RO-ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

CLARITY PSO

A Patient Safety Organization

RO-ILS THEMED REPORT:

DOSIMETRICALLY IMPACTFUL EVENTS

PATIENT SAFETY WORK PRODUCT

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INTRODUCTION

Radiation therapy is a complex medical discipline involving numerous skilled professionals, countless software and hardware technologies, and often multiple treatment sessions. It requires extreme precision. To counteract the endless possible error pathways, a myriad of quality assurance checks are employed to prevent errors from reaching the patient. Unfortunately, errors do reach the patient and may result in harm.

This report examines RO-ILS: Radiation Oncology Incident Learning System® trends and events related to dosimetrically impactful safety events that affected patients between January 2014 and June 2023. Throughout the report, the term "dosimetrically impactful" is used to describe safety incidents where the patient's dose deviation between the planned total prescription and the delivered dose was greater than 5%, or the organ(s) at risk [OAR(s)] received more than intended and exceeded tolerance levels. Such events represent less than 1% of the entire RO-ILS database (Figure 1A).

OVERVIEW

While the word "incident" is in the RO-ILS name, the system collects a wide spectrum of events. The most common event classification is "operational/process improvement." On the other end of the spectrum are "therapeutic radiation incidents" meaning the radiation treatment dose was not delivered as intended, with or without harm to the patient (Figure 1B). Therapeutic radiation incidents represent 12% of the aggregate database.

Figure 1A: Database Drill Down

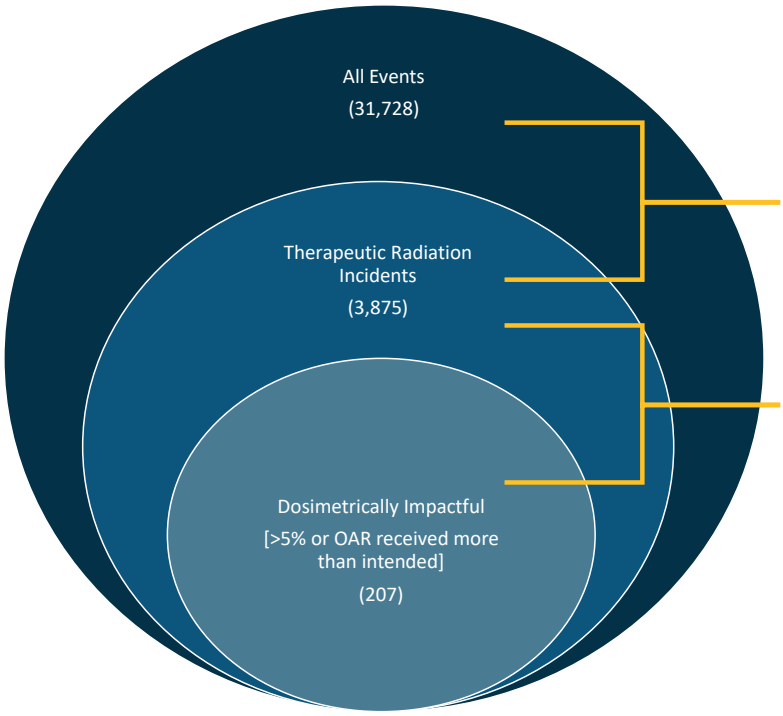


Figure 1B: Event Classification (n=31,728)

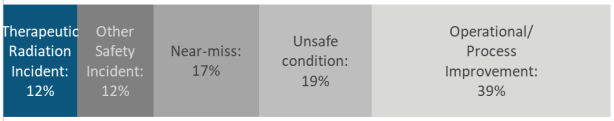
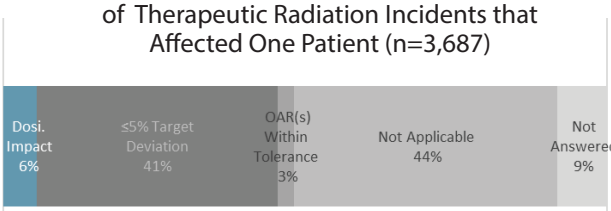


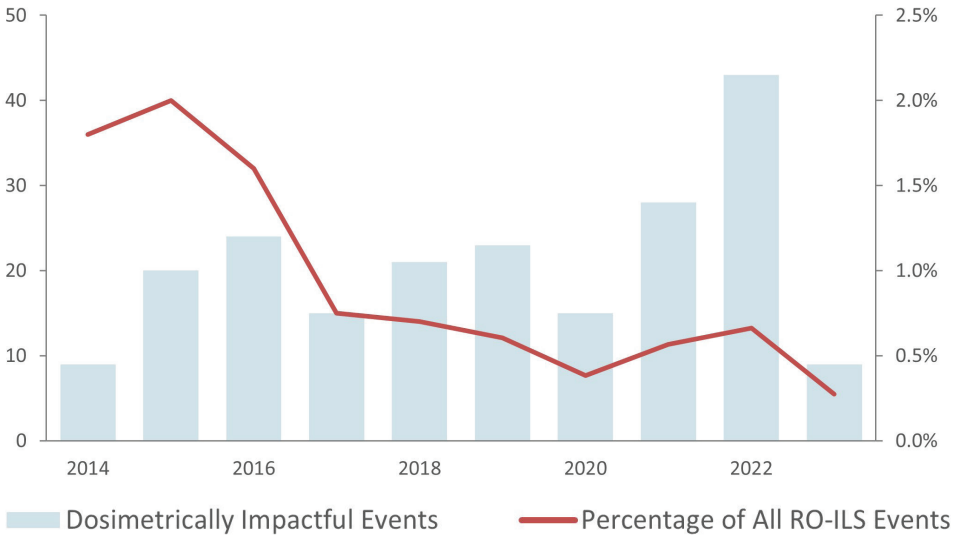
Figure 1C: Dosimetric Impact Distribution of Therapeutic Radiation Incidents that Affected One Patient (n=3,687)



Most therapeutic incidents affected only one patient; in which case the user specified the dose deviation from that specific patient's plan. The vast majority of single patient therapeutic incidents resulted in less than or equal to 5% target dose deviation (Figure 1C). Only 6% of the potentially relevant therapeutic incidents met the pre-determined criteria for "dosimetrically impactful." A total of 207 events were deemed dosimetrically impactful, representing 0.65% of the total aggregate RO-ILS database.

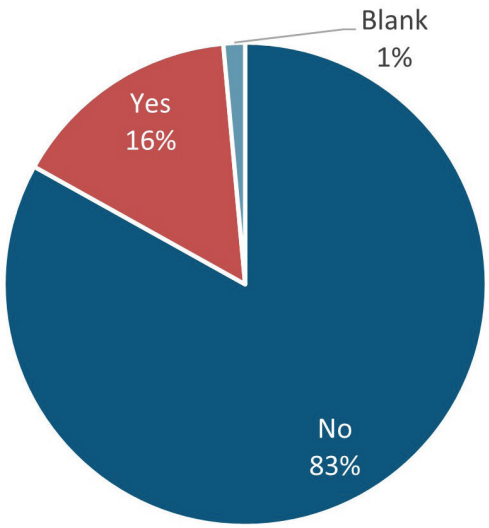
Over time, there has been a slight increase in the absolute number of dosimetrically impactful events reported to RO-ILS per year (Figure 2). However, the number of RO-ILS facilities and total events reported each year has also increased during this time, with the exception of 2020 likely due to the pandemic. When analyzed as a percentage of the total events reported to RO-ILS per year, there is a downward trend, although this may be affected by internally controlled reporting factors (e.g., reporting all or reporting selected events). For instance, if the number of facilities reporting all their events increases, and earlier participants were comprised of mostly selective reporting, then this could appear as a downward trend without any safety improvement.

Figure 2: Number of Dosimetrically Impactful Events Increased Over Time but Represent Smaller Percentage of All RO-ILS Events



Based on state and federal laws, certain medical errors may need to be reported to external agencies. The specific threshold varies but as an example, the Conference of Radiation Program Directors recommends states collect medical events with greater than 20% dose deviation for treatments with more than five fractions. Since most of the RO-ILS dosimetrically impactful events are in the range of 5-25% dose deviation, it is no surprise that 83% of these events were not reported externally (Figure 3). While expected, this is still an important finding. RO-ILS is voluntary and confidential and therefore captures a greater breadth of events than mandatory reporting programs, thus providing a more comprehensive opportunity to gain valuable knowledge.

Figure 3: Most Dosimetrically Impactful Events Not Reported Externally (n=207)



HIGHEST SEVERITY EVENTS

Most concerning are the events in which the dose deviation exceeded 25%. Events that reached this upper threshold have been shared with RO-ILS users and the public in previous education materials. For example, a 2016 report included a theme of delivery to the wrong location and included an event in which the wrong hepatic lesion was treated. The following are RO-ILS cases that were not previously shared.

CASE 1: Incorrectly Contoured Stereotactic Brain Treatment

In delineating the treatment volume for a three-fraction course in the brain, the radiation oncologist contoured the wrong target, and the physicist subsequently planned the treatment based on this incorrect delineation. All three treatment sessions were carried out using this incorrect target volume. Only after the patient completed the final session did the neurosurgeon discover that the post-operative treatment area had not been accurately contoured and treated.

Preventing events like the one described, where the wrong site was irradiated because of an inaccurate target delineation, is crucial to ensuring patient safety and the effectiveness of radiation therapy. In this case, obtaining adequate diagnostic imaging is essential, and the skill of the radiation oncologist in correlating diagnostic imaging with simulation imaging is equally important. The radiation oncologist should leverage all the tools at their disposal in achieving this end. This may include a review with neuroradiology or neurosurgery, implementation of radiation oncology segmentation rounds, or obtaining post-operative imaging in the treatment position as necessary. Conducting a prospective peer review before initiating treatment plays a crucial role in preventing errors and impacting the patient's care. This proactive peer review process becomes especially vital in the case of high-dose, hypofractionated treatments, as a delay in chart rounds may lead to the patient receiving most, if not all, of the prescribed dose before being reviewed by a peer. During the prospective peer review process, another expert (or a team of experts) assesses the treatment plan, further enhancing its accuracy and patient safety.

CASE 2: Re-Irradiation – Wrong Lesion Retreated

A patient had multiple brain lesions treated at an outside clinic. When planning the current course of treatment, the radiation oncologist contoured a lesion that was previously irradiated, instead of the intended, new lesion. This resulted in excessive radiation dose to a critical area of the brain.

Prior radiation treatment adds increased complexity to the treatment planning workflow. With the increasing use of radiosurgery (SRS/SBRT) in patients with metastatic cancer to repeatedly treat new metastatic lesions in the same organ (e.g., brain, lung, liver metastases), it is critical to collect all of the prior radiation plans, including Digital Imaging and Communications in Medicine data when available, to delineate the areas of prior radiation. This is important both to make sure the correct lesion is targeted, and to ensure the new treatment course is safe (i.e., accounts for the prior radiation). Prospective peer review and generation of a composite plan could help decrease the error rate in this complex process. Vendor partners can continue to help improve this complex process by further streamlining transfer of calculated dose between planning systems for a more effective composite plan review.

CASE 3: Wrong Anatomic Site Treated with Brachytherapy

During a prostate brachytherapy procedure, patient was treated with real-time planning in the procedure room. The ultrasound probe was properly inserted during the planning stage, and a plan was generated using stranded seeds. However, when the probe was re-inserted during the seed placement stage, it was not adequately advanced on sagittal imaging to visualize the prostate gland. As a result, 63 of 78 stranded seeds were implanted immediately inferior to the prostate in the perineum and only 15 loose seeds were implanted in the prostate. A post-implant CT confirmed that the prostate D90 (dose that covers 90% of the prostate volume) was only 26.26%, as compared with the pre-planned prostate D90 of 104.8%. A significant volume of the perineum received >100 Gy.

Hypofractionated treatments, such as SBRT or brachytherapy, require additional safety checks prior to, and with each treatment, as a misadministration during one treatment has a significant dosimetric impact on the entire treatment course. Specialized treatments such as brachytherapy also require a high level of expertise and rigorous safety processes to prevent gross misadministration. Although the minimum number of procedures performed per year to maintain proficiency may not be clear, there is a definite skill set which comes with increased procedural experience. Procedures which are image guided need to adequately use the imaging at hand. While proper training and procedural volume is paramount to performing such procedures, additional safeguards such as confirming a consistent measurement of the probe contact with the anus may reduce the risk of this error pathway. Additionally, leveraging peer review can be extremely helpful. For example, other personnel (e.g., the brachytherapy physicist might be skilled in interpreting ultrasound imaging) can concur on image interpretation and thereby serve as a second check. The addition of an explicit checklist item to the process can also improve safety.

TOPICS OF CONCERN

Multiple data points can be used to describe what errors were reported in this cohort. A primary user-driven data element is the RO-ILS Problem Type; these question-and-answer options were adapted from Canadian Institute for Health Information as a simple mechanism to determine the ultimate issue at hand. RO-ILS users are required to select one answer option for each event. Since this data element was introduced in the RO-ILS portal in 2019, it has been answered for 50% of the dosimetrically impactful incidents. For this cohort, patient position, setup point, treatment isocenter, or shift were top problem types (Table 1), which is not surprising given that a high percentage of errors originated during the treatment delivery phase.

Table 1: Problem Type of Dosimetrically Impactful Events

Problem Type	Count
Wrong patient position, setup point or shift	18
Other	16
Wrong prescription dose fractionation or calculation error	15
Wrong anatomical site (excluding laterality)	12
Wrong, missing, mislabeled or damaged treatment accessories	10
Treatment not delivered: personnel/hardware/software failure	7
Inappropriate or poorly informed decision to treat or plan	5
Wrong target or OAR contours	5
Treatment plan (isodose distribution) unacceptable	3
Anatomical site (excluding laterality) incorrect	2
Radiation therapy scheduling error	2
Treatment accessories: incorrect, missing, mislabeled, misused or damaged	2
Target or OAR contours incorrect or omitted	1
Treatment plan acceptable but not physically deliverable	1
Wrong patient	1
Wrong planning margins	1
Wrong side (laterality)	1
Unknown	105

Members of the Radiation Oncology Healthcare Advisory Council (RO-HAC) work with the patient safety organization Clarity PSO to review and analyze the RO-ILS data in a protected and confidential environment. RO-HAC reviewers can select labels when reviewing events from a predetermined list developed by RO-HAC. Most (88%, 184 events) dosimetrically impactful events have at least one label, with an average of three labels per event. The top labels for dosimetrically impactful events were related to broad workflow steps (e.g., treatment (delivery) and planning), followed by topics of setup/positioning, treatment device and documentation. This, again, aligns with the workflow data.

Not all events are designated for RO-HAC review, therefore only 49% of the full aggregate database (15,600 events) has an associated RO-HAC label. For comparative analysis, the number of events with a particular label was calculated as a percentage of that cohort of data. Table 2 displays the percentage difference between dosimetrically impactful event labels compared to the aggregate database. RO-HAC labels such as TREATMENT DEVICE and SHIFT are more common in the dosimetrically impactful events, matching the top user problem types.

Table 2: Percentage of Events with a RO-HAC Label and Difference between Dosimetrically Impactful Events and Aggregate Database

RO-HAC Label	Percent of Dosimetrically Impactful Events (n=207)	Percent of Aggregate RO-ILS Database (n= 15,600)	Percent Difference
Treatment Delivery	33%	10%	24%
Laterality	9%	3%	6%
Field	10%	4%	6%
Shifts	9%	4%	5%
Setup/positioning	17%	12%	5%
Treatment Device	13%	8%	5%
Other	4%	10%	-6%
Simulation	6%	13%	-7%
Scheduling	0%	11%	-11%
Documentation	17%	33%	-16%

An important factor in understanding the error is the associated treatment technique and the number of fractions delivered incorrectly. Table 3 provides the percentage of events in the dosimetrically impactful events and the aggregate database related to a treatment technique and the percent difference.

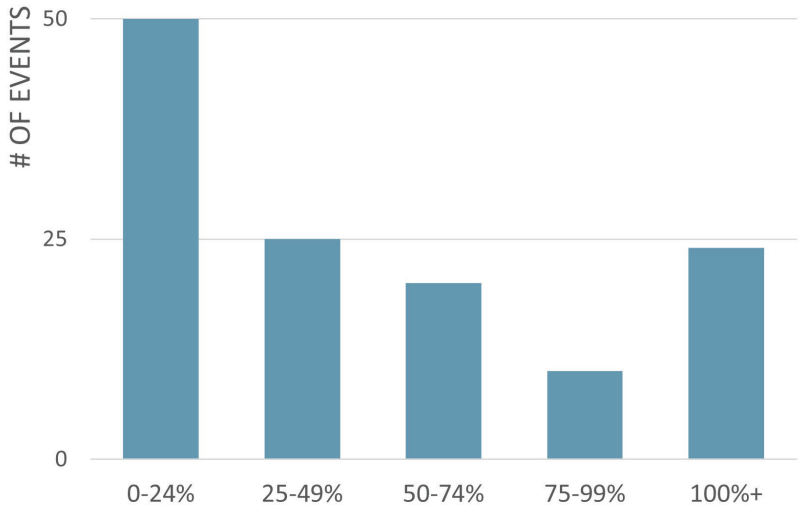
Brachytherapy procedures represent a higher percentage of dosimetrically impactful events than the aggregate database. This could be due to multiple factors: 1) brachytherapy is a specialized procedure and is more prone to error if not performed at a high-volume site; and 2) since there are often only one or a few fractions with brachytherapy, errors during any one treatment delivery have a significant impact on the overall dosimetry of the treatment course. Similarly, total body radiation (TBI), radiopharmaceuticals and intraoperative radiation are also specialized treatments with very few fractions/treatments. It is perhaps reassuring that SRS/SBRT does not represent a higher percentage of dosimetrically impactful events, suggesting perhaps that most centers have adequate expertise and potentially more rigorous peer review and safety checks for these treatment types.

Table 3: Percentage of Events with a Treatment Technique and Difference between Dosimetrically Impactful Events and Aggregate Database

Treatment Technique	Percent of Dosimetrically Impactful Events (n=207)	Percent of Aggregate Database (n=31,728)	Percent Difference	Findings
3D	33%	28%	5%	Techniques Represented **MORE** in Dosimetrically Impactful Events Than Aggregate
Electrons	13%	5%	8%	
2D	6%	2%	3%	
HDR	4%	2%	2%	
Radiopharmaceuticals	2%	0%	2%	
LDR	2%	0%	2%	
TBI	2%	1%	1%	
Intraoperative	1%	0%	1%	
SRS/SBRT	11%	12%	-1%	Techniques Represented **LESS** in Dosimetrically Impactful Events Than Aggregate
Particles (Protons)	3%	4%	-1%	
(Blank)	2%	4%	-1%	
Other	2%	5%	-2%	
kV x-rays (i.e., Orthovoltage and superficial)	0%	1%	-1%	
Not Applicable	0%	10%	-9%	
IMRT/VMAT	25%	35%	-10%	

Optional data elements ask users to provide the number of fractions delivered incorrectly and the total number of fractions prescribed. While 96 of the dosimetrically impactful events (46%) indicated that only one fraction was delivered incorrectly, 43% of events had a total of 10 prescribed fractions or less. Figure 4 displays the number of events grouped by the incorrect fraction percentage. When there are multiple fractions and the error is discovered early in the course of treatment, adjustments might be able to address the incorrect delivered dose. A more recently added data element asks users to indicate whether there was a dosimetric change to the plan as a result of the error. This optional information is only known in 52% of the dosimetrically impactful events; however, if known, 40% (n=43) events were replanned.

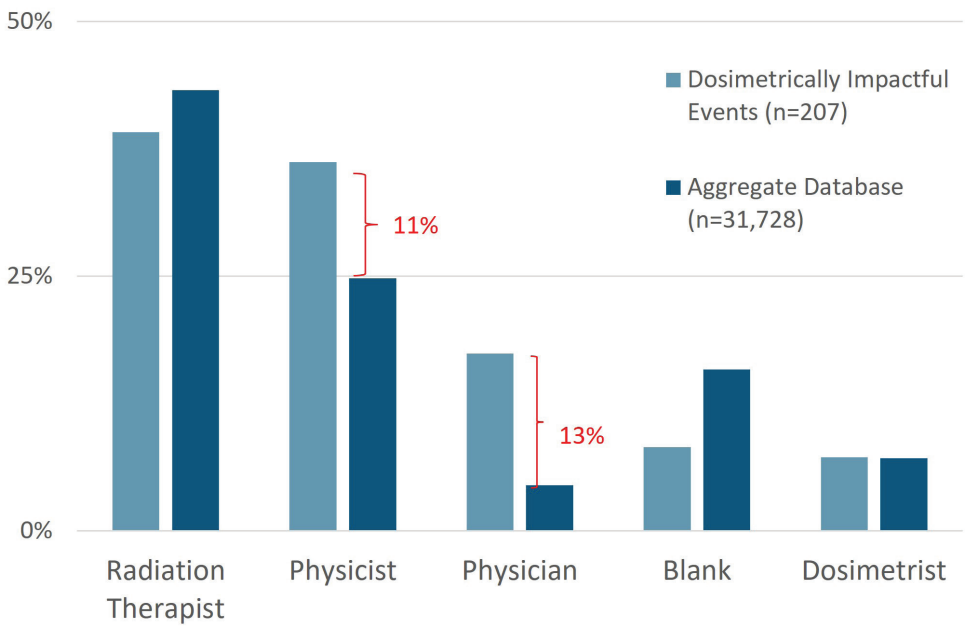
Figure 4: Percentage of Incorrectly Delivered Fractions out of Total for Dosimetrically Impactful Events, if known (n=129)



ERROR DISCOVERER

In the RO-ILS aggregate database, radiation therapists are the leading identifiers of errors, and this is no different for the dosimetrically impactful events (Figure 5). However, physicists and radiation oncologists were more often involved in identifying dosimetrically impactful events versus the aggregate events. This is particularly noteworthy for physicians who seldom report events or are marked as the error discoverer.

Figure 5: Radiation Oncologists and Medical Physicists were Involved in Identifying a Greater Percentage of Dosimetrically Impactful Events

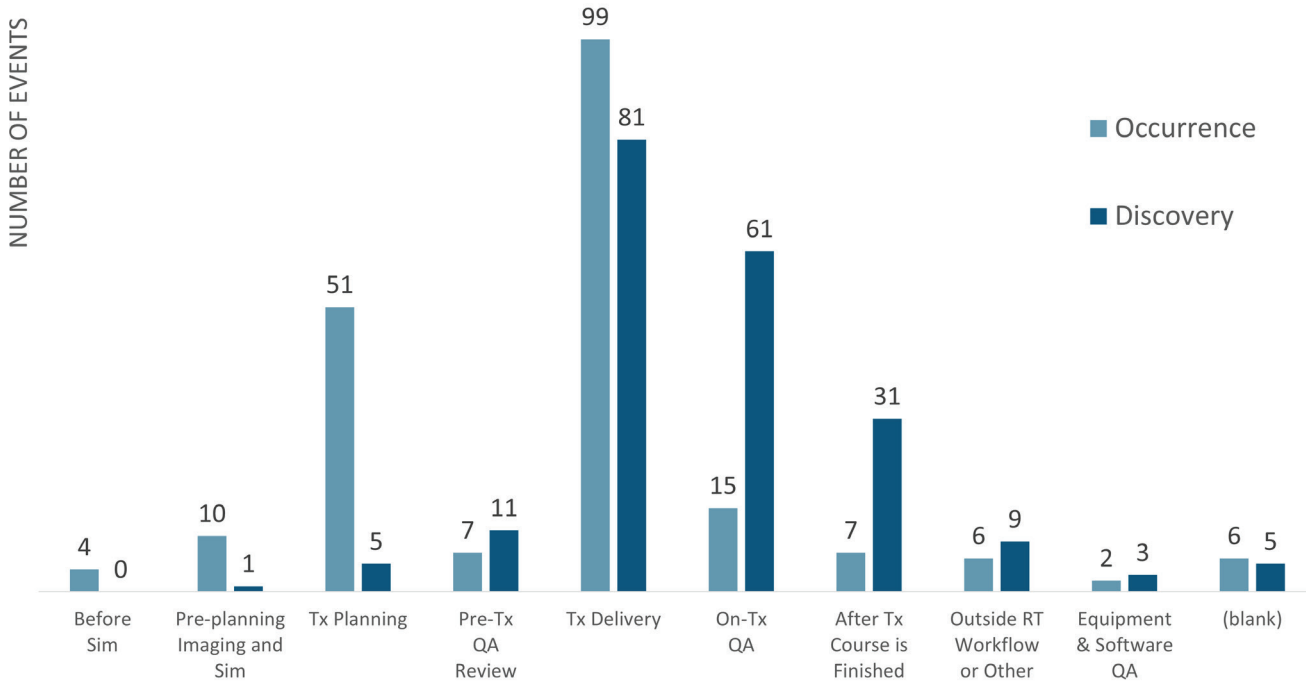


The increased rate of physician reporting for this group of reports is likely multi-factorial. Part of the cause may be related to self-reporting; for example, if a physician submits incorrect contours for planning, then the eventual plan will not cover the clinically appropriate volume. Multiple events are related to this such as: 1) contouring the wrong target; and 2) not expanding target volumes appropriately. Another source of physician error occurred in multiple events where there was a mismatch between the intended and planned prescription doses. This can lead to under- or over-dosing of the treated volume and is often related to lack of documentation of physician intent, or a change in a physician's intent after planning started, which is then not well communicated or documented. Physicians are often the most likely party to catch an error in the target volume (if the wrong site is being treated) or an error in the prescription (if the dose and fractionation are different than intended).

ERROR-PRONE WORKFLOW STEPS

Examining where in the radiation oncology workflow these incidents originated and were discovered can be helpful in identifying areas requiring additional attention. In dosimetrically significant incidents, the errors most commonly took place during treatment delivery, closely followed by occurrences during treatment planning (Figure 6). Since this report focuses on dosimetrically impactful events that actually reached patients, it is expected that many of these events are being discovered after the fact (either after treatment has already started, or when treatment is complete).

Figure 6: Workflow Steps of Occurrence and Discovery for Dosimetrically Impactful Events (n=207)



3D EVENTS

One third of the dosimetrically impactful events were related to 3D treatments. The differences between dosimetrically impactful 3D and IMRT events were further analyzed. Table 4 displays the percentage difference in RO-HAC labels for these two cohorts. RO-HAC labels related to treatment delivery, such as treatment devices, setup/positioning, shifts and reference points, were more frequently found in 3D than IMRT events.

Table 4: Percentage of Dosimetrically Impactful Events with a RO-HAC Label and Difference between 3D and IMRT Events

RO-HAC Label	Percent of 3D Events (n=68)	Percent of IMRT Events (=51)	Percent Difference
Treatment Device	18%	4%	14%
Setup/positioning	25%	12%	13%
Shifts	16%	4%	12%
Reference Point	12%	2%	10%
Isocenter	15%	6%	9%
Contouring – Normal	0%	8%	-8%
Image Registration	4%	14%	-10%
Contouring – Target	3%	14%	-11%

CASE 4: Patient Position Moved for Reference Point and Not Returned

A patient receiving palliative treatment to the chest/neck region was transferred to the couch with the help of a transport team. The patient underwent setup verification using portal images, and the radiation oncologist was called for approval. While waiting for the physician to review images, the radiation therapists entered the room to mark the patient's position on the immobilization mask. Since the lasers fell on the patient's shoulders, the therapists shifted the treatment couch 10 cm higher to mark a more stable reference point on the mask. They also noted a 10 cm inferior shift on one side of the mask to indicate that an inferior couch shift of 10 cm should be made from the reference mark to the treatment isocenter. The physician approved the setup images in the intended couch position, but the therapists delivered the treatment at the incorrect, elevated position. On the second day, the treating therapists used the marks applied on the first day of treatment and noticed shift instructions on the opposing side. They took additional portal images, which revealed a 10 cm shift consistent with the instructions. A 10 cm inferior shift was applied to the treatment couch, and the patient was treated at the intended position. Patient setup instructions were updated to avoid similar errors in the future.

The highest level in the hierarchy of effectiveness focuses on forcing functions, barriers and automation/computerization. For example, vendors could help by setting linear accelerator alerts at the treatment console to notify therapists when the couch location for treatment has been moved since on-treatment imaging was obtained. A standard workflow adjustment would be to confirm that all team members are aware of patient setup changes. Clearly marking these adjustments on both sides of the immobilization mask for reference could serve as visual cues. Surface guidance technologies with the associated proper workflow can be a helpful tool in preventing this error pathway. While admonitions to enhance vigilance occupy the lowest level in the hierarchy of effectiveness, they are the easiest to implement. Staff need to maintain a vigilant focus on every aspect of the treatment process as it unfolds. Paying attention to what is happening during each stage of treatment, especially when adjusting standardized workflows, can help prevent errors from happening.

CASE 5: Patient Aligned to Incorrect Anatomical Landmarks

The patient came in for treatment to an abdominal target but was not aligned to the correct anatomical landmarks during setup imaging with kV orthogonal views. The therapists reviewed the images and were confident that the portal image matched the digitally reconstructed radiograph and that they were targeting the correct thoracic region. However, the treatment was administered with a 3.1 cm superior and 0.5 cm posterior deviation from the target position. A treatment plan was re-created with one out of five fractions delivered at the misaligned location for evaluation. The patient's liver and bowel received a higher dose than planned. In addition, about 3 cm of the inferior portion of the planning target volume (PTV) was outside the field for the misaligned fraction, significantly affecting gross tumor volume and PTV coverage at the prescribed dose.

Radiation therapists face several challenges when aligning patients using the T-spine. Unlike other treatment sites on the body, the T-spine lacks distinct external landmarks that can be easily visualized and aligned to. This makes it more challenging to position patients correctly. Incorrect vertebral body alignment issues were shared in previous RO-ILS education as single events (2015 Report Case 1) and as a featured theme (2018 Report). To avoid similar errors, more comprehensive setup field images encompassing boney anatomy (e.g., 7th cervical vertebra body) and the superior aspect of the lumbar spine may be needed. Using a cone-beam CT field-of-view that captures a larger extent of anatomy in addition to kV orthogonal images may also reduce the likelihood of misalignment. The initial imaging technique can be used for the alignment of the target and the second imaging technique is used for verification and very minimal shifts, if needed. Presumably, this kV-kV alignment would have resulted in a 3 cm shift from where the patient was marked. A useful policy is to have therapists request physician review for any shift greater than a given threshold as a function of anatomical site (often 1-2 cm).

CONCLUSION

Radiation oncology involves the delivery of complex care, which is vulnerable to adverse and near miss events. This comprehensive analysis of dosimetrically impactful safety events within the RO-ILS database sheds light on critical aspects of radiation therapy safety and identifies opportunities for improvement. While these events represent a small fraction of the overall incidents reported, their significance lies in their potential to directly affect patient outcomes. The involvement of physicians in error discovery highlights the importance of a multidisciplinary approach and the active role physicians can play in enhancing patient safety. The focus on workflow, timing and specific problem types provides targeted areas for quality improvement initiatives. Moreover, the detailed exploration of individual cases emphasizes the critical need for proactive measures, such as involving colleagues in segmentation review and implementing prospective peer review, to prevent errors from reaching the patient. Some treatment types might be at higher risk of errors, such as repeat irradiation or brachytherapy, suggesting additional safety checks may be beneficial for higher risk procedures. This report not only serves as a reflective analysis of dosimetrically impactful events but also highlights the importance of initiatives aimed at improving processes and preventing future adverse events to support patient safety.