Role of Quality Audits: View from the IAEA

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Introduction

Comprehensive quality assurance (QA) programs, or quality management systems, in radiotherapy include all components of radiation therapy practice (World Health Organization 1988). A wide range of QA recommendations and guidelines that describe procedures, tests, and tolerances for specific parts of the practice is available (Kutcher et al. 1994; Thwaites et al. 1995). In addition to maintaining the quality of patient treatment and the outcome at the required level, QA is also necessary to reduce the likelihood of dose misadministration, that is, reduce the likelihood of the actual delivered dose being substantially higher or lower than intended (International Commission on Radiological Protection 2000; International Atomic Energy Agency 2000). This is particularly important because radiotherapy is a potentially high-risk procedure.

The quality audit is recognized as an essential element of QA systems in radiotherapy. It is a method of checking that the quality of activities in a radiotherapy center adheres to the standards of good practice. The standards may be recommended nationally or internationally and should be derived from up-to-date evidence-based cancer management data.

The ultimate objective of the quality audit is quality improvement and the tool used is an assessment of a practice, or an activity, by an independent body. The quality audit is equivalent to peer-review or independent evaluation of the practice. The audit involves fact-finding and the interpretation of findings in the context of the evidence-based criteria for good practice. Deficiencies in structure, gaps in technology, or deviations in procedures will be identified by the auditors in the review process. This way the areas for improvement will be documented and a set of recommendations will be formulated for implementation by the center being audited. It is generally considered that the findings of the audit and its outcome are confidential between the auditing body and the audited center.

It is worth mentioning that the quality audit in radiotherapy is not designed for regulatory purposes and the auditors have no power to enforce any actions based on their findings; they can only report their findings and give recommendations. The audit should be understood solely as an impartial source of advice on quality improvement (International Atomic Energy Agency 2007a). Therefore, it is the audited center that decides on any actions required for the implementation of the audit recommendations. A feedback system incorporated in the audit scheme should be in place in order to monitor the changes and to organize a reaudit when appropriate. With this approach, the auditing cycle will stimulate and promote continuous improvement for the benefit of the patient.

Scope and Focus

Quality audits are of a wide range of types and levels, either reviewing the whole radiotherapy practice (comprehensive audit) or selected, important parts of the practice (partial audit).

A comprehensive audit, also called a clinical audit (Eurolot Directive 97/43 1997), will cover the whole clinical pathway of the patient including all interconnected stages of radiotherapy. It addresses the three main elements of the practice: structure, process, and outcome. In contrast, a partial audit has a limited scope and only specific parts of the radiotherapy practice are reviewed. This may be a partial audit of structure (e.g., staffing levels and qualifications) or a process (e.g., a dosimetry audit checking the beam calibration in external beam radiotherapy).

Another example of a partial audit is credentialing for entry into cooperative clinical research studies (Kron et al. 2002; Molineu et al. 2005), which examines the compliance of center's proce-
FIGURE 28.1 Fraction of TLD results within 5% acceptable limit in the IAEA/WHO TLD postal dose audit program.

Dosimetry Audit

Audits of radiation dose have a long tradition (Aguirre et al. 2002; Izewska et al. 2003). Both onsite audit systems and mailed dosimetry programs exist in parallel. Typically, onsite audits review local dosimetry systems, test the dosimetric, electrical, mechanical, and safety parameters of radiotherapy equipment, test the treatment planning system, as well as review the clinical dosimetry records.

Many onsite review programs operate at a national level for a limited number of hospitals, whereas mailed systems provide cost effective audits on a larger scale, involving hundreds or thousands of radiotherapy facilities (Roue et al. 2004; Aguirre et al. 2002; Izewska, Svensson, and Ibott 2002; Izewska and Thwaites 2002).

Typically, postal dose audit programs have a limited scope and are capable of providing verification of a few selected dose points or beam parameters. A four-level flexible audit system may be adapted for such audits (Izewska, Svensson, and Ibott 2002)

- Level 1. Postal dose audits for photon beams in reference conditions (Izewska et al. 2003; Izewska and Thwaites 2002; Aguirre et al. 2002). This is the basic level, recommended for all radiotherapy centers and mandatory in several countries.
- Level 2. Postal dose audits for photon and electron beams in reference and nonreference conditions on the beam axis (Roue et al. 2004).
- Level 3. Audits for photon beams in reference and nonreference conditions off-axis and dose at depth on the beam axis for electron beams (Izewska et al. 2007).
- Level 4. Audits for photon and electron beams in semi- and anthropomorphic phantoms. This step is used to verify the dose distribution for more realistic treatment situations, such as breast, prostate, or lung (Gershkevitch et al. 2008) or special treatment techniques, such as intensity-modulated radiation therapy (IMRT) of head and neck (Molineu et al. 2005).

Figure 28.1 illustrates the improvement in dosimetry practices in radiotherapy centers participating in the IAEA/WHO TLD postal dose audit program. After the regular follow-up of poor TLD results was introduced in 1996 by the IAEA/WHO, the fraction of acceptable results increased to about 0.96.

Comprehensive Audit

To optimize clinical outcomes, it is equally important that the clinical aspects as well as the physical and technical aspects of patient treatment are audited because, though essential for the radiotherapy process, accurate beam dosimetry and treatment planning alone cannot guarantee the required outcome of a patient's treatment. The comprehensive audit methodology is described by the IAEA (International Atomic Energy Agency 2007a) and an EC guidance document (European Commission). The IAEA audit methodology, also known as the Quality Assurance Team for Radiation Oncology (QUATRO) methodology, puts emphasis on radiotherapy structure and process rather than treatment outcome. It includes an assessment of infrastructure as well as of patient-related and equipment-related procedures involving radiation safety and patient protection aspects,
where appropriate. Staffing levels and professional training programs for radiation oncologists, medical radiation physicists, and radiation therapists are also reviewed.

The interpretation of audit results is made against the appropriate criteria of good evidence-based radiotherapy practice. As an example of such criteria, the IAEA has given a description of the design and implementation of a radiotherapy program regarding clinical, medical physics, radiation protection, and safety aspects (International Atomic Energy Agency 2008a, 2008b).

Since 2005, the IAEA has organized approximately 50 QUATRO audits in response to voluntary requests from its member states in Africa, Asia, Europe, and Latin America. The QUATRO audits included the assessment of the ability of centers to maintain the radiotherapy practice at the level corresponding to the best clinical practice in the specific economic setting of a given country. Gaps in technology, human resources, and procedures were identified and areas for improvement in current services were documented. Additionally, centers received advice for further development. Some centers have been acknowledged for operations at a high level of competence. Based on the audit results, it was possible for the IAEA to identify specific areas and items needing improvement (weak links) in the different centers and address the common aspects such as, for example, staff training internationally. Figure 28.2 shows patient throughput on radiotherapy machines analyzed within the QUATRO process; equipment shortages in some centers have been addressed by the national governments following the QUATRO audits.

**Summary**

Radiation oncology requires a strong commitment to QA, including active participation of all staff directly involved in the radiotherapy process and supporting specialists. Using a regular audit system will bring continuous improvement through assessment and implementation of all those planned and systematic actions necessary to provide adequate confidence that the radiation treatment will satisfy the given requirements for quality in patient treatments. The analysis and utilization of the audit findings will help to set targets for improvement and the effects of any changes implemented on the practice should be monitored continuously.

**References**


IAEA. 2008b. Transition from 2-D Radiotherapy to 3-D Conformal and Intensity Modulated Radiotherapy. Vienna: IAEA.


Quality and Safety in Radiotherapy

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Radiation therapy and the associated medical imaging are becoming increasingly complex and computer-driven making it difficult for those in the field to ensure high quality and safe use of these technologies. Although medical physicists are best equipped to understand the technical aspects of these technologies and their applications, most have specialized expertise in only certain areas of radiation therapy or medical imaging. Furthermore, employing these technologies with a level of quality and safety found in other industries is not part of routine training in radiotherapy for any of the professionals involved. To truly be effective, we must all be prepared to function at the intersection of these fields.

Addressing this dilemma, Quality and Safety in Radiotherapy tackles the crucial points that guide best practices in patient care. Divided into seven sections, it begins with a discussion of quality management and improvement, examining cost, access to care, and the application of Lean thinking. Next for consideration are patient safety, risk, and error management, a comparison of cultural biases in North America and Europe, and the application of a new paradigm for quality management in radiation therapy.

The third part covers methods to assure and improve quality, including quality audits, peer reviews, and clinical trials. Continuing in this vein, the fourth part highlights human factors in quality care. It looks at leadership and the changing roles of medical and scientific staff as well as staffing guidelines and training. The final sections encompass quality control specific to radiation therapy, the maintenance and operation of equipment, and patient-specific care.

Drawing on recognized experts in their respective fields, Quality and Safety in Radiotherapy provides healthcare professionals with the information they need to understand rapidly advancing technologies and their applications to the safe and effective delivery of quality care to patients.