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Quality assurance in conformal radiotherapy: DYNARAD consensus report on practice guidelines

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Abstract

Background and purpose: Conformal radiotherapy has only recently been widely implemented. Although not all aspects have yet been adequately proven, it is generally recognized that maintaining a high degree of precision throughout the process is critical to the treatment outcome while the focus for quality assurance and quality improvement will need to concentrate more on human factors, procedures, communication, organization and training. A general consensus document on quality assurance guidelines for institutions that deliver conformal radiotherapy treatments to patients has been elaborated within the framework of the DYNARAD/BIOMED concerted action on conformal radiotherapy. The present paper aims to highlight those issues that were identified as of specific importance to conformal radiotherapy. The work reported here further details this guidance by direct correlation with the issues involved in the special case of conformal radiotherapy.

Methods: The DYNARAD document has been drafted in the form of a desktop guide comprising six sets of guidelines and is based on the ESTRO advisory report on 'Quality Assurance in Radiotherapy'.

Results and conclusions: The document has been endorsed by the DYNARAD group of institutions. As such it can form the basis for further discussions and enter into the subsequent phase of expanding its consensus basis. © 1997 Elsevier Science Ireland Ltd.

Keywords: Quality assurance; Conformal radiotherapy; Quality standards

1. Introduction

1.1. Rationale

Increasing the probability of tumor control, without inducing severe normal tissue damage, still remains the major challenge in curative radiotherapy. Conformal radiotherapy exploits the recent advances in 3D imaging, dose planning and therapy monitoring to tailor the high dose volume as closely as possible to the target with concurrent minimiza-

tion of the dose to non-target tissues. Stereotactic radiotherapy constitutes a specific form of conformal radiotherapy, aiming to deliver a large dose of radiation to a small volume of tissue in a single or multiple fractions.

The present concept of conformal radiotherapy has placed a high technological demand on the relevant processes, requiring professional support of diverse expertise. The techniques profit largely from the implementation of recent technological advances, which hold much potential for improvement of the effectiveness and efficiency of conformal procedures. At the same time, however, the increased complexity and sophistication of this technology

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have imposed great demands on the users, while the improved reliability of modern radiotherapy equipment is causing a shift of the focus for quality improvement to the appropriate, safe and efficient use of this technology. In consequence, the focus for quality improvement will concentrate much more on human factors, procedures, communication, organization and training.

The need to effectively address quality assurance in radiotherapy has been reflected in a number of recent documents [2,7,20–24] which address the global issues for management of the service in order to promote a continuous improvement strategy for the overall process. A recent ESTRO advisory report to the Commission of the European Union for the 'Europe Against Cancer' program has considered the general requirements for quality assurance in radiotherapy [21]. This document has observed the general WHO approach, which emphasizes the need for quality assurance across areas of radiation oncology [24]. Furthermore, the document has maintained consistency with the ISO 9001 and the EN 29000 series of EC standards, which embody a rationalization of the many and various national approaches to quality systems and provide the general guidelines for their implementation and management [17].

A concerted action on conformal radiotherapy amongst 30 European institutions was launched in 1994 within the European Union BIOMED program. The project bears the acronym DYNARAD (development and standardization of new DYNAMIC RADIOtherapy techniques/BIOMED 1, Science Research and Development, Biomedical Health and Research, Directorate General XII, Commission of the European Communities) and is intended to provide a forum for exchange of ideas and to share experiences with the ultimate goal of improving knowledge, establishing broadly accepted practice and promoting a common understanding and concerted activity around the key issues involved. Work is performed across five main lines of action including imaging, treatment planning, special techniques, clinical evaluation and quality assurance.

A document on quality assurance for conformal radiotherapy was formulated within the DYNARAD Quality Assurance Group, reflecting a general consensus on the recommended quality assurance practice for institutions that deliver conformal radiotherapy treatments as part of their radiotherapy service. The previously mentioned ESTRO advisory report on 'Quality Assurance in Radiotherapy' has been adopted as the basic reference document. The work reported here aimed at further detailing this guidance by direct correlation with the issues involved in the special case of conformal radiotherapy. The document has been endorsed by the DYNARAD group of institutions (Vrije Universiteit Brussels, BE; University Hospital of Gent, BE; University of Liege, BE; Paul Scherrer Institute, CH; Radiologische Universitätsklinik Tübingen, DE; Rigshospitalet, DK; Arhus Kommunehospital, DK; Clinica Puerto de Hierro, ES; Universidad de Sevilla, ES; Institut

Curie, FR; Hospital Tenon, FR; Centre Alexis Vautrin, FR; Centre de Protontherapie D'Orsay, FR; Institut Gustave Roussy, FR; Institut Paoli-Calmettes, FR; University College of London, GB; St. Bartholomew's Hospital, GB; University Hospital of Patras, GR; Piraeus Anticancer Hospital Metaxa, GR; CRS Instituto Regina Elena, IT; Borgo Trento Hospital, IT; University of Amsterdam, NL; Academisch Medisch Centrum, NL; Haukeland Hospital, NO; Karolinska Hospital, SE; Centro de Oncologia de Coimbra, PT). As such it can form the basis for further discussions and enter into the subsequent phase of expanding its consensus basis.

1.2. Application of recommendations

From the outset it has been common strategy in radiotherapy to conform the dose distribution within the limits of a given technique as closely as possible to the internal target volume (ITV), a geometrically defined volume which contains or has a high probability of containing target tissues to be treated to a prescribed time-dose pattern in order to raise the dose to the tumor while sparing normal tissue [19].

The term 'conformal radiotherapy' is used today for radiotherapy with the high dose surface tailored to conform to the internal target volume. Individual radiation therapy centers may be utilizing very different levels of effort and technology when applying conformal radiotherapy techniques. This is often a reflection on availability of resources. For the purposes of effectively defining the framework, within which the various issues were addressed in this document, and limiting the scope of the work to the most commonly encountered level of procedures, the classification scheme proposed within DYNARAD was adopted [6]. This scheme proposes four levels of radiotherapy, each representing procedural chains of progressively increasing degrees of sophistication of equipment and practice, tools and methodology. The present document is intended to apply to conformal radiotherapy/level 2 techniques, as defined in Table 1, where the interfacing levels 1 and 3 are also shown. This level has been considered to reflect the most commonly encountered level of procedures applied in institutions that provide conformal radiotherapy services. Level 3, on the other hand, is considered representative of the current status and trends for research in the associated areas of conformal radiotherapy. Level 1 is regarded as representing the standard practice for the majority of curative treatments. A fourth level (level 0), not appearing in this table, encompasses the very simple techniques used for palliative treatments with no attempt to conform the dose to the target volume.

It is understood that the list of items appearing in the columns of Table 1 may not necessarily be exhaustive nor absolute, while there is much overlap between consecutive levels. Nevertheless, this classification has proven valuable in facilitating the discussions and interaction amongst the

Table 1

Classification of conformal therapy according to the methodology and tools associated with each step of the procedure

	Level 1	Level 2	Level 3
Patient data acquisition			
Immobilization	Optional	Individual cast or stereotactic frame	Individual cast or stereotactic frame
Imaging system	Localization films $\pm$ individual CT slices	Thin adjacent CT slices or helicoidal mode	Multimodality imaging and registration (CT + MRI + ...)
Anatomical data:			
Referential	Table + mid line	External markers or frame	Implanted markers or frame
Critical organs	Contours in individual slices	Contouring slice per slice	3D segmentation
Inhomogeneities	Contours in individual slices	Contouring slice per slice	3D segmentation or voxel per voxel
Gross tumor volume (GTV)	Contours in individual slices	Contouring slice per slice	3D segmentation
Clinical target volume (CTV)	Manual contouring per slice	Strictly based on defined margins	Automatic 3D determination from GTV + biological data
Internal target volume (ITV)	Clinical approach	Explicit margins + anatomical boundary	Based on quantification of movements
Beam definition			
Accounting for beam setting uncertainty	Delineation of ITV using $\pm$ arbitrary margins	3D delineation of ITV using quantified margins	Dosimetric simulation of statistical variations
Type of radiation and beam modifiers	Photons and/or electrons $\pm$ wedge filters	Photons($\pm$ electrons) $\pm$ compensators	Photons + intensity modulation protons + compensators
Beam incidence	Coplanar	Non-coplanar	Dynamic non-coplanar sequences
Isocenter	SSD or SAD technique (manual set-up)	SAD technique (auto centering on target) ^a	SAD technique (auto centering f (dose)) ^a
Beam limiting device	Standard shielding blocks	Individualized blocks or multi-leaves collimator	Dynamic multileaves collimator
Shape of the field obtained from	Simulation films $\pm$ slices	Beam's eye view + manual or auto delineation	Beam's eye view + auto calculation
Dose calculation and optimization			
Calculation model	1D or 2D (slice) $\pm$ inhomogeneity	2D or 3D (volume) with inhomogeneity	3D or 4D (dynamic) inhomogeneity + interfaces
Evaluation of treatment plans	Isodoses in several slices $\pm$ CT images	Isodoses in arbitrary slice + dose volume histograms (DVHs)	3D isodose surface/structure + DVH + TCP + NTCP...
Treatment plan optimization	Successive trials + visual appreciation	Successive trials + use of a score function	Solution of the inverse problem
Treatment verification and execution			
Pre-treatment delivery verification at simulator	Yes (sometimes combined with patient data acquisition)	Recommended	Replaced by 'room's eye view'
Immobilization (see above)	Optional	Individual cast or stereotactic frame	Individual cast or stereotactic frame
Aids for positioning	Lasers + light field	Lasers($\pm$ light field)	Useful?
Patient positioning	Coordinates (height, translation) + skin marks	Use of referential linked to patient (frame, markers...)	Use of referential + computer control
Verification imaging system/reference image	Initial port film/simulation film	Films and/or EPID/virtual simulation $\pm$ DRR	EPID and/or X-rays in room virtual simulation and DRR
Record and verify system	Optionally linked to individual machine	Part of integrated network	Mandatory for safe use of automated dynamic sequence
In vivo measurements	Optional	TLD or diodes recommended	Idem + dosimetric use of EPID

^aAutomatic isocenter definition at center of target volume. For level 3, adjustment of the isocenter position can form part of the dose distribution optimization process.

DYNARAD institutions within a commonly understood framework. As such, it has been considered as the most suitable for effectively defining the scope, by providing an appropriate reference within which the relevant issues have been treated.

The DYNARAD document has maintained the overall structure of the ESTRO advisory report on 'Quality Assurance in Radiotherapy'; the relevant guidance has been developed in a set of guidelines which apply to the follow-

ing items: quality requirements for conformal radiotherapy; quality assurance for conformal radiotherapy; organizational structures for conformal radiotherapy; technological infrastructure for conformal radiotherapy services; process control for conformal techniques; securing knowledge and skill in conformal radiotherapy.

In the following sections usage of the term 'conformal radiotherapy' should be taken to mean 'conformal radiotherapy/level 2' and referenced to Table 1.

2. Quality requirements in conformal radiotherapy

‘Quality’ as defined in the ISO standards refers to ‘the totality of characteristics of an entity that bear on its ability to satisfy stated or implied needs’. The term ‘entity’ has a very broad scope since quality, as a concept, is encountered in many different contexts [18]. The concept of quality in health care services has evolved over the years and has closely followed perceptions of importance attached to the various aspects of health care at each stage. Today, quality in the health care sector is regarded as encompassing all medical, technical, economic and ethical aspects of health-care delivery.

Therefore, a high degree of professional excellence, efficiency in the use of resources, minimization of risk to the patient, satisfaction of the patient and the final health impact constitute the main determinants for quality in health care delivery [25]. Within this extended context, requirements for quality in conformal radiotherapy are based on the following considerations: (1) conformal radiotherapy is primarily of curative nature with an intent to treat malignant or benign tumors, lesions or malformations; (2) adequate confidence in the specification of dose and dose distribution to the tumor and the surrounding normal tissues is required in order to permit escalation towards more effective tumoricidal doses; (3) conformal techniques may be labor intensive and technologically demanding; optimization of efficiency is required without compromising safety; (4) conformal radiotherapy has not yet reached a state of ‘stable technology’ and therefore clinical practice needs to undergo frequent changes and adaptations while new knowledge becomes available at high rates and consequently, skills need to be continuously maintained; (5) conformal radiotherapy comprises a complex procedural chain with critical information flow across a multifunctional and often cross-departmental team.

3. Quality assurance in conformal radiotherapy

Achieving the aims of conformal radiotherapy requires a minimum level of staffing, facilities and equipment. The means by which each part of the service will be provided and the standards against which quality is to be assessed will depend on the type of radiotherapy techniques employed and they should be predefined and established prior to the implementation of any new conformal technique. These considerations have led to the following set of basic elements for quality assurance in conformal radiotherapy.

3.1. Aims

Each radiotherapy department or institution should clearly define the level of conformal radiotherapy that can

be offered, taking into account available resources, manpower and expertise at a local, regional and national level; such aims should be explicitly stated and understood by all staff involved in the process.

3.2. Criteria and standards

The criteria by which the quality of both the radiotherapy process and the eventual treatment outcome will be assessed should be defined. The corresponding standards should be locally established and/or existing standards should be adopted.

3.3. Procedures

Effective and efficient procedures that will lead to the intended outcome should be designed and implemented. These should allow for flexibility to accommodate specific clinical cases and/or changes for improvements.

3.4. Responsibilities

All staff involved should understand the purpose and rationale of all procedures and be in a position to unambiguously identify their role in the process.

3.5. Documentation

Procedures should be described in adequate detail in a departmental quality manual. Such documentation should be updated whenever changes in the procedures have been deemed necessary and have been introduced in practice.

3.6. Resources

Adequate resources, both technological and human, should be allocated to the service in order to run it effectively, in compliance with the stated aims and the respective criteria and standards.

3.7. Evaluation

Compliance should be systematically monitored.

3.8. Feed-back

Mechanisms for prompt identification and effective treatment of problems and implementation of corrective actions should be established.

3.9. Attitudes

A culture for quality in the department should be established and sustained and a focus on continuous quality improvement should be promoted.

4. Organizational structures for conformal radiotherapy

It is considered imperative that departments which aim to provide conformal radiotherapy (at level 2 or higher) should design and maintain effective quality assurance procedures by establishing and maintaining an appropriate quality system. The issues relating to the responsibility for quality, organizational relationships and staff qualifications have been discussed in detail in the ESTRO report [21]. In addition to this guidance, the following issues are specifically emphasized: (1) a thorough review of new or modified conformal treatment techniques and equipment should be carried out prior to their incorporation into clinical routine. The design, implementation, testing and validation of such techniques may be carried out by project groups established to carry out the particular projects; (2) communication between different individuals and groups involved in the process of conformal radiotherapy should be clearly structured; (3) communication pathways and information content to be exchanged should be specified and documented; (4) specific quality related problems identified at any point should be addressed by teams having representatives from all categories of staff involved in the processes under consideration; (5) each individual member of staff must have the appropriate qualifications to carry out his or her duties relating to any part of the process of conformal radiotherapy; (6) staff assigned particular responsibilities in connection with conformal radiotherapy should have several years of previous experience with the lower levels of conformal radiotherapy; (7) all personnel, including medical doctors, medical physicists, technologists, dosimetrists and medical engineers, involved in conformal radiotherapy should receive adequate theoretical and practical training prior to their engagement in conformal radiotherapy.

5. Technological infrastructure for conformal radiotherapy services

The following guidelines focus on the equipment requirements which are necessary to ensure the establishment of effective and efficient conformal radiotherapy facilities. The minimum set of performance standards relating to the functionality and accuracy of this equipment are treated extensively in a number of relevant reports and do not fall within the scope of the present document.

The guidelines are as follows: (1) all equipment required to perform the tasks involved in conformal radiotherapy effectively should be available at or accessible to the department; (2) all equipment used in conformal radiotherapy should comply with existing national and international technical standards; (3) such equipment should, additionally, meet requirements for a minimum level of automation necessary to support efficient implementation of conformal

radiotherapy techniques on a routine basis and improve staff working conditions.

Equipment used in conformal radiotherapy should maintain its designated performance as well as acceptable safety standards for patients, staff and the general public throughout its lifetime. Fulfillment of the above requirement should be ensured by means of systematic maintenance and quality control programs of every item of medical equipment used in conformal radiotherapy. Quality control comprises the set of operations intended to verify quality, including evaluation and monitoring of performance for maintenance of characteristics at the optimum level. The general considerations for these aspects are provided in the reference document. Further specialized technical guidance may be sought in a number of technical reports [1–5,8–16].

The following is intended to provide a comprehensive list of equipment that should be available according to the definition of conformal radiotherapy/level 2. These items constitute the essential technological infrastructure required to appropriately implement conformal treatment procedures.

5.1. Patient data acquisition

(1) A CT scanner with fine spacing between slices should be available for treatment planning; automatic 3D reconstruction for visualization of the treatment volume should be available; acquisition of a dedicated CT scanner as part of the basic technological infrastructure of the radiotherapy department should be pursued; a helical CT is particularly recommended for busy departments in order to increase efficiency of the procedures; (2) patient movement restriction devices in the form of casts or frames should be available as appropriate.

5.2. Beam definition

(1) Photon and electron beams should be available in a broad range of beam energies; (2) linear accelerators should be equipped with multileaf collimation and if this type of collimation is not available automatic (or manual) individualized block molding equipment should be used; (3) beam modifying devices should be available; such devices may be present in the form of automatic or manual compensator equipment; beam intensity modulation available on the treatment unit is considered a particularly useful option; (4) laser alignment systems should be installed in all treatment and simulation rooms.

5.3. Treatment planning

A computerized treatment planning system should be available bearing the following features: (i) 3D delineation of target volume; (ii) 3D dose calculation with corrections for inhomogeneities and changes in scatter in all directions within the irradiated volume; (iii) non-coplanar

beam set-up; (iv) beam's eye view (BEV) of the anatomical area; field simulation via digital reconstructed radiographs (DRRs) is considered a particularly useful option; (v) multileaf collimation field shaping, compensator and individualized blocks design functions; (vi) treatment plan evaluation tools including dose volume histograms (DVHs), isodose scan views (cine loops) and display of isodose surfaces in relation to the target volume; (vii) calculation of the mean and the standard deviation of the dose to the target volume, as well as the maximum and the minimum values; (viii) an autocentering facility, as an option.

5.4. Treatment verification

5.4.1. Pre-treatment verification

Pre-treatment verification should be performed by means of either (i) a conventional simulator and subsequently verified on the treatment machine by portal imaging or (ii) DRR and BEV functions, if both are available with the treatment planning system, verified on the treatment machine by portal imaging.

5.4.2. Treatment delivery verification

(1) A portal imaging system should be available in all cases. This may be either an electronic imaging device or a film-cassette system; (2) a record and verify system should be used for the electronic recording of the treatment related data, verification of the treatment parameters and monitoring of the treatment sessions; (3) an in vivo dosimetry system should be used to monitor dose during treatment.

6. Process control for conformal techniques

Conformal radiotherapy has only recently been widely implemented on a routine basis. To date, not all aspects of conformal radiotherapy have been adequately proven, as long-term follow-up of patients that have undergone such treatment is not yet complete. Consequently, the techniques which are currently implemented in institutions are based on promising but not necessarily proven clinical studies [6]. As a result, best practice guidelines are not currently available for conformal radiotherapy. In addition to the general guidelines for process control provided in the ESTRO report [21], the following considerations for conformal radiotherapy have been addressed.

6.1. Practice

(1) The greatest part of the total effort is expected to be expended in treatment planning, preparation and pre-treatment evaluation of any conformal treatment. These parts of the radiotherapeutic chain should therefore be strengthened and reinforced by an appropriate resource allocation; (2) local consistency for conformal techniques should be main-

tained; to this end, conformal treatment protocols should be established and maintained in each radiotherapy department based on current knowledge and existing scientific evidence; (3) any new techniques and dose escalation studies should be carefully designed and adequately supported by the necessary preparatory investigations. Such preliminary investigations should address specific problems, such as movement of the target and changes in position of organs at risk during therapy.

6.2. Treatment planning and optimization

(1) Clear identification and precise outlining of anatomic structures, particularly the target volume(s) and organ(s) at risk, is a prerequisite of efficient conformal radiotherapy. This part of the medical decision process is particularly critical to the entire radiotherapy process; (2) a thorough review of the isodose distributions with regard to tumor coverages and doses to surrounding tissues as well as an inspection of the DVHs and other plan evaluation outputs should precede any new treatment; (3) feasibility of the treatment set-up with particular regard to the patient's safety during execution of treatment should be checked carefully. Computer simulations of the machine movements provide a particularly useful tool for this purpose; (4) treatment verification should be performed prior to all new or modified treatments as well during the course of the treatment. The required frequency of such verifications should be determined at each department and should be based on evidence from treatment verification records; (5) conformal treatment may require considerable delivery times. The expected overall session time should be taken into account as part of the biological considerations of the treatment.

6.3. Records

(1) Treatment data records should include the mean dose to the target volume, the standard deviation and the maximum and the minimum values. The overall session time should also be recorded. Such records can be part of the data recorded by the record and verify systems; (2) treatments should be documented in a systematic and clear fashion, so as to provide feed-back for analysis in case of recurrences and local complications in a clear, straightforward fashion; (3) records should include the minimum required imaging data for visualization of the target volume and organs at risk, all relevant treatment planning information as well as record and verify data on the treatment delivery; (4) dosimetric data should be appropriately referenced for interdepartmental studies. The dose to the ICRU reference point should be recorded and used for this purpose.

6.4. Information flow

(1) Communication and information flow throughout the whole process is a critical factor. Integration of the process,

via digital data communication, should be pursued in order to maximize usage of error free transmission means; (2) Utilization of record and verify systems should reinforce the link between the treatment planning and treatment delivery sub-processes.

7. Securing knowledge and skill

Departments aiming at delivery of conformal techniques should take actions to promote continuous learning and maintenance of knowledge and skills and establish effective communication with institutions with similar aims. Furthermore, commitment to research and advancement in this particular area is of particular importance.

(1) All personnel, including medical doctors, medical physicists, technologists, dosimetrists and medical engineers, involved in conformal radiotherapy should keep updated on current developments in the field; (2) key personnel involved in conformal radiotherapy should attend on-site training at established centers with experience in the particular techniques.

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