

Safety stance: programs and initiatives to minimize errors in radiation therapy

Mary Beth Massat

Patient safety is at the crux of medicine, from the Hippocratic Oath to government regulations to accreditation programs and beyond. And for good reason: If it's not safe medicine, it's not good medicine. In radiation therapy, patient safety is crucial not only to successfully target cancer, but to limit damage to healthy tissue and prevent potentially devastating human errors. At minimum, maximizing safety requires a team commitment and knowledge of the intricacies of advanced technologies. It also means knowing what field-specific resources to harness, including learning systems, accreditation opportunities and task group initiatives.

But the first step in any safety program is developing a safety culture, says Jennifer L. Johnson, MS, MBA, senior medical physicist in the Department of Radiation Physics, Division of Radiation Oncology, University of Texas MD

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Anderson Cancer Center in Houston. “Without a safety culture—which is neither a blame culture nor a blame-free culture, but an accountable culture—other efforts may fall short,” she says. “Part of that means having active engagement by all members, including physician and administrative leadership.”

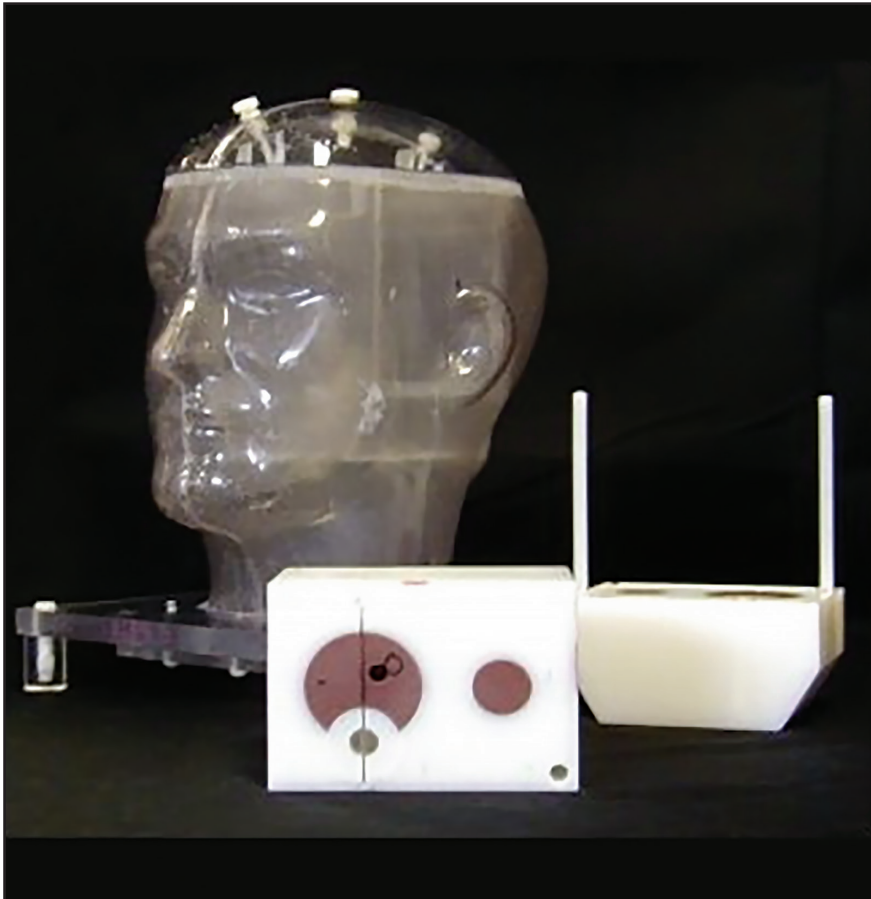
Improving the process also requires communication and feedback mechanisms, Johnson adds. “If people submit information and don't hear of the outcome or see improvements, then you may not get continued involvement. ‘Near misses’ or ‘good catches’ are also very useful for learning and improving the process since these...can give clues as to where to focus efforts to prevent actual incidents.”

The RO-ILS Treatment

Toward this end, the American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM) launched a patient safety initiative last year called RO-ILS: The Radiation Oncology Inci-

dent Learning System. The only medical specialty society-sponsored radiation oncology learning system within a federally recognized patient safety organization (PSO), RO-ILS is a platform that collects and shares information anonymously to identify potential errors, minor deviations, procedural issues or an event that occurred with a machine, explains Bruce G. Haffty, MD, FASTRO, chair of the ASTRO board of directors and professor and chair of the Department of Radiation Oncology, Rutgers, Cancer Institute of New Jersey, Robert Wood Johnson Medical School, New Jersey Medical School.

“The goal of the initiative is to communicate any patient safety issue in a transparent and open way, so if a similar issue occurs in another facility, all members can be informed and take the proper corrective action,” he says. “By signing up...facilities are participating in a quality improvement program,” Dr. Haffty continues. “While the rate of known errors is quite small, and radiation therapy is extremely safe for



During a 2-week period, institutions use the IROC Houston head and neck phantom to image, plan and treat the phantom to become credentialed for this protocol.

the number of treatments delivered, there is always room for improvement and the sharing of information.”

“RO-ILS is an extremely important initiative,” adds Bruce R. Thomadsen, PhD, FAAPM, professor of medical physics and biomed engineering at the University of Wisconsin. “We don’t know what events take place in radiotherapy because we haven’t collected that data. In some cases an individual institution does not have the depth [of experience] to determine how to fix the issue. Collectively, professionals who perform analyses often can provide a deeper analysis and generate a deeper understanding—and hopefully a better solution.”

In addition to RO-ILS is the PSO offered through the Center for Assessment of Radiological Sciences (CARS), which Dr. Thomadsen helped spearhead. With a broader mission than ROI-ILS, CARS-PSO centers on education and working with vendors when equipment problems arise. Also of help, 27 states and the District of Columbia have an adverse event or medical error reporting system. Even New York City has in the health code a reporting requirement and list of reportable events, notes Jean M. St. Germain, MS, vice chair, Department of Medical Physics and chief of Radiation Safety Service at Memorial Sloan Kettering Cancer Center (MSKCC).

“Not all states have a reporting system, and it varies from state to state,” says St. Germain. “Some of it is voluntary reporting, so there could be some underreporting of events.”

Task Group 100

Since its inception, The AAPM has likewise launched numerous other safety-oriented initiatives, including more than 250 task groups that primarily assess quality assurance (QA) and quality control (QC) in healthcare. Over the last 10 years, Task Group 100 has focused on evaluating QA needs in radiation therapy, and has embraced the systems engineering approach to safety, says Dr. Thomadsen. Results and recommendations will be published this year. “The task group is bringing a systematic approach to developing quality and safety at any institution,” he says, “including the equipment, people, and organization, and how it all works together.”

In most cases, facilities that experienced an event have missed core safety components, says Dr. Thomadsen. Although obvious, the following items bear emphasis for a safe, quality radiation therapy program:

1. Complete training.
2. Resources to carry out procedures.
3. Communication lines across team members.
4. Preventive equipment maintenance.
5. Standardized procedures and policies.

Regarding item 5, Dr. Thomadsen adds that while every patient is different, many similarities span clinicians’ work, patient to patient. “Have a standardized approach within the institution for patients who are similar, rather than approach every patient differently,” he advises. “If a patient is outside the normal case, then look at that more closely.” By streamlining efforts, clinicians can improve safety and bolster efficiency.

St. Germain says the AAPM task group reports remain an important tool for safety officers and medical physicists—or anyone involved in QC and safety of radiation therapy programs. These reports, and ASTRO’s book, “Safety is No Accident: A Framework for Quality Radiation Oncology and Care” (part of ASTRO’s Target Safely initiative), also provide guidance for equipment maintenance and testing. The key lies in continuing education, she says, which many societies now require. “It’s a matter of people availing themselves of the information out there—the task group reports, annual meetings, and maintenance of certification programs,” stresses St. Germain.

Safety and self-referral

At the legislative level, ASTRO, the American College of Radiology (ACR), the Radiology Business Management Association (RBMA) and several other societies support H.R. 2914, the Promoting Integrity in Medicare Act, which aims to close the loophole in the federal physician self-referral law that excludes radiation therapy among other healthcare services. While this bill has not been brought to the floor of the House of Representatives for a vote, it received additional support in December from the American Association of Retired Persons (AARP).

“It makes common sense to discourage physicians to make a referral for complex services in which they have a vested financial interest,” stresses Dr. Haffty. “The bottom line is to give patients an unbiased, informed choice and encourage the appropriate use of radiation and safety.” Dr. Haffty cites a 2013 study in the *New England Journal of Medicine* that “scientifically and statistically demonstrated the fact that physician self-referral leads to doctors altering practice based on that financial interest.” The authors found that nearly

all of the 146% increase in IMRT for prostate cancer among urologists with an ownership interest in the treatment was due to self-referral.¹

IROC and APEX

MD Anderson, in conjunction with AAPM and the National Cancer Institute (NCI), also supports IROC (Imaging and Radiation Oncology Core) Houston QA Center, which provides integrated radiation oncology and diagnostic imaging QC programs in support of NCI’s National Clinical Trial Network (NCTN). While the focus of the NCTN is on clinical trials, Johnson says facilities that are implementing new technologies and/or procedures, such as volumetric modulated arc therapy (VMAT), can request QA phantoms and other QA services from the IROC Houston center for an independent peer review before or early in the release to the clinic.

Accreditation is another method for obtaining an independent review of a facility’s equipment, personnel, and treatment planning, as well as assessing patient safety, QA and QC activities. The ACR provides accreditation services, and ASTRO is launching the Accreditation Program for Excellence (APEX) this year, which includes self-assessment, processes and policies to improve safety and quality of care. With a four-year accreditation cycle, APEX was created to ensure accountability in radiation therapy practices, and offers transparent, measurable, evidence- and consensus-based standards that emphasize commitment to safety and quality.

“Even though accreditation is not yet mandated by law, it is important, and ASTRO would like to see greater involvement by all the radiation oncology facilities in the U.S., as most have staff who are ASTRO members,” says Dr. Haffty. “Accreditation...raises self-awareness and enhances quality.”

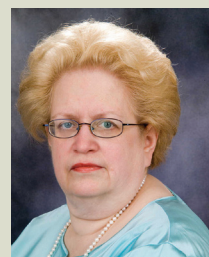
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New technologies drive need

When implementing a new technology or procedure, the first step is understanding the process, Dr. Thomadsen says. Map it out and examine flow so everyone understands what to expect, he says. At each step, perform a risk assessment, create fault trees, and project the fall-out in case something goes awry. Then, design a quality management program for the procedure with safety barriers that can halt the error before it impacts the patient, he adds. Finally, go through equipment commissioning and walk through the procedure so each team member knows what information to share, and include checks and balances so each member knows how to flag a concern.

As technology changes, so will standards. As mentioned above, information within RO-ILS and accreditation-driven self-assessment will become increasingly important as technologies and techniques evolve. “With new procedures comes a learning curve, and that curve can benefit by sharing information,” Dr. Haffty says. “If early adopters share their experi-

ence and any events through RO-ILS, then other facilities that follow will have a better understanding of what to expect.”

Understanding potential risks before implementing new technology is critical, adds Johnson. Independent validation through an organization such as IROC Houston before treating patients is an important first check. Practices can also participate in peer review processes by ACR, ASTRO and others.

Certainly, when implementing hypofractionated treatment or stereotactic body radiation therapy, the room for error is virtually non-existent, explains St. Germain. “In a typical fractionated treatment over the course of 5 or 6 weeks, subsequent doses can be adjusted to account for any error. With hypofractionated treatment, we can’t afford to make any mistakes, so these techniques are physics-driven and require a commitment to quality control, assurance and assessment.”

Both Johnson and St. Germain agree that patients being re-treated warrant additional treatment planning and safety considerations as well. They

both say the most important aspect for these patients is access to prior treatment records. Whether they can be re-treated safely is a complex paradigm, and the physicians and physicist must consider the person’s overall health and physical condition, St. Germain explains.

The most important person

Patient education plays a role as well, although it can be challenging, Johnson adds. “Patients are likely overwhelmed with making decisions and understanding potential consequences. Ongoing communication and education is key, as [is] documenting and addressing their concerns.”

“There is a lot of information out there—some of it on websites—and many institutions have patient resources,” adds St. Germain. “Make sure the right information gets into the patient’s hand.”

REFERENCE

1. Mitchell JM. Urologists’ use of intensity-modulated radiation therapy for prostate cancer. *N Engl J Med.* 2013; 369:1629-1637.