Patient safety in an environment of rapidly advancing technology in radiation therapy

Cancer is one of the leading causes of deaths worldwide. The World Health Organization (WHO) reports that there were 8.2 million cancer deaths in 2012[1,2] and that annual cancer cases are expected to rise from 14 million in 2012 to 22 million in the next two decades.[2] According to WHO, more than 60% of the world's total new annual cases occur in low and middle income countries and these cases account for 70% of the world's cancer deaths.[1,2] India carries a significant share of global cancer burden and cancer-related mortality. The WHO estimates indicate approximately 1 million new cancer cases and 0.7 million cancer deaths annually in 2012.[2] A ratio of 67% deaths per new case indicates a significant scope for improvement in cancer mortality in India.

Radiation therapy (RT) continues to play an important role in the treatment of cancer with approximately 50% of cancer patients receiving RT treatment in curative, adjuvant, or palliative setting.[3,4] Recently, there has been intense news media coverage of incidents involving overexposures in RT.[5-8] Sensational but credible headlines such as "Radiation offers new cures, and ways to do harm"[5] and "Radiation Boom-As Technology Surges Radiation Safeguards Lag"[6] on patient safety in RT has contributed to sensitizing opinions of the public and health care professionals alike. These and other similar events have led to various important initiatives taken by international organizations such as International Atomic Energy Agency (IAEA),[9] WHO,[10] multiorganizational initiative in UK,[11] Canadian Partnership for Quality Radiotherapy (CPQR),[12] American Association of Physicists in Medicine (AAPM), and American Society for Radiation Oncology (ASTRO).[13,14] Mobilization of public and professional opinion in USA has resulted in a congressional hearing and the introduction of the Consistency, Accuracy, Responsibility, and Excellence (CARE) Act in the US Congress.[15] A statement "Radiotherapy is widely known to be one of the safest areas of modern medicine, yet, for some, this essential treatment can bring harm, personal tragedy, and even death" in the WHO report on risk profiles in RT draws a serious attention to its benefits and pitfalls.[10]

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In the past few years, there has been a boom in the introduction of new technologies and sophisticated techniques in RT. State-of-the-art external beam therapy treatment linear accelerator systems, e. g. Truebeam, Cyberknife, Tomotherapy, Vero Stereotactic Body Radiation Therapy (SBRT) and Proton therapy accelerators, and ViewRay cobalt-60 units now adorn RT facilities worldwide. These treatment units are equipped with sophisticated image guidance systems, e. g. cone-beam computed tomography (CBCT), and more recently magnetic resonance imagers (ViewRay). There have been similar developments in computed tomography (CT) simulation with the introduction of multislice four-dimensional CT (4DCT) imaging units. Treatment planning systems now utilize "super-computers" with ever increasing computing power driven by elegant mathematical and image processing algorithms, often opaque or semi-transparent to the end users. In addition, radiation oncology information systems (ROIS) provide elegant interface between various imaging, planning, dose calculations, on-board imaging, treatment delivery, quality assurance (QA), and record and verification systems. These technologies have facilitated the evolution of treatment techniques such as SBRT, SRS, IMRT, VMAT, proton IMRT, respiratory gating, and real-time brachytherapy planning.

Today's RT has evolved into a multistep process involving numerous systems communicating with one another through a complex network of software, hardware, and human interfaces, which require a meticulous coordination and attention to detail to facilitate the accurate delivery of the planned treatment. These interfaces are designed to be robust and seamless, and yet are known to be prone to errors in the form of software glitches, hardware malfunctions, incompatibility of multiple vendor components, and human fallibility, which if undetected or ignored can result in serious consequences to patient safety. The flood of new technology has improved efficacy and reduced the likelihood of some types of errors in RT, but advances have created opportunities for new errors.[16] New technologies have also greatly increased the number of mechanical and dosimetric parameters requiring measurement and validation to be maintained within tight tolerances.[11] The pace of advancements has often strained existing clinical

and QA processes, and the process of adopting such new techniques is often complicated by continually changing workflow processes that further increase the risks of error.[17,18]

Some experts challenge the general belief that new technology ought to be better and advocate that adoption of new technologies in radiation oncology should rely on strong evidence showing that they are at least as safe and efficacious as existing and perhaps less expensive technologies.[19] Other experts argue that obtaining the relevant high quality evidence through rigorous processes associated with new technology can be challenging, expensive, and time-consuming.[19] Hence, compelling arguments have been made that the requirement for justification can cause a tremendous drag on the implementation of leading edge technologies and, therefore, deprive cancer patients' access to potentially better therapies. Many policy experts believe that new technologies account for a large portion of health care spending and its growth.[20,21] The low and middle income countries burdened with high cancer patient throughput and related deaths[1,2] with limited available healthcare spending are often compelled to acquire new technologies at a burden of their relatively scarce financial resources, which must also be directed to other life-threatening diseases. Multiple reports caution that technologies intended to reduce the risk of treatment inaccuracy might paradoxically act as a new source of error if not used correctly.[10,11,16-19] The WHO report further emphasizes that rapid adoption of new technologies and increased complexity of RT processes in the setting of high patient throughput has a potential to create more treatment-related accidents.

On the other hand, availability of novel technologies and techniques have infused an unprecedented confidence and empowered radiation oncologists, physicists, dosimetrists, and therapists to image, plan, treat, verify, and evaluate complex dose deliveries. With the help of such new tools, it is now possible to boldly contemplate a reduction in target volume margins, dose escalation with significant normal organ sparing, and design of novel clinical trials.

In the care of RT patients, the principle of C-A-R-E (i.e., Consistency, Accuracy, Responsibility, and Excellence)[15] is the hallmark of patient safety, quality of treatment, and its intended outcome. Maybe it is beyond human endeavor to fully escape random errors, but systemic errors that can have consequences to a large patient population can be significantly avoided by learning from past mistakes. Therefore, it is important that systemic mechanisms are established and followed to avoid systemic errors resulting in risk to patient safety. There are several global initiatives to collate, analyze, and learn from adverse incidents in order to increase patient safety.[9,11-14,16]

The IAEA initiative - Radiation Protection of Patients (RPoP) provides guidelines on basic safety standards, accident prevention, and radiation safety of patients in RT and places a strong emphasis on incident reporting.[9] Its patient safety in radiation oncology (SAFRON) enables radiotherapy centers worldwide to report patient radiation safety incidents to an international learning system, allowing them to pool information on the incidents and their resulting remedial actions.[9]

The AAPM and ASTRO's combined initiatives emerged from their working meeting called "Safety in Radiation Therapy: A Call to Action," which yielded 20 recommendations intended to provide a pathway to reducing errors and improving patient safety in RT facilities.[13] The ASTRO has also launched its own Target Safely initiative.[14] The Canadian initiative, (CPQR),[12] is an elegant example of an alliance among Canadian national professional organizations of radiation oncologists, medical physicists, radiation therapists, and federal government. The CPQR has four main focuses including QA guidance for radiation programs nationally and establishing a mechanism for national reporting of radiation treatment incidents.[12] All of these initiatives place a strong emphasis on mechanisms such as establishing national incident reporting system, independent external audits of the operation of the radiation oncology services, facility accreditation, development of new staffing standards, establishing nationally recognized consistent team qualifications, and development of written standard policies and procedures in radiation oncology.

Many advanced radiation treatment facilities in India have well thought and written institutional guidelines on patient safety to guide their practitioners. Regulatory guidelines laid out in the Atomic Energy Regulatory Board (AERB) Safety Code provide a strong framework for overall radiation protection in RT facilities.[22] However, many vital patient safety issues, including radiation safety, are related to hospital-based clinical workflow and processes. These processes require a smooth and clear communication, coordination, and cooperation among different arms of patient care team, e.g., medical physicists, technologists, oncologists, dosimetrists, QA technicians, information system professionals, and so forth, as well as the hardware and software systems. These professionals thus may require an elaborate and clear understanding of one another's roles and responsibilities in the process chain leading to the patient treatment and circumvention of an untoward patient safety incident.

India has well established professional associations and colleges of radiation oncologists, medical physicists, and radiological technologists. These professional and government radiation safety regulatory institutions should collaborate to form *inter- and intra-professional task groups* to formulate new and strengthen existing nation-specific radiation treatment quality management, treatment

technique implementation, patient safety, and incident reporting guidelines suited to India.

The international guidance documents on patient safety initiatives may often be specific to an individual country's healthcare system. However, the underlining ethics and the core principles of patient safety and practice of RT worldwide, such as CARE, remain the same.[9-14] The international guidelines provide a source of already researched and debated ideas, which may be considered while formulating new and strengthening existing patient safety initiatives.

These initiatives originating from inter- and intra-professional collaborations, apart from enhancing nationwide consistency and quality of cancer patient care, will also provide an intense inter- and intra-professional development platform to all involved and help in achieving a noble, compassionate, and professional goal:

Image Wisely -Target Safely -Treat Responsibly -Report Honestly -Interact Respectfully -Learn Collectively.

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References

1. World Health Organization Media Centre, Cancer Fact sheet N°297 (Feb 2014). Available from: http://www.who.int/mediacentre/factsheets/fs297/en/[Last accessed on 2014 Feb 20].
2. GLOBOCAN Cancer fact sheets, IARP, World Health Organization: All cancers (excluding non-melanoma skin cancer) estimated incidence, mortality and prevalence worldwide in 2012.
3. Barton MB, Frommer M, Shafiq J. Role of radiotherapy in cancer control in low-income and middle-income countries. Lancet Oncol 2006;7:584-95.
4. National Cancer Institute Fact Sheet, US National Institute of Health. 2004. Available from: http://www.cancer.gov/cancertopics/factsheet/Therapy/radiation [Last accessed on 2014 Feb 20].
5. Bogdanich W. Radiation offers new cures, and ways to do harm. (Jan 24). New York Times; 2010. Available from: http://www.nytimes.com/2010/01/24/health/24radiation.html.
6. Bogdanich W. Radiation Boom-as technology surges radiation safeguards lag. (Jan 27). New York Times; 2010. Available from: http://www.nytimes.com/2010/01/27/us/27radiation.html?pagewanted=all.
7. Bogdanich W. West Virginia hospital over irradiated brain scan patients, records show. (March 6). New York Times; 2011. Available from: http://www.nytimes.com/2011/03/06/health/06radiation.html.
8. Poling S. Critical error- the lisa norris story (June 10). BBC News; 2007. Available from:http://news.bbc.co.uk/2/hi/uk_news/scotland/6731117.stm.
9. Radiation Protection of Patients, IAEA. Improving Patient Safety in Radiotherapy: SAFRON. Available form: http://rpop.iaea.org/RPOP/RPoP/Content/News/safron.htm [Last accessed on 2014 Feb 18].
10. World Health Organization, radiotherapy risk profile-technical manual, 2008. Available from: WHO/IER/PSP/2008.http://www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf [Last accessed on 2014 Feb 18].
11. Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology. Royal College of Radiologists, London. Towards Safer Radiotherapy. 2008. Available from: http://www.rcr.ac.uk/index.asp?PageID=149 and PublicationID=281 [Last accessed on 2014 Feb 20].
12. Canadian Partnership for Quality Radiotherapy. Available from: http://www.cpqr.ca/[Last accessed on 2014 Feb 18].
13. Hendee WR, Herman MG. Improving patient safety in radiation oncology. Med Phys 2011;38:78-82.
14. American Society for Radiation Oncology-Target Safely. Available from: http://www.astro.org/Clinical-Practice/Patient-Safety/Index.aspx [Last accessed on 2014 Feb 20].
15. H. R. 2104-Consistency, accuracy, responsibility, and excellence in medical imaging and radiation therapy act of 2011, 112th Congress (2011-2012). Available from: https://www.govtrack.us/congress/bills/112/hr2104 [Last accessed on 2014 Feb 20].
16. Yorke E, Gelblum D, Ford E. Patient safety in external beam radiation therapy. AJR Am J Roentgenol 2011;196:768-72.
17. Marks L, Jackson M, Xie L, Chang, Burkhardt KS, Mazur L, *et al*. The challenge of maximizing safety in radiation oncology. Pract Radiat Oncol 2011;1:2-14.
18. Patton GA, Gaffney DK, Moeller JH. Facilitation of radiotherapeutic error by computerized record and verify systems. Int J Radiat Oncol Biol Phys 2003;56:50-7.
19. Njeh CF, Langton CM, Orton CG. Point/counterpoint. The adoption of new technology in radiation oncology should rely on evidence-based medicine. Med Phys 2011;38:2825-8.
20. Fuchs VR. Major trends in the U. S. health economy since 1950. N Engl J Med 2012;366:973-7.
21. The Kaiser Family Foundation report, "Health care costs: A primer- Information On Health Care Costs and Their Impact" May 2012. Available from: http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7670-03.pdf [Last accessed on 2014 Feb 20].
22. Atomic Energy Regulatory Board, Mumbai, India, Radiation Therapy Sources, Equipment and Installations, AERB Safety Code No. AERB/RF-MED/SC-1 (Rev. 1), March 2011. Available from: https://www.aerb.gov.in/AERBPortal/pages/English/t/publications/CODESGUIDES/SC-MED-01R.pdf.

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