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REVIEW ARTICLE

Quality assurance in Health Services: the paradigm of radiotherapy

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Summary

Introduction: *In radiotherapy, a team of highly specialised professionals co-operate in planning and delivery of treatment and are responsible for the effectiveness and safety of the service. The aim of this article was to present the necessity and features of a quality assurance (QA) program in radiotherapy through literature review.*

Methods: *A search was carried out in Scirus, Medline/PubMed databases using the keywords "clinical oncology", "radiation oncology", "radiotherapy", "oncology practice", "quality assurance" and "quality of care". Twenty-nine articles were chosen covering the period 1995-2007. Further information was obtained from the Royal College of Radiologists' UK website.*

Results: *QA was relevant to three aspects of radiotherapy: 1) clinical, involving resources (staffing and equipment), procedures (treatment planning, follow up) and results (tumor control, toxicity); 2) medical physics, involving the measurements necessary for the safety and precision of equipment; and 3) technical, involving the accurate plan implementation and the smooth function of treatment machines. International guidelines defined best practice in diagnosis and treatment of cancer patients. Moreover, the principles of quality management provided the tools not only for a reasonable use of limited resources but also for continuous improvement of organisations towards patient-centred services.*

Conclusion: *Quality in radiotherapy is a dynamic concept that needs to be measured and re-evaluated using scientific methods and feedback by the users. Successful implementation of a QA program in radiotherapy requires expertise, training and co-ordination in an environment of teamwork.*

Key words: *clinical oncology, health services, oncology practice, quality assurance, quality of care, radiotherapy*

Introduction

QA means certainty about the right procedures that lead to the intended results. The confirmation comes from periodic and systematic audits, however, the first step towards quality in radiotherapy is good management and planning from the beginning, through appropriately selected professionals, equipment and procedures [1]. The likelihood of error in radiotherapy increases with the increasing complexity of new techniques, the automation of many procedures and the demand for better local disease control with minimal toxicity through accurate targeting of tumour. Nevertheless, errors do happen even under the best circumstances, so there is a need for inspection of every step of the radiotherapy process, as can be achieved with quality control, which can trigger the necessary corrective action, before errors have an impact on patient care. Finally, the success of this effort as a whole needs to be re-evaluated and modified when necessary, so as to further decrease the likelihood of error in the future (quality improvement) [1].

It has been suggested in several studies and reviews that the systematic implementation of a QA programme in radiotherapy contributes to the prevention of systematic errors and the reduction of the frequency and severity of random errors [2-7].

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The first QA programmes were focused on dosimetry and the validation of the proper function of the mechanical and electrical parameters of the equipment. Then, they gradually expanded to include treatment planning processes, patient set-up immobilisation and treatment implementation. Lately, the scope of a QA programme in radiotherapy has expanded to include the radiotherapy process as a whole, from the decision to treat a patient, to follow up. Moreover, parameters such as staffing and organising a radiotherapy department, including the necessary expertise and continuous training of the personnel, can be determined by a QA programme in radiotherapy.

It is worth mentioning that it is the responsibility of the managers and the scientific personnel of the radiotherapy department (radiation oncologists, medical physicists and radiotherapy technologists) to design and apply a QA programme. On the other hand, the aim of compulsory inspection of radiotherapy departments by formal authorities, which is determined by national legislation in accordance with European and International regulatory authorities, is to control the use of radiation, to ensure safety and serve as an external audit. In Greece, the relevant regulatory authority is the National Committee of Atomic Energy (EEAE).

Examples of quality controls and their results

In a review of the literature [8], an excessive radiation exposure of 1,700 patients was reported between 1976 and 2007 and, ultimately, 2% died in mid and high-income regions of USA, Latin America, Europe and Asia. In most of the cases (98%), errors occurred during treatment planning, particularly on commissioning of new equipment. Among the errors that did not have a major impact on patient's health, 7% involved treatment planning, 39% information transmission, and 19% treatment implementation. The rest 35% of errors occurred during treatment decision, patient set up, simulation or within a combination of treatment phases (communication errors).

The report of mailed Thermoluminescent Dosimetry (TLD) audits by International Atomic Energy Association (IAEA), which has been implemented during the past 30 years and controls more than 1,600 radiotherapy departments in 120 countries [9], describes a steady improvement of results, so that 95% of the participating departments are within tolerance limits (5% deviation in beam calibration). Several countries have applied the IAEA methodology in the development of national regulatory audits [10].

Since 1982, the European Organisation for the Research and Treatment of Cancer (EORTC) – RT Group has established a Quality Assurance Programme in Radiotherapy. Dosimetry audits in particular were the most important and widely spread interventions and it became evident early, after only two consecutive controls that deviations in dosimetry for both photons and electrons can be minimised [11]. Nowadays, the EORTC QA methodology is applied in clinical trials in Europe.

In Japan, the results of a phase III clinical trial [12] revealed limited conformity to the study protocol (40%), so in 2002 the Japan Clinical Oncology Group (JCOG) initiated a QA programme in clinical trials and the first results showed good compliance to the protocol and revealed the necessity of a systematic QA programme [13].

In the UK, in 1993, the results of the treatment of cervical cancer were discouraging. While treatment toxicity was still low (6.1% compared with 5% which is valid for most radical treatments), the 5-year survival rates were alarming, since they were significantly poorer than FIGO had announced for 1990-92 (stage Ib 62 vs 72%, stage Iib 47 vs 63% and stage IIIb 23 vs 41%) [14]. Although no convincing explanation could be given, the need for auditing results of treatment and for developing the best available treatment protocols was revealed. The cost was estimated to be only 1% of the cost of screening, ensuring at the same time that the benefit of early diagnosis would be accompanied with the best clinical outcome possible.

It has been widely accepted that prolonged waiting times for starting radiotherapy may result in disease progression [14] and patients may lose a chance for radical treatment [15], having lower chances of cure and worse outcome [16-20]. In the UK, an effort has been made since 1998 to reduce patient waiting times for radiotherapy. Investment in equipment, personnel and training programmes were implemented, with visible benefits for the patients. In 4 consecutive audits (1998, 2003, 2005, 2007), which were held nationwide, the reasons for the delay in starting radiotherapy were noted, as well as the result of the interventions to reduce waiting times which showed a decreasing trend. In the evaluation of 2007 [21] the percentage of patients exceeding the target of waiting for less than 28 days for radical radiotherapy dropped from 53% in 2005 to 32% in 2007, while efforts to meet the target that had

been set in 1993, for all patients, are ongoing [22]. They make continuous effort not only to reduce waiting times for radiotherapy but also to tackle additional quality issues, such as avoiding treatment interruptions that have a negative radiobiologic impact, as well as the availability of new technologies that enable more sophisticated techniques to be applied nationwide which improve tumor control while minimise toxicity.

In Greece, the first dosimetry study in all radiotherapy departments was held during 2002-2006 by the EEAE [23]. In 23 departments the mechanical parameters and the dosimetry of the treatment units were evaluated. The worst performance was noticed in cobalt units (28% of the cases were beyond tolerance limits at least in one mechanic parameter). Similarly, in terms of dosimetry, 61% of the cobalt units had a deviation of more than ±3% and 31% had a deviation of more than ±5%. The benefit of this study was the implementation of IAEA TRS-398 protocol so as to achieve uniform and consistent results in dosimetry throughout the country, while at the same time providing guidance for minimising sources of error. Moreover, it was proved in practice that there is a need for frequent quality control to ensure precision and safety in radiotherapy, along with appropriate equipment maintenance, early intervention and prevention of possible errors.

ISO 9001 in radiotherapy

Both the European Society for Therapeutic Radiation Oncology (ESTRO) and EORTC have published papers and guidelines for quality assurance in radiotherapy and in clinical trials, involving dosimetry, treatment planning evaluation, treatment volumes delineation, infrastructure, staffing and organization standards for radiotherapy departments [24-28].

In order to evaluate the organisation and the services provided by a radiotherapy department, the PACE Foundation criteria can be used, which are based on ISO 9001 standards and adjusted for use in health services. Both PACE criteria and ISO 9001 describe what needs to be assessed rather than suggesting ways of organisation, they tend to be less detailed and more flexible [24]. PACE criteria refer to the processes within a department as a whole and in relation to other departments (Figure 1). Input for PACE model are the patients referred for radiotherapy and output are considered to be the patients discharged having completed treatment. The output, which is the result of the processes within the system, can be considered successful or of good quality if the following prerequisites are met:

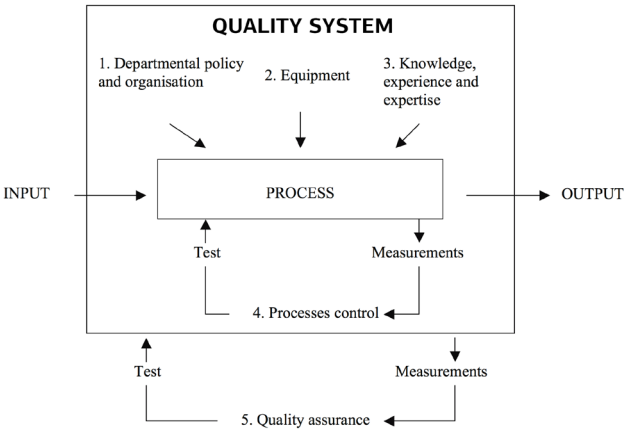

Figure 1. Quality assurance model based on PACE criteria [26].

1. Departmental policy: it is the responsibility of the Head of the department to describe the vision and the aim for the implementation of a QA programme and to ensure that the procedures run smoothly. All the hierarchical connections and the links between the processes must be clearly defined.
2. Equipment: detailed records of the processes involving equipment commissioning and maintenance must be kept.
3. Knowledge, experience, specialization: continuing professional development of personnel (skills and qualifications) is the responsibility of the Head of the department.
4. Control of processes: protocols that describe all the processes from patient referral to discharge and follow up are particularly useful.
5. Quality control: an internal process of quality control needs to be designed in order to ensure continuous evaluation of the QA effectiveness, so as to be updated when needed.

Quality control and continuous improvement

Through systematic evaluation, a radiotherapy department can examine to which extend the processes meet both the internal and external demands for quality and ensure continuous improvement.

Internal evaluation of processes and quality control of the department's suppliers enable management:

a) To perceive emerging problems before they

become urgent.

b) To pinpoint errors, bottlenecks that hinder the flow of a process, so as to be dealt with instantly.

c) To assess the effectiveness of quality controls.

Quality control of suppliers: ensures that the internal processes of the department's suppliers meet predefined quality standards. They are usually yearly and when deviations are noted, compliance can be requested.

Internal audit: refers to both preventive and corrective actions. It is a snapshot of the departments' performance and can detect deviations from the targets so as to trigger corrective actions to eliminate problems [29]. Elements that need to be addressed are:

a) Clear definition of processes and evaluation criteria.

b) Record keeping of progress in time by registering prior inspections, interventions and their results.

c) Ways of early error detection, effectiveness of quality control (percentage of errors detected), responsiveness (how soon they are corrected).

d) Defining the type of feedback that the personnel needs.

Table 1. Seven basic quality measurement tools

Tool	*Description*
Cause-and-effect diagram (fishbone diagram/Ishikawa diagram)	Identifies many possible causes of a problem
Check sheet	Data collection form for the frequency of certain events
Control chart (process behavior chart)	To quantify and predict the outcome of a process
Histogram	Recording and schematic depiction of the distribution of data
Pareto chart	Data analysis to illustrate the most important events
Scatter diagram	Schematic method for determining the correlation between two variables
Stratification	Categorizes data in order to highlight the situation of a substrate (alternatively used flowchart)

The success of a QA programme is based on the automation of the following steps, which are considered to be key elements of successful internal and external quality control and form the cycle of continuous improvement, through re-evaluation and feedback (Figures 2-4). Moreover, Table 1 illustrates the 7 basic quality measurement tools in summary.

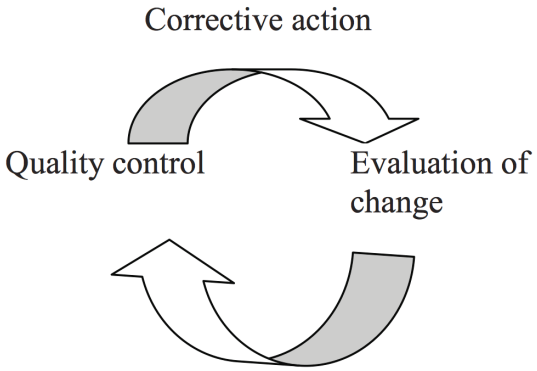

Figure 2. The cycle of continuous improvement

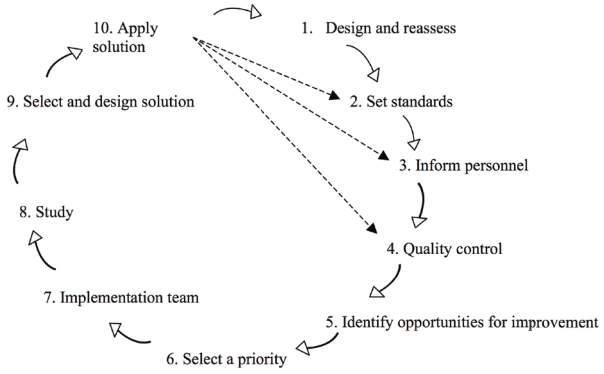

Figure 3. The quality circle [30].

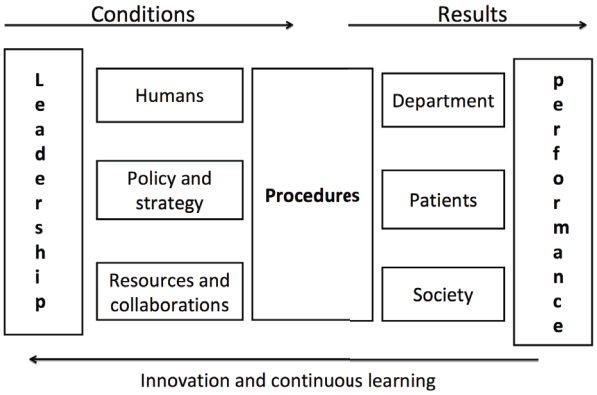

Figure 4. The model of quality management EFFQM [31].

1. Scheduling: determines who is responsible for the process, when and what is to be evaluated, what kind of documents and resources will be necessary.
2. Planning: includes detailed description of the aim of the QA programme, the time-frame, what will be monitored, when and by whom.
3. Managing: the Head of the department ensures that the QA programme runs as planned, offers solutions to problems, coordinates the participants, and promotes professionalism to draw useful conclusions.
4. Reporting: written comments and lists of deviations can form the basis of discussions for improvement.
5. Verification: seeking for causes, suggesting and implementing solutions, verification that causes of deviation from targets have been eliminated.

Conclusions

Quality in radiotherapy demands use of scientific methods. It is dynamic and needs to be measured and re-evaluated. Quality is based on a bidirectional relation between the service and the user, so it needs feedback in order to be enriched by the user experience. Successful implementation of a QA program in radiotherapy requires expertise, training, coordination by talented leaders, in an environment of team-work.

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