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Conference paper

SAFETY CONSIDERATIONS IN RADIOTHERAPY

Mirjana Budanec[1], Iva Mrčela[1], Marin Gregov[1], Mihaela Mlinarić[1], Ante Matanić[1,2] and Ana Fröbe[1]

[1]Department of Oncology and Nuclear Medicine, Sestre milosrdnice University Hospital Centre, Zagreb, Croatia; [2]School of Dental Medicine University Zagreb, Zagreb, Croatia

Considering healthcare, we have to face ourselves with an uncomfortable truth: mistakes happen. These mistakes can lead not only to injuries of the exposed individuals but even to death. Radiotherapy is widely recognized as one of the safest treatments of modern medicine[1]. Errors happen rarely, but the consequences of these errors can be significant for one patient or even a large number of patients.

Radiotherapy must be considered as a complex and multistep process involving several health professionals dealing with health aspects: radiobiology, physical principles, radiation safety, dosimetry, radiotherapy planning, interaction with other treatment modalities etc. Radiation oncologists, radiation technologists and medical physicists work together in the process of planning and delivering radiotherapy to patients and should also assure safety in that process.

There have been several publications dealing with the safety of the patient in the framework of radiotherapy[2,3]. The WHO publication[2] analyses serious incidents that have occurred in radiotherapy environment and had been described in literature. The analyzed incidents mostly originated from developed countries. It was shown that many institutions have suffered from the same type of incidents and accidents in different place and time, without knowledge of each other. Many of them were not a consequence of failures in devices and software but rather failures in workflow and process.

An effort has been made to establish databases of the incidents and near misses at the international, national or local hospital level. They are called "incident reporting/learning system". There are several voluntary international reporting systems (ROSIS by ESTRO, SAFRON by IAEA). Following the "no blame policy", radiotherapy professionals are encouraged to report any adverse event that they are aware of during their routine work with the intention of learning from mistakes.

The report on adverse event analysis has to follow certain *classification system*[1]. There are several existing classification systems that have been modified to include radiotherapy-specific details. Classification of events is based on the way in which the event affects the patient (i.e., consequences). A fully developed risk classification system in radiotherapy should include causes, contributing factors, description of the event (date, stage in the process, sequence of events leading to the event, etc.), a description of how the event was discovered, severity of consequences, probability of recurrence, management of the event, and recommendations to avoid future repetition.

To gain systematic understanding of the likelihood and clinical impact of possible failures throughout a course of radiotherapy there is a possibility to use proactive (prospective) or reactive (retrospective) approach.

In proactive approach each institution dealing with radiotherapy practices determines the hazards and risks at their own facility based on their own processes and procedures. This way the institution can direct resources towards patient safety and treatment quality more effectively[4].

The reactive approach is used in the cases where the adverse event already happened. By retroactive inspection using a dedicated method, it is possible to find causes of the mistake(s) which led to the accident.

Correspondence to: *Mirjana Budanec*, Department of Oncology and Nuclear Medicine, Sestre milosrdnice University Hospital Centre, Zagreb, Croatia
E-mail: mirjana.budanec@kbcsm.hr

Having the causes of the accident, it is possible to act in the direction of minimizing the possibility for the accident recurrence. Actions can include a large variety of demands: changes in software or equipment, protocols, work organization, quality control procedures, or they would indicate the need for additional education of the staff, or the need for additional staff, etc. The use of this method in clinical practice may improve patient safety and clinical service. It can provide assessment of success or failure of the quality assurance program in preventing error and allow for better process optimization.

Proactive risk assessment and reactive analysis of events should be used in parallel in order to provide optimum results for risk management.

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 doses to patients" in radiotherapy. 97/43/Euratom has been replaced by 2013/59/Euratom[5] and should have been transposed into European national legislation untill 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 a part of their Quality Assurance program.

References

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