Risk Factors and Mitigation Strategies in Radiation Therapy: A Study of Patient Safety Events From 40 Hospitals

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Abstract

Background: Radiation therapy is a common lifesaving practice in the treatment of cancer, yet there is the potential for error that may cause patient harm or death.

Methods: Using a retrospective mixed-methods design, we studied a two-year period of event reports submitted by hospitals to the Pennsylvania Patient Safety Reporting System (PA-PSRS) database and targeted those reports that described errors in radiation therapy. We analyzed the relation between the following primary variables: event type, whether it reached the patient, phase of radiation therapy when the risk factor originated, and risk factor (i.e., event impetus).

Results: Our sample included 245 event reports from 40 hospitals. Among the 245 reports, 60% of the errors reached the patient, 71% of the sample were a wrong dose, and 29% described a delay in treatment. Across all six phases of radiation therapy, 38% of events originated from the treatment planning phase and 40% were from the treatment delivery phase. We identified 23 unique categories of risk factors that acted as the impetus. The most frequently identified were malfunction of hardware/software, wrong contour, absent or wrong accessory, wrong position, and wrong or low-quality images.

Conclusions: The present study expanded upon many of the prior radiation therapy studies by exploring the relation among the various combinations of the primary variables. The study highlights the current risks in the practice of radiation therapy and the broad range of conditions in which errors may occur. **Online Supplement Appendix S1** provides a list of mitigation strategies aimed at detecting and preventing the risk factors identified in the present study.

Introduction

Radiation therapy (RT) is a cornerstone of cancer treatment[1] and has been in clinical use for over a century.[2] Studies have estimated that approximately 50% of all cancer patients could benefit from RT as part of their treatment plan,[3,4] underscoring its widespread use and critical role in oncology. Despite the therapeutic benefits, RT creates risk of harm, and patient and staff safety remains a significant concern.[5-7] Previous publications have estimated between 0.07% and 6% of patients undergoing RT experience a safety event,[8-12] with a subset of these resulting in clinically significant harm. Events can include a range of adverse outcomes, such as overdose or underdose of radiation, anatomical sites with unintended exposure (i.e., wrong site or side), delays in treatment, or equipment-related failures—all of which may compromise treatment efficacy, increase toxicity, or lead to long-term morbidity.[12-14] As RT techniques become increasingly complex, understanding and mitigating these risks is essential to ensuring safe and effective cancer care.

The purpose of this retrospective-mixed-methods study of Pennsylvania Patient Safety Reporting System (PA-PSRS)[a] event reports was to explore the frequency and nature of the patient safety events directly involving RT. We expand upon prior studies by analyzing the relation among event type, whether it reached the patient, phase of RT when the risk factor originated, and risk factor (i.e., event impetus) across the sample of events. Furthermore, we provide a list of strategies that may mitigate the risk factors identified in this study.

Methods

Data Source and Sample

Data in this study were derived from event reports submitted by licensed healthcare facilities to the PA-PSRS acute care database. Pennsylvania laws mandate reporting of patient safety events ranging from a near miss to those resulting in serious harm. Event reports do not include medical records, but do contain information from structured fields (e.g., event date, patient age, care area) and unstructured fields (e.g., free text), which are used to summarize the conditions and actions related to the event.

Our query of the PA-PSRS database for event reports used both inclusion and exclusion criteria. The inclusion criteria were a two-year period (event occurrence dates: January 1, 2022–December 31, 2023), 10 care area types (Bone Marrow Unit, Imaging – MRI, Imaging – Nuclear Medicine, Medical/Oncology Unit, Medical/Surgical/Oncology Unit, O/P Oncology Clinic, O/P Oncology/Hematology, Pediatrics Oncology Unit, Radiation Oncology, Surgical Oncology Unit), and presence of one or more

[a]PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety–related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002). All reports submitted through PA-PSRS are confidential and no information about individual facilities or providers is made public.

What is radiation therapy and when is it used?

Radiation therapy (RT) is used to treat localized and metastasized cancers,[7] and also can be used to treat benign conditions (e.g., noncancerous tumors).[15] The goal of RT can be curative or palliative.[7,16] RT is effective by using doses of radiation to treat, slow progression, or reduce the size of the disease by causing damage to the cells associated with the disease, while preserving the surrounding healthy cells (i.e., organs at risk, OARs).[7,17,18] RT can be used alone to treat a disease or along with surgery, chemotherapy, and/or immunotherapy.[2,7,17,18] There are several types of RT, and the choice of RT can be influenced by the type, size, location of the condition requiring treatment, patient's past medical history, tolerance of treatment, age, and other treatments/care that are anticipated.[17]

What are the different forms of RT and the timing of each?

RT can be administered to the patient's body through external or internal sources of radiation.[17,18]

External beam radiation therapy (EBRT) is the most common and can be administered in as few as one session or in excess of 35 sessions. External radiation can be administered once or twice per day,[19] and the frequency of sessions per week can range from one to 10. The duration of most treatment sessions are 15 to 30 minutes, depending on the setup.[19] External RT includes many subtypes, such as three-dimensional conformal radiation therapy (3D-CRT), intensity-modulated radiation therapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiation therapy (SBRT), and image-guided radiation therapy (IGRT).[18,19]

Internal RT (i.e., brachytherapy) is less common and is administered to the patient by radioactive sources temporarily being inserted into their body (e.g., vaginal cylinder) or implanted permanently (e.g., prostate seeds).[16,18]

What staff are involved in RT?

Planning, administration, and monitoring of RT involves many staff, including radiation oncologists, medical physicists, dosimetrists, radiation therapists, radiation oncology nurses, information technologists, and administrators.[16] RT is frequently described as a complex and multidisciplinary specialty involving an intense cognitive load with time constraints and requiring a wide range of staff skills and expertise in both clinical information and technology.[7,11,16]

of 67 keywords related to RT.[b] Event reports were excluded from the query output if they were assigned to the PA-PSRS Event Type Description of "Falls," "Patient Self-Harm," or "Transfusion."

The query produced 671 event reports, which were de-identified and managed by the first author. The first author then reviewed the reports with co-authors for the following inclusion and exclusion criteria:

- Patient safety events were included if they did or could have led to erroneous RT, either external RT or internal RT. We defined erroneous RT as treatment that deviated from what was intended or appropriate, and had the potential to cause harm. All included events were *directly* related to the planning for, administration of, and/or monitoring of RT. Only events that led to or would have led to a wrong dose or delay in treatment were included in the study sample.
- We excluded the following types of event reports from our study that were not directly related to erroneous RT: intravenous infiltration, skin tear, health complication without a description of safety concerns, medication overdose during CT simulation (e.g., propofol), misdiagnoses (e.g., leading to unnecessary treatments), and inefficient processes that had no clear implications for patient safety.

After reviewing the events and applying the inclusion and exclusion criteria, the study sample consisted of 245 event reports.

Design, Analysis, and Variables Coded

We applied a retrospective mixed-methods design with an exploratory sequential approach,[20] beginning with qualitative data collection followed by quantification for further analysis. The qualitative data from PA-PSRS event reports were analyzed through directed content analysis,[21,22] utilizing a framework method[20,23,24] with variable categories informed by existing literature.[11,25-29] These variables were quantified by frequency and examined through descriptive analysis. Descriptive analysis is a quantitative approach that aims to explore phenomena, identify patterns, and enhance understanding of their occurrence.[30,31] This is often achieved through visual data presentations highlighting various combinations of variables, facilitating triangulation of the findings.

In each of the event reports, the event date, facility size, and patient's age and gender were obtained from the structured fields. By examining the unstructured fields in each report, the authors coded for one phase of RT, one risk factor (see **Table 1** for a list), one event type (see **Table 2** for a list) and whether the report described an event that reached the patient (i.e., non–near miss).

The phases[11,16,32] of RT correspond with the primary categories of activity performed by the physician, medical physicist, radiation therapist, dosimetrist, and supporting staff. The phase of RT was coded based on when the risk factor originated. The risk factor represents the variable that was the impetus and influenced, or likely influenced, the occurrence of the event type. The event type represents how the patient was or could have been affected. The event was classified as reaching the patient if it affected the patient or interrupted care, as opposed to a near miss that did not reach the patient due to chance or active intervention.

Results

Demographics

Of the 245 event reports that met inclusion criteria, 229 specified the patient's sex at birth. Among those reports, 58% (132 of 229) involved a female and 42% were male (97 of 229). The patients ranged in age from 2 years to 99 years, with a mean of 65 years and a median of 66 years (25th percentile was 57 years and 75th percentile was 75 years). The 245 event reports were submitted by 40 different acute care hospitals that ranged in size from fewer than 100 beds to more than 300 beds. Across the 40 hospitals, nine hospitals reported eight or more event reports (maximum of 53 event reports from two hospitals, which were also among the largest hospitals in Pennsylvania).

Event Types

Within the sample of 245 event reports, 71% (173 of 245) described a wrong dose and 29% were a delay in treatment (see **Figure 1**). Among the wrong dose events, 43% (75 of 173) reached the patient and 57% (98 of 173) did not reach the patient (i.e., near miss). Wrong dose events included instances where treatment was administered to the wrong site, side, or patient. All delay in treatment events reached the patient (100%, 72 of 72).

Event Types and Phases of Radiation Therapy

Figure 2 shows the distribution of event types by phases of RT, which represents the timing of the risk factors that acted as the impetus to the event. Across the six phases of RT, a majority of the events were related to the treatment planning phase (38%, 92 of 245) and the treatment delivery phase (40%, 98 of 245), while the fewest events were related to the after treatment completion phase (1%, 2 of 245) and the pretreatment QA review phase (5%, 13 of 245). The figure also shows that the impetus of each event type varied by phase, with a majority of the wrong dose events being attributed to the treatment planning phase (51%, 87 of 173) and a majority of the delay in treatment events being due to the treatment delivery phase (67%, 48 of 72). Overall, **Figure 2** shows a strong association between the phase and both overall frequency of events and specific event types.

[b]The query of PA-PSRS explored four free-response fields in the event reports for one or more of the following 67 keywords: "radiation oncolog," "rad onc," "radiation onc," "rad oncolog," "radiation treatment," "rad treatment," "radiation tx," "rad tx," "radiation therap," "rad therap," "radiotherapy," "external Beam radiation," "ebrt," "brachytherapy," "seed," "contour," "treatment planning," " delineation," "organ at risk," "organs at risk," "oar," "isocent," "megavoltage," "electron therap," "electron treatment," "photon therap," "photon treatment," "proton therap," "proton treatment," "dosimetr," "laterality," "wrong side," "wrong site," "wrong patient," "wrong name," "wrong procedure," "wrong treatment," "wrong therapy," "ptv," "ctv," "itv," "breath hold," "motion management," "setup," "shifted," "fiducial," "sbrt," "srs," "stereotactic," "radiation field," "fraction," "irradiat," "tbi," "reference point," "physics," "physicist," "gamma knife," "cylinder," "hdr," "simulation," "sim order," "electron block," "field weighting," "accelerator," "simulator," "collimat," and "margin."

Table 1. Phases of Radiation Therapy and Risk Factors

Phases of RT	Risk Factors	Definitions	Examples
Before Simulation	Error involving consent form	Patient consent form had inaccurate information or was incomplete.	Listed wrong side, site, or body part; missing patient signature
	Error involving patient medical history	Patient medical history was incomplete, incorrect, or not reviewed.	Wrong or missing diagnostic imaging, failure to account for patient's implant/device
	Error involving scheduling or ordering	Scheduling or ordering was delayed, not done, or made with wrong provider, or had incorrect information.	Failure to send referral, referral sent to wrong scheduling pool, order for right side instead of left
Simulation	Error in simulation documentation	Required documentation for simulation was missing, incomplete, or inaccurate.	Wrong setup notes, wrong patient photograph
	Error involving patient medical history	Patient medical history was incomplete, incorrect, or not reviewed.	Wrong or missing diagnostic imaging, failure to account for patient's implant/device
	Failure in ongoing QA	Quality assurance for hardware, software, and/or overall system performance was not completed on schedule and/or within specifications.	Calibration expired, failure to maintain hardware/software
	Malfunction of hardware/software	Hardware/software failed to operate or function properly.	Artifact in CT scan, CT hardware failure
	Wrong position	Patient body position was improper or not reproducible for treatments.	Supine instead of prone, error in breath-hold technique, failure to evaluate breath-hold scans, missing or wrong marker, incorrect chin position
Treatment Planning	Absent accessory	Accessories used for a treatment field were unavailable or not used.	Bolus was missing from the field
	Error in clearance	Clearance check between gantry and equipment/patient was absent or inaccurate.	Gantry collided with patient and/or supporting structure
	Error involving patient medical history	Patient medical history was incomplete, incorrect, or not applied to treatment plan.	Failure to account for patient's implant/device or previous treatment
	Inaccurate or missing field	Treatment field absent or had incorrect parameter.	Wrong location, wrong size, incorrect beam time factor
	Wrong contour	Volume planned for target/OAR was incorrect or missing.	Wrong segmentation, incorrect expansion of volume, low-quality fusion
	Wrong dose prescribed	Prescription for dose of radiation was incorrect.	Prescribed 68 Gy instead of 73 Gy
	Wrong fractionation	Dose per treatment or number of treatments was incorrect.	Wrong dose per fraction or wrong number of fractions
	Wrong isocenter	The location in the patient where treatment fields are centered (i.e., isocenter) was incorrectly selected.	Isocenter was not correctly adjusted from CT origin
	Wrong laterality	Incorrect side of anatomy was planned or label of target/OAR was incorrect.	Selected wrong side in directive, incorrectly labelled laterality of target
	Wrong or absent constraint	Dose objectives and limits for target or OARs were missing or not appropriate for treatment.	Physician chose wrong dose limits, OAR constraints were missing
	Wrong or low-quality images	Incorrect image, unacceptable quality of image, or feature of image was incorrect.	Wrong image orientation, low-quality image registration, low-quality image, incorrect diagnostic image used for volumes
	Wrong shift	Shift of treatment fields from CT origin were inaccurately programmed into treatment machine.	Wrong shift values, wrong table height
	Other	This included various factors that were not aligned with the above 12 risk factors within the treatment planning phase.	Inaccurate couch tolerance, plan notes, motion management or MLC file, linked prescription, or target label
Pretreatment QA Review	Error involving scheduling	Scheduling tasks were incomplete or incorrect.	Scheduled on wrong machine, failure to schedule replan, failure to schedule care path tasks
	Failure in ongoing QA	Necessary QA was absent or performed improperly.	Failure to perform patient specific QA, manual calculation error, unable to reproduce imaging

Table 1. (continued)

Treatment Delivery	Absent or wrong accessory	Treatment accessories were missing or improperly used.	Missing vaclock, wrong electron cutout, missing bolus, wrong bolus location, wrong head cup, device not FDA approved
	Error involving patient medical history	Patient medical history was incomplete, incorrect, or not applied to treatment delivery.	Failure to account for patient's previous treatment, or failure to account for or monitor implant/device
	Failure to confirm patient identification	Patient identification was absent or insufficient.	Failure to verify name and/or date of birth
	Inaccurate or missing field	Treatment field was absent or had an incorrect parameter.	Used the QA field instead of treatment field, wrong MUs input following use of service mode
	Malfunction of hardware/ software	Hardware/software failed to operate or function properly.	Issues with hardware, software, and interconnectivity among the following equipment: chiller, MLC, treatment table, ultrasound, HDR accessories, linac imaging
	Wrong or missing patient-specific adaptation	Adjustment due to change in patient anatomy or condition was absent or improper.	Failure to account for patient weight change or change in target
	Wrong position	Patient body was not properly positioned for treatment.	Incorrect extremity position, error in breath-hold technique, error in empty/full bladder, wrong shift, wrong SSD
	Other	This included various factors that were not aligned with the above seven risk factors within the treatment delivery phase.	Insufficient staff, miscommunication, wrong type of imaging
After Treatment Completion	Failure to close plan	Closing out of patient chart was incorrect or incomplete.	Loaded past plan that should have been closed out

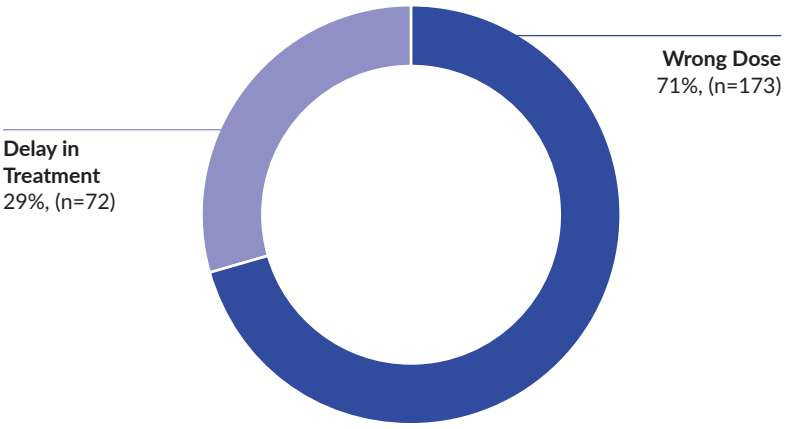
Note: Only one risk factor was coded per event report. Each of the factors within the category of "Other" had a frequency of one. CT=computerized tomography, FDA=Food and Drug Administration, Gy=standard radiation dose value is given in Gray, HDR=high-dose rate, MLC=multileaf collimator, MU=monitor unit, OAR=organ at risk, QA=quality assurance, SSD=source-to-surface distance

Table 2. Categories of Event Type, Which Identified How the Patient Was or Would Have Been Impacted

Event Types	Definition
Wrong Dose	The dose ordered, planned, and/or administered was different in quantity and/or location from what was intended or appropriate. This event type includes instances where treatment was administered to the wrong site, side, or patient.
Delay in Treatment	Onset of treatment was delayed and/or there was an interruption in treatment. In this study, all delays are defined as deviations from the intended timeline by one or more days.

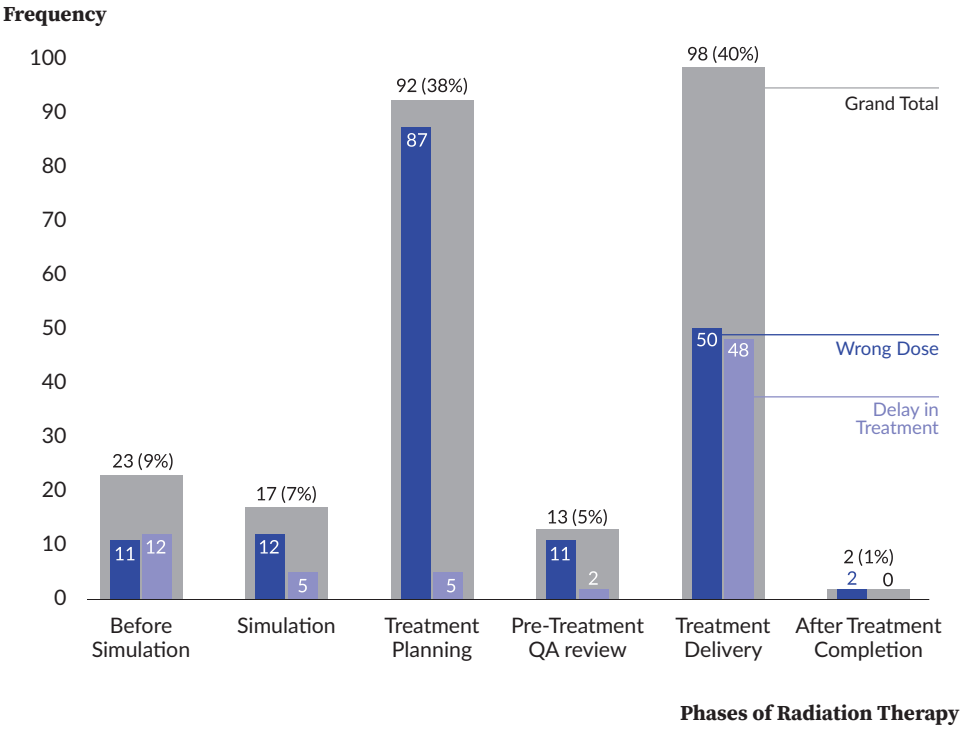
Note: Only one event type was coded per event report.

Figure 1. Radiation Therapy Events by Event Type (N=245)



Note: Only one event type was coded per event report.

Figure 2. Events by Phase of Radiation Therapy and Event Type (N=245)



Note: The primary bar per phase represents the grand total across the two subcategories of bars, which represent the two Event Types. Only one phase and one event type were coded per event report. QA=quality assurance

Event Types, Phases of Radiation Therapy, and Risk Factors

Table 3 shows that the phases of RT and risk factors had varying influence on the two event types, wrong dose and delay in treatment. For example, the treatment planning phase had a notable influence on the occurrence of wrong dose events (95%, 87 of 92); however, the treatment planning phase had little relation with the delay in treatment events (5%, 5 of 92). As another example, we also found that many of the categories of risk factors had an uneven effect on the two event types. Within the treatment planning phase, 12 different categories of risk factors contributed to the occurrence of the wrong dose events, while only 2 different categories of risk factors influenced the delay in treatment events.

In contrast with the prior examples, we also found instances where the phase and risk factors had a similar influence on both event types. For example, when the risk factor occurred within the before simulation phase, a wrong dose was the result in 48% (11 of 23) of the events and a delay in treatment occurred in 52% (12 of 23) of the events. Additionally, two-thirds of the risk factor categories within the before simulation phase were associated with both the wrong dose and delay in treatment events. A further review of **Table 3** will reveal additional findings where the phases and risk factors have similar or differing influence on the wrong dose and delay in treatment event types.

A notable finding was related to the delay in treatment events and where the impetus was within the before simulation phase, due to an error involving scheduling or ordering. We found that in 67% (6 of 9) of these events the patients had a *preventable* delay of 20 or more days, with a maximum of approximately 60 days. In one of the events, the report described the patient as experiencing a total lung collapse due to the extent of tumor progression during the delay in treatment. In another event, the patient had to have their lymphoma restaged.

Wrong Dose Event Type, Whether it Reached the Patient, Phases of Radiation Therapy, and Risk Factors

Table 4 expands upon **Table 3** by showing the frequency of wrong dose events that either reached the patient or did not reach the patient, by phase of RT and risk factor. Readers should note that **Table 4** relates only to the wrong dose event type because, unlike the delay in treatment event type, only a portion of the reported wrong dose events reached the patient (43%, 75 of 173). **Table 4** reveals that the wrong dose events that reached the patient varied proportionally based on the phase and risk factor. For instance, when the risk factor originated in the treatment delivery phase, the wrong dose reached the patient in 86% of the reported events (43 out of 50). In contrast, when the event stemmed from the treatment planning phase, only 26% (23 out of 87) of the reported wrong dose events reached the patient.

Within each phase of RT, some risk factors were more likely to be reported as being related to a wrong dose event that reached the patient than other risk factors. For example, within the treatment planning phase, 80% (4 of 5) of the events reported as having an absent accessory resulted in a wrong dose that reached the patient, while 0% (0 of 6) of the events with a wrong shift led to a wrong dose reaching the patient. Overall, these results and others within **Table 4** underscore the need to examine the risk factors in order to understand the conditions that appear to be more or less likely to lead to an event that reaches the patient.

Table 3. Frequency of Events by Event Type, Phase of Radiation Therapy, and Risk Factor (N=245)

	Event Types		
Phases of Radiation Therapy and Risk Factors	**Wrong Dose**	**Delay in Treatment**	**Grand Total**
Before Simulation			
Error involving scheduling or ordering	2	9	11
Error involving patient medical history	4	3	7
Error involving consent form	5	-	5
Phase Total	11	12	23
Simulation			
Wrong position	6	-	6
Error in simulation documentation	3	-	3
Error involving patient medical history	2	1	3
Malfunction of hardware/software	-	3	3
Failure in ongoing QA	1	1	2
Phase Total	12	5	17
Treatment Planning			
Wrong contour	28	-	28
Wrong or low-quality images	16	-	16
Inaccurate or missing field	6	-	6
Wrong fractionation	6	-	6
Wrong shift	6	-	6
Absent accessory	5	-	5
Wrong dose prescribed	5	-	5
Error in clearance	-	4	4
Error involving patient medical history	3	-	3
Wrong laterality	3	-	3
Wrong or absent constraint	3	-	3
Wrong isocenter	2	-	2
Other	4	1	5
Phase Total	87	5	92
Pretreatment QA Review			
Error involving scheduling	7	1	8
Failure in ongoing QA	4	1	5
Phase Total	11	2	13
Treatment Delivery			
Malfunction of hardware/software	-	41	41
Absent or wrong accessory	17	5	22
Wrong position	17	-	17
Inaccurate or missing field	9	-	9
Failure to confirm patient identification	3	-	3
Wrong or missing patient-specific adaptation	2	-	2
Other	2	2	4
Phase Total	50	48	98
After Treatment Completion			
Failure to close plan	2	-	2
Phase Total	2	-	2
Grand Total	**173**	**72**	**245**

Note: Only one event type was coded per event report. All delay in treatment events reached the patient, while only a portion of the wrong dose events reached the patient. Only one risk factor was coded per event report. Each of the factors within the category of "Other" had a frequency of one. Dash indicates a zero frequency.

Table 4. Frequency of Events by Wrong Dose Event Type, Whether it Reached the Patient, Phase of Radiation Therapy, and Risk Factor (N=173)

	Wrong Dose		
Phases of Radiation Therapy and Risk Factors	Reached Patient	Did Not Reach Patient	Grand Total
Before Simulation			
Error involving consent form	-	5	5
Error involving patient medical history	2	2	4
Error involving scheduling or ordering	-	2	2
Phase Total	2	9	11
Simulation			
Wrong position	2	4	6
Error in simulation documentation	-	3	3
Error involving patient medical history	-	2	2
Failure in ongoing QA	-	1	1
Phase Total	2	10	12
Treatment Planning			
Wrong contour	3	25	28
Wrong or low-quality images	4	12	16
Inaccurate or missing field	3	3	6
Wrong fractionation	2	4	6
Wrong shift	-	6	6
Absent accessory	4	1	5
Wrong dose prescribed	2	3	5
Error involving patient medical history	2	1	3
Wrong laterality	-	3	3
Wrong or absent constraint	1	2	3
Wrong isocenter	1	1	2
Other	1	3	4
Phase Total	23	64	87
Pretreatment QA Review			
Error involving scheduling	2	5	7
Failure in ongoing QA	3	1	4
Phase Total	5	6	11
Treatment Delivery			
Absent or wrong accessory	15	2	17
Wrong position	15	2	17
Inaccurate or missing field	8	1	9
Failure to confirm patient identification	1	2	3
Wrong or missing patient-specific adaptation	2	-	2
Other	2	-	2
Phase Total	43	7	50
After Treatment Completion			
Failure to close plan	-	2	2
Phase Total	-	2	2
Grand Total	**75**	**98**	**173**

Note: Only one event type was coded per event report. Only one risk factor was coded per event report. Each of the factors within the category of "Other" had a frequency of one. Dash indicates a zero frequency.

Discussion

The present patient safety study expands upon many of the prior RT studies[11,13,25-29,33-37] by analyzing the event type, whether it reached the patient, phase of RT when the risk factor originated, and risk factor (i.e., event impetus). Methodologically, the current study is comparable to several of the previous studies;[11,25-29] however, there are substantial methodological differences between the current study and others that preclude comparison.[13,33-37]

Our study appears to have made a novel contribution to the literature by categorizing delays in treatment as a distinct event type, which was a substantial portion of the sample (29%, 72 of 245). Among the treatment delays, we found that errors during initial scheduling or ordering of RT frequently resulted in *preventable* treatment delays of 20–60 days in duration and posed a high potential for harm. In the present analysis, 71% (173 of 245) of the events were a wrong dose, and 43% (75 of 173) of these reached the patient, which is similar in distribution to a prior study[11] and different from another.[27] Readers should note that our wrong dose event type included instances where treatment was administered to the wrong site, side, or patient, as the dose was different in quantity and/or location from what was intended or appropriate.

In the current study, 38% of the events originated from the treatment planning phase and 40% were from the treatment delivery phase. These findings resemble those reported by two prior studies,[11,28] but differ from another,[29] which found that events relatively frequently originated from their version of the before simulation phase and simulation phase.

Among the previous research on RT patient safety events, many included a variable representing the cause or risk factor to the event.[11,25,26,28,33,35,36] However, some of the studies[33,35,36] used variables with categories that were broad themes (e.g., inadequate standard/procedure/practice, availability of materials/tools/equipment, personnel availability, inadequate training) and were not comparable to the more specific categories of risk factors used in the present study.

Our five most frequently coded categories of risk factors—malfunction of hardware/software (44 of 245), wrong contour (28 of 245), absent or wrong accessory (27 of 245), wrong position (23 of 245), and wrong or low-quality images (16 of 245)—were similar to those in two prior studies,[11,28] but our findings diverged from two other studies.[25,26] The discrepancies in the latter two studies could be attributed to several methodological differences: both studies had a relatively small sample size (110 or fewer event reports);[25,26] one study was from more than 30 years ago and may have introduced selection bias into their sample;[25] and the second study included events only from a single institution, restricted the sample to only those that originated from the treatment planning phase, and involved only external radiation beam therapy.[26]

Standout Findings: Relation Between Risk Factors and Mitigation Strategies

The greater detection of wrong dose events, prior to reaching the patient, within the treatment planning phase (87% did not reach patients, 64 of 87), when compared with the treatment delivery phase (14% did not reach patients, 7 of 50) highlights a fundamental issue: There are fewer and less effective checks for treatment delivery than for treatment planning in the field of RT.[38] Real-time verification during treatment delivery remains a challenge; therefore, enhanced time-out procedures and automation that specifically address accessories and positioning likely would improve treatment accuracy.[39] In events that described spine treatments with vertebral body identification errors (i.e., wrong position errors), we anticipate that mandatory cone beam computed tomography (CBCT) could prevent wrong-site treatments;[40] however, this would increase treatment time and imaging dose.

The extensive treatment delays caused by scheduling or ordering errors in the before simulation phase represent a challenge that was primarily caused by workflow and communication failures, such as the referral not being sent or being sent to the wrong scheduling pool, or order for treatment to the wrong side of the body. As an example, the delays in scheduling and ordering with the RT department may have also led to insurance authorization delays, a need for reimaging (e.g., MRI for risk of metastasis), delayed coordination between radiation therapy and chemotherapy, further metastasis of cancer, and greater complexity of and potentially less effective treatment. Automated tracking systems are a potential solution,[41] but implementation would require integration across multiple departments and often involves asynchronous software platforms, which can require substantial resources to execute.

The events that described a treatment delay and were caused by a malfunction of hardware/software (44 of 72) likely could have been prevented by using redundancy in planning, which many facilities may lack.[42] Our data suggest that having preassigned backup linear accelerators (linacs) and formal downtime protocols could prevent most of these treatment delays. Some institutions have reported success with predictive maintenance systems,[43,44] although the initial investment may be prohibitive for facilities with limited resources.

Prioritization of Risk Factors and Mitigation Strategies

We recommend readers use the risk factors identified in this study, along with other studies[11,25,26,28] and those from their incident learning system (ILS), to guide intervention within their organization. See **Online Supplement Appendix S1** for a list of mitigation strategies to help detect and prevent the risk factors identified in the present study. The list of strategies were primarily derived from prior literature that had varying levels of evidence, including expert opinion.[45] When readers review **Appendix S1**, we urge them to critically evaluate these strategies prior to their implementation. To support the individualized prioritization of risk factors and strategies outlined in **Appendix S1**, we recommend readers consider the following variables and approaches/tools.

- *Risk factor–related variables*: Frequency or likelihood of risk factor occurrence, amount of risk associated with one factor when compared to another, severity of harm caused by the risk factor, and detectability of the risk factor.
- *Strategy-related variables*: Impact of strategy, high/low-leverage strategy, risk of unintended outcome and degree of harm associated with unintended outcome, effort/feasibility to implement and maintain the strategy, resources and cost associated with strategy, return on investment/value, and whether the strategy aligns with a strategic plan. Readers should note that RT is a complex system where small changes in part of the process can ripple through the entire system.
- *Approaches/tools*: Pareto analysis of risks, risk assessment matrix, Kano model for risks, pairwise comparison of risks or strategies, weighted scoring model of strategies (i.e., solution selection matrix), strategic alignment mapping, and impact effort matrix for strategies.

Limitations

Many of the event reports did not provide sufficient information to determine the anatomical site being treated, specific type of simulation or RT, whether the dose was delivered beyond the planned margin (i.e., wrong site), or the extent of dose deviation from what was prescribed or intended. This information would allow for comprehensive comparisons with previous research and help pinpoint the variables that led to greatest risk of patient harm.

Due to insufficient detail in many of the event reports, it was not possible to reliably determine the causal factors underlying each event. As a result, we coded for risk factors, which were the variables that were the impetus and influenced, or likely influenced, the occurrence of each event. Furthermore, the event reports often lacked necessary information to determine the broader contributory themes, such as deficiencies in standard/procedure/practice, training, communication, or organizational management.

Two of the 40 facilities contributed 43% (106 of 245) of the event reports in this study, which may have introduced potential bias into the distribution of the results. Nonetheless, we chose to include all events that met inclusion criteria rather than using a selection method to reduce the proportional representation of those two facilities within our results. We made this choice because the exclusion of reports from these two facilities could remove valuable data not captured by other facilities. Overall, we prioritized conducting an analysis of the complete dataset over balancing the distribution of event reports across facilities.

Finally, readers should not interpret these findings as the absolute frequency of RT events in Pennsylvania, as underreporting to PA-PSRS is likely, despite mandated reporting. Given this limitation and the unreliability of available treatment data, we elected not to calculate a potentially misleading RT event rate.

Conclusion

Our analysis of 245 radiation therapy events identified 23 distinct risk factors across six phases of RT, each contributing to either wrong dose or delay in treatment events. The majority of the events resulted in a wrong dose event type (71%), while a sizeable portion led to a delay in treatment (29%). As shown in **Table 3**, the distribution of event types varied depending on the phase and associated risk factors. For instance, over half (51%) of the wrong dose events originated from the treatment planning phase and a majority (67%) of the delay in treatment events were associated with the treatment delivery phase. As another example, within the treatment planning phase, 12 categories of risk factors contributed to wrong dose events, compared to only two categories leading to treatment delays, illustrating the differential influence of risk factors on event types. The collective results underscore the need to examine the risk factors in order to understand the conditions that appear to be more or less likely to lead to a wrong dose and/or delay in treatment.

As a standout finding, the study showed that wrong dose events were frequently related with accessory and positioning issues during the treatment delivery phase, which indicates that real-time verification during treatment delivery is a notable challenge. This finding suggests that enhanced time-out procedures and automation likely would improve treatment accuracy. As another standout finding, we found that lengthy treatment delays were frequently attributed to scheduling or ordering errors in the before simulation phase. These workflow and communication failures likely could be addressed by implementing automated tracking systems. Given the complexity and nuanced nature of RT, we developed **Online Supplement Appendix S1**, which provides a list of mitigation strategies aimed at detecting and preventing the risk factors identified in the present study. The objective of **Appendix S1** is to serve as a resource to facilitate intervention and reduce patient harm in radiation therapy.

Notes

This analysis was exempted from review by the Advarra Institutional Review Board.

Data used in this study cannot be made public due to their confidential nature, as outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Pennsylvania Act 13 of 2002).[46]

Artificial intelligence was used only to improve sentence clarity. No AI was used for data analysis, interpretation, or generation of original content. The authors take full responsibility for the accuracy and integrity of the manuscript.

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Online Supplement to "Risk Factors and Mitigation Strategies in Radiation Therapy: A Study of Patient Safety Events From 40 Hospitals"

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This supplementary material has been provided by the authors to give readers additional information and strategies to help detect and prevent the risk factors in radiation therapy identified in the study.

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Online Supplement Appendix S1. Strategies to Mitigate Risk of Patient Harm by Phase and Risk Factor

Phases of RT	Risk Factors	Strategies
All Phases	**All risk factors**	• Use an ILS to document and learn from patient safety events, including near misses. For example, this strategy could be used to address events related to patient positioning, simulation documentation, and malfunctions of hardware/software.[12,34,35,47,48] • Foster a culture of safety where any individual is empowered to request additional resources and time to complete their task accurately, even in a busy environment. This will help to prevent rushing and a range of associated errors, such as errors involving scheduling and simulation documentation.[11,49]
Before Simulation	**Error involving consent form** (e.g., listed wrong side, site, or body part; missing patient signature)	• Implement a standardized, site-specific consent form template that clearly outlines the treatment site, side, and body part.[47,50] • Utilize a checklist to ensure all required fields on the consent form are completed, including patient signature and date, before proceeding with simulation.[27,51] • Require a double-check of the consent form by two independent qualified staff members (e.g., the ordering physician/provider and a member of the simulation team) to verify accuracy against the referral and initial order prior to the simulation appointment.[52]
	Error involving patient medical history (e.g., wrong or missing diagnostic imaging, failure to account for patient's implant/device)	• Develop a protocol requiring the collection and review of relevant prior diagnostic imaging (e.g., CT, MRI, PET) prior to simulation to accurately define the target and organs at risk. This may involve direct download from PACS if available.[47,53] • Implement a standardized form or checklist to document the review of the patient's medical history, specifically noting any implants, devices (e.g., pacemakers), and prior treatments, which may impact simulation and treatment planning.[13,27,52-54] • Establish a communication pathway between the ordering physician/provider and the simulation team to ensure all necessary medical history and relevant information are shared and reviewed before the simulation appointment. Daily morning huddles can facilitate this communication.[53] • Establish a robust process for obtaining and creating a plan sum of records (i.e., composite summary of past treatments) for patients with prior RT at outside facilities. This will inform the current treatment course, allowing sufficient time for this complex task. Longer simulation-to-start time frames may be necessary in such cases.[11]
	Error involving scheduling or ordering (e.g., failure to send referral, referral sent to wrong scheduling pool, order for right side instead of left)	• Establish a clear and standardized process for referral submission and order entry, including defined roles and responsibilities for each step.[53] • Implement a verification step to confirm receipt of the referral and accuracy of the order (e.g., correct patient, site, side) by the scheduling team.[53] • Consider utilizing an EHR system with built-in checks to ensure referrals are sent to the correct pool and orders match the intended treatment plan.[53]
Simulation	**Error in simulation documentation** (e.g., wrong setup notes, wrong patient photograph)	• Implement and consistently use comprehensive simulation checklists to ensure accurate documentation of patient setup, immobilization, imaging parameters, and specific instructions (e.g., breath hold, markers).[47] • Utilize OIS-integrated, logic-driven systems for simulation directives to ensure accurate and complete documentation based on selected procedures (e.g., 4D scan prompts for motion management documentation).[53] • Develop and strictly adhere to SOPs outlining clear documentation requirements for all simulation aspects, specifying content, recording methods, and storage locations (e.g., paper, OIS, EHR).[47] • Provide comprehensive training to all staff involved in simulation on proper documentation procedures, emphasizing the importance of accuracy and completeness. Training should cover the specific documentation requirements outlined in the SOPs and the use of any relevant documentation tools, including electronic systems and checklists. Competency should be assessed regularly.[53] • Standardize the format and terminology used in simulation documentation. This can reduce ambiguity and the potential for misinterpretation. Clear and consistent language in setup notes, position descriptions, and other documentation elements is essential.[34,36] • Implement a system for reviewing simulation documentation as part of the overall quality assurance process.[53] This review can identify incomplete or inaccurate documentation and provide an opportunity for correction before treatment planning proceeds. • Ensure that any changes or deviations from the standard simulation protocol are clearly documented with appropriate signatures and justifications. This is particularly important for factors like patient position or breath-hold techniques.[11] • Incorporate documentation requirements into FMEA and other risk analysis processes to proactively identify potential documentation errors and design mitigation strategies.[47] • Consider electronic systems with built-in checks and prompts to guide documentation, reducing errors and facilitating seamless information transfer to subsequent treatment stages.[34] • Establish clear communication channels and protocols between simulation staff and other team members (e.g., radiation oncologists, dosimetrists) regarding any specific documentation needs or clarifications. Miscommunication can lead to errors in documentation.[27,36]

Simulation	**Error involving patient medical history** (e.g., failure to account for patient's implant/device, previous treatment, physiological tolerance of simulation, missing or wrong document attached to EHR)	• Implement comprehensive checklists for simulation procedures that include verification of relevant medical history, such as previous treatments and presence of implants/devices.[13,27,52-54] Huq et al. provide example checklists for pre-IMRT workup and preparation of patient data for planning,[54] which include verifying previous treatments and correct image datasets. • Establish clear protocols and procedures for reviewing the patient's medical history before and during simulation, ensuring all relevant information is accessible and considered by the involved staff (radiation oncologists, medical physicists, dosimetrists, and therapists).[53] • Ensure effective communication between all members of the radiation oncology team regarding the patient's medical history and any special considerations for simulation.[34] Poor communication is a common causal factor in RT events.[12] • Utilize the EHR effectively to store and display relevant medical history, ensuring that all necessary documents (e.g., prior treatment plans, device information) are attached and readily available during simulation. • Employ image registration techniques to compare current simulation images with prior imaging studies, especially when accounting for previous treatments. • Perform thorough reviews of simulation data before proceeding to treatment planning, involving multiple qualified professionals to identify any discrepancies or missing information related to the patient's medical history.[26] Prior literature describes the process of physics plan review which could potentially catch errors originating from inaccurate simulation due to unaccounted medical history.[26]
	Failure in ongoing QA (e.g., calibration expired, failure to maintain hardware/ software)	• Establish and adhere to QM programs, encompassing both QC and QA activities, to prevent failures related to equipment maintenance and overall processes. • Implement rigorous QC procedures for all equipment, including regular checks, adherence to tolerance levels, and documented procedures, as essential for a comprehensive QA program.[32] • Ensure proper and independently verified equipment calibration to prevent dose errors, addressing issues like misinterpretation, insufficient education, and lack of procedures.[55] • Develop and follow vetted, regularly updated, and accessible SOPs for equipment maintenance and calibration to prevent errors and rushing.[55] • Vendor should perform preventative maintenance for all clinical hardware and software to address defective equipment, including regular maintenance, updates, and retesting.[55] • Implement independent checks and redundancies in processes related to equipment QA to enhance safety. For example, independent verification of commissioning measurements, potentially performed sometime after the initial verification, can evaluate stability.[55] • Utilize checklists to help standardize procedures related to equipment checks and maintenance, ensuring critical steps are completed and verified.[16] • Providing adequate training and competency assessments for staff on equipment operation, maintenance, and QA procedures is crucial.[16] • Regularly review and update the QM program using an ILS, log books, and risk assessments (e.g., FMEA, FTA) to proactively identify and mitigate hardware/software failure modes and develop effective QA measures.[48] • Utilize automation and forcing functions in equipment operation and QA where practical to minimize manual errors.[16,56] • Conduct thorough acceptance testing and clinical commissioning for new RT systems, considering design, capabilities, tolerances, hazards, training, usability, and technical specifications, ideally with independent external validation. • Maintaining data transfer integrity between systems, such as the treatment planning system and treatment delivery system, is also important and relies on properly functioning hardware and software.[11,32,47,52,53]

Simulation	**Malfunction of hardware/software** (e.g., artifact in CT scan, CT hardware failure)	• Implement comprehensive QA procedures for simulation equipment, including regular hardware and software checks and maintenance, with medical physicists responsible for program consistency and accuracy.[47,52] • Establish processes for identifying and addressing image artifacts that may arise due to hardware or software issues during simulation.[57] This might involve departmental protocols for artifact correction.[53] • Provide thorough training to staff on how to recognize and respond to simulation equipment malfunctions.[47,53,58] This training should cover the efficient and effective use of complex TPS hardware and software. Competency assessment should be provided at orientation and prior to changes in protocols. • Incorporate automation for QA checks during simulation where possible.[34,53,57] Logic-driven systems for developing simulation directives can help eliminate errors. Automated plan checking can identify inconsistencies and potential problems early in the process. • Employ checklists for individual QC steps during simulation.[27,53] These checklists can ensure that critical parameters and procedures are correctly followed (e.g., correct patient orientation, appropriate calculation algorithm). Checklists are more effective if they are focused and believed in by the user, and their use is enforced. • Implement peer review processes that include aspects of the simulation process, such as target volume definition on simulation images.[52,53] Peer review of general treatment strategy should occur before the planning process. • Ensure thorough commissioning of new or upgraded simulation hardware and software.[47,52,53] Information obtained during commissioning should establish baseline performance. • Consider end-to-end tests that encompass the simulation process to validate the delivered dose and overall system integrity.[16,52] • Proactively identify hardware/software failure modes in simulation using risk analysis methods (e.g., FMEA, FTA, as recommended by Task Group 100 of the American Association of Physicists in Medicine on risk assessment methodologies) to design mitigation strategies.[12,28,47,53] • Implement independent checks of critical parameters and data transfers related to simulation.[53] This can include verifying the correct transfer of data from the simulation system to the treatment planning system. • Strive for standardization in simulation protocols, including nomenclature for targets and OARs, which can reduce confusion and the likelihood of errors.[28,53] Standard treatment practices should be vetted through a review committee. • Develop logic-driven systems for simulation and treatment planning directives/orders to help prevent errors.[53] • Perform regular reviews of workflows, policies, and procedures to ensure they remain relevant to current practice.[53] An FMEA approach can be used for such reviews. • Consider designing systems for success by using simplification, standardization, and automation, and forcing functions to create robust workflows.[53]
	Wrong position (e.g., supine instead of prone, error in breath-hold technique, failure to evaluate breath-hold scans, missing or wrong marker, incorrect chin position)	• Select a reproducible and appropriate patient treatment position. This selection should consider the target location, anticipated treatment beam orientation, and patient comfort. A personalized approach is needed, considering the patient's unique anatomy.[53] • Utilize appropriate patient positioning and immobilization devices (e.g., masks, alpha cradles) to allow for reproducible positioning. The selection or construction of these devices should facilitate treatment but not restrict the technique.[53] • Clearly document the selected patient position (e.g., supine, prone) in the SOPs and on checklists used during the simulation process. This ensures that the intended position is communicated to all staff involved.[6,11] • Provide thorough training to staff on proper patient positioning techniques for various treatment sites and the use of immobilization devices. This training should emphasize the importance of adhering to established protocols and recognizing potential positioning errors.[59] • Establish clear protocols for breath holds that include instructions for the patient, the method of monitoring breath-hold, and the acquisition and evaluation of breath-hold scans. Failure to evaluate breath-hold scans can lead to treatment without verifying the intended respiratory state.[47] • Utilize markers (e.g., wires, ball bearings, fiducials) as needed to facilitate planning. Ensure that the placement of markers is accurate and well-documented on simulation images and in the patient's record. Missing or wrongly placed markers can lead to incorrect isocenter localization.[28,53] • Pay attention to specific positioning details such as chin position, which can affect the treatment of head and neck regions. Standardized protocols should address these specific requirements for different treatment sites.[53] • Implement image-based patient position verification (e.g., portal images, CBCT) on day 1 and throughout treatment to detect and correct discrepancies and setup errors (e.g., wrong shifts, alignment to incorrect landmarks).[11,48] • Establish a policy for reviewing setup images and any deviations from the planned position. Some facilities may have a policy requiring physician review for shifts greater than a certain threshold.[11] • Conduct a prospective peer review before initiating treatment. This review can include verification of the planned patient position and setup based on the simulation documentation and images.[11] • Consider designing systems for success by using simplification, standardization, and automation, and forcing functions to create robust workflows.[53] For complex cases or treatments involving reirradiation, collect all prior treatment plans and imaging data to ensure the correct anatomical site and position are targeted.[11] • Clearly communicate all aspects of the patient's required position and setup instructions to all members of the treatment team (radiation oncologist, medical physicist, dosimetrist, therapist). Poor communication can contribute to setup errors.[11,36] • Use checklists for individual QC steps during simulation and setup, including verification of the patient's position relative to the intended position (e.g., supine vs. prone).[11] • Implement, for spine treatments, more comprehensive setup field images and potentially CBCT with a larger field of view to ensure correct vertebral body alignment. Mislabeling vertebral bodies is a known source of risk due a lack of distinct external landmarks. Contouring adjacent structures as landmarks in DRR can also be a mitigation strategy.[59]

Treatment Planning	**Absent accessory** (e.g., bolus was missing from the field)	• Implement QM checks for the first day of treatment to verify the correctness of parameters and treatment accessories defined or added to the plan. This check should ensure that these additions are correctly continued through the treatment course.[47] • Perform a QM check of the entire treatment delivery script before treatment and automation.[47] • Develop procedures for changes needed in the treatment process, including necessary QA.[55] • Avoid rushing to prevent issues with incorrect, missing, mislabeled, misused, or damaged treatment accessories.[11,52]
	Error in clearance (e.g., gantry collides with patient and/or supporting structure)	Include checks in treatment planning and setup procedures to ensure the planned isocenter and associated setup parameters are within the physical limits of the equipment and patient/support structure geometry.[57]
	Error involving patient medical history (e.g., failure to account for patient's implant/device or previous treatment)	• Identify patients with prior radiation history and account for other patient-specific considerations that were documented during the initial consultation.[53] • In cases of reirradiation, collect all prior radiation plans, including DICOM data when available, to delineate the areas of prior radiation. This is crucial for targeting the correct region and ensuring the new treatment course is safe by accounting for prior radiation.[11] • Include in the initial directive a statement of previous treatment and request a review of previous treatments; the prescription must account for any previous treatments.[47] • Dosimetrists should perform QC checks of the inputs into the planning process by comparison against the treatment protocol, which includes reviewing previous treatments.[47] • Use more comprehensive downstream physics checks of the plan that use the same information for the final QA check, including reviewing previous treatments.[47] • Use chart rounds to ensure accounting of previous treatment.[37] • Consider implementing prospective peer review for complex cases or procedures like reirradiation.[7]
	Inaccurate or missing field (e.g., wrong location, wrong size, incorrect beam time factor)	• Select appropriate beam sizes and shapes to adequately cover the target volumes.[7] • Ensure that all parts of the plan are validated before treatment, including verifying the correctness of parameters and accessories added to the plan on the first day of treatment (day 1).[11] • Provide longer simulation-to-start time frames to allow for thorough checks during complex cases or procedures.[11] • Implement checklists for critical workflow steps like simulation and planning.[47] • Develop a policy describing the process for day-1 imaging, setup, and verification of patient position and treatment isocenter(s). Patient-positioning errors need to be corrected via the appropriate image guidance strategy.[47] • Standardize patient class tolerances for setup accuracy (e.g., prostate vs. lung) beforehand to remove ambiguity and possible errors at the time of imaging.[47] • Consider implementing automated field-labeling in the TPS as an option for users.[26]
	Wrong contour (e.g., wrong segmentation, incorrect expansion of volume, low-quality fusion)	• Radiation oncologists should review treatment plan(s) generated during the dosimetric planning process, including a review of image fusion/registration and OARs delineated by planning staff, for accuracy.[16] • Compare plans against a documented standard, such as output from a knowledge-based planning system or a practice's protocol.[16] • Radiation oncologists should take the lead in developing QM for this step, as they are the only personnel with the specialized knowledge needed to define the contouring protocols for most radiotherapy targets and other critical structures.[47] • QA check of the target volumes defined by the prescribing physician, before significant planning effort takes place, is likely the most efficient way to prevent this risk factor, which is virtually undetectable otherwise. This check should include labeling of images to distinguish between those used for delineation and those used for the treatment plan.[47] • Address failures to utilize correct Boolean combinations of delineated structures by including the process of Boolean combination, including standardized structure creation, in standardized site-specific protocols. A QA check to intercept these errors can be incorporated into the dosimetrist/attending physician preplanning contour check.[47] • Consider the application of automatic localization and segmentation of contours as potential solutions to mislabeling and contouring errors. However, time-saving tools like auto-segmentation require manual checks for accuracy.[47] • Peer review of key physician inputs to planning, before planning starts, is a QC step that should be embraced more frequently.[47]
	Wrong dose prescribed (e.g., prescribed 68 Gy instead of 73 Gy)	• Radiation oncologists should review treatment plan(s) and quantitative metrics describing the dose to the target(s) and OARs. They must verify that the plan satisfies the clinical requirements and prescription(s).[16] • Independent checks of treatment plans and calculations can be used to detect dose errors.[55] • Avoid certain dose/fraction errors by having the correct dose prescription digitally entered and approved into the TPS by the radiation oncologist and linked to the plan.[26,55] • Use of a standardized prescription structure could help by limiting crucial communications to approved pathways and standardizing the communication between physician and planner to confirm key plan elements.[34]

Treatment Planning	**Wrong fractionation** (e.g., wrong dose per fraction or wrong number of fractions)	• Ensure the fractional dose and total dose in the prescription agrees with the treatment plan.[16] • Develop written procedures for treatment prescription to avoid errors arising from unclear verbal prescriptions or complex plans.[55] • Implement a system where a "stop" mark is placed in each patient's daily treatment log indicating the projected final day of treatment for each site, for complex treatments involving different fraction numbers per site.[55] • Independent checks of treatment plans (treatment times) are a safety provision and are effective for identifying a change in the regimen.[55] • Use independent reviews to help identify instances where there was confusion of fractional dose and total dose.[55] • Avoid certain dose/fraction errors by having the correct dose prescription digitally entered and approved into the TPS by the radiation oncologist and linked to the plan.[26,55]
	Wrong isocenter (e.g., isocenter was not correctly adjusted from CT origin)	• Provide to the treatment planner documentation of isocenter coordinates, measurements, patient positioning, etc., from the simulator.[47] • Implement QM procedures to mitigate the risk of high-severity treatment failure that may result if an incorrect isocenter placement remains uncorrected or if anatomy is misidentified/misinterpreted during the day-1 procedure.[47] • Implement a prompt into the TPS if the isocenter was not set by the user.[26]
	Wrong laterality (e.g., selected wrong side in directive, incorrectly labeled laterality of target)	• Ensure that the correct target is identified in both the plan and documentation.[34] • Verification at the point of care, by involving the patient, can be a last line of defense.[34] • Use software automation to check for accuracy of labeled laterality.[34,53]
	Wrong or absent constraint. (e.g., physician chose wrong protocol, OAR constraints were missing)	• Define site-specific treatment planning and delivery protocols that serve as the basis for QM procedures. These protocols should be vetted through a review committee and regularly updated. They should be easily accessible.[47] • Agree on standard approaches and nomenclature for common diseases, targets, and OARs to avoid confusion.[47] • Specify optimization goals and limits, using applicable departmental or other protocols. • Develop a patient-specific form based on the treatment protocol to be inserted in the patient's chart. Default or standard choices (e.g., DVH planning or evaluation constraints) should be printed, and deviations written by hand to eliminate transcription error, while being aware of the potential failure of using the default in error.[47] • Dosimetrists should perform QC on the inputs to treatment planning and subsequent steps by comparing against the treatment protocol, which should include specified goals and constraints. This check should detect variances from established policies and provide a mechanism for negotiating either compliance or a documented variance with the attending physician.[47]
	Wrong or low-quality images (e.g., wrong image orientation, low-quality image registration, low-quality image, diagnostic image used for volumes)	• Radiation oncologists should obtain up-to-date imaging data sets.[25] • Radiation oncologists should leverage all tools at their disposal, such as a review with neuroradiology or neurosurgery, implementing radiation oncology segmentation rounds, or obtaining postoperative imaging in the treatment position as necessary.[25] • Check image datasets input into the planning process for correct dataset choice (correct study of the correct patient), documentation, quality, etc.[11] • Verify correct orientation of images.[11] • Document achieved registration accuracy of primary and secondary datasets during image registration cases.[47] • Correct image artifacts (e.g., contrast, metal) per department protocols.[47] • Physicians should specify image sets to be used for target delineation, particularly when obtained outside a radiation oncology department (e.g., number of images and date).[47] • Make errors in secondary-to-primary image registration more detectable by ensuring that treatment protocol documents specify the standard registration process to be used for the given clinical site (which image set is primary, type of registration, which landmarks to align, etc.).[47]
	Wrong shift (e.g., wrong shift values, wrong table height)	• Develop a policy describing the process for day-1 imaging, setup, and verification of patient position and treatment isocenter(s), including patient-positioning errors needing correction via appropriate image guidance.[34,47] • Use automation to verify the correct shift.[56]
	Other (e.g., The following were wrong: couch tolerance, plan notes, motion management or MLC file, linked prescription, target label)	• Ensure treatment planning instructions are clear and unambiguous.[47] • Standardize treatment practices and QA mechanisms through a review committee and regular updates. Standard treatment practices and protocols should be easily accessible.[47] • Use automated QA functions, such as comparing target volumes and OAR doses to constraints.[11] • Consider using treatment planning templates where many parameters are already set, limiting manual (error-prone) interaction by the user.[26] • Consider using artificial intelligence to check treatment plans for quality and inconsistencies, potentially detecting errors such as wrong dose/number of fractions or wrong gantry angle.[26] • Implement technical barriers in the TPS that can detect errors by denying final approval until correction.[26] • Ensure adequate commissioning of equipment and software, determining limits of reliable operation and types of errors with misuse. This includes thorough commissioning and validation of the TPS.[55] • Address hardware/software failures and design deficiencies through commissioning, periodic QA, and preventive maintenance.[55] • Verify all fluence patterns to confirm their correct behavior and resulting intensity distributions before any clinical use. This will help to reduce potential for day N (each day of treatment) delivery problems, such as lost MLC trajectories during plan transfer.[47] • Ensure complete and accurate documentation of patient charts for all aspects of treatment planning. Avoid misleading workflow documentation.[36]

Pretreatment QA Review	**Error involving scheduling** (e.g., scheduled on wrong machine, failure to schedule replan, failure to schedule care tasks)	• Establish reasonable timelines by assessing where and how rushing is introduced into the workflow and adjust standard or specialized timelines as necessary. Provide longer simulation-to-start time frames for complex cases.[11,49] • Implement mechanisms to protect time for critical steps in the process. A "no-fly policy" is one option, mandating that workflow processes adhere to designated timelines and rescheduling treatment if deadlines are not met.[49] • Schedule more staff during peak periods, if rushes are known to occur at certain times. This will counteract unsafe conditions.[49] • Consider adjusting patient loads and start times, potentially by "batching of cases," to manage workload and promote patient safety. Analyzing rushing trends can help identify times of day when therapists should be given more time between treating patients.[47] • Improve scheduling practices as a quality management tool.[47] • Recognize workflow issues that can lead to compressed timelines, such as coordinating with other healthcare providers (e.g., chemotherapy/infusion) or dealing with incomplete pretreatment steps (e.g., no consent at simulation, undocumented pacemaker).[49]
	Failure in ongoing QA (e.g., failure to perform patient specific QA, manual calculation error, unable to reproduce imaging)	• Create and maintain a periodic (e.g., monthly or biannual) QA program for treatment planning and delivery systems. This should be consistent with the desired accuracy for the treatment technique.[52] • Standardize site-specific treatment planning and delivery protocols, including written procedures and staff education, to address common failure modes and prevent training/procedure lapses.[47,52] • Implement independent checks of critical parameters. Employ "defense-in-depth" measures, such as having multiple checks of the treatment plan or machine output. The assignment of functions and lines of authority should ensure no gaps and establish necessary human redundancy.[55] • Address imaging-related issues by documenting standard registration processes in treatment protocols and check inputs against these protocols. Specify in protocols which images are used for tasks like ITV creation, dose calculation, and DRR generation for techniques like 4D motion management. Review motion management techniques during physics plan review. Prepare IGRT reference data (annotated DRRs or data for CBCT comparisons) as required for techniques like SBRT.[47] • Improve dose calculation verification by implementing robust automated checks of delivery-system parameters, using process control charts for variability, and defining QM goals (e.g., dose uncertainty limits).[47] • Automate checks and use forcing functions (e.g., computerized verification, automated monitoring, order entry) where possible, as these are more effective than relying solely on policies and procedures.[16,52] • Consolidate QM steps by identifying recurring causes in fault trees/process maps, improving efficiency, and positioning early checks (e.g., preplanning) to cover multiple downstream failures.[47] • Implement a departmentwide preventive maintenance program for all clinical hardware and software to address the cause of "defective equipment." Periodic testing and preventive maintenance are components of ongoing QA.[47] • Ensure continuous improvement of QM programs through detailed analysis, systematic process redesign, and FMEA to optimize procedures, requiring ongoing team enhancement and updates.[47]
Treatment Delivery	**Absent or wrong accessory** (e.g., missing vac lock, wrong electron cutout, missing bolus, wrong bolus location, wrong head cup, device not FDA approved)	• Verify treatment accessories as part of routine procedures.[48] Use manual checks or automation during verification. • During day-1 QM, verify the correctness of parameters and treatment accessories that may have been defined or added to the plan in a way that bypasses the standard flow and checks. Ensure these are correctly continued through the treatment course.[47] • Implement a QM check of the entire treatment delivery script before treatment to validate all parts of the plan, including accessories.[47] • Ensure efficient procedures are in place for checking key parts, such as the tube connector for brachytherapy, before treatment.[55] • Use effective procedures or noncompliance checks to ensure the technologist observes the patient during irradiation, which can help detect issues like incorrect machine settings related to accessories.[55] • Implement procedures for the commissioning and maintenance of brachytherapy applicators.[55] • Address potential errors related to incorrect, missing, mislabeled, misused, or damaged treatment accessories.[11]
	Error involving patient medical history (e.g., failure to account for patient's previous treatment, or failure to account for or monitor implant/device)	• Collect all prior radiation plans, including DICOM data when available, to delineate the areas of prior radiation. This is important both for ensuring the correct lesion is targeted and that the new treatment course is safe by accounting for prior radiation.[11] • Generate a composite plan to help decrease the error rate in this complex process.[11] • Utilize prospective peer review to help decrease the error rate in reirradiation cases.[11] • Use vendor partners to help streamline the transfer of calculated dose between planning systems for a more effective composite plan review.[11]
	Failure to confirm patient identification (e.g., failure to verify name and/or date of birth)	Verify patient identity as the initial step for radiation therapists by two independent verification methods, such as full name, birthdate, address, Social Security number, and/or treatment site.[60]

Treatment Delivery	**Inaccurate or missing field** (e.g., used the QA field instead of treatment field, wrong MUs input following use of service mode)	• Implement independent checks of all delivery-system treatment-plan parameters against those originally approved for use.[47] • Develop robust automated checks of these parameters, which is crucial for modern treatments with many parameters.[47] • Establish policies that implement electronic and procedural "permissions" so that change approvals (such as changes to prescription dose or MU) are performed by appropriate staff.[47] • Use file checksums to confirm the validity of files, which can increase the detectability of issues like file corruption or incorrect leaf motions.[47] • Implement automated monitoring that might demonstrate MLC descriptions were identical and unchanged day to day (e.g., use of EPID dose or dose back-calculated from MLC log-files with corresponding calculations from the TPS or with pretreatment data).[47] • Test all fluence patterns to confirm their correct behavior and resulting intensity distributions before any clinical use.[47] • Verify that the combination of calculational checks and generic MLC performance QA can truly confirm the correctness of a delivery. Physical deliveries of any new fluence pattern and confirmation of their correctness are recommended if this verification is not possible.[47] • Use day N checks to confirm the accuracy of patient delivery and dosimetric recording.[47] • Address errors related to wrong data transfer or setting.[13] • Implement independent verification of treatment parameters.[52] • Include inspection of the resulting isodose distribution as a check.[52] • Ensure written procedures for treatment prescription are followed to avoid misunderstandings, especially for complex treatments.[52] • Implement independent checks of calculations, especially when treatment plans are revised.[52] • Ensure personnel have sufficient awareness when performing calculations, particularly for unusual treatments or changes.[61] • Ensure staff are appropriately trained and follow standardized procedures to prevent human failures in calculations.[16,25]
	Malfunction of hardware/software (e.g., issues with hardware, software, and interconnectivity among the following equipment: chiller, MLC, treatment table, ultrasound, HDR accessories, linac imaging)	• Maintain sufficient hardware and software redundancy.[47] • Implement a departmentwide preventive maintenance program for all clinical hardware and software.[32,47,52] • Detect and compensate for hardware/software failures during commissioning or via periodic QA and preventive maintenance.[47] • Adequately commission all IMRT hardware/software changes (e.g., new, replacements, upgrades) to determine reliable operation limits and misuse-related errors.[47] • Use commissioning information to establish the baseline performance of systems for periodic QA.[53] • Address the impact of equipment changes on training needs and policy/procedure documents.[53] • Ensure the interconnectivity and interoperability of devices and systems.[52,53] • Verify data transfer integrity across the entire system chain (e.g., CT simulator to TPS to TMS to TDS) as part of the QA process.[53] • Create and use a robust information technology infrastructure, which is a critical requirement.[47] • Implement periodic (e.g., monthly) beam data integrity checks.[61] • Address equipment failures, including intermittent, unresolved issues.[58] • Implement and ensure compliance with procedures for transferring the machine to and from the maintenance technician.[62] • Ensure the accelerator cannot be operated in a "nonclinical mode" that disables safety features.[55] • Address deficiencies in the design of accessories or machines.[55] • Use file checksums to confirm file validity and increase problem detectability.[47] • Develop efficient and effective routine check features within treatment management systems.[47] • Implement procedures for checking key parts, such as the tube connector, before brachytherapy treatment.[55] • Address errors related to incorrect operation of the treatment machine.[55] • Investigate the root causes for QA failures, including examining equipment performance QA method/equipment used.[52]
	Wrong or missing patient-specific adaptation (e.g., failure to account for patient weight change or change in target)	• Restart the double-check process if there is a change in the patient geometry or other factor that requires a new simulation and/or a new treatment plan.[52] • Routine checks throughout the treatment course should confirm the accuracy of patient setup, delivery, dosimetric recording of the treatment information, and documentation, and correctness of image guidance decisions by physicians and other staff.[47] • Conduct day N checks for highly hypofractionated treatments.[47] • Address issues such as the immobilization device allowing movement during treatment.[52] • If the patient shows unusual toxicity, review the treatment plan and QA, review patient setup (positioning, beam placement), verify accuracy of data in TMS, review possible confounding clinical factors (e.g., medication use, chemotherapy), and consider performing supplemental measurements on a phantom or the patient (e.g., in vivo measurements).[52] • Recognize workflow challenges that can lead to compressed timelines, such as coordinating with other healthcare providers or dealing with incomplete pretreatment steps.[52] • Implement automation or weekly physics chart checks to detect for physician's change in prescribed dose.[47]

Treatment Delivery	**Wrong position** (e.g., incorrect extremity position, error in breath-hold technique, error in empty/full bladder, wrong shift, wrong SSD)	• Perform day-1 patient setup, including confirmation of setup and use image guidance often to position the patient. Document the correctness of the patient's position.[47] • Day N checks should include confirming the accuracy of patient setup.[47] • Address errors related to wrong patient position, setup point, or shift.[28,59] • Develop a detailed and comprehensive policy on 4D motion management. This protocol should address which images are used for tasks like ITV creation, dose calculation, and DRR generation.[47] • Address issues involved in registering 4D images, such as which landmarks are to be used by therapists in performing online registration. These should be addressed in the protocol.[47] • Use written procedures that clearly identify indications for techniques like gated treatment, including immobilization, setup, and intrafraction motion monitoring.[47] • Ensure adequate immobilization is employed to mitigate external motion.[52] • Use motion management and planning techniques to account for internal changes such as breathing or bladder/bowel filling.[52] • Prepare IGRT reference data (annotated DRRs or data for CBCT comparisons) as required for techniques like SBRT.[47] • Implement the time-out procedure before starting treatment to catch setup errors like treating the wrong site.[11] • Consider revising procedures to require cone beam CT for localization of spine fields to prevent setup errors.[36] • Address mislabeling vertebral bodies, which can cause positioning errors, by contouring adjacent structures within the treatment field to act as landmarks during image guidance or considering the application of automatic localization and segmentation of vertebral bodies.[29,37,59] • If toxicity is observed, review patient setup (i.e., positioning, beam placement).[52] • Ensure procedures for simulation are successful in ensuring the technologist understands the treatment plan.[55] • Perform radiographic verification of the location of the source during brachytherapy to detect issues like a kinked catheter.[55,63] • Use dummy seeds to test the proper movement of sources before brachytherapy implants.[55] • Observe the patient during irradiation.[16]
	Other (e.g., insufficient staff, miscommunication, wrong type of imaging)	• Ensure adequate staffing to prevent human failures caused by rushing, lack of time, or fatigue, as it is fundamental for quality.[47] • Address miscommunication issues, because inadequate direction or information exchange is a common cause of patient safety events.[33] Improve communication between the radiation oncologist and radiation technologist during simulation.[55] • Recognize workflow challenges that can lead to compressed timelines, such as coordinating with other healthcare providers or dealing with incomplete pretreatment steps.[11] • Ensure effective communication/transfer of essential information between technical systems.[61] • Ensure physicians provide dosimetrists and medical physicists with clear, unambiguous documented guidance.[34] • Mitigate communication errors by using a standardized prescription structure and standardizing communication to confirm key plan elements.[34] • Implement time-out/verbalization/callback procedures.[48] • Address wrong imaging type by clearly specifying image sets for target delineation (especially external ones), as physician detection of incorrect datasets is crucial due to independent verification limitations.[47] • Specify image sets to be used for ITV creation, dose calculation, and DRR generation in protocols.[47] • Address errors related to using the wrong CT image or wrong registration.[28] • Perform QA for imaging devices.[53]
After Treatment Completion	**Failure to close plan** (e.g., Loaded past plan that should have been closed out)	Establish and enforce clear policies and procedures for closing out completed treatment plans or courses within the R&V System or the TMS.[11,47]

Note: "Day N" represents each day the patient is treated between the first and last day of treatment. CBCT=cone beam computed tomography, CT=computerized tomography, DICOM=Digital Imaging and Communications in Medicine, DRR=digitally reconstructed radiograph, DVH=dose-volume histogram, EHR=electronic health record, EPID=electronic portal imaging devices, FDA=Food and Drug Administration, FMEA=failure modes and effects analysis, FTA=fault tree analysis, Gy=standard radiation dose value is given in Gray, HDR=high-dose rate, IGRT=image-guided radiation therapy, ILS=incident learning system, IMRT=intensity-modulated radiation therapy, ITV=internal target volume, MLC=multileaf collimator, MU=monitor unit, MRI=magnetic resonance imaging, OAR=organ at risk, OIS=oncology information systems, PACS= picture archiving and communication system, PET=positron emission tomography, QA=quality assurance, QC=quality control, QM=quality management, RT=radiation therapy, R&V=record and verify system, SOP=standard operating procedure, SBRT=stereotactic body radiotherapy, SSD=source-to-surface distance, TDS=treatment delivery system, TMS=treatment management system, TPS=treatment planning system