

## Review

Quality assurance and quality control for radiotherapy/medical oncology in Europe:  
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Abstract

The past two decades have brought tremendous changes to the practice of radiation oncology and medical oncology. To manage all the complexities related to the new technologies and the new drugs, the radiation and medical oncologists have to enhance their clinical action and professional skill profile. To accomplish this they have to find reliable tools in the quality of their medical practice and in future research activities. Quality assurance (QA) and quality control (QC) for radiation and medical oncologists mean to clarify the different components of the clinical decision, to supervise with proper methodology the required steps needed to accomplish the agreed outcomes and to control them. Quality for radiation and medical oncology means to supervise each clinical and technical component of the whole process to guarantee that all steps together will arrive at the final and best possible outcome. Key components are guidelines, specialization and a multidisciplinary approach. The research of global quality could represent a further complexity, but it is the best tool to give a perspective and a chance to further improvements of our disciplines and to promote better outcome in all cancer patients.

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## Introduction

Since the 1960s, i.e. for 4–5 decades the clinical practice of radiation oncology has been refined and mastered through a greater understanding of radiobiology and physics and greater possibilities to target the dose to the relevant volumes, through great attention to acute and late morbidity, and through the publication of clinical results. Radiation oncologists have established their pivotal role in cancer care from diagnosis to death. They participate in staging and treatment decisions, prescribe and monitor treatments, follow the patients through the course of their disease, and offer palliative and terminal care if disease

control is not possible. Radiation oncologists in many parts of the world, particularly the United Kingdom, the Netherlands, Canada, and Australia, took on the responsibility of giving chemotherapy and remain “clinical oncologists” to this day. In other countries, like the Nordic countries, medical and radiation oncology is one speciality, clinical oncology.<sup>1</sup>

The past two decades have, however, brought tremendous changes to the practice of radiation oncology and medical oncology. Nowadays, radiation oncology is a medical speciality with rich traditions of clinical care and evidence-based practice that has become increasingly absorbed with technological advances.<sup>1</sup> Medical oncology developing from haematology, since the first advances in drug treatment were seen in haematologic malignancies, is today a medical speciality, in most countries separated from haematology, although in others closely linked to radiation oncology. Drugs, not only traditional cytotoxics, but also many new molecular entities directed against specific targets, have proven efficacy at least to some extent in

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several tumour types. The evolution is rapid, the gains frequently only incremental, with important exceptions, although proven in high-quality studies, and costly. The demands for better prediction of those who will benefit are enormous.

To manage all the complexities related to the new technologies and the new drugs, the radiation and medical oncologists have to enhance their clinical action and professional skill profile. To accomplish this they have to find reliable tools in the quality of their medical practice and in future research activities. Quality assurance (QA) and quality control (QC) for radiation and medical oncologists mean to clarify the different components of the clinical decision, to supervise with proper methodology the required steps needed to accomplish the agreed outcomes and to control them. Quality for radiation and medical oncology means to supervise each clinical and technical component of the whole process to guarantee that all steps together will arrive at the final and best possible outcome. Key components are guidelines, specialization and a multidisciplinary approach.

### Clinical decision

The clinical decision represents the interaction between the knowledge and attitudes of the physician, the expectation of the patient and the offer of the health care system. With different level of awareness and responsibility along the own professional life, the radiation and medical oncologists base the clinical decision on information from different sources; scientific evidence, physician and patient preferences, external rules and constraints.<sup>2</sup>

Although surgery remains the most important treatment of rectal cancer, used in this article for illustration, the management of this disease has evolved to become more and more multidisciplinary. The availability of guidelines can help the specialists of a multidisciplinary team to address the diagnostic and treatment recommendations prospectively, and to monitor and evaluate the outcome properly. Multidisciplinary management is the preferred approach and offers the best clinical outcome also when the clinical presentation is complex and the reference guidelines are not enough to support the clinical decision.<sup>3</sup>

Guidelines represent an evidence-based reference collection of recommendations edited by a group of recognized providers of knowledge and behaviours. Many organizations are the provider of guidelines at international, national and regional level. In oncology they address not only clinical recommendations but also technical aspects of the daily practice in the different oncological specialities. They are promoted and founded by international organizations and societies (e.g., IAEA, ICRU, ASCO, ESMO, ESTRO, ASTRO) or by national institution and societies; some of these are used widely across oncology (e.g., PDQ, NCCN).

A variety of endpoints may be measured and reported from clinical studies in oncology to promote evidence (mortality, cause-specific mortality, quality of life, or indirect

surrogates such as event-free survival, disease-free survival, progression-free survival, or tumour response rate). End-points may also be determined within study designs of varying strength, ranging from the gold standard—the randomized, double-blinded controlled clinical trial—to case series experiences from non-consecutive patients. A system of levels of evidence has been created to help the reader judge the strength of evidence linked to the reported results of a therapeutic strategy. Depending on perspective, different expert panels, professional organizations, or individual physicians may use different cut points of overall strength of evidence in formulating therapeutic guidelines or in taking action; however, a formal description of the level of evidence provides a uniform framework for the data, leading to specific recommendations.

Subspecialization, the presence of a multidisciplinary team and of the agreed guidelines are the three foremost fundamental indicators of the management of the clinical decision also in rectal cancer treatment under a QA umbrella.

### Treatment monitoring

Nowadays, the methodology to guarantee the appropriateness of this aspect of the quality of the radiation and medical oncologists' practice is well established, even if the unstoppable development of new technology and new drugs and targets offer new pitfalls to identify and overcome. Different agencies can offer guidelines and independent accreditation programmes. To accomplish such programmes is very challenging because of the amount of time and changes in the organization they require, but there are many related benefits. Of great relevance behind a QA programme is the educational opportunity for the teams. A QA programme promotes the awareness of the relevance of every detail in each step of the staging, treatment and follow-up procedure, the importance of the verifiability of the daily practice to enhance its reliability, and the significance of the contribution of every member of the staff and of the patients to the perspective optimization of all procedures. The quality governance of the delivery processes does not only minimize the team from any legal issue, but it increases the consciousness of the overall reliability of own practice in the team, in the hospital and in the related community.

In radiation oncology new laws and directives at national and European levels on protection against the dangers of ionising radiation connected to medical exposures together with the rapid technological developments, have directed particular attention to the subject of QA.<sup>4</sup> Well defined recommendations are available. Together with the QA programmes the different steps and actors of the Radiation oncology procedure can function properly.

The main features of each step which are under an assurance program in radiation oncology are:

**Consultation:** A Radiation Oncologist (RO) must demonstrate that he/she performs an adequate clinical

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