CAPÍTULO 22

WHAT IS BEHIND THE QUALITY ASSURANCE PRINCIPLES

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1. INTRODUCTION

The main treatment modalities used for the treatment of malignant cancer comprise of radiation therapy, surgery, chemotherapy, immunotherapy, and hormonal therapy. These modalities may be used separately or in combination with each other to eradicate cancer (curative treatment) or to relieve the symptoms associated with it (palliative treatment). Radiation therapy remains an important component of cancer treatment with approximately 50% of all cancer patients receiving radiation treatment during their course of illness; it contributes towards 40% of curative treatment for cancer.

To gain insight into the question "why quality management in radiation therapy", it will be important to undertake the journey that a cancer patient takes as he/she undergoes the radiation treatment and appreciate the impact of quality, technologies used for radiation treatments, sources of errors in radiation therapy, safety, accuracy in dose delivery, etc on the clinical outcome.

2. QUALITY AND QUALITY MANAGEMENT

The Institute of Medicine (2000) defines "quality" of care as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. This definition can be adapted for use in radiation therapy: it can be defined as the degree to which radiation therapy is consistent with current professional knowledge; the prescription is appropriate, i.e., evidence-based and the prescription is delivered within consensus determined tolerances. It is the physician's responsibility to make sure the prescription is appropriate; the delivery of prescription dose is primarily the responsibility of the technicians (therapists), dosimetrists and physicists.

Quality management (QM) in a radiation therapy clinic represents the planning, deployment, coordination, monitoring, evaluation, and modification of all activities to ensure that diagnostic testing, imaging and treatment planning, delivery and follow up processes are controlled, and patient treatment is optimal and safe. QM program therefore consists of all the activities designed to achieve the desired quality goals.

This concept is consistent with how Task Group (TG) 100 of the American Association of Physicists in Medicine defined QM in their report, "The report of Task Group 100 of the AAPM: Application of Risk Analysis Methods to Radiation Therapy Quality Management" AAPM TG100. Huq *et al* (2016).

3. TECHNOLOGIES USED FOR RADIATION TREATMENT

In the past two decades, rapid advances in technology have pushed the development of technology-intensive, image-guided modalities for cancer treatment that we recognize as modern radiotherapy. Anatomic and biologic information from various imaging modalities is used increasingly to delineate target volumes accurately and is becoming an integral part of the treatment design process. Some of the newer technologies and associated complex treatment procedures include, but are not limited to, MR linac, PET linac, conventional linacs with advanced treatment capabilities, proton machines, Gamma Knife, CyberKnife, image-guided high dose rate brachytherapy, stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT), intensity modulated radiotherapy (IMRT), image registration and fusion from various imaging modalities, and image-guided radiotherapy (IGRT). Image-guided radiotherapy, SRS, SBRT, and IMRT require image guidance combined with immobilization devices such as breathing control or gating devices to minimize the impact of geometric uncertainties of organ motion and setup error. Accelerators are being marketed with integrated imaging devices to provide a means of seamless target identification, real time monitoring, delivery modification, delivery verification, dose reconstruction, and adaptive radiotherapy.

There has been an explosion of technologies, and this is happening at a rate much faster than the user can keep up with it. Professional societies often take years to publish authoritative guidance documents on the safe use of these technologies. This leaves early adopters of new technologies to decide for themselves how best to use these technologies in a safe manner. Major academic centers may have the resources to invest to determine how best to use these technologies, but the community centers do not always have such resources and thus are vulnerable to potentially using these technologies in a manner not meant to be used thereby causing significant harm to the patients.

The developments in radiotherapy technology and the improved performance of modern equipment cannot be fully exploited to deliver safe and high quality care to patients unless a high degree of accuracy and reliability in dose delivery is reached. Existence of a good "Quality Management Program" within an organization ensures that the clinical benefits of the use of these advanced technologies, consistent with the current professional knowledge, will likely be fully realized and that errors arising from various failure modes in the treatment process using these technologies will be mitigated and not reach the patient to cause harm.

4. ERROR IN RADIATION THERAPY AND THEIR POTENTIAL IMPACT ON PATIENTS

Errors will likely occur in radiotherapy treatments because radiotherapy treatments are complex using very sophisticated technologies, technologies can malfunction, handoff misunderstandings among professionals can occur, humans are involved, etc. When an error occurs, then depending on the type and the severity of the error, there is the potential to underdose a tumor resulting in compromised clinical outcome or overdose normal tissue resulting in severe toxicities; catastrophic errors can lead to death of patients. There is a large body of reported errors in the literature that ranged from insignificant errors in the dose delivered to the tumor to major events that injured or killed patients. Examples of these include, but are not limited to, publications in New York Times in 2010 Bogdanich (2010) of 621 events and two deaths resulting from 1264 causes. The author of the article "The Radiation boom. Radiation offers new cures and ways to do harm" investigated data from New York State records from 2001-2008 and reported that 46% of the events missed target volume, 41% of the patients received wrong dose, and 8% of the patients treated were incorrect patients. The author also reported that 94% of the errors were due to human errors. Shafique *et al* (2009) analyzed 7741 radiotherapy incidents and near misses over a period of 1976-2007. They found that 3125 patients were affected that resulted in harm to patients; 38 deaths were reported. The British Institute of Radiology (2008) published a report "Towards Safer Radiotherapy" in 2008. The author analyzed 181 incidents affecting 338 patients covering a period from 2000-2006. They found an error incident rate of 40 per 100,000 courses; 3 cases were clinically significant. World Health Organization (WHO) (2008) published a report "Radiotherapy Risk Profile" in which they analyzed 3125 patients and near misses and 4616 adverse events. The International Commission on Radiation Protection (ICRP) published a report ICRP 112 (2009) in 2009 which reviewed 11 safety issues with incidents: all these reports discussed various errors that occurred during radiotherapy treatments in different countries, identified the causes of errors and provided various quality management recommendations on how to mitigate them. The International Atomic Energy Agency (IAEA) has also published reports analyzing various events, identifying sources of major and minor errors, and providing quality assurance and quality management recommendations on how to reduce errors in radiation therapy (IAEA Report 17).

These data clearly establish the importance of developing a good Quality Management Program, the objective of which will be to minimize the number of occurrences of errors and to identify them at the earliest possible opportunity, thereby minimizing their consequences. There is evidence in the literatures that show how the development and implementation of good quality management program reduces the likelihood of occurrence of errors in radiation treatments.

5. SAFETY

More than 20 years ago, the Institute of Medicine published a report called “To Err Is Human: Building a Safer Health System” Institute of Medicine (2000). This report estimated that as many as 98,000 people die in any given year from medical errors that occur in the hospitals in the US. A key theme of the book is that errors are not generally reported because of legitimate liability concerns. The book emphasized further that the problem is not bad people working in the hospital but is that good people are working in bad systems that need to be made safer and the book provides guidance for raising the level of patient safety in American healthcare. This report highlighted the need to make patient safety a major priority for health care authorities. Since then, the pressure to enhance patient safety has continuously grown in western countries. Priority has focused on identifying and reducing preventable events. Important changes have already been made to the accident and incident reporting system, and the associated techniques of analysis. However, the upper limit of harm prevention remained unclear. Many investigators have proposed that adapting the success strategies and tools of ultra-safe systems, such as those used in the aviation and nuclear power industries, will lead to comparable successes and safety outcomes in health care. The reality is probably more complicated.

6. RADIOTHERAPY PROCESS AND RISK-BASED PROSPECTIVE QUALITY MANAGEMENTPROGRAM

To meet the requirements of quality and safety, sustained efforts will have tobe applied to all areas of the radiotherapy process. Modern radiotherapy process isa multi-disciplinary process involving professionals from different disciplines, complex equipment, and procedures for the delivery of high-quality safe treatment.Every step in the process will need to be carefully controlled and executed so that patients can receive the intended prescribed treatment correctly and safely.

Current quality assurance (QA) and QM guidelines are provided by various scientific, professional, regulatory organizations, or vendors. These are, for example, AAPM, ACR, ESTRO, IAEA, NRC, FDA, IEC, NEMA etc. The guidelines from AAPM, ACR, IAEA etc are generally operations oriented; those of NRC, FDA are generally regulatory oriented, those from vendors are device safety oriented, and those of IEC, NEMA are product quality oriented. The main source for AAPM QA guidance is the various QA reports such as AAPM TG 40, 45, 53, 56, 142, 100 etc. Other QA recommendations can be found in the publications by Mayles *et al* (1999); Leer *et al* (1995, 1998); McKenzie *et al* (2000); Thwaites *et al* (1995); Van Dyk *et al* (1993); World Health Organization (1988). The focus of all current QA recommendations is, for example, on measuring functional performance of radiotherapy equipment by measurable parameters with tolerances set at strict but achievable values. Except for the recommendations of TG-53, these QA/QC guidelines are device centric and prescriptive in nature.

Task Group 100 of the AAPM performed a prospective analysis of the causes of failure for the planning and delivery of intensity modulated radiation therapy (IMRT) treatment. Their findings are summarized in Figure. 1. They found that 35% of the failures for IMRT arise from human failure, 15% from lack of standardized procedures, 15% from inadequate training of professionals, 10% from inadequate communication, 9% from hardware and software failure, 6% from lack of resources, 5% from design failure, 3% from inadequate commissioning, and 2% from defective materials/tools.

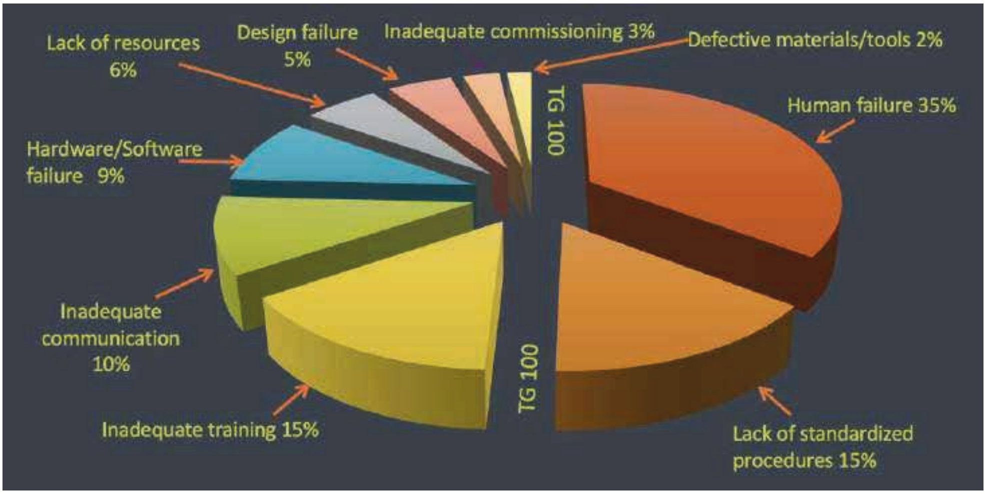

Figure 1 – Causes of failure for intensity modulated radiation therapy as identified by the Task Group 100 of the American Association of Physicists in Medicine. For details see text.

Since one of the goals of radiation therapy is to give high confidence that patients receive the prescribed treatment correctly and safely, the Task Group 100 recommended that a cross-disciplinary team of professionals involved in the care of patients should work together and design and develop a risk-based prospective quality management program such that for a given process one identifies prospectively the various failure modes (i.e., what can go wrong), the potential causes of failures, the severity of failures, and the risks associated with them. Then put various controls in place such that the failures arising from both technological and other aspects (as shown in Figure. 1) do not propagate through the process and cause harm to the patient. Establishment of such a comprehensive quality management program will likely ensure that all requirements for quality of care will be met and patients will receive the intended treatment safely and correctly.

The TG100's analysis of IMRT process produced several observations regarding root causes of radiotherapy errors, mistakes, or incidents (collectively, potential failure modes) and quality controls that could eliminate or mitigate them. After completing the process tree, performing failure modes and effects analysis (FMEA) and Fault Tree Analysis (FTA) for IMRT treatment, the TG100 group notedthat a significant number of potential-failure modes that they identified had the same,or very similar root causes. Potential root causes of failure modes which appeared frequently included:

- Inadequate communication
- Lack of formal procedures or processes
- Inadequate resources (specifically a lack of trained operators, technicians, professsionals, etc.)
- Stress
- Inadequate training

These categories of root causes are often identified as leading to potential failure modes or errors. Radiation therapy clinics could benefit by closely examiningtheir policies, practices and guidelines in these areas and making improvements in their quality management program Teixeira (2016).

7. ACCURACY OF DELIVERED DOSES NEEDED FOR THE BENEFIT OF RADIATIONTREATMENT

The clinical requirements of accuracy of delivery of prescription dose are based on evidence from dose response (dose effect) curves for tumor control probability (TCP) and normal tissue complication probability (NTCP). These curves are typically sigmoid in shape, have a threshold dose, and a relatively steep rise and reaches a saturation effect at high enough doses. Analysis of such curves show that high accuracy is necessary to attain a high tumor control rate while maintaining complication rates within acceptable levels. Fig. 2 shows a schematic of a TCP and NTCP curve as a function of dose for a hypothetical situation. As can be seen from the curve, the steepness of the TCP and NTCP curve determines the change in response that can be expected from a given change in delivered dose. Therefore, any uncertainty in delivered dose results in a reduction in TCP or an increase in NTCP, both of which contribute to an adverse clinical outcome.

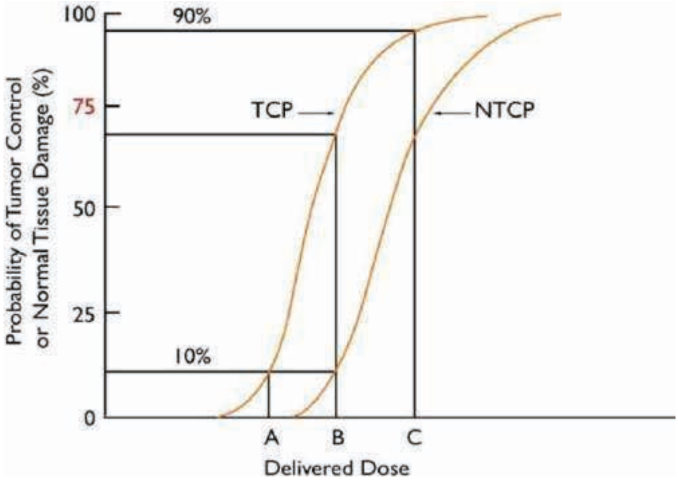

Figure 2 – Tumor control probability (TCP) and the probability of normal tissue complication (NTCP) as a function of radiation dose, in a hypothetical case. Point A on the curve represents a dose level at which there is no radiation injury; however, the TCP is low at this dose level. At point B, there is a certain probability for normal tissue complication; but at this dose level the TCP is high. Beyond point C, the NTCP increases significantly with not much improvement in TCP.

The International Commission on Radiological Units and Measurements report 24 (1976) reviewed TCP data and recommended that patients would benefit from radiation treatment if the dose delivered to the target volume is within +/- 5% of the prescription dose. This is shown by the orange histogram in Figure.3: the central vertical line (shown in red) represents the prescription dose, and the width of the histogram (orange region) represents +/-5% uncertainty from the prescription dose. So, according to ICRP 24, if a patient receives dose within this orange region, the patient will benefit from radiation treatment. Despite being quoted widely as a standard; it was not made clear what confidence level this represented. It is generally interpreted as 1.5 or 2 times the standard deviation (s.d.).

Absence of a good quality management program can also contribute to patients being underdosed or overdosed. The long tails and the regions outside of the orange rectangle show the regions of underdose and overdose. Patient treatments are compromised if the delivered doses lie in these regions.

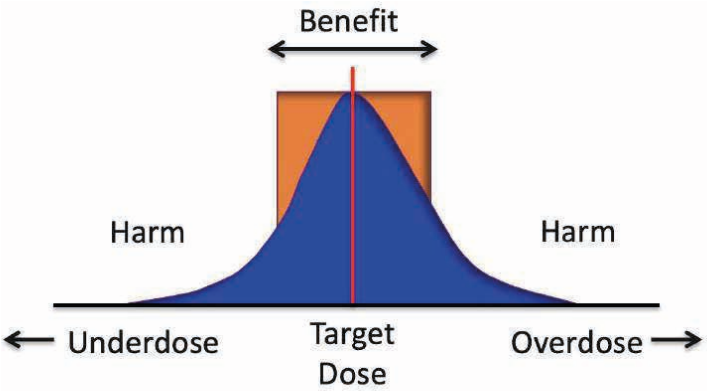

Figure 3 – ICRU 24 states that patients will benefit from radiation treatment if the delivered dose is within +/- 5% of the prescription dose. Absence of a good quality management program can contribute to patients being underdosed or overdosed. This Figure shows a schematic of this concept. The red line represents the prescription dose, and the width of the rectangular histogram (shown by orange color) represents +/-5% uncertainty from the prescription dose. So, if a patient receives radiation dose within this orange region, then according to ICRU 24 analysis the patient will benefit from radiation treatment. The regions outside the orange-colored rectangle and the longtails show regions where patients are either underdosed or overdosed which will cause harm to thepatients.

Mijnheer *et al* (1987), investigated dose-effect curves in terms of absorbed dose needed to produce a change in the probability of normal tissue complication from 25% to 50% and arrived at a value of 3.5%, as one relative standard deviation as the general accuracy requirement of on absorbed dose delivery. Brahme *et al* (1988), considered the effect of dose variations on TCP, and recommended a general Figure of 3% (relative s.d.) on the dose delivered to the patient as the tolerance level on accuracy of dose delivery, to keep variations in the probability of tumor control within acceptable limits. So, a 3% (relative s.d.) Figure can now be taken as a recommended value for general accuracy requirement on the value of the dose delivered to the patient at the dose specification point. When combined with systematic uncertainties, (of say better than 1-2%), the overall required accuracy in absorbed dose distributions should be in the range of 3-5%. This accuracy level may change for high dose per fraction hypo-fractionated treatments. In addition to dosimetric accuracy, one also needs to consider geometric uncertainties in radiotherapy treatments because geometric uncertainties translate into dosimetric uncertainties. The sources of geometric uncertainties are manifold. Examples include uncertainties in machine specifications and tolerances, patient setup, patient motion, organ motion and deformation etc. Margins are used around the clinical target volume to account for these uncertainties. Analysis of published data has led to recommendations on spatial uncertainty of between 5 and 10 mm (at the 95% confidence level). Of these, the 5mm uncertainty is generally associated with equipment related (mechanical and geometric) problems and 8-10 mm spatial uncertainty is used for clinical setup error.

Good quality management programs need to be in place to ensure that accuracy requirements for dosimetric and geometric uncertainties are met for all radiotherapy treatments. Otherwise, patient can receive sub-optimal treatments.

8. ADDITIONAL BENEFITS OF GOOD QUALITY MANAGEMENT PROGRAMS

In addition to the benefits discussed above, there are other advantages of having a good quality management program. A few examples are:

8.1 Opportunities for building a more cohesive work environment

As mentioned earlier, TG 100 of the AAPM recommended that all cross- functional members involved in the care of patients should get together and develop process maps, perform risk analysis, and develop a risk based prospective quality management program for every process used for patient treatment in radiation therapy. There is already data in the literature that show that implementation of TG100 recommendations has changed the culture at workplaces and significantly enhanced the camaraderie among the multidisciplinary professionals. One reason for this positive change is that professionals from each discipline learn, understand, and appreciate what others do for the care of the patient. Additionally, they all feel ownership of the program because each member of the team contributes to the development of the quality management program.

8.2 Continuing Quality Improvement (CQI)

A Quality Management Program provides the framework for implementing the organizational structure, responsibilities, procedures, and resources. Continuous evaluation of the program and implementation of constructive changesfacilitates continual improvement of quality of care provided to patients.

8.3 Increase of Efficiency

The prospective risk-based approaches to quality management program that TG100 recommended, includes a recommendation that states that all processes and associated controls should be reviewed at a certain frequency to determine whether the quality controls put in place to mitigate risk and severity of a process have indeed lowered the risk of harm and severity caused to patients. By feeding the improved results of the quality analysis back into the process, this mechanism provides the means to increase the efficiency.

8.4 Morale of Personnel

Strong support and active engagement of senior administration is essential to develop and implement a good quality management program. Education and training of professionals, mentoring of future leaders etc are an integral part of a good QM program.

This helps with professional growth and individual members of the organization feels that the organization pays attention to their needs and professional development. This aids in boosting the morale of all personnel. Additionally, staff members feel good about being part of an organization that focuses on staff involvement in activities for improving patient care, engages team members to develop clear requirements or standards for prevention of problems and improved communication among professionals, and encourages the team to create a roadmap for enhancing safety and quality of care provided to patients. The overall result of this is a general awareness of being part of a well-run organization, which, itself, contributes to the raised morale.

8.5 Reduction of Litigation?

It was mentioned earlier that a key theme of the book "To Err Is Human: Building a Safer Health System" is that errors are not generally reported because of legitimate liability concerns. We live in a society where litigation has become a part of our daily lives. There are many stories of patients suing the healthcare organizations for errors in the management of their care. Since a good quality management program reduces the likelihood of errors, this will also reduce the likelihood of litigation. Litigation also requires access to various documentation related to the incident. A good quality management program ensures maintenance of good documentation of patient care and thus can very easily provide access to such documentations even years after rendering full patient care.

8.6 Increase of Competitiveness

We live in an era of digital communication. Patients these days are very savvy and routinely review websites of different radiotherapy centers to determine where they will get the best quality of care. Quality and safety are paramount in their minds. Radiotherapy centers routinely provide information on their websites about their team of professionals, technologies used, and programs in place for providing efficient, safe, and high-quality care. Thus, centers with advanced technologies, good professionals and an efficient, safe and good quality program will be at an advantage to attract patients and bring positive benefits to them compared to their neighbors who may not have these capabilities. To be competitive and attract patients, all centers will thus make best effort to develop a good quality program.

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