

## QUALITY ASSURANCE IN RADIATION ONCOLOGY

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**Abstract**

Quality assurance is important for any medical procedure or intervention to ensure that patients receive management that is suited to their medical condition and that which has been described in textbooks, literature or by expert opinion. Currently many procedures are complex and require a multi-step process, each stage of which may be prone to mistakes, deviations or variation in interpretation. Radiation oncology involves a very complex process of consultation, preparation or planning and execution or treatment. Each of these processes requires stringent adherence to accepted standards both within a particular radiation oncology department or within a national health system. This is particularly important with rarer conditions, or where there is some debate regarding appropriate management. When conducting research it is vital that conformity across all researchers exists. While protocols go some way to ensure this, there have to be quality assurance mechanisms to ensure uniformity and compliance to the protocol. Some deviations may have minimal effects on outcome, while others may have a profound effect and compromise patient outcomes and results of clinical trials.

Radiotherapy is a local treatment for cancer. Hence the methodology used is highly operator dependant. In this case, the operator is not one person but a team of professionals including the radiation oncologist, planning radiation therapists, physicist and treating radiation therapist. Because of this sometimes complex, multi-step process, there is margin for error which may affect outcomes in tumour control and thus survival. It is important that the process of tumour assessment, treatment planning and treatment delivery be subject to acceptable standards in order to ensure optimal outcomes for the patient. Failure to do this can result in inadequate tumour control (due to inadequate doses to the tumour) or unacceptable complications (due to excessive doses to normal tissues). The process of ensuring that both these goals are met is the core of quality assurance in radiotherapy and should be present at a departmental, national and international level.

**Departmental quality assurance**

Radiotherapy departments either exist as stand-alone treatment facilities or as a department within a tertiary referral hospital. Most departments consist of more than one radiation oncologist with a team of radiation therapists and medical physicists. Radiation oncologists tend to have a major interest in one or more disease sites, but in smaller departments tend to be 'multi-skilled' with no particular tumour site interest. Radiation therapists tend to rotate through both planning and treatment areas and the frequency of this rotation may vary. Medical physicists may have special interests in specific areas, but may share the quality assurance role for various disease sites. Quality assurance within departments serves both as an educational tool for training staff, as well as a point of discussion whereby participants improve their knowledge about the management of rarer tumours, complex treatment situations and controversial settings.

**Incident reports**

Contemporary linacs are extremely reliable but complex machines with many potential areas of malfunction. The quality of therapy delivered by the linacs is however, dependent on the staff operating the machine and their compliance to the patient's plan. Much of a patient's treatment is now automated via record and verify systems, however minor faults can still occur due to human error in the treatment room. These 'incidents' usually occur only during a small segment of a patient's overall treatment and do not result in a major outcome issue. Typical examples are a misplaced field, an under or overdose for a few fractions, or the inappropriate use of associated features such as skin build-up and wedges. It is important the all incidents be reviewed regularly and reported to the treating clinician. If an incident is seen as a recurring problem associated with a staff member or machine, suspension of treatment involving those vectors should be considered until the problem is rectified.

**Chart rounds**

Typically, chart rounds may take the form a discussion of all or the more complex cases in a weekly forum. In such meetings the case is presented, any imaging displayed, the contoured volumes demonstrated and finally the proposed plan displayed on a large screen. Where controversy may exist, comments may be noted in order that the treating radiation oncologist may customise the patient's plan to obtain optimum results. The areas which frequently undergo debate are the coverage of the tumour volume by the appropriate target volume, the tolerance of dose-limiting tissue close to target volumes, the optimal dose and fractionation and sometimes the technique used, whether it be three dimensional conformal treatment or intensity modulated radiation therapy. Most national accreditation bodies mandate this activity for departments to remain viable as radiotherapy training centres.

### **Morbidity and mortality meetings**

Most curative or radical radiotherapy treatments are associated with some degree of toxicity or morbidity. Over the past two decades much the toxicity has been offset by the employment of dedicated teams of allied health professionals aimed at minimising morbidity and keeping patients out of hospital. Most of the toxicity that requires admission revolves around the development of concurrent infections during therapy and difficulty in breathing or swallowing as a result of a compromised upper aerodigestive tract. While there is little that can be done to prevent infections, most require relatively short admissions and respond well to antibiotic therapy. Aero-digestive tract problems however, can be suitably prevented in any cases. Airway compromise from tumour of the larynx or bronchus can be prevented with steroids and nutritional compromise can be prevented with alternative forms of nutritional support such as percutaneous gastrostomy or nasogastric feeding. Nevertheless, some patients are admitted to hospital during and after therapy and a small proportion may die as a result of therapy. In the modern era the number of radiotherapy treatment related acute deaths is very low.

The other major reason for admissions is palliative care. Most departments still list up to 40% of treatment intents as being palliative or aimed at symptom relief rather than cure. The aim in such therapy is to make sure toxicity from therapy is minimal, however admissions occur due to patients being unable to cope at home as a result of poor pain control, fungating tumours, lack of social support and many other reasons.

With the increasing costs of health care, it is important that all radiotherapy departments review their admissions and severe morbid events on a regular basis to see if any unforeseen activity may reduce or prevent those events.

### **National quality assurance**

In Australia, quality assurance between the radiotherapy departments is suboptimal. Most departments follow the International Convention of Radiation Units recommendations for dosimetry, which means that within the department, target volume coverage is specified to the 95% isodose line for photons and the 90% isodose line for electrons.<sup>1</sup> This essentially means that receiving 60 Gy to a tumour at institution should be equivalent to receiving 60 Gy at another institution. However, not all departments obey the International Convention of Radiation Units conventions, which means that subtle dose variations exist between departments and this can lead to problems in clinical trials and if patients move from one site to another.

There are also variations in the way clinicians interpret clinical findings and treatment protocols, which may mean a patient may receive different treatments according to the way the department operates. For instance, one department may treat localised prostate cancer with 74 Gy and weekly kilovoltage image guidance and another with 78 Gy and daily image guidance using cone beam CT scans. The second of these practices is more labour intensive and much more costly than the first, but any

evidence to support the second approach is based on intuitive data and no formal comparison between the two approaches exists or is planned.

For the management of cancer patients, various attempts to try and standardise therapy have been made using guidelines for each tumour site. These guidelines are based on all available evidence, including the experience of known experts in the field. Even then controversy and disagreement exists and so most guidelines are just that, with many having a set of options for treatment available. Radiotherapy is clearly a cornerstone of cancer management and does form part of the guidelines for the management of common tumours, but the less common cancers tend to get managed in a variety of ways with a range of doses, fractions and techniques being used. Fortunately in most common cancers, this has a minimal or very marginal impact on outcomes.<sup>2-4</sup> There have however, been cases where an accepted radiation dose schedule was thought to be both safe and effective and yet resulted in several patients developing late toxicity and disabling morbidity.<sup>5</sup>

### **Clinical trials**

In national clinical trials, quality assurance is vital to ensure consistency across all participating sites. Each trial has a rigid protocol which specifies doses (to both the target volume and dose limiting tissues), number of fractions, techniques and modalities. To ensure constancy, participating sites need to be accredited before talking part in the trial. This can involve several different approaches. The most costly involves a site visit by an independent team of radiation therapists, physicists and occasionally a radiation oncologist. This is to ensure that the participating site has the experience and expertise to comply with the protocol and provide accurate data for the trial. Sometimes it can involve the site doing a 'dummy run' on an imaginary patient, with the processes carefully evaluated for compliance before the first real patient is treated. The commonest method however, involves a review of a sample of patients treated by each site by an independent review committee. Once the trial management committee is satisfied that the site is fully compliant with the sample, accrual may continue without review. Some trials of a highly technical nature will insist that all the data from all the patients be reviewed throughout the trial to ensure a minimum of violations.

The Trans Tasman Radiation Oncology Group (TROG) is the peak body in Australia and New Zealand that coordinates clinical trials in radiotherapy. Since its inception in 1989, it has built up a formidable infrastructure in quality assurance to manage its portfolio of clinical trials. One of the first studies published by TROG members involved a survey looking at contouring localised lung cancer using the available imaging.<sup>6</sup> To everyone's surprise, there was great variation among the volumes generated and even considerable variation among so-called experts in the field. More recently the importance of quality assurance in clinical trials has been highlighted by the outcomes of the 'Headstart' trial, which compared two different radio-sensitisation regimens in the definitive management of locally advanced head and neck cancer.<sup>7</sup> While there

was no significant difference in outcomes related to the regimens, there was a highly statistical negative impact on local control when plans were found to comply poorly with the radiotherapy protocol. This clearly showed that when using definitive radiotherapy, strict compliance to the protocol is essential and that all definitive radiotherapy trials should have a strong quality assurance component.

The cornerstone of the current TROG infrastructure is the Central Quality Management Scheme, a computer based program which can compare plans of individual patients with an 'ideal' plan and thus immediately generate data relating to possible violations.<sup>8-10</sup> These can then be reviewed to see if they are significant and if so, whether they are major or minor. The quality assurance program run by TROG for its clinical trials has led to other international trials groups adopting a similar approach.

## New technologies

The field of radiation oncology is plagued by the desire to try new technologies and this interest exists at all staff levels. Whether it is driven by industry or just the desire to be one better than one's neighbour is unknown. It is however, clearly an attraction for new staff and the program of getting a new technology up and running represents a challenge which many staff actually enjoy. One of the problems alluded to earlier is that comparisons between old and new technologies seldom take place. Most departments adopt the new technology based on intuitive data and the charm of the vendor. TROG has over the past three years made an honest attempt to evaluate some of these technologies in a scientifically acceptable program known as the Assessment of New Radiation Oncology Technologies And Treatments (ANROTAT) study. The study aims to evaluate the efficacy, toxicity and cost-effectiveness of intensity modulated radiation therapy at three sites (nasopharynx, anal canal and post-prostatectomy). It also aims to evaluate the same criteria for image guided radiation therapy in the definitive management of localised prostate cancer. The evidence currently available to support the use of these therapies compared to three dimensional conformal radiotherapy is currently based on retrospective data. The ANROTAT study involves 20 institutions across Australia (public and private, rural and metropolitan) which means it will give clinicians and the rest of the world some idea as to the true value of intensity modulated radiation therapy and image guided radiation therapy.

## Conclusion

This review has covered the major areas where quality assurance is important in radiation oncology. There are some areas not mentioned which are probably only of minor importance. In conclusion, it is quite clear that all definitive radiotherapy plans are dependent on operator, patient and tumour factors which are subject to variation. This in turn can compromise outcomes, so it is essential that some sort of quality assurance be performed where possible. It may be only a discussion with a colleague or be subject to expert review as part of a clinical trial. Adjuvant and palliative treatments clearly have much less impact on clinical outcomes and perhaps don't require the same resources as a definitive therapy.

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