Medical Physics Letter

Improving patient safety in radiation oncology[a)]

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Beginning in the 1990s, and emphasized in 2000 with the release of an Institute of Medicine report, healthcare providers and institutions have dedicated time and resources to reducing errors that impact the safety and well-being of patients. But in January 2010 the first of a series of articles appeared in the *New York Times* that described errors in radiation oncology that grievously impacted patients. In response, the American Association of Physicists in Medicine and the American Society of Radiation Oncology sponsored a working meeting entitled "Safety in Radiation Therapy: A Call to Action." The meeting attracted 400 attendees, including medical physicists, radiation oncologists, medical dosimetrists, radiation therapists, hospital administrators, regulators, and representatives of equipment manufacturers. The meeting was cohosted by 14 organizations in the United States and Canada. The meeting yielded 20 recommendations that provide a pathway to reducing errors and improving patient safety in radiation therapy facilities everywhere. © *2011 American Association of Physicists in Medicine*. [DOI: 10.1118/1.3522875]

I. THE PROBLEM

In the early 1990s articles began to appear in the scientific literature[1,2] describing the frequency of medical mistakes that put patients at risk. Soon thereafter, reports surfaced in the public media about medical errors (e.g., chemotherapy overdose, wrong-sided surgery, anesthesia error) that caused the death or severe disability of patients. Partly in response to these reports, an international conference was held in 1993 in Rancho Los Verdes, CA to examine the causes and consequences of severe errors in medicine. The conference was hosted by the American Medical Association and had several organizational cosponsors. This conference spawned the National Patient Safety Foundation[3] and several other initiatives (e.g., the Veterans Administration National Patient Safety Partnership) that devoted substantial resources to the identification and mitigation of medical errors. The National Academy of Sciences Institute of Medicine formed a Committee on Quality of Health Care in America that, in 2000, published a seminal report entitled "To Err is Human: Building a Safer Health System."[4] This report, which estimated that between 44 000 and 98 000 patients died in the United States in 1997 as a consequence of medical errors, captured the attention of healthcare providers and public interest groups. Over the past decade, programs to reduce medical errors have been established in most of the nation's hospitals and healthcare organizations.

Errors are known to occur in radiation oncology. The treatment of cancer patients with radiation is complicated for several reasons: the complexity of the disease, the sophistication of the technologies employed, the intricacies of communication among members of the treatment team, and, probably foremost, the involvement of humans throughout the treatment regimen. For these reasons, the practice of radiation oncology includes several quality control steps designed to detect and correct mistakes and equipment failures before they negatively impact the well-being of patients. Over the past decade, the practice of radiation oncology has expanded substantially in both complexity (e.g., intensity-modulated radiation therapy, image-guided therapy, high dose rate brachytherapy), and number of treatment facilities (Fig. 1). This expansion has required more medical physicists working in more institutions to provide quality assurance for machines and treatments and to verify that equipment malfunctions and human mistakes are not putting patients at risk.[5,6] The investment in new technologies and quality control measures led to the belief that patients were being treated more effectively and safely with new technologies of increased complexity.

It is true that the new technologies provide more precise treatments and that more patients benefit today from radiation oncology than at any time in the specialty's history. But it may not be true that patients are treated more safely. Beginning in early 2010, front-page articles appeared in the *New York Times* describing "accidents" in radiation therapy in which patients lost their lives or were severely handicapped by radiation therapy treatments. The first of these articles was entitled "The Radiation Boom: Radiation Offers New Cures and Ways To Do Harm,"[7] and succeeding articles presented similarly provocative headlines. These articles captured the attention of the public, professionals in radiation oncology, federal agencies, and the U.S. Congress. A single error that harms a radiation therapy patient is one error too many.

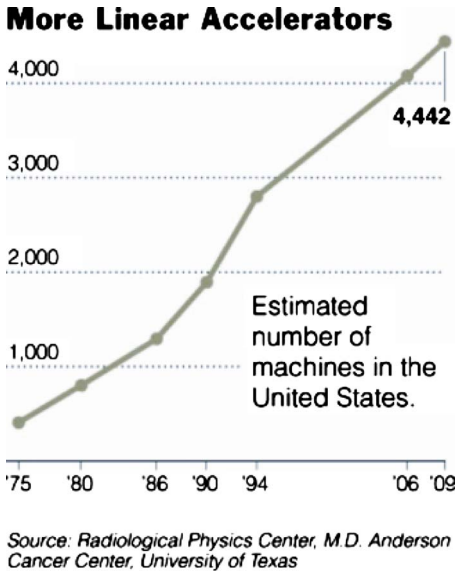

FIG. 1. Growth in linear accelerators in U.S. 1975–2009. Courtesy of the Radiologic Physics Center, Houston, Texas.

II. ADDRESSING THE PROBLEM: THE MEETING ON SAFETY IN RADIATION THERAPY

To address the heightened concern over errors and malfunctions in radiation oncology, a meeting was convened on 24–25 June 2010 in Miami. The meeting was entitled "Safety in Radiation Therapy: A Call to Action," and was sponsored by the American Association of Physicists in Medicine (AAPM) and the American Society of Radiation Oncology (ASTRO). Hosting organizations for the meeting included the American Association of Medical Dosimetrists, American Board of Radiology, American College of Medical Physics, American College of Radiology, American College of Radiation Oncology, American Society of Radiologic Technologists, Canadian Association of Provincial Cancer Agencies, Canadian College of Physicists in Medicine, Canadian Organization of Medical Physicists, Conference of Radiation Control Program Directors, The Joint Commission, National Patient Safety Foundation, Persons United Limiting Substandards and Errors in Health Care, and Society for Radiation Oncology Administrators. The intent of the meeting was to convene experts from within and outside of radiation therapy to identify the causes of mistakes and equipment failures in radiation oncology and to make radiation therapy safer for patients by developing approaches to address the causes. The meeting attracted 400 participants with the composition described in Table I. Among the "others" present at the meeting were senior officials of manufacturers providing equipment and computer systems used in radiation oncology.

Presentations and discussions at the meeting delineated several causes of potential errors in radiation oncology, including the ever-growing dependence on computer-aided design of treatment plans and computer-control of treatment machines. This dependence has led to diminished knowledge about and direct control over the actual treatment by the radiation therapist at the point of care of the patient. The therapist has no real-time independent verification at the point of care that the actual treatment is being delivered exactly as intended.

TABLE I. Composition of participants at Safety in Radiation Therapy: A Call to Action.

Who was there?
45% medical physicists
15% administrators
10.5% radiation oncologists
7% radiation therapists
2.5% dosimetrists
2.2% regulators
6.8% other
11% nonresponders

Other factors identified as contributing to errors included cluttered therapy workstations containing multiple computer monitors depicting various aspects of treatment; staff traffic patterns that do not shield the therapist from extraneous conversations and interruptions; inadequate warning systems to alert the operator when a treatment plan or treatment delivery parameter is outside normal range, or when something is amiss during treatment; inattention of medical staff to the day-by-day progress of patients undergoing treatment; insufficient quality oversight or inaccurate calibrations by physicists; failure of manufacturers to respond to problems in treatment devices identified by physicists; inability or unwillingness of users to attend product training educational sessions for complex equipment; lack of empowerment of staff to challenge decisions made higher in the hierarchy; the absence of specific policies and procedures defining treatment processes and responsibilities of the treatment team; and the absence of explicit directions on how to react to unexpected conditions or events during treatment.

Participants at the meeting concluded that these problems are best addressed through a multidisciplinary approach that includes members of treatment teams (radiation oncologists, physicists, dosimetrists, radiation therapists, nurses) working with vendors, administrators, and regulators.

Participants at the meeting acknowledged that although errors in radiation oncology can be reduced, they cannot be eliminated because the treatment process is complex, hardware and software technology can malfunction, communications can be misunderstood, and, especially, because humans are involved. Therefore, treatment approaches must be fault-tolerant—i.e., they must be designed to catch and correct errors before they can harm the patient. There was considerable discussion about the hierarchy of effectiveness in mitigating errors presented in Fig. 2. In this illustration, short-term effectiveness in reducing error increases from the bottom to the top of the figure, suggesting that for quick results, automated forcing functions and constraints on operation are most effective, and education and training are least effective.

The American Society of Radiation Oncology has re-

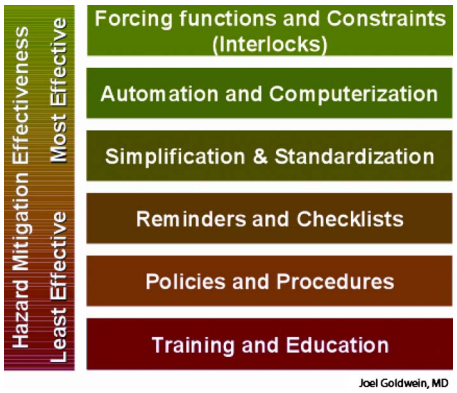

FIG. 2. Hierarchy of short-term effectiveness in hazard mitigation, where the top is most effective. Courtesy of J. Goldwein, Elekta, AB.

sponded to the challenge of improving quality and reducing errors in radiation oncology by developing a six-point action plan to improve the safety of patients undergoing radiation therapy. The action plan is outlined in Table II.

Presentations and discussions at the meeting yielded several recommendations. These recommendations are presented in the remainder of this article.

III. RECOMMENDATIONS

(1) *As the complexity of treatment devices increases, control over the devices should be simplified.* The interface of operators with treatment machines should be streamlined, layered, and standardized to the extent possible. Therapist workstations should not be a collection of monitor screens and multiple keyboards simultaneously depicting and controlling multiple treatment features and variables that are displayed differently from one treatment machine to the next. Instead, they should present information in a tiered fashion, and a single keyboard should be sufficient to access the information. The interface should be ergonomically engineered to provide logical access to and control over treatment variables in a call-up and early-alert fashion under control of the radiation therapist.

(2) *Radiation therapist workstations should be designed according to principles of human factors engineering.* Workstations should be clutter-free and designed to access information on demand and with an integrated early warning system. Traffic near the workstation should be minimal, as should extraneous noise and idle conversations. Therapists should not be interrupted while treatments are underway.

(3) *Return control to the point of care.* The therapist must have greater knowledge of the correctness of radiation delivery to the patient during treatment. This knowledge is essential if the therapist is to maintain control over the delivery process and is to take appropriate action should something happen that is inconsistent with the treatment plan. Greater control must be provided to the operator so that treatment can be terminated if something unexpected occurs.

(4) *Provide improved early warnings.* Early warning systems alert the operator to an unusual feature of the treatment plan or a possible malfunction in the treatment device. These systems should be more comprehensive and fail-safe than those currently available, and an operator should be instructed to pay attention to early warnings and not reset the system to continue operation unless he/she is sure that the warning is erroneous or the problem has been corrected. Early warning systems should include automated treatment system and process checks that compare performance with established performance metrics. Checks that fall outside a window of acceptable performance should trigger an alert that identifies the aberrant condition and offers possible solutions.

(5) *Vendors should quickly and intelligibly address concerns reported by physicists and other members of the treatment team.* Qualitative and dismissive responses are not satisfactory answers to a problem. Every question raised by a user deserves an answer, and the answer should be useful, timely, understandable, and comprehensive.

(6) *User Groups.* Professional associations (AAPM and ASTRO) should sponsor "user groups" of individuals who use complex treatment machines from particular vendors. Vendor representatives should be included in the groups, but agendas should be set and meetings should be run by members of the sponsoring organizations. User groups should provide a forum for open discussion between users and vendors about operational issues, including safety concerns, related to the vendor's equipment.

(7) *The billing process should be simplified, and the radiation therapist should not be burdened with billing duties while overseeing patient treatments.* Some institutions expect radiation therapists to handle billing forms while patients are being treated. This expectation of therapists to multitask during patient treatments risks devoting inadequate attention to either task and providing insufficient diligence over the process of treatment delivery.

(8) *Develop recommended staffing levels.* Radiation treatment technologies have become highly complex devices that require greater diligence over their use by all members of the treatment team. Staffing levels recommended years ago when treatments and treatment devices were

TABLE II. ASTRO six point action plan.

ASTRO six point action plan
Creation of an anonymous national database for event reporting
Enhance and accelerate the ASTRO/ACR Practice Accreditation Program
Expand education and training programs to include intensive focus on quality and safety
Develop tools for cancer patients to use in discussions with radiation oncologists
Accelerate development of the IHE-RO (Integrated Health Enterprise—Radiation Oncology) program
Advocate for passage of the CARE (Consistency, Accountability, Responsibility, Excellence in Medical Imaging and Radiation Therapy) act

much simpler are no longer relevant. A task force should be appointed by professional organizations to develop new staffing levels for oncologists, physicists, and therapists involved in radiation oncology procedures. The task force should be sponsored by ASTRO, AAPM, and the American Society of Radiologic Technologists.

(9) *Radiation therapy facilities should employ techniques such as failure mode effects analysis (FMEA) to identify potential sources of error and root-cause analysis (RCA) to identify and correct errors when they occur.* Methods for assessing the potential for error (e.g., FMEA) and the cause of errors (RCA) when they occur are very useful approaches for identifying and reducing errors and malfunctions.[8] These methods should be used by all radiation oncology facilities in their efforts to improve the safety of patients. An AAPM task group (Task Group 100 on Methods for Evaluating QA Needs in Radiation Therapy) is completing a report on improved quality measures based on risk analysis and techniques that employ FMEA, fault tree analysis (FTA) and other analytical tools. This report should be useful in establishing baseline quality measures for radiation therapy facilities.

(10) *Error reporting systems should be developed in radiation therapy.* There is growing interest in the anonymous reporting of mistakes and equipment failures in radiation oncology. Through a reporting process, members of a treatment team could be alerted to problems occurring elsewhere that may be relevant to their institution. Multiple reports of an equipment problem would notify vendors to the need for rapid action. Regulatory agencies (U.S. Food and Drug Administration and the Nuclear Regulatory Commission) and state regulatory authorities acting through the Conference of Radiation Control Program Directors have all expressed interest in establishing a reporting process. At the international level, the International Atomic Energy Agency is developing a voluntary reporting system entitled SAFRON (Safety in Radiation Oncology) to compile reports of medical radiation "incidents" that put patients at risk. An error-reporting system should be a centralized, modality independent repository that is easy to use, universal, anonymous, and nonpunitive. It should use clearly defined nomenclature and provide a mechanism for comprehensive analysis and dissemination of information.

(11) *A covenant and commitment to safety should be expected of the treatment team.* The radiation therapy team should work under a radiation safety covenant, and each member of the team should pledge a commitment to protect the safety of each and every patient. The covenant should express the priority of patient safety and recognize the responsibility of each member of the treatment team working under the covenant. It should also state the commitment of each team member to working together with courtesy and mutual respect.

(12) *Any member of the treatment team can declare a Time Out.* Each member of the treatment team should have the right and the responsibility to speak out (i.e., declare a "time out") if he/she has concerns or questions about the plan or course of treatment for a patient. There must be an understanding by all members of the team that when someone calls "time out" and asks for clarification, it is to be respected and addressed appropriately before proceeding. A time out should also be declared if any member of the treatment team is treated with disrespect.

TABLE III. Institution passing rates with the Radiological Physics Center phantoms.[a]

Phantom	Head and neck	Prostate	Thorax	Liver
Irradiations	250	64	24	4
Pass	179	55	17	3
Fail	71	9	7	1
Year introduced	2001	2004	2004	2005

[a]Reprinted from International Journal of Radiation Oncology Biology Physics, Vol. 71, No. 1, Supplement, G. S. Ibbott, *et al.*, "Challenges in credentializing institutions and participants in advanced technology multi-institutional clinical trials," pp. S71–S75, 2008, with permission from Elsevier.

(13) *Checklists should be employed.* A recent book on medical checklists by Gawande[9] emphasizes the usefulness of checklists in reducing the likelihood of errors in healthcare services. The model for medical checklists is the checklist procedure used by airline pilots before take-off. Every therapy facility should employ checklists as an integral component of quality control and treatment delivery.

(14) *Audits should be performed.* Periodically, independent audits should be conducted of the operation of the radiation oncology service and the attention paid to accuracy, quality, and safety. One audit method is that provided by the Radiological Physics Center, in which dosimetric computations by the institution are compared against doses measured in phantoms. An example of these comparisons is depicted in Table III.

(15) *Facility accreditation should be attained.* A model practice accreditation program in radiation oncology should be developed at the earliest opportunity. Once this is accomplished, all radiation oncology facilities should seek accreditation as an indication of their dedication to high quality and safe care of patients. The American College of Radiology and ASTRO are developing a practice accreditation program in radiation oncology.

(16) *Standard operating procedures should be available and revised as necessary.* Each radiation oncology facility should provide a policy manual of standard operating procedures (SOPs) to all employees, and employees should be expected to be familiar and comfortable with the procedures. Deviations from a SOP should not be implemented by an employee without full discussion and approval by others who have responsibilities relevant to the SOP. The institution should have "zero tolerance" for any extemporaneous shortcuts to established SOPs.

(17) *Patient safety should be a competency.* The American Board of Radiology (ABR) expects six competencies of

every radiologist, radiation oncologist, and medical physicist certified by the ABR. Dedication to patient safety should be added to this list as a competency, perhaps by changing the competency of patient care to patient care and safety.

(18) *Safety champions should be present.* Every radiation oncology facility should have one or more "safety champions" who are empowered to emphasize patient safety as a facility priority and who are encouraged to identify ways to improve the safety of patients in the facility. Champions should be senior members of the facility who have the respect of all employees. Each facility should also have a patient safety committee to review potential and actual events and to make and implement recommendations on mechanisms to improve patient safety.

(19) *Treatment team qualifications must be consistent and recognized nationally.* Individuals involved in the use of ionizing radiation for radiation therapy should demonstrate their competence through nationally recognized qualifications to ensure that proper education, clinical experience, and certification have been achieved.

(20) *The FDA review process should be improved.* Safety test data should be uniformly reported in the 510 (k) process and the test results should be made available to users in a transparent manner. Robust safety checks should be well documented and demonstrated.

IV. CONCLUSIONS

Three general conclusions evolved from the meeting. The first conclusion was that policies and procedures to improve patient safety are successful only if senior management emphasizes their importance. At the institutional level, safety must be supported and encouraged by the institution's board of directors and senior management. At the level of individual services such as radiation oncology, the physician director, departmental administrator, chief physicist and chief therapist must emphasize the importance of patient safety.

The second conclusion was that Patient Safety is Everyone's Responsibility. This statement is more than a slogan; it is a commitment that should be inculcated into every employee in the institution and radiation oncology service. But it should go further because a commitment to safety also involves persons outside the institution. In particular, representatives of equipment vendors and members of regulatory agencies must be willing to work with the radiation therapy team to improve the safety of patients.

The third conclusion was that everyone in the radiation oncology service and beyond should work together to ensure the safety of patients, and *each person should be respected, supported, and appreciated for his/her commitment to safety*. It is only through the valuing of opinions of others, and treating all persons with courtesy and respect, that a radiation oncology service can achieve the goal of providing the greatest possible level of effectiveness and safety for patients.

[a]By consent of the two editors, this paper is being published simultaneously in Medical Physics and Practical Radiation Oncology to ensure that it reaches both medical physicists and radiation oncologists.
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