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Importance of Quality in Radiation Oncology

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Given the very narrow window of complication-free locoregional cancer control, radiotherapy of high quality is imperative. It is important in clinical trials that the quality of radiotherapy be of sufficient uniformity and standard that the results of the trials are not confounded. The landmark Headstart study[1] showed that the variation in quality of radiotherapy had a similar impact (20% local control detriment in case of insufficient quality control) to the intervention being investigated. Interestingly, the investigators found the greatest variation in centres enrolling small numbers of patients. Quality assurance is even more important with the increasing use of advanced technology and techniques in radiation oncology trials such as Stereotactic Body Radiotherapy (SBRT) and Adaptive Radiotherapy, as centers may use trials for the introduction of such techniques. An example is TROG 15.03 FASTRACK Study of SBRT for primary renal cell carcinoma, where both the technique (Stereotactic body radiotherapy to upper abdomen) and the indication for radical treatment of primary renal cell carcinoma are novel for a number of participating centres.

Rahim et al[2] highlight that despite the evidence for the importance of the quality of the intervention, very few systematic reviews included mention or acknowledge such activities. The authors[2] suggest that this needs to be rectified, as otherwise the value of systematic reviews such as the Cochrane library are diminished. This importance becomes obvious when one considers that patient numbers and statistical significance are fundamental for high quality systematic reviews. In a very elegant study Pettersen et al demonstrated over 10 years ago that quality assurance in clinical trials can reduce the number of participants required or in other words minimize the risk of the study being under-powered[3].Therefore it is is essential that quality assurance activities of radiation oncology needto be included in systematic reviews. In the same way it is essential that radiation oncology investigators,

collaborative trials groups and funding bodies work to make sure such quality assurance components are both rapid and cost appropriate.

There are perceived drawbacks to extensive quality assurance activities. The speed of individual site activation when dependent on benchmarking and dummy runs can be longer than investigators and sponsors often appreciate. For investigators, such delays can reduce enthusiasm for the trial, delay participant recruitment, and impact on funding timelines. For commercial sponsors, especially pharmaceutical companies, delays in trial activation and recruitment, often have major financial implications, as the investigational agent was developed at a significant cost and reduced patent lifespan diminishes the opportunity to recoup such costs.

A number of methods are available to streamline quality assurance components and increase the speed of trial and site activation. Clinical trials organizations are increasingly taking a pragmatic approach. For example, the Trans Tasman Radiation Oncology Group (TROG) is committed to minimizing delays while maintaining intervention and trial quality assurance. With a large portfolio of radiation oncology trials it is possible to "grandfather" institutions already credentialed for techniques such as intensity modulated radiotherapy, volumetric arc therapy, and SBRT to specific body sites. International groups such as the Global Harmonization Group (GHG) support this goal by providing guidance for standardized quality assurance measures in clinical trials[4]. Also use of technology such as web based training can provide rapid transfer of trial specific information[5]. Finally, the emergence of review software such as MIMS Maestro (MIM Software, Cleveland, United States) make dummy runs and real-time review much more user friendly, rapid, and convenient.

The cost of radiation oncology quality assurance remains a vital factor, especially those involving new techniques and technologies. For many studies and trials, the assessment of quality of the radiotherapy delivery isdependent on volunteer radiation therapy, medical physics and radiation oncologist reviewers. It is very important to acknowledge the time and effort provided by such reviewers. The volunteer nature of such reviews often results in delays, as the reviewers often do not have scheduled review times, for such reviews and have to fit them into busy clinical practice.

The quality assurance activities are vital and acknowledging them in systematic reviews would be an important step towards this. It not only allows the authors of the systematic review to focus on the most robust studies, but it also encourages readers (and therefore present or future authors) to consider quality assurance as an essential part of reporting practice. Radiotherapy has important reasons and

ability to be ahead of the field: as there is already a healthy culture of quality assurance in radiation oncology, and being a highly technology and technique dependent modality, quality control activities are relatively easy to describe and implement.

It would help if reporting of the various quality assurance components in clinical trials and systematic reviews was standardized. Journals could consider a requirement for inclusion of specific trial radiotherapy quality assurance in submissions. In addition, systematic review handbooks should include specific guidance on such inclusion. Quality needs to be an integral part of radiation oncology trials, and without such quality there is a risk that outcomes of such studies could be confounded. As Rahim et al[2] have indicated there remains work to include such in high impact systematic reviews such as the Cochrane group.

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