

Risk analysis

Risk analysis in radiation treatment: Application of a new taxonomic structure

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Abstract

Background and purpose: Radiation treatment (RT) for cancer is susceptible to clinical incidents resulting from human errors and equipment failures. A systematic approach to collecting and processing incidents is required to manage patient risks. We describe the application of a new taxonomic structure for RT that supports risk analysis and organizational learning.

Materials and methods: A systematic analysis of the RT process identified five process domains. Within each domain we defined incident type groups. We then constructed a database reflecting this taxonomic structure and populated it with incidents from publicly available sources. Querying this database provides insights into the nature and relative frequency of incidents in RT.

Results: There are relatively few reports of incidents in the *Prescription* domain compared with the *Preparation* and *Treatment* domains. There are also fewer reports of systematic and infrastructure incidents in comparison to sporadic and process incidents. Infrastructure incidents are mainly systematic in nature, while process incidents are more likely to be sporadic.

Conclusions: The lack of a standard, systems-oriented framework for incident reporting makes it difficult to learn from existing incident report sources. A clear understanding of the potential consequences and relationships between different incident types will guide incident reporting, resource allocation, and risk management efforts.

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Patients have a reasonable expectation that they will not suffer harm from an encounter with a health care system. Providers have an obligation to meet this expectation. Patient safety programs directed towards meeting this obligation are the subject of intense activity [1,3,9,18].

Radiation treatment (RT) is a complex medical process involving health professionals, hardware, and software.

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Unlike many other types of medical care, RT is tightly monitored and regulated by both national and provincial/state agencies. Yet, despite great care to ensure accurate and precise administration of RT, there are many published instances of incidents in RT that have led to adverse events [2,7,8,11,12,14,19]. For systematic management of incidents in health care, we need to establish standard taxonomies, track and learn from incident causal pathways, and employ proactive analytical methods such as probabilistic risk analysis [10]. The proactive and systematic approach that we propose in this work is one from which the whole RT community can learn.

An important aspect of a systems approach to patient safety is incident taxonomy and classification [6,13,15–17]. Common concerns with regard to existing incident reporting systems are that there are often disparate data fields as well as conflicting patient safety terminologies, classifications, characteristics, and uses that make communication difficult [4]. This has led to efforts to define

standard incident taxonomies. A recent contribution is by Chang et al. [4], who address a patient safety incident taxonomy in general health care settings. We contribute to the body of work with a focus on incidents in RT.

Our first contribution is the development of a clear taxonomic structure for classifying incidents in RT. This taxonomic structure supports risk analysis, incident learning, and risk management. Our taxonomy classifies incidents into four categories (domain of occurrence, affected prescription elements, occurrence type and incident source). This is the first step in allowing useful information to be gathered from the incidents so that it can effectively feed back into the management of health care systems.

Our second contribution is a database, based on the taxonomic structure, populated with reported RT incidents from three public sources. We categorize incidents according to the taxonomic structure and draw conclusions about the state of the system from which they were collected. Querying the database not only sheds light on those domains and incident types that are most prone to error but also highlights the often conflicting lessons which can be learned from these public databases.

Materials and methods

Clear terminology is necessary for a clear taxonomy. We provide the following definitions [5]: An *incident* as an unwanted or unexpected change from normal system behavior that causes, or has the potential to cause, an adverse event, and a *misadministration* as an incident in which a deviation from a prescription exceeds a predetermined value. An *adverse event* is an incident that occurs during the process of providing health care and results in sub-optimal clinical outcome including unintended injury or complication leading to disability, death or prolonged hospital stay for the patient. An *error* is defined as the failure to com-

plete a planned action as it was intended or a situation in which an incorrect plan is used in an attempt to achieve a given aim. Errors often result in incidents. However, only a few incidents result in adverse events. Therefore, not all errors result in adverse events.

Incidents in health care delivery can be classified as clinical or non-clinical. In this paper we are concerned with classifying clinical incidents. We have developed a system map, based on a systematic analysis of the clinical aspects of the RT process (Fig. 1). The map has been designed to be as generic as possible; i.e. the five main process sectors identified, hereafter called domains [4], are common to most encounters with a health care system. These five domains are: *Assessment*, *Prescription*, *Preparation*, *Treatment* and *Follow-up*.

In RT, *Assessment* includes all diagnostic and investigative procedures undertaken to define the state of disease, and provides the information required for a radiation oncologist's prescription. *Prescription* involves the decision making process conducted by a radiation oncologist when defining the treatment plan. The treatment prescription includes the definition of treatment intent (palliative or curative) and prescription elements (dose and volume). All processes that are undertaken to implement the prescription (simulation, treatment planning, etc.) occur in the *Preparation* domain. In the *Treatment* domain, the patient is set up according to the prescription and the instructions on the treatment chart developed in the *Preparation* domain, and then the treatment unit is configured to deliver the required dose distribution. *Follow-up* includes all activities that monitor the patient's health and cancer response after the completion of a course of treatment. In some cases, a patient will go through the treatment cycle several times until they are discharged from the process.

In this paper, we consider incidents reported in the *Prescription*, *Preparation* and *Treatment* domains. Within each

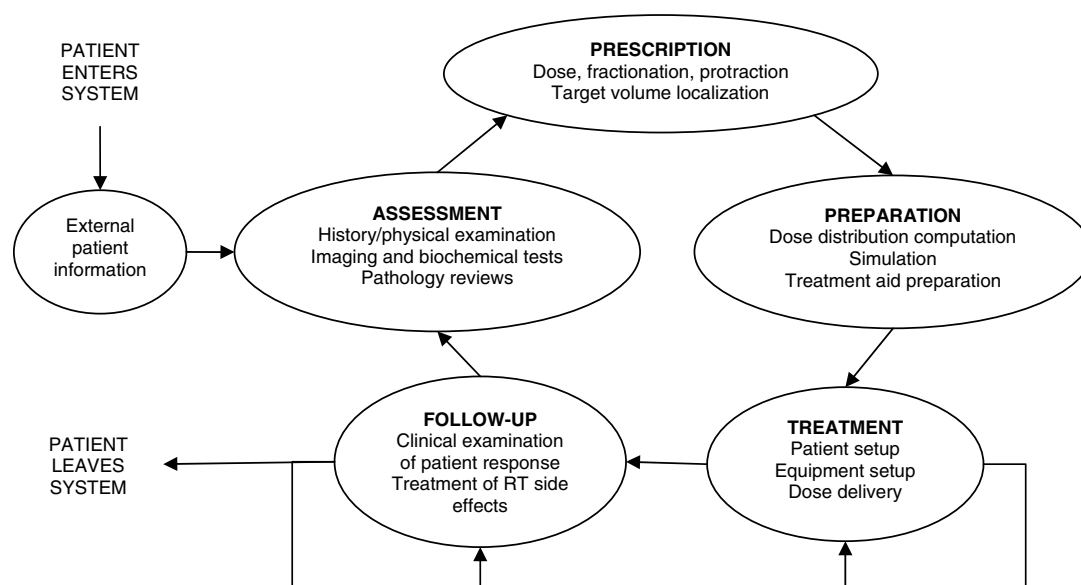


Fig. 1. Radiation treatment system map with five main domains of activity: assessment, prescription, preparation, treatment, and follow-up.

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