Lawmakers Investigate Medical Radiation Excesses

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 the Feb. 26 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.

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.

"It turns out [that] you get prettier pictures if you turn the dose up higher," she explained. "And those default settings are crucial in terms of what [dose levels] most patients receive. ... And if those default settings are set in such a way that you get the most beautiful pictures, then it turns out the patients are getting higher radiation doses than they need to [in order] to support those pictures."

Manufacturers have many ways they can help lower patient dose, Dr. Smith-Bindman said, noting that doses for the most typical scans that patients undergo could be reduced by 50% without reducing image quality.

CT scan vendors have recently developed software algorithms that work with existing equipment to help lower dose dramatically, Dr. Smith-Bindman added.

On Feb. 25, a day ahead of the hearing, the Medical Imaging & Technology Alliance announced a pledge by several CT makers to incorporate radiation dose alerts in software updates for existing CT scanners (see sidebar).

The Feb. 26 hearing was called largely in response to a Jan. 24 New York Times article that described 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."

"It is further recommended that such dangerous equipment never be operated by anyone not fully trained and qualified," Mr. Parks 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."

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.

CT Makers Unveil Safety Features

Manufacturers of computed tomography machines have agreed to standardized features to ensure that patients receive appropriate radiation doses.

In a conference call with reporters, Dave Fisher, executive director of the Medical Imaging & Technology Alliance (MITA), said the industry had been working for years to make CT machines safer and that the timing of the announcement (Feb. 25) was not related to the Food and Drug Administration's recent heightened interest in radiation or the impending House Energy & Commerce Health Subcommittee hearing.

The FDA planned to hold an advisory committee meeting on radiation safety March 30-31.

The five CT manufacturers—General Electric, Siemens, Philips, Toshiba, and Hitachi—agreed to participate in the MITA "dose check" initiative, said Mr. Fisher.

First, machine operators will receive an on-screen alert—possibly a pop-up window—when they exceed recommended dose levels. The alert is akin to a yellow caution flag, said Mr. Fisher. The recommended (reference) dose will be determined by clinicians at hospitals and imaging centers, not manufacturers, he said.

The second safeguard will be a warning if the dose reaches hazardous levels that could result in burns, hair loss, or other injuries. This "red flag" can be configured to prevent the scan, Mr. Fisher said.

Finally, manufacturers will standardized the storage of images so they can be incorporated into a registry proposed by the Obama administration.

The new features should be available by early 2011 as software upgrades to older machines or add-ons to new scanners. The process may be delayed for possible regulatory clearance by the FDA, said Mr. Fisher.

—Alicia Ault

CMS Names Accrediting Organizations for Advanced Imaging

BY ALICIA AULT

The Centers for Medicare and Medicaid Services has named the national accrediting organizations charged with oversight of physician and nonphysician organizations that provide computed tomography, magnetic resonance imaging, positron emission tomography, and nuclear medicine exams under the technical component of the Medicare Fee Schedule.

The American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), and the Joint Commission will furnish accreditation services and report back to the CMS on their survey processes.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires that all suppliers of advanced imaging become accredited by Jan. 1, 2012.

"The three organizations that will be accrediting suppliers have the expertise and authority to set a standard of excellence industry-wide," Dr. Barry Straube, chief medical officer of the CMS, said in a statement announcing the selection of the accrediting bodies.

The groups will be responsible for judging and verifying the qualifications of nonphysician personnel who perform the imaging as well as the qualifications of medical directors and supervising physicians; checking safety procedures; verifying procedures to ensure reliability, clarity, and accuracy of imaging; and checking procedures to help patients obtain imaging studies upon request.

Providers of x-rays, ultrasound, and fluoroscopy will not be subject to the accreditation process.

The American College of Cardiology will be working with members to make sure they understand the accreditation requirements, said an ACC spokesperson. The professional society is working closely with the IAC, but cardiologists are free to choose any of the three accrediting organizations, she said.

Rheumatologist Norman B. Gaylis applauded the required certification of other imaging used in the office setting. "This action is not punitive. It is intended to achieve quality," said Dr. Gaylis, Aventura, Fla., who is in president and a founding member of the International Society of Extremity MRI in Rheumatology.

The certification process may increase payers' willingness to reimburse for office-based imaging. Furthermore, it gives patients the assurance that the staff and equipment have met accrediting standards, he added.

Office-based MRI has been exempt from certification requirements. However, that will end in January 2012, when all physician offices that use MRI will have to be accredited to do so. ■