# Incident reporting and learning in radiation oncology: Need of the hour

*"Mistakes are a fact of life. It is the response to the error that counts"*

- American writer and educator Nikki Giovanni

Medical errors are happening at an alarming rate in the health care industry. The figures are worrisome to say the least. A recent review estimated at least 210,000 deaths per year due to preventable harm in hospitals and called for addressing the issue seriously.[1] Figures for serious harms could be 10 to 20 times higher. Against this backdrop of high incidence of preventable errors in hospitals, radiotherapy is considered as one of the safest areas of modern medicine. Yet there is no room for complacence and well-laid out strategies are required to keep their rate low. This becomes all the more important considering the fact that radiotherapy errors can result in serious personal harm and can even be lethal. Some of the recent unfortunate incidents have proven this.[2] Howsoever uncommon these incidents may be, they leave scars in the memories of patients, even to the extent of dissuading them from receiving important and life-saving treatments.

A systematic international review of radiotherapy-related events that happened during 1976-2007 identified a total of 7,741 incidents and near-misses out of which 3,125 incidents resulted in patient harm of variable intensity. These harms ranged from underdosing tumor, thus increasing the risk of recurrence, to overdosing, causing unacceptable toxicities. Thirty-eight deaths were also reported.[3] In a period of 6 years spanning from 2000 to 2006 in the United Kingdom (UK), 181 incidents affecting 338 patients were reported amounting to an incidence rate of approximately 40 per 100,000 courses of radiotherapy. The incidences that were likely to have a clinically significant adverse outcome were estimated at 3 per 100,000 courses.[4] In an editorial, Ford and Terezakis estimated a figure of 1,225 mistreatments for an 8-year period (2001-2009) for the United States (US)

population equating to a misadministration rate of about 1 per 600 courses.[5] How do these incidence rates compare to those reported for other industries? For example in the US, the chances of getting injured or dying on a domestic flight is estimated at 1 in 10 million or about 16,000 times lower than the risk of getting a wrong dose in a radiotherapy course in that country. Even after excluding errors of little or no clinical significance, the US rate of serious injury resulting from radiotherapy was still 1,000 times higher as compared to the risk in airline industry.[5]

One of the major contributing factors for the radiotherapy incidences is the introduction of newer technologies and the increased level of computerization in the radiotherapy treatment workflow.[2] Human errors in understanding the complexities involved in the latest technologies and failure to anticipate possible failure routes and take prior efforts to mitigate them have resulted in tragic events and even deaths. The previously mentioned incidence rates largely belonged to a period which was a decade ago. Since then much more sophisticated technologies have arrived. It is likely that incident rates are on the higher side than before. Though the radiotherapy equipment manufacturing industry have learnt valuable lessons from the past incidences and have incorporated several redundant safety features in their products, one cannot assure a perfectly safe product. Besides that, human inattentions and mistakes cannot be ruled out. A database of radiotherapy misadministration incidents, maintained by the US Nuclear Regulatory Commission, shows that 60% or more of those incidents were related to human errors.[3] Given these factors, there is a constantly increasing burden on all the team members involved to be extra vigilant to prevent incidences from happening.

In its quest to keep occurrences of errors comparable to other industry standards, of late, radiotherapy community has increasingly adapted strategies and methods from other industries like airlines, nuclear power, manufacturing, and engineering. Process mapping, failure modes and effects analysis (FMEA), and fault-tree analysis are some of the examples of such methodologies that are being increasingly incorporated in the health care industry to prevent errors and avoid mishaps. The American Association of Physicists in Medicine (AAPM) has formed a Task Group (TG 100) with a mandate to identify a structured systematic quality

assurance program approach that balances patient safety and quality versus resources commonly available and strike a good balance between prescriptiveness and flexibility. The TG report is expected to present a proactive quality management (QM) program that is largely based on three well-tested industrial tools namely process mapping, FMEA, and fault-tree analysis to identify and address the most important risks in all clinical processes related to radiotherapy.[6]

Another methodology that has found its way from industry to radiotherapy is the incident learning system. Howsoever we may try, incidents will happen in any system. Radiotherapy is no exception. Some of them may directly or indirectly lead to cause an adverse event that harms the patient. Recognizing this important fact is the first step in the process of building fault-tolerance and robustness into the health care system. Developing an incident learning system is the second step which will identify and respond to incidents and in the process creates an atmosphere for institutional learning.[7] Such a system of identifying and learning from errors by developing a nationwide public mandatory reporting system and through voluntary reporting systems is recommended in the four-tiered approach formulated by the Institute of Medicine (IOM) to improve patient safety. The report by IOM stated that it was imperative all health care providers develop comprehensive patient safety systems that promote learning.[8]

The foundation of incident learning system lies on the realization that incidents do not happen overnight. "Everything was OK till yesterday and today this occurred"—*it never happens this way!* In a landmark publication, Bird and Geramin[9] showed that for every incident involving loss of life or disabling injuries, there are hundreds of potential incidents (near-misses) and minor incidents. They proposed the 1:10:30:600 ratios for critical: major: serious: minor categories in an incident triangle. Going by that proposition, for a critical incident to happen, it will require 600 minor incidents to happen before. It is totally up to us in the radiotherapy community to identify these 600 minor incidents and near-misses, respond to them, take corrective measures, and learn from them so as to prevent in future more serious incidents from happening. Our safety strength depends on how good is our work culture in promoting such an incident reporting and learning system.

A well-designed incident learning system in a radiotherapy program consists of several steps starting with occurrence of incidents, their identification and response, reporting, investigation, causal analysis, corrective actions, learning—all included in a cyclic feedback loop.

All departments must encourage incident reporting and strive to nurture a suitable environment. "Blame culture" should give way to "Learn culture!". Blaming someone for fault or taking disciplinary actions do not serve any purpose and will not yield the desired results. On the other hand, a "Learn culture" recognizes that error is a fact of life; it cannot be eliminated but its frequency can be reduced. The system should be sensitive enough to catch incidents that have potential to cause adverse effects—"near-misses" or "good catches"—which are difficult to identify. Reporting is a critical step in the entire learning process. It is the narrative that makes incident reports meaningful says Charles Billings, the designer of the Aviation Safety Reporting System in the US. The investigating team should investigate and submit its report on time. An inordinate delay would discourage participating members from reporting incidents in future. Characterizing incident type is another crucial step. Incidents are seldom the result of a single cause. The causal analysis will identify all the causes leading to the incident and the causal structure. Actions necessary to prevent repeat occurrences should be identified and documented. Every incident culminates in learning of lessons out of it and their feedback into the system. The lessons learnt are communicated to all individuals concerned and if required circulated to wider audience. A quality assurance committee shall collectively review all such lessons learnt to identify any system-wide improvements. Such a learning system can reduce errors is evident from a Canadian study which found a significant reduction in actual incidents of 28% and 47% in the second and third year following its implementation.[10] Authors attribute the success to the many interventions prompted by the analysis of incidents reported.

There are few global resources available for willing individuals and departments to participate either voluntarily or anonymously in radiotherapy incident learning systems. These include The Radiotherapy Incident Reporting and Learning System from the Center for Assessment of Radiological Sciences (http://www.cars-pso.org), Radiation Oncology Safety Information System (ROSIS) (http://www.rosis.info), International Atomic Energy Agency's Safety in Radiation Oncology (SAFRON) (https://rpop.iaea.org/SAFRON), and the recently introduced Radiation Oncology Incident Learning System (RO-ILS) (http://www.astro.org/roils) sponsored by American Society for Radiation Oncology (ASTRO) and AAPM.

While the significance of having such an incident reporting learning system in radiotherapy cannot

be overemphasized, it is disturbing to note that no detailed reports on radiotherapy-related adverse events are available from low-resource countries in Asia and Africa.[3] Does no incident reported mean that no incident happened? Most certainly not! It simply points out to the lost opportunities for learning valuable lessons and on the unsafe conditions prevailing.

The probable reasons for under-reporting include peer pressure (intra-department, inter-department, and inter-institutional), fear of regulatory bodies, and defamation. Possibility of legal suits for compensation by patients who are victims of such errors is another reason for not reporting. All these need to be tackled in a systematic manner to encourage reporting of incidents. The onus for issues related to incident reporting and learning partly lies on the regulatory bodies as well. Many incidents may not get reported for fear of punitive action from these bodies. While there should be a deterrent for such errors, the regulatory bodies should also sensitively deal with such cases ensuring complete anonymity, thus encouraging voluntary reporting.

It is time for developing countries to move toward learn culture that prevail in developed countries. The sheer volume of treatment courses delivered in developing countries will for sure provide valuable lessons to the global radiotherapy community to learn from and make their health care delivery systems safer. The pace with which sophisticated technologies and treatment techniques are introduced in some of the developing countries further underlines the need to have this learning system in place.

**T. Ganesh**

Department of Radiation Oncology, Fortis Memorial Research Institute, Gurgaon, Haryana, India

**Address for correspondence:**
Dr. T. Ganesh
Chief Medical Physicist, Department of Radiation Oncology,
Fortis Memorial Research Institute, Sector - 44,
Gurgaon - 122 002, Haryana, India.
E-mail: t.ganesh@fortishealthcare.com

## References

1. James JT. A new, evidence-based estimate of patient harms associated with hospital care. J Patient Saf 2013;9:122-8.
2. International Commission on Radiological Protection (ICRP). Preventing accidental exposures from new external beam radiation therapy technologies. ICRP Publication 112. Ann ICRP; 2009.
3. Shafiq J, Barton M, Noble D, Lemer C, Donaldson LJ. An international review of patient safety measures in radiotherapy practice. Radiother Oncol 2009;92:15-21.
4. The Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology. Towards safer radiotherapy. London: The Royal College of Radiologists; 2008.
5. Ford EC, Terezakis S. How safe is safe? Risk in radiotherapy. Int J Radiat Oncol Biol Phys 2010;78:321-2.
6. Thomadsen B, Brown D, Ford E, Huq MS, Rath F. Risk assessment using the TG-100 methodology. In: Quality and safety in Radiotherapy: Learning the new approaches in Task Group 100 and beyond Medical Physics Monograph No. 36. Thomadsen B, Dunscombe P, Ford E, Huq MS, Pawlicki T, Sutlief S, editors. Medical Physics Publishing Inc.: Madison, 2013. p. 95-112.
7. Cooke DL, Dubetz M, Heshmati R, Iftody S, McKimmon E, Powers J, *et al*. A reference guide for learning from incidents in radiation treatment. Health Technology Assessment Unit, Alberta Heritage Foundation for Medical Research; 2006.
8. Institute of Medicine (IOM) report. Patient safety: Achieving a new standard for care. National Academy Press; 2004.
9. Bird FE, Germain GL. Practical loss control leadership, 1986. Institute Publishing, A Division of the International Loss Control Institute: Loganville; GA.
10. Clark BG, Brown RJ, Ploquin JL, Kind AL, Grimard L. The management of radiation treatment error through incident learning. Radiother Oncol 2010;95:344-9.