several witnesses called for the immediate passage of the CARE Act (Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009), which was introduced in the Energy and Commerce committee last September by Rep. John Barrow (D-Ga.). The CARE Act would mandate minimum education and training requirements, as well as state licensure, for personnel who plan or perform radiation oncology treatments or medical-imaging scans.

Subcommittee members and witnesses suggested that additional oversight may be needed as well, in the form of new regulatory agencies, quality standards, specialty practice guidelines, facility accreditation programs, and increased manufacturer participation in the process.

Industry Asked To Play Its Part

Manufacturers could move patient safety forward by immediately adopting agreed-upon standards for reporting radiation dose information from CT scans, said Dr. Rebecca Smith-Bindman, a radiology professor at the University of California, San Francisco.

Industry has said that it supports an FDA plan to collect and track data on patient dose from CT scans. "If these standards were adopted by the manufacturers, we could quickly know what's going on and then determine how closely different facilities abide by those guidelines that we have put out," Dr. Smith-Bindman said.

Manufacturers can also help ensure that patients receive the lowest possible dose from CT scans, she added, urging industry to draft and adopt guidelines on how device representatives set default settings as they install equipment and help establish treatment protocols with hospital physicians and physicists.

Doses for the most typical scans that patients undergo could be reduced by 50% without reducing image quality, Dr. Smith-Bindman said. CT scan vendors have recently developed software algorithms that work with existing equipment to help lower doses dramatically, she added.

News Report Led to Hearing

The Feb. 26 hearing was called largely in response to a Jan. 24 New York Times article that described in graphic detail the adverse effects of too much medical radiation, including a fatal overexposure from image-modulated radiation therapy received by a patient named Scott Parks.

At the hearing, the patient's father, James Parks, described how an error in equipment setup went unnoticed for 3 days of his son's treatment, in part because the supervising physicist was off site. He asked manufacturers of such "deadly machines" to develop "fail-safe, interactive, expert systems that can interact with human technicians to reduce or eliminate human errors."

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Under the CARE Act, radiology personnel would be subject to new education, training, and licensing requirements.

"It is further recommended that such dangerous equipment never be operated by anyone not fully trained and qualified," he stated. "Oncologists and supervising physicists must learn to micromanage every aspect of the radiology department. It is outrageous that any untrained and unskilled personnel can get anywhere near such dangerous equipment."

Need for User Training Highlighted

Other witnesses supported the need for radiation therapists and physicists to be trained on new equipment as it is installed, and on an ongoing basis.

Kenneth Mizrach, director of the Veterans Affairs New Jersey Health Care System, said his group decided to shut down its radiation oncology program in East Orange, N.J., after an internal investigation confirmed concerns over quality standards.

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As the program was rebuilt, the facility established continuous education for all staff, with a major component dedicated to initial and ongoing training on new technology and equipment, Mr. Mizrach said. Manufacturers were brought in to work with the staff and observe simulations in preparation for the facility's reopening.

"We are conducting routine tests of our machines, simulating patient encounters, checking dose calculations, tracking patient outcomes, and instituting routine quality reviews of care, including peer review," he said.

Eric Klein, Ph.D., professor of radiation oncology at Washington University in St. Louis, suggested that equipment vendors could send independent physicists to hospitals to help them become accustomed to new machines.

Referring to a case in Florida in which 77 brain cancer patients were overradiated when a new machine was not properly set up, Dr. Klein noted that manufacturers do not typically have any direct control over the hospital personnel who determine the patients' dose rate.

"If the manufacturer had said, 'Okay, you're buying this very expensive piece of equipment. It's complex and is potentially dangerous. We are going to supply an expert physicist to come in from the outside to validate what you're doing,' [that is] a very simple solution that would have caught what had happened," he said.

Although radiation oncology equipment goes through much manufacturer testing, users could be trained better on exactly what "fault" messages mean, Dr. Klein continued.

Inconsistent Error Reporting

Dr. Klein added that there is wide variation among manufacturers in reporting machine malfunctions to all their customers.

Sometimes, malfunctions are reported anecdotally or via Listserv, rather than by direct communication to all users of this equipment, Dr. Klein explained. "It might be better to do overkill communication. Right now, it's just scant and irregular." In most states, hospitals are not required to report errors with linear accelerators as they occur, he noted.

Dr. Tim R. Williams, chair of the American Society for Radiation Oncology, said that ASTRO's 6-point plan to improve patient safety and quality includes a recommendation to work closely with regulatory authorities to create a national database for the reporting of linear accelerator medical errors. The ASTRO plan also attempts to ensure that radiation therapy technologies from different manufacturers can transfer treatment information seamlessly to help reduce medical errors.

CMS Could Foster Safety

Michael Herman, Ph.D., representing the American Association of Physicists in Medicine, called for rigorous minimum standards for accrediting clinical practices, specifically including the oversight of dose and quality assurance for medical-imaging and radiation therapy technology. He asked that reimbursement from the Centers for Medicare and Medicaid Services be directly tied to such accreditation.

The CMS could also help foster radiation safety by funding residencies for physicists in the field, as it does for physicians, said Dr. Klein. He noted that starting in 2014, the American Board of Radiology will allow only physicists who have completed a residency program to sit for board certification.

John Donahue, vice chairman of the radiology benefits management company Medicalis Inc., suggested that the CMS specify radiation safety among the appropriateness criteria it will test in its pilot program on advanced imaging. MIPPA (Medicare Improvement for Patients and Providers Act of 2008) calls for a 2-year demonstration project to test appropriateness criteria for CT scans and other advanced imaging technology.

The American College of Radiology wants accreditation requirements for advanced imaging centers to be extended to hospitals and all clinical settings that perform advanced imaging and radiation therapy procedures, according to Dr. E. Stephen Amis Jr., former ACR chair. ■

Monica Hogan is with "The Gray Sheet." This publication and "The Gray Sheet" are published by Elsevier.

FYI

Coping With Medical Debt

Families USA is offering a free, downloadable consumer guide, "Your Medical Bills: A Consumer's Guide to Coping With Medical Debt," which provides step-by-step guidance to people who are overwhelmed by medical bills. To download the guide, visit the Families USA Web site at www.familiesusa.org/assets/pdfs/medical-debt-guide.pdf.

Video on Drug Interactions

The Food and Drug Administration has posted a consumer update video, "Avoiding Drug Interactions" (including those between drugs and supplements, food, beverages, and other drugs) on its Web site. For more information, visit the FDA at www.fda.gov/ForConsumers/ConsumerUpdates/ucm182745.htm.

New FDA Video on Vitamins

The Food and Drug Administration has posted a consumer update video, "Fortify Your Knowledge About Vitamins," on its Web site. Visit www.fda.gov/ForConsumers/ConsumerUpdates/ucm182737.htm.