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Original Paper

Enhancing clinical safety in radiation oncology: A data-driven approach to risk management

Lukas Sölkner, Dietmar Georg, Uwe Wolff, Andreas Renner, Joachim Widder, Gerd Heilemann [1,*]

Department of Radiation Oncology, Medical University of Vienna/University Hospital Vienna, Vienna, Austria

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ABSTRACT

Purpose: To demonstrate a data-driven risk management (RM) strategy in radiation oncology using an in-house developed web-based incident reporting system. The system leverages real-time analytics to enhance clinical risk prioritization and management, improving patient safety and treatment efficiency.

Methods: We developed and implemented a web-based incident reporting system that allows any staff member to report incidents in real time, supporting anonymous submissions and capturing detailed incident data. The collected data are followed up in monthly meetings of a dedicated multidisciplinary RM team that decides on respective interventions. Over five years, incident data were analyzed to assess the effectiveness of safety barriers—pre-planning, physics, and pre-treatment checks—in capturing incidents before they impact patient care and safety. The analysis focused on incident frequencies and the workflow steps where errors originated versus where they were detected, highlighting deficiencies and guiding improvements. When specific issues increased, a Failure Mode and Effects Analysis (FMEA) was initiated to identify and prioritize failure modes and implement corrective actions, such as new safety barriers or refining existing safety measures.

Results: The web-based incident reporting system enhances responsive incident reporting and tailors RM strategies effectively. Data analysis reveals incident frequencies and detection points, identifying errors that bypass safety barriers and enabling targeted countermeasures. Despite safety barriers intercepting many incidents, critical gaps were identified. Since implementing data-driven RM in 2019, the average number of process steps between incident cause and detection could be halved. Resource analysis indicates increased allocation is needed; development required approximately 150 h, and RM averages 20% of a full-time equivalent position.

Conclusion: Implementing the web-based incident reporting system has advanced RM in radiation oncology, ensuring legal compliance and enhancing safety through real-time analytics. The system effectively identifies and mitigates risks, strengthening QA barriers as evidenced by decreased time between error origin and detection. Adequate resource allocation is essential to sustain these improvements. Increasing full-time equivalent allocations for RM activities is recommended.

Introduction

Risk management (RM) in radiation oncology has always been an integral and essential element in an overall quality management system to ensure patient safety. During the last decades, the complexity of imaging and dose delivery technology, the treatment techniques, including fractionation, and the associated workflows have increased enormously. Moreover, today's image-guided treatment concepts with reduced margins and increasingly applied hypofractionated treatments necessitate an interdisciplinary RM group and a robust incident reporting system to detect and mitigate risks promptly. In light of the transition of clinical practice in radiation oncology towards highly streamlined workflows with AI tools automizing entire processes like auto-segmentation [1,2] or treatment planning [3,4], RM needs to comply with these developments [5].

Several traditional procedures like patient-specific quality assurance (PSQA) involving dosimetric verification by either measurements or calculations and patient chart checks are generally accepted and widely implemented methodologies to minimize the risk of treatment errors [6–8]. Due to equipment improvement and the computerization

* Corresponding author: Gerd Heilemann, PhD, Währinger Gürtel 18-20, 1090 Wien, Austria.
E-mail address: gerd.heilemann@meduniwien.ac.at (G. Heilemann).
[1] Author responsible for statistical analysis.

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of the workflow, the feedback towards RM generated from these procedures has diminished in value. A more recent approach for enhancing patient safety is process analysis as a more prospective than reactive methodology [9–11]. Despite the various measures to prevent dose delivery errors, incident reporting, and learning systems are a key element in identifying systemic vulnerabilities in a department to provide an organized platform for learning from events and appropriately reacting to minimize future risk [12].

In Austria, legal requirements based on the national radiation protection legislation and updates to the ISO standards for hospital certification have generally intensified the need for effective RM strategies. As a first step, during the last few years, workflow automation and process management have been implemented in our department, which improved efficiency, reduced stress, and helped distribute the workload more evenly. It ultimately resulted in increased safety for the patient [13]. Nevertheless, process management is only one element. The interdisciplinary RM group has been enlarged by including at least two representatives from each profession, i.e., radiation oncology, medical physics, radiation technology, administrative personnel, and nurses. By intention, no member of the department's management board (head of department, head of medical physics, or head of RTT) was included in the RM group. It was concluded that the traditional incident reporting systems suffered from underreporting and delays in data analysis, which limited their effectiveness in improving patient safety, especially in a precision radiotherapy setting. To address these challenges, an in-house web-based incident reporting system was developed at our department. This reporting system was designed to facilitate real-time reporting and analysis of incidents, enabling a proactive approach to RM to minimize the potential for severe consequences arising from errors.

This contribution aims to demonstrate how implementing this web-based system enhances RM practices by utilizing real-time data analytics for improved prioritization and management of clinical risks.

Materials and methods

Development of a web-based incidence reporting system

The web-based incident reporting system was developed in-house over several stages to ensure functionality and user-friendliness. It is accessible from the clinical workflow management platform, which is widely used by all clinical staff, irrespective of professional background [13]. Key features of the system include real-time reporting, which allows staff to report incidents as they occur, reducing delays in data collection. The reporting supports both anonymous and non-anonymous reporting to encourage participation. An emphasis on detailed data capture was incorporated, which allows collecting comprehensive information on the timing, occurrence, and detection of incidents. Fig. 1 illustrates the underlying process steps of the reporting systems.

Ultimately, data visualization tools were developed to help better understand the prevalences of incidents, e.g., in the form of histograms.

The visualized workflow encompasses not only processes that carry out the treatment process (therapy selection, imaging, planning, treatment...) itself, but also includes intermediate checks that evaluate the conformity of the previous process' outcome with the underlying quality standards and standard operating procedures (SOPs). Based on the outcome of those checks, action has to be taken, i.e., if the established quality standards are met, the scheduled subsequent process can be initiated according to the designed workflow. If the result is not satisfactory, it must be corrected based on previous process steps related to the outcome. These checks between the processes are called "safety barriers" and have been implemented along the entire workflow to mitigate error propagation and detect deviations from the quality standards early enough. Examples of such safety barriers are "Pre-planning Check", "Plan Approval", "Physics Check", "Case Peer Review", "Pre-

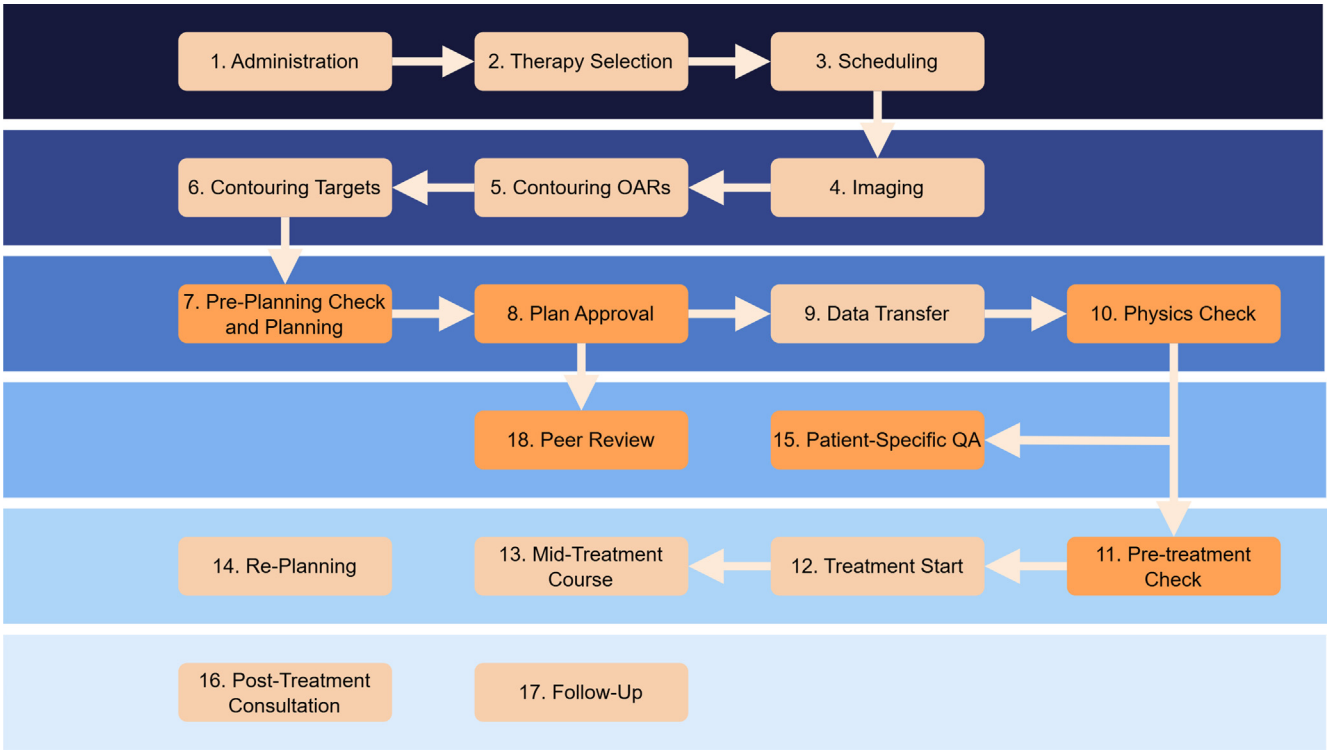

Figure 1. Our process steps that describe the radiation oncology workflow. These steps can be selected as events for cause and detection of incidents. Safety barriers are highlighted.

treatment Check" and "Patient-Specific QA" (see also highlighted process steps in Fig. 1).

Implementation and risk management in our clinic

Safety barriers are the workflows' visible reflections of a lived safety culture in the service of RM. Therefore, a dedicated multidisciplinary RM team, led by a risk manager, was established in 2016 and consists of radiation technologists (RTTs), physicians, nursing staff, and medical physicists. The RM team is committed to an active safety culture and the enhancement of risk awareness to ensure patient safety. Accordingly, the entire workflow is subject to a continuous improvement process in which the ongoing development and refinement of safety barriers is the most effective tool.

The crucial basis for enabling a lively safety culture and the continuous improvement process is the establishment of communication channels between the interdisciplinary staff and the RM team. On the one hand, this is achieved by contacting persons, with RM team members serving as mouthpieces for their professional group and the specific process steps they are working on and are responsible for. On the other hand, the web-based incident reporting system serves as the main source of information for potential risks that may affect patient safety. These reports are analyzed and discussed in a monthly RM meeting, where safety measures are developed to reduce risk. The RM team can initiate additional subject-specific working groups to deal with complex issues at shorter intervals. This reactive practice of RM is known as "retrospective approach". Suppose a process needs to be redesigned or an existing one needs to be checked as it turned out to be sensitive to errors. In that case, it is recommended to initiate a "prospective approach" by a failure mode and effects analysis (FMEA) to proactively derive safety measures before an incident actually occurs.

The safety proposals (whether they were developed reactively or proactively) are forwarded via an official protocol to the head of the department before they are discussed in the executive board, where the risk manager is a permanent member. In this council, the execution of possible implementations based on the recommendations by the RM team is decided. In this respect, the RM team is an advisory commission to the head of the department.

Safety barriers analysis

Over five years, we conducted an extensive analysis of incident data to evaluate the effectiveness of our existing safety barriers within the radiation oncology workflow. The safety barriers under scrutiny included in particular pre-planning checks, physics checks, and pre-treatment checks (see highlighted processes in Fig. 1). These barriers are integral components of our safety protocols, designed to detect and intercept errors at various stages before they can impact patient care [8]:

The "**Pre-planning Check and Planning" (7)** is performed by RTTs or medical physicists in between the confirmation of the treatment prescription and confirmation of volumes-of-interest by the radiation oncologist and the plan setup in the treatment planning system (TPS). The check includes verifying imaging quality, evaluating the accuracy and adherence of delineated structures—such as target volumes and organs at risk—to established quality standards, and ensuring consistent naming between the treatment planning system (TPS) and the record-and-verify (R&V) system. Please note that this step also includes the planning process.

After the plan has been approved by the radiation oncologist, the "**Physics check" (10)** – a plan review performed by a medical physicist who wasn't involved in the planning process – double-checks all parameters of the plan created in the TPS and evaluates whether the dose distribution has met the quality criteria according to the therapy concept and international standards. In addition, the dose calculation is verified by an independent dose calculation procedure. If the independently acquired results display deviations from the original plan, PSQA involving dosimetric verification by measurements needs to be performed at the treatment machine in order to verify the delivered 3d dose output in accordance with the plan's dose distribution before the initial treatment. The pretreatment physics plan review is generally regarded as an effective standard tool for ensuring treatment quality [14].

The **"Pre-treatment Check" (11)** is performed by the RTTs at the Linac before the initial treatment. The immobilization devices are prepared in order to reproduce the conditions during the imaging of the planning CT. Furthermore, all parameters of the plan are double-checked to confirm compliance with the prescribed treatment guidelines.

The analysis focused on three primary aspects:

- Frequency of Incidents: We aimed to identify patterns or recurring issues within the workflow by examining how often incidents occurred. A high frequency of incidents in a particular area could indicate systemic problems requiring attention.
- Process Steps of Error Detection vs. Origin: Understanding where errors were detected in relation to where they originated provided insights into the effectiveness of each safety barrier. This comparison helped assess whether errors were being caught promptly and at the appropriate stage or slipping through multiple barriers undetected.
- Steps Between Incident Cause and Detection: Analyzing the duration in terms of process steps between when an error occurred and when it was detected allowed us to evaluate the responsiveness of our QA processes. A shorter time interval suggests that the QA barriers effectively identify errors, thereby reducing the potential for adverse outcomes.

By focusing on these aspects, we were able to pinpoint deficiencies in our existing safety barriers. For instance, if certain errors consistently originated during the pre-planning stage but were not detected until pre-treatment checks, this indicated a need to enhance the sensitivity of the pre-planning safety barrier. Consequently, targeted improvements were made to strengthen these barriers, such as refining protocols, enhancing staff training and implementing additional verification steps.

Failure mode and effects analysis

Upon observing an increase in incident reports related to specific issues, we initiated a FMEA to proactively identify and mitigate potential failures within our clinical processes. The FMEA is a systematic, step-by-step approach for identifying all possible design, process, or service failures.

The FMEA process involved the following key steps: 1) Identification of failure modes, 2) impact assessment, 3) prioritization, and finally 4) corrective actions.

We thoroughly analyzed specific process steps to uncover potential risks that could cause deviations from the defined workflow. This involved mapping out the entire workflow and pinpointing where errors could occur due to system vulnerabilities, human factors, or procedural gaps. Each identified failure mode was evaluated for its potential severity (S) and the probability of occurrence (O). Thus, a high rating of O signals that the safety barrier is repeatedly catching a potential failure mode, underscoring an increased risk that the barrier may eventually fail and allow undetected errors to reach the patient. Severity assessment considered the potential impact on patient safety and treatment outcomes, while probability assessment estimated how likely the failure was to occur based on historical data and expert judgment. In order to classify each failure mode, scales were applied for the evaluation parameters S and O. The probability of O ranges from 1 to 5, and the severity grade from 1 to 4. While the lower values correspond to an unlikely scenario that causes no or negligible harm (O-1, S-1), the higher values indicate a monthly (O-4) or even weekly

O-5 Frequently	5-1	5-2	5-3	5-4
O-4 Occasionally	4-1	4-2	4-3	4-4
O-3 Rarely	3-1	3-2	3-3	3-4
O-2 Very rarely	2-1	2-2	2-3	2-4
O-1 Unlikely	1-1	1-2	1-3	1-4
	S-1 Low	S-2 Medium	S-3 Critical	S-4 Catastrophic

Figure 2. Risk matrix with classified risk potentials by their probability of occurrence (O) and severity (S)

(O-5) occurrence of an event that can cause severe impact on the patient with catastrophic consequences like permanent injuries (S-4).

The grade of the potential risk of each failure mode indicates the need to initiate corrective action and is displayed by a 2-dimensional color-coded risk matrix, which is shown in Fig. 2. The red areas correspond to intolerable high-priority risk potentials that require urgent preventive measures, whereas the yellow areas correspond to restricted acceptable risk potentials with reduced priority. The green areas represent tolerable risks.

The color-coding of the failure mode's risk classification can also be transformed into a numerical quantity by summing up the two evaluation parameters O and S. The result is our definition of the risk priority number (RPN), which reflects the color-code of the risk matrix (Fig. 2) as the red areas (high risk) correspond to the values 7–9, the yellow ones (medium risk) to 5–6 and the green ones (low risk) to 2–4. The higher the RPN, the higher the need to initiate corrective actions to mitigate the evaluated risk potential of the respective failure mode.

This definition of the RPN contrasts with international common practice like the TG-100 of AAPM [15]. Usually, the RPN is calculated by multiplying three parameters: the severity (S) is multiplied by two probabilities, the occurrence (O) and detectability (D). The different in-clinic approach of the RPN calculation was recently recommended by a national task group of the Austrian Society for Medical Physics (ÖGMP) [16]. Only two out of three evaluation parameters are classified, O and S. The third parameter representing the detectability (D) was eliminated to simplify the evaluation system and avoid uncertainties because of the unclear distinction between O and D [17]. Moreover, the scale ranges (from 1 to 10 for each parameter according to the TG-100) were reduced according to Fig. 2 in favor of enhanced distinguishability by applying a time-correlating gradation. Finally, the RPN is not the product but the sum of the two remaining evaluation parameters. Thus, the high variability (with results ranging from 1 to 1000 according to the TG-100) is reduced to a shorter scale range (from 2 to 9), enabling less complex and less misleading comparisons between single failure modes and FMEA performed by other task groups.

Prioritizing the identified failure modes according to the RPN allowed us to focus our resources on addressing the most critical risks that posed the greatest threat to patient safety. Based on the prioritization, we implemented targeted corrective actions. These actions included introducing new safety barriers, such as additional checks or fail-safes, and refining existing precautions by updating protocols or enhancing staff training. The goal was to reduce the RPNs by decreasing the likelihood of occurrence or minimizing the potential impact of failures.

Results

Frequencies of incidents and identification of hotspots

During the evaluation period from January 2019 to July 2024, a total of 207 incident reports were filed. In the period of paper-based reports from January 2019 to April 2020, 54 reports were filed. Fig. 3 illustrates the frequency of incidents by their point of origin and detection, mapped to the corresponding process steps outlined in Fig. 1.

Detection points varied across the workflow, with some errors being caught during initial stages like pre-planning checks. In contrast, others were identified much later, such as during treatment delivery or post-treatment barriers (e.g., PSQA). This variance indicated pathways where incidents passed through safety barriers, and it emphasized the need to strengthen detection mechanisms at earlier stages to prevent errors from progressing unchecked.

We plotted Sankey diagrams to visualize and comprehend how errors traversed through the system before detection (see Fig. 4). These diagrams effectively illustrated the pathways of errors, showing the flow from their points of origin to where they were eventually detected. This graphical representation allowed us to pinpoint critical junctures where errors bypassed existing safety barriers, thereby informing strategic enhancements to our RM practices. In our approach, QA barriers are designed to identify and address common errors at specific steps in the process. As such, staff were instructed not to report mistakes that were successfully caught by these barriers, as their resolution is inherent to the barrier's function. This methodology ensures a focus on errors that bypass the QA barriers, enabling a more targeted risk assessment.

Improvement in safety barriers

Leveraging the data-driven insights from our incident analyses, we undertook targeted efforts to strengthen existing safety barriers and implement new ones where necessary. Adjustments were made to increase the sensitivity of safety checks, particularly in the stages identified as incident hotspots. For instance, we refined protocols to include additional verification steps during the pre-planning and pre-treatment phases, ensuring potential errors could be detected and addressed promptly.

New safety barriers were introduced at critical points within the workflow to further safeguard against errors. These included the integration of advanced automated checks within the treatment planning software, the establishment of multidisciplinary peer review sessions for treatment plans, the creation of well-defined SOPs for each process step along the workflow, and the provision of elaborated checklists emphasizing the crucial points to be checked of a previous process' outcome at safety barriers. By fortifying the RM framework, we created multiple layers of defense, significantly reducing the likelihood of errors progressing through the system undetected.

These enhancements led to reduction in the average number of process steps by about 48% between incident cause and detection, depicted in Fig. 5 as a reduction of the average step length over the past 5 years. The decrease signifies that errors are identified more quickly, allowing for timely corrective actions and minimizing the potential impact on patient care. This improvement underscores the effectiveness of our proactive, data-driven approach in enhancing safety barriers within the radiation oncology workflow.

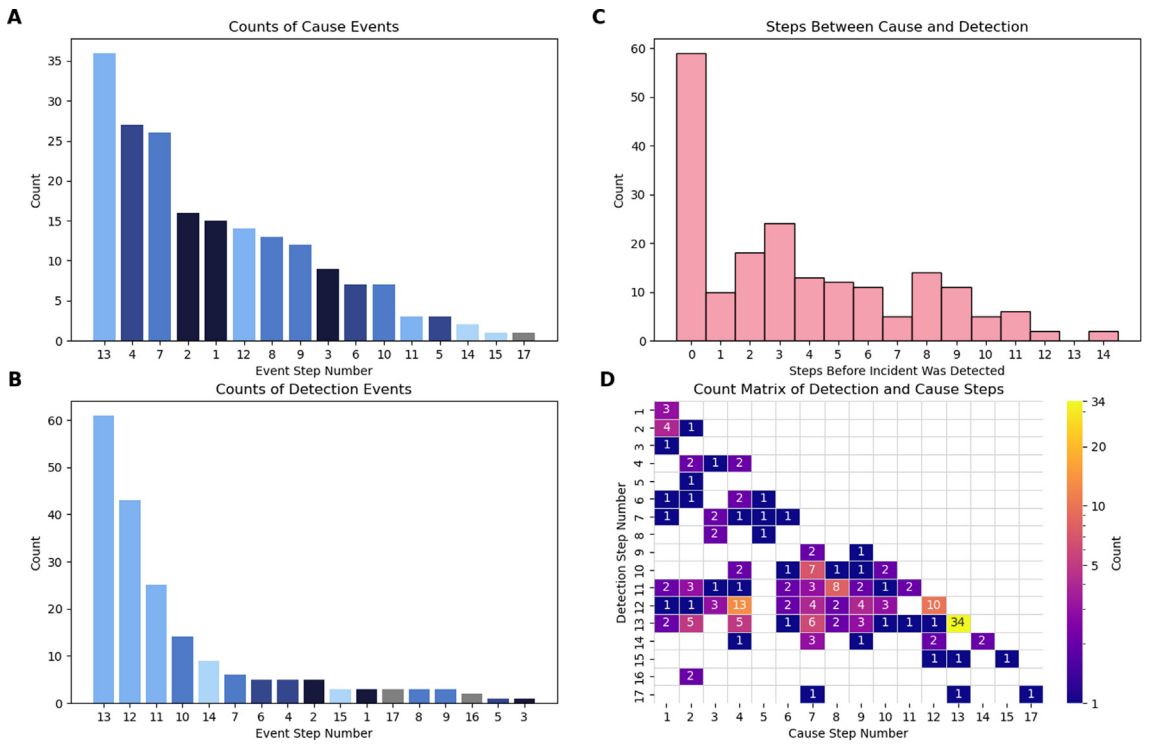

Figure 3. (A) Counts of the process steps identified as the cause of incidents. (B) Counts of the steps where incidents were detected. (C) The length between the cause and detection events is plotted relative to the overall radiotherapy workflow. (D) The correlation illustrates the probability of cause and detection events occurring at specific process steps. Detailed descriptions of the process steps can be found in Fig. 1. Note that the color scheme in A) and B) matches the scheme used in Fig. 1.

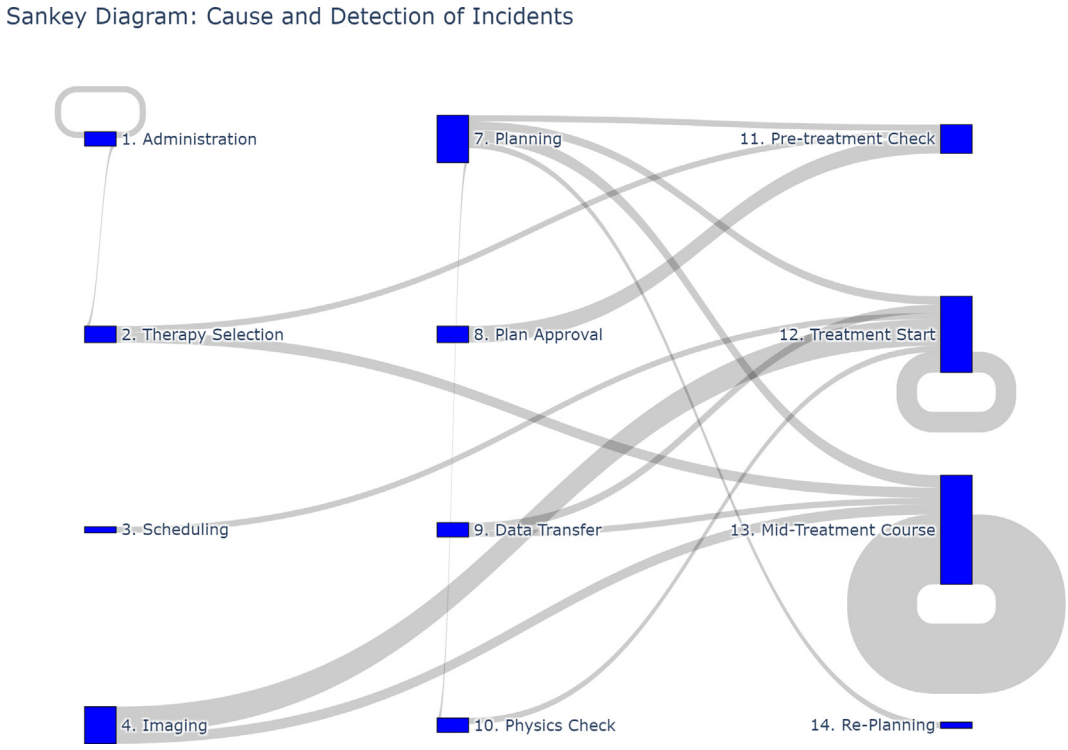

Figure 4. Sankey plots showing the process steps, where incidents were caused (source), and where they were detected (targets). To enhance clarity, only pathways with at least three incidents are depicted. Please note that circular references depict incidents caused and detected in the same process step.

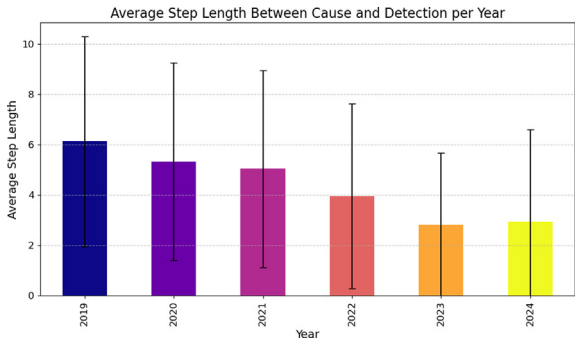

Figure 5. Average step length between cause and detection per year. The average number of process steps between the cause and detection of an incident has decreased since the implementation of data-driven RM. This reduction reflects the effectiveness of targeted interventions, where reported incidents were analyzed, and QA barriers were strengthened to capture and address errors early in the workflow more effectively. Whiskers indicate one standard deviation.

Case study: FMEA on positioning and immobilization

A practical application of our data-driven RM strategy is exemplified in the FMEA conducted on patient positioning and immobilization processes. Accurate positioning and consistent immobilization are critical in radiation therapy to ensure precise dose delivery and to minimize exposure to surrounding healthy tissues.

Through the FMEA, we identified critical failure modes where patient positioning errors were most likely. Specific steps such as the incorrect application of immobilization devices, misalignment during setup, and insufficient verification procedures were pinpointed as high-risk areas. These failures could lead to significant deviations in treatment delivery, potentially compromising treatment efficacy and patient safety.

In response, we implemented targeted corrective actions. Enhanced staff training programs were introduced, focusing on proper positioning techniques and the use of immobilization equipment. New verification steps were integrated into the workflow, including additional imaging checks and peer reviews before treatment initiation. These measures aimed to improve the reliability and accuracy of patient setup procedures.

The reason for the FMEA on the topic of immobilization and positioning was the increased number of incident reports containing similar issues. Five reports that were received via the reporting system around the turn of the year 2022/23 dealt with a discrepancy between the positioning documentation in the R&V system (part of Task 4 in Fig. 1) and the actual positioning conditions during the treatment phase (Task 12 in Fig. 1). These discrepancies were always noticed shortly before the first radiation treatment as part of pre-treatment checks including IGRT (Image-guided radiation therapy) evaluation, where the patient positioning is compared with the planning CT as a reference. This failure mode occurred frequently (high O-rating), passed several safety barriers before its detection, and could have caused severe effects on the patient's safety (high S-rating). Consequently, the most prominent passing of failure modes from their origin to their detection through the workflow is displayed in Fig. 4 between Task 4 (Imaging) and Task 12 (Treatment Start).

As part of the root cause analysis for this failure mode, an RM Task Group was set up to carry out an FMEA to investigate its origins. In this case, a workflow-related vulnerability was indicated by the incident reporting system, which led to a more comprehensive proactive RM approach. The focus was on the reproducibility of the positioning conditions and identifying pitfalls that might negatively affect those. The aim was to harmonize different processes through consistent and complete documentation. Since patient positioning during the radiation phase depends on the documentation of the positioning during the imaging phase, the task group comprised RTTs from the CT and Linac. In addition, a medical physicist from the RM team, who is active in the planning process between the imaging and treatment phases, took over the moderation.

The processes analyzed were "Initial immobilization/imaging" and "Reproduced immobilization/irradiation". Both processes were divided into three substeps, the first two of which were identical: 1) "Preparation of work" (patient is not involved) and 2) "Instructing and positioning of the patient". The third substep is inherent to the particular process: 3) "Imaging and documentation" and "Irradiation and documentation", respectively. The interconnection of the documentation during the imaging phase and preparation in the pre-treatment phase was of particular interest.

The FMEA revealed that the imaging phase was inadequately described as an SOP because a process change made it necessary to rearrange the workflow, as the immobilization masks were no longer generated in advance in a separate therapy preparation room but directly before imaging at the CT. Moreover, the image documentation of the patient's positioning in the R&V system was not sufficiently documented regarding reproducibility and needed to be redesigned.

The FMEA results led to the adaptation of the imaging phase's SOP according to the current workflow. In this context, process-immanent changes were initiated: A specific person was subsequently assigned to create the patient's positioning and immobilization documentation by a note in the R&V system, while another person carried out the double verification principle on the same day and checked the documentation for plausibility and reproducibility. In addition, the image documentation must reflect both the equipment used and its settings for patient-specific positioning. This must be harmonized with the positioning note in the R&V system and be checked for consistency by the double verification principle before the imaging and documentation phase can be considered completed and forwarded to the follow-up process.

In addition to the process-immanent revision of the imaging phase, the associated sensitization and adaptation of the subsequent safety barriers such as "Pre-planning Check", "Physics Check" and "Pre-treatment Check" is necessary. Changes in the documentation must be harmonized with the controls of subsequent processes. Protocols and checklists for the individual safety barriers have been updated accordingly and communicated in internal training courses.

This case study demonstrates the effectiveness of utilizing FMEA within our RM framework to proactively identify and mitigate risks. The successful reduction of positioning-related incidents highlights the value of a systematic, data-driven approach in enhancing the quality and safety of radiation oncology services.

Resource allocation

The resource analysis highlighted the substantial efforts invested in developing and sustaining the RM system. Approximately 150 h were dedicated to developing, testing, and rolling out the web-based incident reporting system. This significant initial investment was essential to create a robust platform capable of supporting real-time incident reporting and comprehensive data analytics.

The ongoing management of RM activities, as currently implemented, requires approximately 20% of a full-time equivalent (FTE) position within the medical physics team. This allocation covers continuous data monitoring, conducting regular meetings of the RM team and RM task groups for both reactive and proactive RM, developing safety recommendations for the executive board, implementing corrective actions, and providing staff training. Furthermore, the core of the RM team comprises a multidisciplinary team by the represented professions all along the workflow: 3 medical physicists (for Tele-, Brachytherapy and radiation protection), 2 radiation oncologists, 4

RTTs (imaging, planning and treatment) and 1 nursing staff. Additionally, specific RM task groups can be initiated on demand depending on the treated issue. The commitment of these resources has been instrumental in maintaining the effectiveness and responsiveness of the RM system.

The analysis recommends increased resource allocation to sustain and further enhance the RM efforts. Additional resources would facilitate more in-depth data analysis, quicker implementation of interventions, and the expansion of RM initiatives. Investing in increased FTE allocations for RM activities is crucial to support the ongoing success and continuous improvement of patient safety measures within the department.

Discussion

Adopting our web-based incident reporting system has significantly transformed RM practices in our radiation oncology department. By enabling real-time reporting and analysis, the system built a state-of-the-art tool to overcome the limitations of traditional incident reporting methods, which often suffer from delays and underreporting. Aligning with international RM standards facilitates benchmarking and promotes continuous improvement by allowing us to compare our performance against global benchmarks.

Other groups have also recognized the importance of digital systems in risk assessment. For instance, a study by Kornek *et al.* [18] developed a similar digital platform for risk assessment, highlighting the growing trend towards digitization in healthcare RM. These systems have been instrumental in enhancing the accuracy and efficiency of incident reporting, thereby improving patient safety outcomes.

Implementing FMEA has been a versatile and complementary component of our RM strategy. Based on our data-driven approach, we were able to prioritize failure modes and allocate resources accordingly more effectively. This targeted approach significantly decreased undiscovered incidents across various safety barriers, particularly along the longest and most critical pathways identified in our workflow, such as Task 4–12.

Our enhanced ability to detect and address incidents promptly has direct implications for patient safety and treatment efficiency. The reduction in the number of process steps between error occurrence and detection indicated a more responsive and effective RM system. This improvement was particularly evident in the irradiation phase (Task 13), which is the most critical point in the entire workflow as it involves the actual application of the dose to the patient. Any anomaly during this phase was reported regardless of its clinical relevance. This helped to potentially prevent mis-irradiations, reducing the impact to only a five-minute delay. This “hermetic” reporting behavior around the irradiation process, as depicted in the Sankey plot with origin and detection both in Task 13, underscores the heightened vigilance during this crucial phase. Active reporting during irradiation is expressly encouraged by the RM team to ensure patient safety, with classification and prioritization of reports handled during the RM meetings.

In general, the reporting behavior of staff was influenced by the performance of safety barriers. Reports were typically made when there was a deviation from the workflow outside of the safety barriers. If a safety barrier effectively fulfills its task promptly, incidents were often not reported because the barrier had functioned as intended within the workflow. However, if passing through one or more safety barriers was noticed as critical, it was reported (again as seen in the case of Task 4 to 12). In this context, the reporting behavior serves as continuous monitoring that evaluates and highlights weaknesses of established safety barriers and provides a basis for further improvement processes.

The comprehensive analysis of incident frequencies over the five years showed critical insights into specific workflow steps that were more susceptible to errors. By meticulously categorizing incidents based on their origin within the treatment process, we identified certain stages that consistently exhibited higher incident rates. These “incident hotspots” became focal points for immediate attention and improvement to enhance overall patient safety.

To address these hotspots, targeted FMEA initiatives were launched. Dedicated task groups were assigned to make process-inherent adjustments and to refine safety barriers as part of a continuous improvement process. The successful application of FMEA demonstrates the value of proactive risk assessment tools in identifying and mitigating potential failures within the workflow. However, it should be noted that conducting a comprehensive, proactive FMEA for every process with interdisciplinary review was not feasible due to time constraints and limited resources. Instead, in our RM practice FMEA is initiated in a targeted, data-driven manner based on reporting behavior, particularly when triggered by specific incidents.

The increased workload associated with managing the system highlights the need for appropriate resource allocation. Our resource analysis indicates that the development of the system required approximately 150 h, and ongoing RM activities require on average 20% of a full-time equivalent position. This workload could increase if activities and more proactive actions are intensified. Ensuring that the RM team has sufficient support is essential for the sustainability of these improvements.

The introduction of the traffic light system, as described by Heilemann et al. [13], also contributed to easing resource utilization by drastically reducing the frequency of last-minute plans. This likely had a positive impact on the workflow's susceptibility to errors, as timeouts and cross-checks can be conducted more comprehensively and thoroughly. While the effect on reporting behavior cannot be directly evaluated, it likely had an underlying influence by promoting a more structured and less error-prone workflow.

By aligning the risk classification with international RM systems, our system facilitated benchmarking against global standards. This alignment not only enhances the credibility of our RM practices but also enables us to participate in broader discussions and collaborations aimed at improving patient safety in radiation oncology.

Conclusion

In conclusion, the implementation of the web-based incident reporting system has advanced RM in our radiation oncology department by ensuring legal compliance and enhancing safety through real-time analytics. The system effectively identifies and mitigates risks, strengthening quality assurance barriers as evidenced by the decreased number of process steps between error origin and detection. However, adequate resource allocation is essential to sustain these improvements. Increasing full-time equivalent allocations for RM activities is recommended to maintain the momentum of continuous improvement.

Data Availability

Research data are stored in an institutional repository and will be shared upon request to the corresponding author.

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CRediT authorship contribution statement

Lukas Sölkner: Writing – review & editing, Writing – original draft, Validation, Supervision, Investigation, Data curation, Conceptualization. **Dietmar Georg:** Writing – review & editing, Writing – original draft, Funding acquisition. **Uwe Wolff:** Writing – original draft, Validation, Methodology. **Andreas Renner:** Writing – review & editing, Writing – original draft, Software, Methodology, Conceptualization. **Joachim Widder:** Writing – review & editing, Writing – original draft, Funding acquisition. **Gerd Heilemann:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

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