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Editorial

# Doing the right thing: Quality in radiotherapy, a European perspective

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> "You must never be fearful about what you are doing when it is right!"
>
> [Marie Curie]

Only few months ago, on November 7th 2017, we celebrated Marie Sklodowska Curie's 150th birthday. She was a Polish chemist-physicist, a brilliant scientist, the first woman ever being awarded a Nobel Prize. She discovered Radium and Polonium, and, together with the discovery of X-rays by Roentgen, paved the way for the medical application of radiation. Radiation therapy has since evolved to be a corner stone of oncology treatment, effectively saving and prolonging lives of cancer patients, while improving or preserving their quality of life. As one out of two cancer patients should receive radiotherapy at least once during the course of their disease, the impact of her work, and of radiation oncology, is major [1].

Radiotherapy is widely recognised as one of the safest treatments of modern medicine: errors are rare. But if they occur, the consequences may be significant for the patient concerned, or may affect a large number of patients [2–4]. Moreover, nowadays' radiotherapy is a complex and multi-step process, necessitating input from various individuals that operate high-tech equipment, which calls for a structure supporting continuous quality management and improvement. And within these quality management systems (QMS), risk management must be formally integrated in order to react to or assess any errors that could affect patient safety.

The European Medical Exposure Directive of 1997 (Council Directive 97/43/Euratom) required that Member States take *"all reasonable steps to reduce the probability and the magnitude of accidental or unintended [radiation] doses of patients*" in radiotherapy. The main aim of these guidelines was to help national authorities and radiotherapy services plan and undertake activities to fulfil the above legal obligation. 97/43/Euratom has now been replaced by 2013/59/Euratom and is due to be transposed into national legislation in February 2018. This Directive makes reporting and learning from incidents a legal requirement and states that all radiotherapy practices should include a prospective risk analysis of all the processes involved as part of their Quality Assurance programme.

Even if radiation oncology has a long history of performing risk assessment and documenting and reporting adverse error-events or near misses, there is no worldwide consensus on reporting mechanisms, terminology or classification. There is also a lack of a systematic methodology for prospective risk analysis in radiation therapy, and it is not homogeneously performed across departments in Europe. Hence the need to review in detail the current state of implementation of the Euratom Directive regarding radiotherapy risk management and to propose broadly-accepted guidelines focusing on risk analysis of accidental and unintended exposures in radiotherapy.

The ACCIRAD project ("Guidelines on risk analysis of accidental and unintended exposures in radiotherapy"; http://www.accirad.eu/), contracted by the European Commission and executed by a consortium of 6 institutions and organisations including the European Society for Radiotherapy and Oncology (ESTRO), aimed to respond to this need. The project reviewed a wide range of national and international reporting and learning systems and carried out an analysis of the main tools used in risk management. After surveying 38 European countries, it was found that although steps have been taken to implement European directives to reduce the probability and magnitude of accidents in radiotherapy, variability between countries remains substantial. The legal frameworks are diverse, and a wide range of tools to conduct proactive risk assessment and reactive event analysis are used [5,6]. The third and final report of the ACCIRAD project, presented in this issue, sets forward general recommendations for radiotherapy departments to establish systems for reporting, analysing and learning and provides guidelines on prospective and retrospective risk analysis methods [7]. It also provides national authorities with a set of strategies to promote and improve patient safety culture. The use of a consistent terminology being considered fundamental, one important conclusion of the consortium merits to be highlighted: it is suggested that the term "accident" should no longer be used but be replaced by the term "adverse error-event". This terminology, indeed, is still the topic of debate, with many systems retaining the use of accident, incident or near-incident, depending on the legal requirements of the system under which they are operating.

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## Allying reactive analysis and proactive assessment

As highlighted in the ACCIRAD publications, a few European countries have established national systems for reporting and analysing near-miss and adverse error-events. The PRISMA-RT platform was initiated in the Netherlands and has been adopted in other countries such as Belgium. It allows for the identification and classification of root causes leading to adverse error-events and near-misses using the Eindhoven Classification system, thus supporting benchmarking and the establishment of national initiatives to improve patient safety [8,9]. Other countries as France and the United Kingdom also have well-established national adverse error-event reporting systems, driven by their national regulatory bodies.

International radiation oncology organizations have also invested in radiotherapy-specific reporting systems. ESTRO has a long-standing history of radiotherapy quality assurance and supports its members to comply with the requirements of 2013/59/Euratom [10]. In this context, it adopted ROSIS (Radiation Oncology Safety Information System), one of the very first international reporting systems, which now after incorporation of educational aspects forms the ROSEIS (Radiation Oncology Safety Education and Information System) incident learning system. ROSIS also laid out the basis for the SAFRON (SAFety in Radiation Oncology) initiative, through which the International Atomic Energy Agency (IAEA) has established a voluntary incident-learning system.

Whatever the reporting system, it must be comprehensive and adaptable, capturing the full spectrum of possible near-misses and adverse error-events throughout the entire radiation treatment process, in order to stimulate system-level changes that will prevent future problems [11]. In addition, radiotherapy-specific detail is crucial: where generic hospital-based national systems are still in use, modifications should be considered, allowing for the in-depth analysis of the stage in the radiotherapy process where safety barriers will be most effective.

Aside from the European initiatives mentioned above, several radiotherapy-specific systems have been developed worldwide. Examples include the RO-ILS (Radiation Oncology Incident Learning System) in the USA, a collaborative effort of the American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM), as well as reporting systems in Canada and Australia, developed by their respective national radiotherapy organizations using experience from local initiatives. There is great opportunity to further enhance learning and reduce risks by establishing international partnership between radiotherapy-specific systems. Recognising this, the ESTRO Radiation Oncology Safety and Quality Committee (ROSQC) instigated an international collaborative group to discuss findings and recommendations from the different national and international reporting systems, and to highlight matters of importance to the radiation oncology community.

Proactive risk assessment, supplementing retrospective analysis and reporting, can be extremely resource- and time-consuming and difficult to implement, especially in small departments. Any national or international initiative to facilitate its implementation can therefore be a real aid for departments aiming to deliver radiotherapy in a safe and efficient manner. As described in the second ACCIRAD paper, guidance on proactive risk assessment in radiation oncology has been undertaken by national professional societies as well as regulatory agencies [6]. For instance, the French Agency of Nuclear Safety developed a guide to help radiotherapy departments in self-assessing risks associated with external beam radiotherapy based on the FMECA (Failure Mode, Effects and Criticality Analysis) methodology [12]. The similar FMEA (Failure Mode and Effect Analysis) was adopted by AAPM Task Group 100 for a risk assessment-based framework for quality management activities in radiation therapy [13]. The "Foro Iberoamericano de Organismos Reguladores" developed a methodology based on Risk Matrix, facilitating prospective risk analysis through a software application. Originally tested for 3D-conformal radiotherapy in Spanish departments, the software can now be customised to department-specific radiotherapy processes. Moreover, in collaboration with the IAEA and SAFRON, a common prospective risk analysis tool is under development. Although adaptation to the specificities of each departmental workflow and procedures will remain unavoidable, such initiatives can support departments in taking the first steps towards proactive risk management and integrate risk assessment in their Quality Management System (QMS).

## Towards an all-encompassing quality management system

Primum non nocere, first do not harm, is core to any risk assessment initiative. However, radiotherapy not only has to be safe, but also be delivered according to the highest quality standards. Risk management should therefore be an integrative part of an overarching QMS, including other important quality assurance tools, such as quality audits and quality indicators.

An audit is a methodical and independent process in which conformance to standards and/or good practice is evaluated. More specifically, a clinical audit is an appraisal that seeks to improve patient care and outcomes through systematic review of the current care against explicit criteria, and to suggest areas where the quality or safety of the processes could be improved. Audits can range from review of a specific aspect to a full comprehensive external audit. They are not aimed as a regulatory procedure, but as collaboration between the auditors and the auditees in view of improving practice.

Consistent with the prior directive, 2013/59/Euratom requires facilities to carry out clinical audits of practice. This is, however, no sinecure. In 2009, a working group on behalf of the European Commission prepared "Guidelines on Clinical Audit for Medical Radiological Practices", including radiotherapy-related aspects, and recognised that clinical audits remained poorly understood and implemented [14]. Over the last decade, the IAEA has significantly contributed to this field, building-up experience in performing comprehensive external audits with their "Quality Assurance Team in Radiation Oncology" (QUATRO) project, in Europe as well as world-wide [15,16].

In contrast to such an external review, quality indicators (QI) allow departments themselves to monitor and assess the quality of their services and treatments. The use of QIs in medicine was first introduced by Donabedian in 1966 [17]. With the aim to measure health care performance, he proposed three categories of QIs: structure, process and outcome indicators. A well-defined set of QIs allows to extract and benchmark the information relevant in supporting continuous improvement of the radiotherapy infrastructure and clinical practice. QIs can be collected and monitored within a department, where the evolution of a set of quality criteria over time can be translated into local improvement actions. At a next level, monitoring QIs amongst departments or at country level, allows for clinical practice benchmarking leading to exchange of best practice and the delivery of best-quality care [18]. There are limited examples showing how collaborative efforts in radiotherapy QI collection can change practice. Already in the mid-seventies, a pattern of care study collected data on quality-of-care, including outcome data, from radiotherapy practices across the USA [19]. It then revealed that radiotherapy facilities that did not have simulation capabilities had higher recurrence rates. The project was furthered, renamed into Quality Research in Radiation Oncology (QRRO) and published various reports on QIs and adherence to standards [20].

This is, however, not yet common practice in Europe. A survey showed that only in one out of three European countries radiotherapy QIs are currently collected at national level, while projects are in development in an additional one out of five countries [21]. Overall, guidance in this field remains poor, highlighting the need for national and international recommendations on which radiotherapy-specific QIs to collect and analyse [22]. Some specific initiatives have started to address this. In 2007, a first set of 13 general radiotherapy QIs was defined by an Italian workgroup; a recent update addresses the changing needs in the intensity-modulated and image-guided radiotherapy era [23,24]. In 2012, a Dutch project proposed indicators for international benchmarking of radiotherapy centres based on a set of QIs initially defined through literature, but fine-tuned using stakeholders' feedback [25]. In addition, national radiation oncology societies such as CARO (Canadian Association of Radiation Oncologists) or SEOR (Sociedad Española de Oncología Radioterapica) are using a Delphi method to reach consensus on a minimum set of radiation oncology-specific QI to be collected at national level.

In all these initiatives, the actual challenge lies in the definition and validation of those QIs that do not only best express the quality of care, but also highlight those improvement actions that will have the greatest impact on the patient's care and quality of life.

In conclusion, radiation oncology has come a long way since its onset in the beginning of last century. To bring the best value to all cancer patients in need of radiotherapy, continuous improvement of and equal access to radiotherapy should go hand in hand with high safety and quality standards. Acknowledging the remaining gaps between the Euratom directives and the radiation safety programmes currently available in European countries, the ACCIRAD project provides a framework and a set of recommendations to support countries and individual departments in achieving safe radiotherapy for each individual patient. Incorporated into an overarching quality management system, the ACCIRAD recommendations will help us, radiation oncology professionals, to do the right thing and give additional endorsement to our adage: "*Radiation oncology cures cancer safely, today.*"

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