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Original article

Patient safety in external beam radiotherapy, results of the ACCIRAD project: Recommendations for radiotherapy institutions and national authorities on assessing risks and analysing adverse error-events and near misses

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ABSTRACT

The ACCIRAD project, commissioned by the European Commission (EC) to develop guidelines for risk analysis of accidental and unintended exposures in external beam radiotherapy (EBRT), was completed in the year 2014. In 2015, the "General guidelines on risk management in external beam radiotherapy" were published as EC report Radiation Protection (RP)-181. The present document is the third and final report of the findings from the ACCIRAD project. The main aim of this paper is to describe the key features of the risk management process and to provide general guidelines for radiotherapy departments and national authorities on risk assessment and analysis of adverse error-events and near misses. The recommendations provided here and in EC report RP-181 are aimed at promoting the harmonisation of risk management systems across Europe, improving patient safety, and enabling more reliable inter-country comparisons.

Radiotherapy, together with surgery and anti-tumour drug therapy (including chemotherapy, hormone therapy, targeted therapy and immunotherapy), is a mainstay of cancer treatment [1,2]. Despite the potential risks of high-dose ionising radiation, the rigorous safety protocols used in clinical radiotherapy have made this field one of the safest of modern medicine. Nevertheless, faced with constant technological changes, all phases of the radiotherapy process must be continuously monitored to detect and prevent errors. Numerous studies have demonstrated the value of comprehensive quality assurance (QA) systems that have explicit, uniform protocols that permit users to quickly assess and correct safety-related adverse events [3–5]. A variety of systems have been developed to classify, record, and report these events [6], with SAFRON and ROSIS (Radiation Oncology Safety Educational and Information System) being the most widely-used international event reporting systems [7,8]. The ROSIS system, created in 2001 under the auspices of the ESTRO, is managed by a Radiation Oncology Safety Committee and includes a web reporting system that is updated as new events are reported. The ROSIS platform provides a common approach to risk management and the implementation of reporting and learning systems.

Comprehensive guidelines and regulations governing radiation safety have been developed by the European Commission (EC) [9]. The EC has also commissioned the ACCIRAD project to assess the status of radiation safety (and regulation thereof) in European countries and compliance with these regulations. The final version of the ACCIRAD recommendations, which have been approved by the EC and endorsed by ESTRO, was published in 2015 as "EC report RP-181" (available at https://ec.europa.eu/energy/sites/ener/files/documents/RP181.pdf).

To ensure wide dissemination of the key findings from RP-181, three separate journal articles (including the present document) addressing key aspects of the report have been published. The first article described the project's main aims, organisation, and the initial results of the surveys [10]. The second article [11] provides details on the current status of (a) proactive risk assessment, (b) reporting and learning systems, (c) and reactive analysis of events

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in European countries. The present document, which provides recommendations to improve safety in radiotherapy risk management, is the third and final article in this series.

The present paper describes the key features of the risk management process and sets out the project's main recommendations for conducting the risk assessment and analysing adverse error-events and near misses. These recommendations are primarily aimed at institutions providing radiotherapy services and the national authorities and other regulatory bodies that oversee and govern safety in radiotherapy.

Methods

The methods of the ACCIRAD study are described in detail in the first publication [10]. The content of the present article is based primarily on the following: (1) evidence-based findings from the ACCIRAD study, (2) professional meetings amongst experts involved in conducting the present study, and (3) the individual expertise and experience of the members of this project. Consequently, the recommendations given here are primarily based on expert consensus opinion.

Results

Key features of risk management

Terminology

Since the same term can have different meanings or connotations, it is essential to clearly define the most important terms, particularly those that could potentially cause confusion. Therefore, defining and establishing common terminology is crucial to permit the analysis and comparison of data from different sources. Below we provided a detailed definition of three important terms; the key terminology recommended for use in radiotherapy is described in Fig. 1 and Table 1.

Adverse error-event

The commonly-used term "accident" is far too broad to be of real use in this field [12–14]. Similarly, while the term "adverse event" (defined as an event which, by an act of commission or omission, leads to unintentional harm to the patient) is more specific than "accident", it is not appropriate because this term could be understood to encompass all types of adverse events that negatively affect the patient. Since the main focus of risk management is to avoid preventable errors (rather than side-effects), we advocate for the term "adverse error-event", defined as any adverse event caused by human and/or organisational failures or machine malfunction.

Risk

The word "risk" refers to "radiation risk"—that is, the various ways in which a patient could be harmed in the context of radiotherapy, including any adverse error-events (such as over- or under-dosing, or a geographic miss). The concept of risk thus includes any aspects of the radiotherapy procedure that can negatively impact treatment outcome.

Risk management

This refers to all risk prevention measures carried out to assure patient safety, including all processes intended to improve safety and reduce risks to limit their consequences. Risk management can be divided into two broad categories: proactive risk assessment (*a priori*) and reactive events analysis (*a posteriori*).

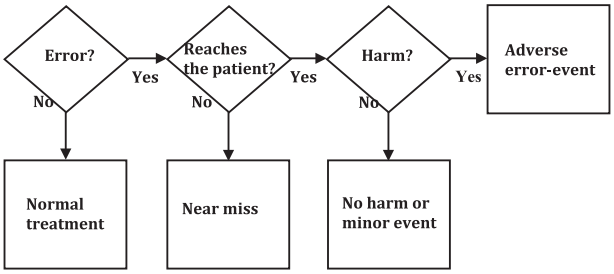

Fig. 1. Scheme for recommended basic definitions.

Organisation and resources

The first step is to determine the specific organisational needs so that the necessary resources can be properly allocated. Importantly, since all or nearly all institutions will have a quality management system in place already, implementation of a new risk management structure only requires the addition of a risk management programme. Several organizations, including ASTRO [16], the NHS [17], and WHO [18] provide support and information about risk management programmes.

The minimum provisions necessary for such a programme include: (1) the designation of a management team to allocate dedicated resources and provide risk management training; (2) an organizational and/or departmental culture of quality management and safety; (3) a risk management committee; (4) a risk manager and multidisciplinary team within the radiation oncology department; (5) dissemination of results.

Proactive risk assessment

Proactive risk assessment is typically required when changes in practice, equipment, or procedures are implemented. These must be evaluated to determine their impact on broader radiotherapy processes. Such changes could be minor (the quality control schedule) or major (new treatment techniques or equipment) or could affect the entire system or department (e.g., transitioning from paper to digital records) or only a work group. In most cases, a good starting point is the risk assessment conducted by manufacturers during the pre-marketing phase (as per article 78 of the European Union [EU] Basic Safety Standards [BSS] [19]).

Risk assessment should be performed regularly and may include any or all of the following: (a) equipment; (b) processes; (c) human and organizational factors; and (d) external factors.

Radiotherapy-specific proactive risk assessment methods

Only two methods have been specifically developed for EBRT: a specific Failure Mode and Effect Analysis (FMEA) developed by the French Nuclear Safety Authority (ASN) [20] and a "Risk Matrix" approach developed by the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) [21]. Both of these methods are described in detail in our previous publication [11].

Reactive analysis of events

The reactive analysis of events is a multi-step process initiated upon detection of an error. It is essential that errors be addressed quickly to reduce their potential negative effects and to assure they do not recur [22–24]. The first step in this process is local recording and reporting within the radiotherapy department accompanied by a rapid analysis of the causes and consequences of the event; this should be followed by immediate actions to safeguard the

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