Safety and Accidents in Radiotherapy: What AAPM can and cannot do

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The recent NYT reports about patient injuries in radiotherapy reminded that accidents can happen in radiotherapy. We all feel for the patients, but also for the individuals who have been involved with this tragedy. For them, life will no longer be the same, the burden that they could have done better will remain on their conscience for as long as they live. The thought that a similar accident could happen on his/her watch weighs on every therapy physicist.

The dictionary defines safety as freedom of danger. No medical procedure can ever be "safe" in the sense of this definition. With millions of radiation beams applied every year, even a very unlikely mistake can occasional pass the most stringent quality assurance tests. Since resources are limited, any expenditure to improve safety in one area necessarily takes resources away from another one. Hence, all AAPM recommendations need to take into account that the best we can do is to maximize safety.

Learning from other industries

In manufacturing and most service industries, a judicious compromise between quality and customer satisfaction optimizes the bottom line. In radiotherapy, like in the aviation industry, safety must dominate. Considering its outstanding safety record – during the last two years there were no fatal crashes in the USA involving a scheduled airliner – the aviation industry is a good example to learn from.

How did the FAA make it so safe?

They learned from mistakes. Every accident is thoroughly investigated by the Federal Aviation Administration (FAA). Investigators determine causes, contributing factors and root causes with the aid of witness accounts and information provided by flight data and voice recorders that are required equipment on airliners. Accident reports are published so that others can learn from them.

Based on the vast information provided by those investigations, the FAA makes recommendations and binding regulations to prevent similar occurrences, while taking practicality into account. Scheduled airliners are regulated most strictly, whereas small commuter airlines, sightseeing operators, and medical helicopters are treated more leniently. Private airplanes enjoy even more freedom. Understandably, accident and fatality rates go up as the strictness of regulations lessens.

Intelligent regulations do save lives – many have been written with the blood of accident victims

FAA regulations cover equipment, operators, and working conditions. Airplanes must have minimum structural strength, have reasonable "user friendly" flying characteristics, and be equipped with ground proximity and other warning devices to guard against operator errors.

Pilots, air traffic controllers and mechanics must meet stiff health and performance standards, and their age range lies between upper and lower limits (upper limits only for airline pilots). They must show adequate training and experience before they can take the respective tests. Knowledge is verified by written, oral and practical tests. The continued compliance with health and performance standards is monitored at regular intervals. To fly an airplane that is substantially different from the one they were originally tested in, pilots must pass an additional

test (type rating). Non-adherence to regulations has consequences, although the FAA shows lenience toward inadvertent mistakes.

During flight, strict operational standards have to be followed. Airliners must have the required number of crew members, including flight attendants, and the weather must meet minimums. The ultimate authority for each flight lies in the hands of the pilot in command, and the entire crew must be well coordinated. The Air Florida flight crash into the Potomac River in 1982, which happened after the co-pilot's repeated warnings of engine trouble during takeoff were brushed aside by the pilot, taught the industry an important lesson. *Irrespective of rank and experience, warnings of the most cautious crew member need to be taken seriously.*

To prevent the omission of essential tasks like proper flaps settings ("human errors"), checklists are used before takeoff, landing and throughout the flight, and the performance of each task is verified by a second person. Distractions are minimized by keeping cockpit doors closed during the entire flight, and "small talk" during critical phases is discouraged. The latter was another one of the lessons of the Air Florida crash, where chatter about unrelated issues before takeoff may have diverted attention.

Recognizing the effect of fatigue on safety, the FAA now limits the duty hours in the cockpit of airliners and requires minimum rest periods. It took several accidents and near-accidents to overcome the resistance of airline management and their political lobbies to make into regulations what seemed so obvious to even the most uninformed passer-bys. A recent (March 23, 2011) incident where the sole tower controller at the Washington DC airport had fallen asleep will likely lead to new requirements that at least two controllers must be on duty, even when the workload is light. Regulations are being fine-tuned to recognize work intensity, e.g. that flying for eight hours between busy airports is more demanding than an eight-hour crossing of the Atlantic. Consideration of poor morale as a contributing factor of accidents is still taboo.

Safety in medicine is lagging

An article by the Institute of Medicine, Errors in Health Care: A Leading Cause of Death and Injury, pp. 26, points out that "***Preventable adverse events are a leading cause of death in the United States."*** It continues: *"When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of these two studies imply that at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors.3 Even when using the lower estimate, deaths in hospitals due to preventable adverse events exceed the number attributable to the 8th-leading cause of death.4 Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).5"*

An important factor for the poor safety record may be that the health care industry is not overseen by a strong federal agency. The absence of accident investigations and published results make it difficult to learn from experience of others and to develop meaningful regulations. The Nuclear Regulatory Commission (NRC) investigates only accidents that involve radio-nuclides, and only in non-agreement States where radiation safety is provided directly by the NRC. Accelerators are generally regulated by the States and reports, if any, are not accessible to the public. Legal settlements between plaintiffs and hospitals or their insurance carriers typically disallow disclosures of details.

The Tyler, TX accident is a good example of the benefits derived from the few cases where a detailed analysis is available. It happened when a therapist used an unusual, although legitimate sequence of key strokes to program a treatment. The author of this article benefitted from this incident in the 1980s while testing a new HDR unit for this error and discovering a similar flaw. Accelerator manufacturers are now circumventing this accident scenario by allowing only a well-defined order of key strokes to program for treatment.

Device safety standards are loose

The Food and Drug Administration (FDA), which regulates medical devices, does not set specific safety standards. The 510(k) clearance required for new devices is only intended to verify that equipment meets specifications. For example, a regulatory requirement of a conspicuous warning or interlock could have prevented the fatal incorrect x-ray jaw setting during radiosurgery on a patient using an add-on collimator. Similarly, a treatment planning system can be 510(k) cleared yet yield highly inaccurate dose computations. If the manufacturer does not specify accuracy, the FDA does not require it to be verified.

Loose personnel standards

Medical physicists have to be licensed only in Texas, Florida, New York and Hawaii, with New York requiring only a written exam. Requirements in the remaining states vary, from zero to several years of experience plus a preceptor statement from a person who is registered with the state as a radiation expert. There are no practical tests, so that an individual may operate a complex treatment planning system or accelerator that he has never seen before. The recently introduced Maintenance of Certificate (MOC) requirement is a first attempt of a continued performance test, although only voluntary since ABR certification is not a legal standard. Unlike aircraft mechanics, linac service engineers require no tests or license to work on even the most sophisticated accelerators. Medical physicists are expected to safely commission and operate linacs, often without specific training. Physicists and other key personnel do not need to undergo medical tests, nor are there any limits on age.

Operational standards are absent

There are no binding requirements how a treatment facility has to be operated. Independent verification of dose computations is largely voluntary, and the suitability of a treatment plan is rarely checked by a second radiation oncologist. (The AAPM report 38 essentially puts this duty on the shoulders of the medical physicist). Therapists are often distracted while a patient is under treatment, and there are no specified limits on the duty hours of key personnel. If only one therapist is available at an accelerator, he/she has to divide attention between the medical needs of the patient, setting up the patient on the machine, record keeping, and observing progress of the treatment. Verification of the setup parameters by another person is not required.

The authority of physicists is not universally established, and varies among institutions. Their workload is often determined by administrators whose primary responsibility is, understandably, the financial bottom line of the facility. Despite recognition of ABR certified physicists as medical specialists by the ABMS, Medicare law does not recognize them as providers, in contrast to other professionals, including clinical psychologists and certain social workers. This lack of recognition diminishes their professional standing, their authority, and their ability to provide optimally safe patient care. A combination of these factors was a likely contributor to the Riverside Radiation Tragedy. *Radiation oncologists are largely protected from such pressures by their provider status and the professional CPT codes. They can work at their own pace and make quality and safety their only concern.*

What AAPM can do to promote safety

AAPM has done an excellent job in providing medical physicists with the means to generate and acquire the knowledge to safely treat patients. These include annual meetings, summer schools, local meetings and publications like Medical Physics and task group reports.

AAPM needs to be cautious with safety recommendations

Being primarily a scientific and all-volunteer organization, AAPM needs to recognize its inherent limitations and act cautiously. State regulators are inclined to make into law large sections of AAPM recommendations, often taken out of context. Such regulations can burden physicists with additional tests that take time away from their clinical duties and shortchange safety. What should physicists do if the standards exceed the capabilities of their older-generation machines?

The physicists who work 60+ hours per week in small hospitals and private practices could undoubtedly provide the most valuable input, as it would be based on real-life incidents and close-calls. Unfortunately, these same long working hours prevent active engagement in lengthy task group activities. By necessity, task groups are then disproportionately manned by academics and others who have the necessary flexible working hours, but often lack clinical radiotherapy experience. The ensuing recommendations are typically based on the adequate staffing and quality equipment found at academic centers, but not always available at small institutions. Lacking an adequate data base, reports are largely speculations and extrapolations from the sparse accident reports provided by investigative newspapers like the *New York Times* or the *Columbus Monthly*. A meaningful probabilistic risk assessment (PRA) is elusive.

The diverse membership puts additional challenges on the development of meaningful recommendations, especially if they involve "professional" issues such as staffing, authority, and money. A recommendation for additional linac tests may be welcome by a consulting firm if the fees are based on individual services, whereas the owner of an annual global services contract may see it differently. Provider status is an essential safety feature required for physicians in California, but is opposed by members within AAPM who are not primarily clinical therapy physicists. Even tenured college professors sometimes feel restrained by their employment situation when dealing with sensitive issues.

Other medical societies with broad membership have similar difficulties. ASTRO and later ACRO were established to address the specific needs in radiation oncology that could not be tackled by large organizations like ACR and RSNA. ACRO, focused primarily on professional issues in radiation oncology, provides specific recommendations that involve the financially sensitive issue of physics staffing.

Concluding remarks

Menachem Begin, the Prime Minister of Israel, once said that nowadays one has to believe in miracles to be considered a realist. So there is realistic hope of a miracle that a federal agency similar to the FAA will emerge to oversee the medical field, especially radiotherapy. Regulations will be written by salaried professionals who do not have any personal interests other than the satisfaction of contributing to patient safety, and who can act without fear of retribution by their employers. Regulations will be based on well-substantiated probabilistic risk assessments, will prevent financial gains from cutting corners, and provide for a safe working environment. AAPM can make a substantial contribution by providing scientific input.