

Lessons Learned

RO•ILS®

**RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM**

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Why Incident Learning? Why RO-ILS?

1 Collect safety data.

2 Identify and address error pathways.

3 Educate the community.

4 Reduce adverse events.

5 Promote safety culture.

Background

- *Patient Safety and Quality Improvement Act of 2005 (PSQIA)*

Congress recognized the need to collect patient safety data in a protected space. PSQIA authorized the following:

- *Patient Safety Organizations (PSOs)* – entity with expertise in patient safety authorized to work with providers under the protections of PSQIA.

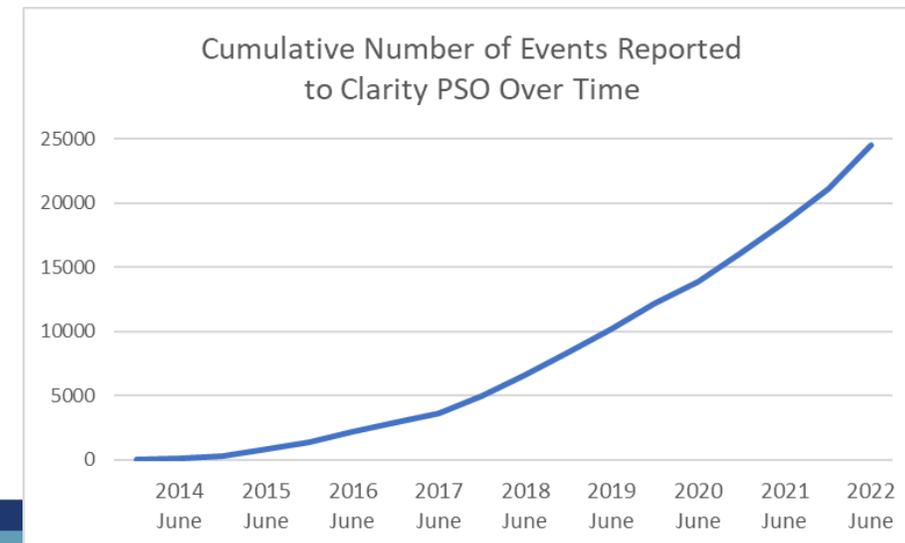
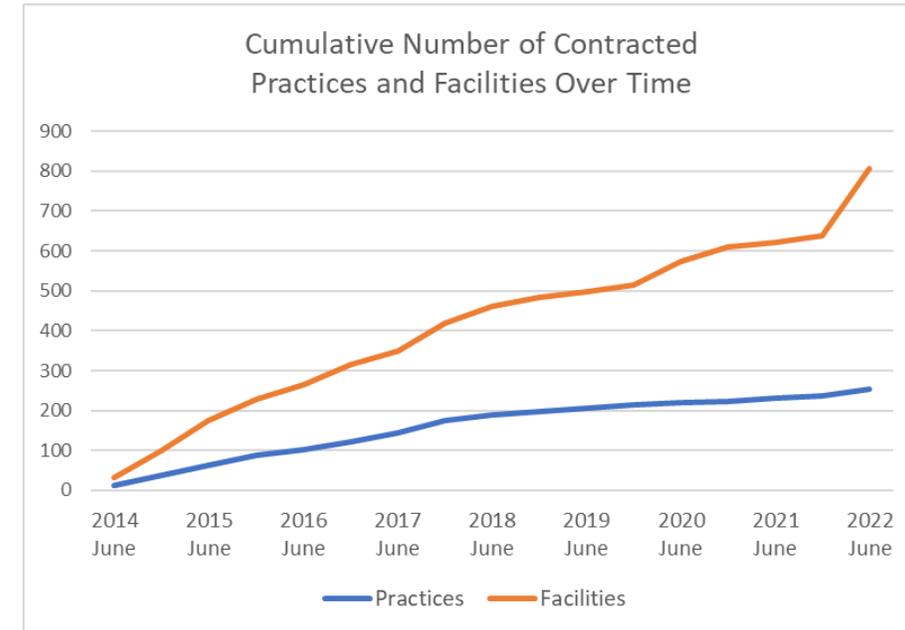
- Clarity PSO provides PSO services for RO-ILS.
- One of the first AHRQ-listed PSOs.



- *Agency for Healthcare Research and Quality (AHRQ)* oversees the PSO program on a national level.

Program Update

- Established program 8 years.
- Practices can be comprised of one or more facilities.
- **800+** facilities enrolled.
- **~35%** of U.S. facilities are enrolled.
- Facilities in **47** states and Puerto Rico enrolled.
- **24,000+** events have been reported to the PSO.



Data Collected

- RO-ILS collects incidents, near misses, and unsafe conditions.
- RO-ILS can be used as a comprehensive practice improvement system – collect operational/process improvement events and suggestions.

Event Classification:

Therapeutic Radiation Incident: Radiation dose not delivered as intended, with or without harm

Other Safety Incident: Event that reached the patient, not involving radiation dose, with or without harm (examples: collision, fall, etc.)

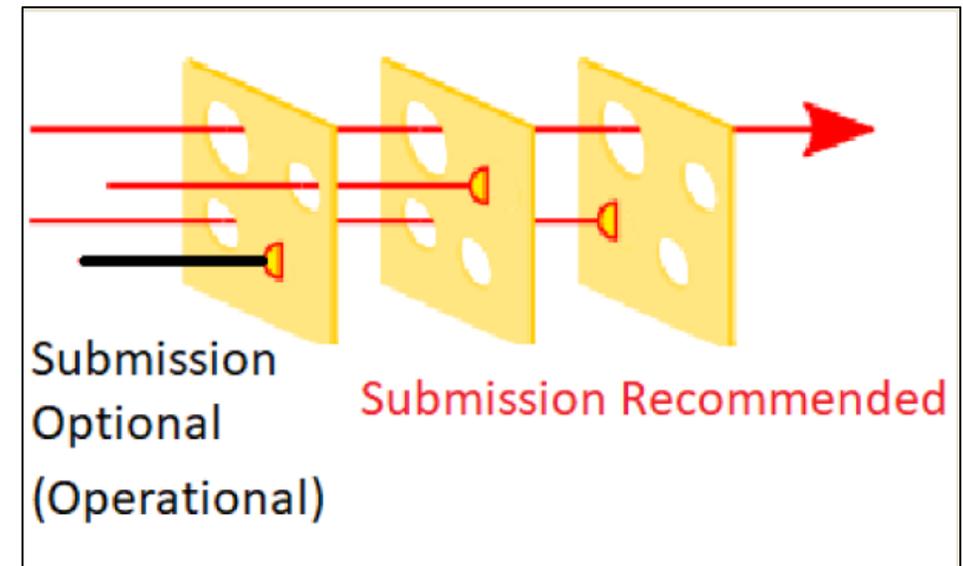
Near-miss: A safety event that did not reach the patient

Unsafe condition: Any condition that increases the probability of a safety event

Operational/Process Improvement: non-safety event

*Event Classification:

Therapeutic Radiation Incident
Other Safety Incident
Near-miss
Unsafe condition
Operational/Process Improvement



Advantage: RO-ILS is flexible

- Disadvantage: RO-ILS is flexible
- There is no one way to use RO-ILS!

*RO-ILS is trying to determine better guidance around this area and to be able to identify and split different user types.



With a national ILS, there are lots of expectations/dreams that the community might have which aren't program missions...

- The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment.
- Provide RO specific ILS for institutional learning; promote safety culture
- Produce Educational material for the RO community at large

RO-ILS: Dreams versus Reality

- Dream: Easily Searchable Database by anyone anywhere anyhow anytime
 - Free text
 - HIPAA
 - User privacy protections
 - all practices have an agreement and BAA with the PSO; so this is totally appropriate to facilitate internal follow up

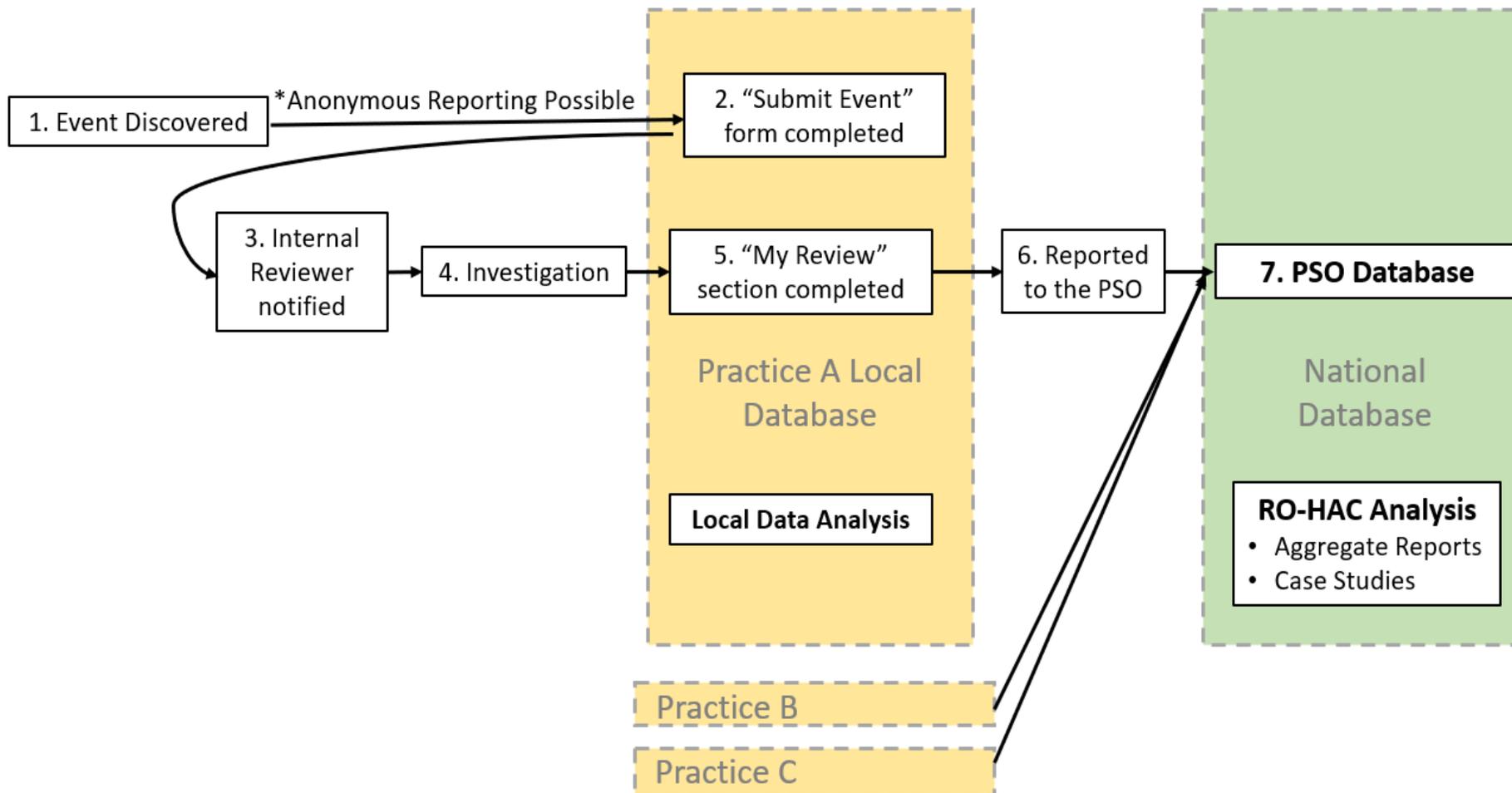
Example of PHI in narrative

- Patient LASTNAME was treated with a different patient's plan instead of his on EXACT DATE 14:30 pm.
- Dr. LASTNAME was late with contours, causing a rushed treatment plan
- At the _____ TREATMENT MACHINE (ONLY PLACE IN THE COUNTRY THAT USES THIS TECHNOLOGY)

RO-ILS: Dream versus Reality

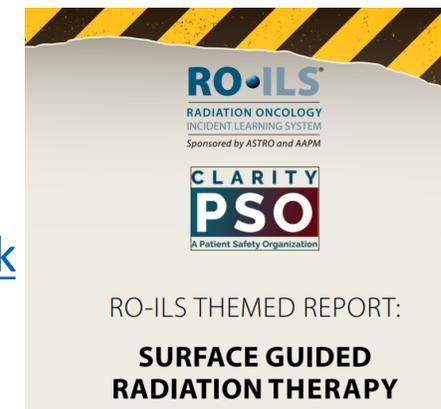
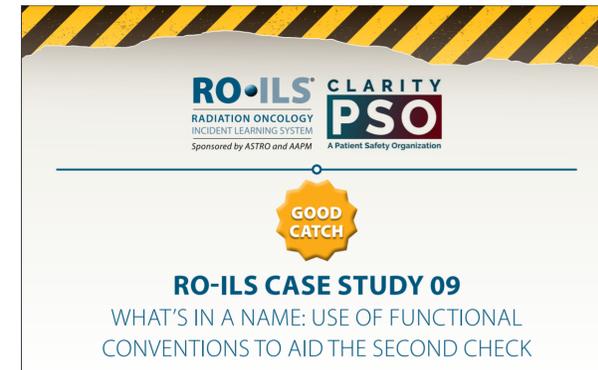
- Dream: With 24,000+ events, will be able to meaningfully say what % of events dominate the RO space
 - Varied uses of RO-ILS which limits utility of strict numerical analyses

RO-ILS Data Entry Workflow



RO-ILS Education

- RO-HAC review national events/trends and develop education.
- Safety Notices
 - Important findings that may be novel to the community, of higher clinical significance and/or deserve more prompt review.
 - [SRS Heterogeneity corrections.](#)
- Case Studies
 - Summarize one RO-ILS event.
 - [Case Study 8: IT Permissions Disrupt HDR Delivery](#)
 - [Case Study 9: Use of Functional Conventions to Aid the Second Check](#)
- Themed Reports
 - Topic-based; Include multiple case examples.
 - [SGRT Themed Report.](#)
- Aggregate Data Reports
 - High-level look at the trends; “Report Card” and graphs.
 - [Q2 2021](#)



Quarter	Discovered Workflow	Occurred Workflow								Grand Total	
		Before Simulation	Pre-planning Imaging and Simulation	Treatment Planning	Pre-Treatment QA Review	Treatment Delivery Including Imaging	On-Treatment QA	After Treatment Course is Finished	Equipment and Software QA		Outside the Radiation Therapy Workflow or Other
2020 Q4	Before Simulation	90%	5%							5%	100%
	Pre-planning Imaging and Simulation	43%	47%	3%						2%	100%
	Treatment Planning	5%	10%	73%	5%	3%	1%			1%	100%
	Pre-Treatment QA Review	5%	11%	47%	33%	1%			2%	1%	100%
	Treatment Delivery Including Imaging	2%	6%	24%	9%	55%	1%			3%	100%
	On-Treatment QA	3%	7%	19%	11%	29%	30%			1%	100%
	After Treatment Course is Finished	5%	10%	24%	19%	10%	10%	19%		5%	100%
	Equipment and Software QA	17%				17%			50%	17%	100%
	Outside the Radiation Therapy Workflow or Other									10%	100%

This graph displays the overlap of when in the workflow events occurred (20% Occurred Workflow) and when it was discovered (20% Discovered Workflow) for the most recent quarter. The percentage is based on the total number of events that occurred in that workflow step (e.g., of events that occurred "before simulation", 90% were discovered "before simulation").

RO-ILS: Dream versus Reality

- Dream: We can categorize and fully understand all the events entered
 - Jargon
 - Lack of standard narrative (TG-288)
 - Data clarity
 - Data management

Data Clarity Rating

Excellent

- Event description provides detailed/thorough explanation of what happened, causes to the error, key players and their role in the event, and effect on the patient/clinic.
- Majority of the structured data elements appear to be correct.
- No clarifying questions for the practice.

Reasonable

- Event description provides general information about the event, but key details are missing (e.g., why or how the error occurred).
- Some of the structured data elements appear questionable.
- Clarifying questions for the practice but education could proceed without user input.

Data Clarity Rating

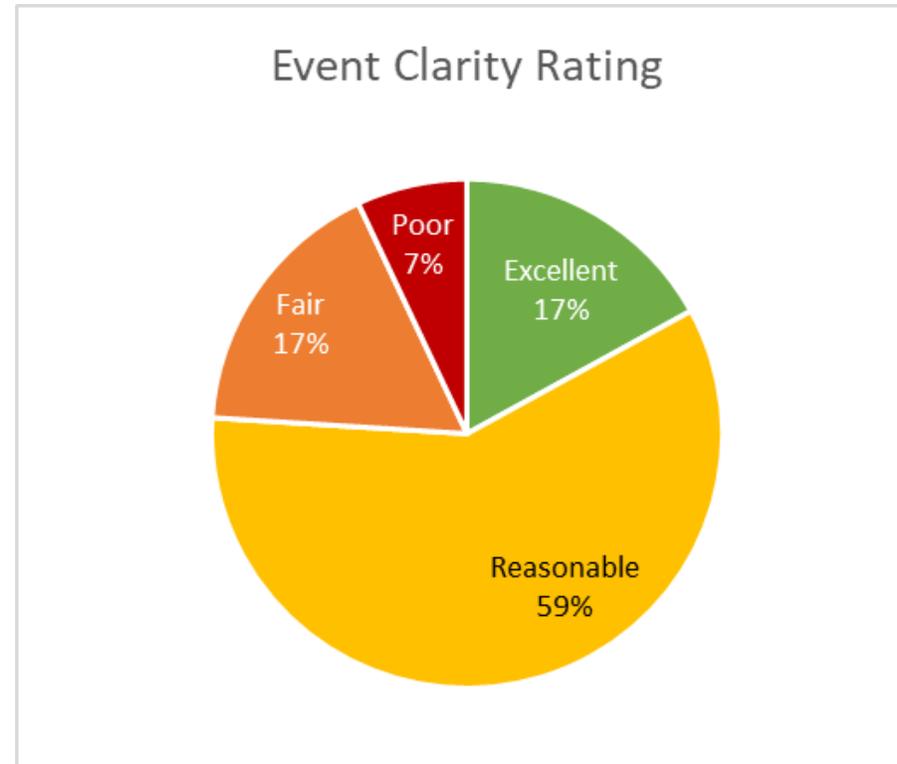
Fair

- Event description provides limited information about the event.
- Some of the structured data elements appear to be incorrect.
- Clarifying questions for the practice which makes sharing the event/developing education impractical.

Poor

- Event description is incoherent and/or incomplete. RO-HAC member is unable to understand what occur, why, how, and overall impact of the error.
- Majority of the structured data elements appear to be incorrect.
- Significant clarifying questions for the practice which makes sharing the event/developing education impossible.

Event Clarity Rating by RO-HAC members



Structured data elements

- Taxonomy is a universal challenge.
- RO-ILS adapted Canadian's "Problem Type" data that was extensively tested.
- Still many events are identified as "Other".
- Current work underway to improve this data element.

*Problem Type:

Wrong side (laterality) ▾

Wrong side (laterality)

Wrong anatomical site (excluding laterality)

Wrong patient

Wrong prescription dose fractionation or calculation error

Wrong patient position, setup point or shift

Wrong target or OAR contours

Wrong planning margins

Wrong, missing, mislabeled or damaged treatment accessories

Treatment plan (isodose distribution) unacceptable

Treatment plan acceptable but not physically deliverable

Treatment not delivered: personnel/ hardware/ software failure

Excess imaging

Failure to perform on-treatment imaging per instructions

Systematic hardware/software (including dose-volume) error

Inappropriate or poorly informed decision to treat or plan

Untimely access to medical care or radiotherapy

Inadequate coordination of combined modality care

Radiation therapy scheduling error

Fall or other patient injury or medical condition ▾

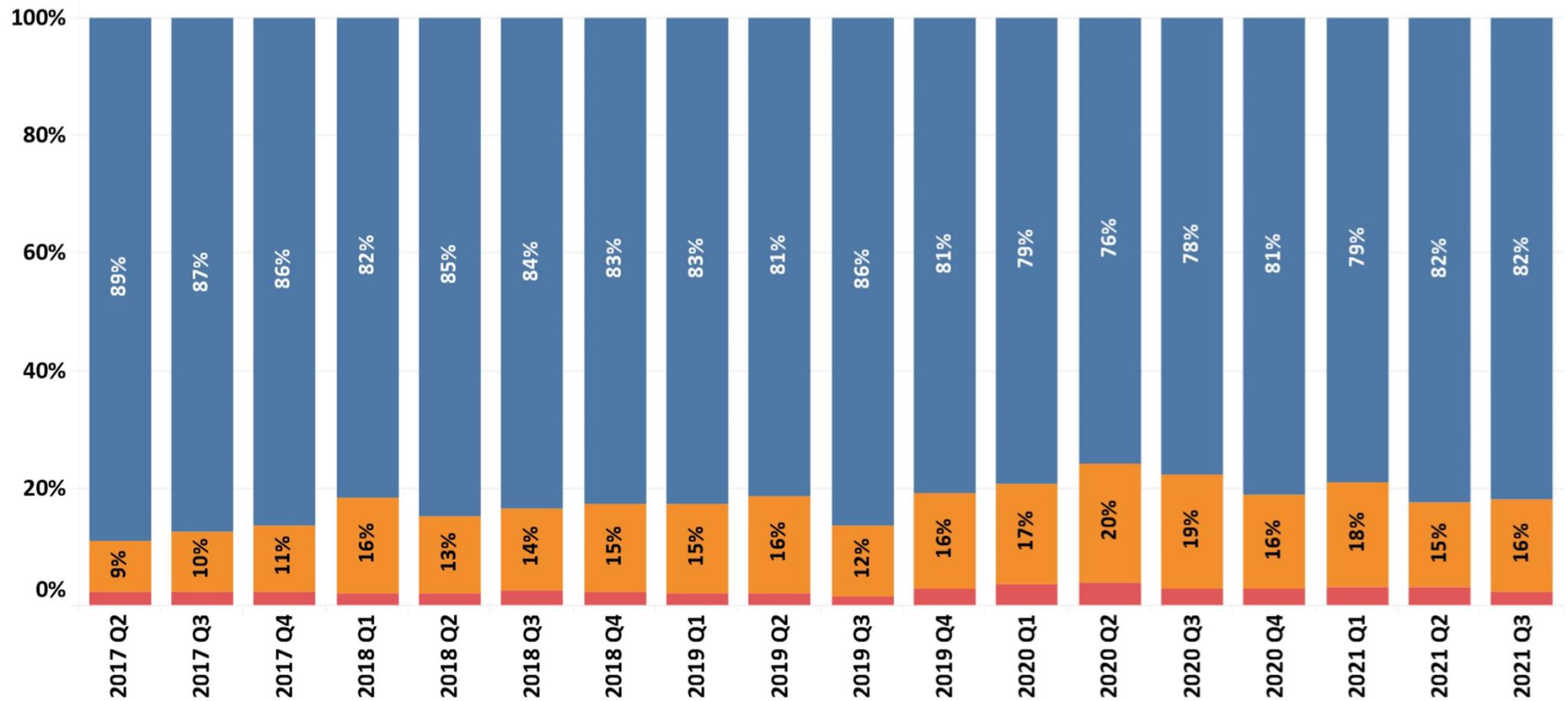
Example of unclear narratives:

- pt got resimmed. pt in lot of pain, setup changed.
- Prescription for radiation was 3000cGy after receiving total dose of 600cGy, patient entered hospital for surgical procedure. Patient passed away in hospital.
- Pacemaker was not stated in WD

RO-ILS Dream versus Reality

- **Dream=Reality:** We can identify high level trends in events nationally

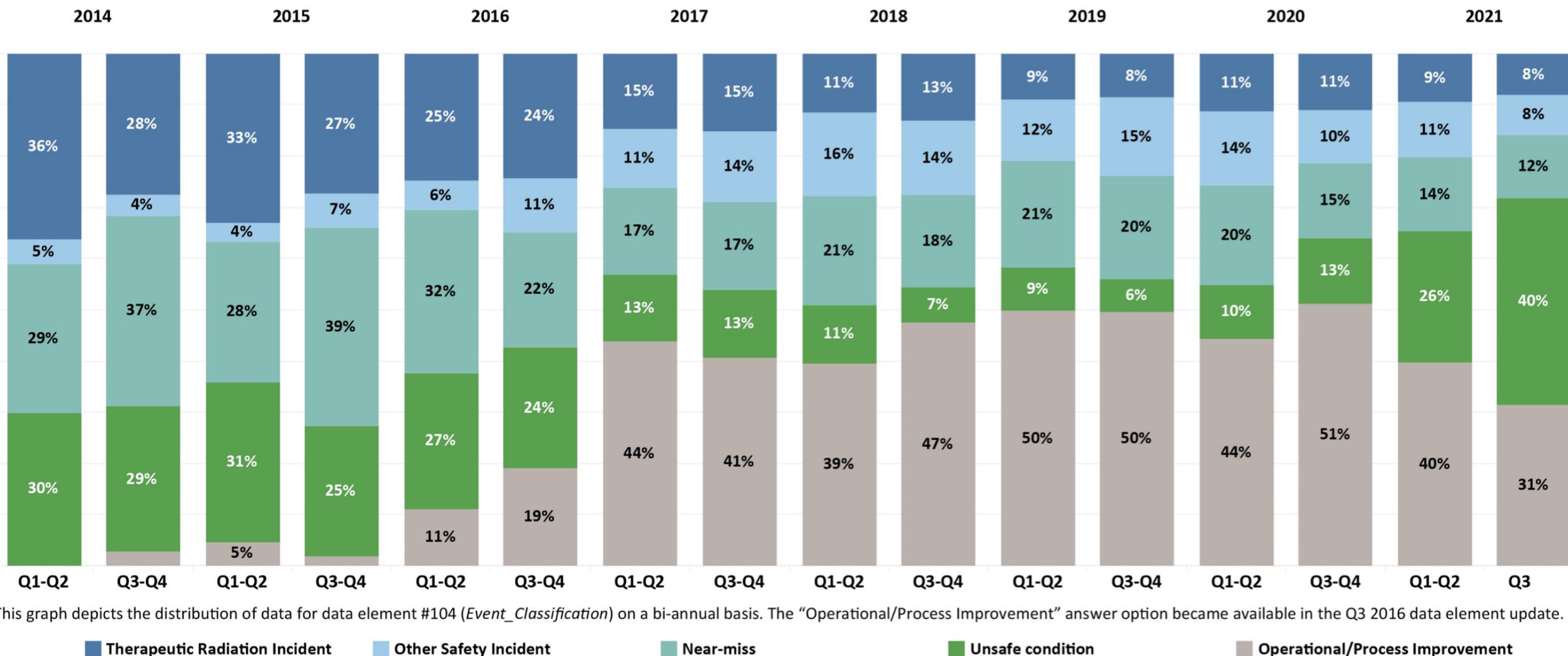
Aggregate: Significance Scale



This graph shows the frequency of answers for data element #225 (*Significance_Scale*) which asks, “In terms of risk to patient safety, how significant was this event?” This question was introduced in Q3 2016. The graph and table provide the severity percentages per quarter since 2017.

■ Mild
 ■ Moderate
 ■ Severe

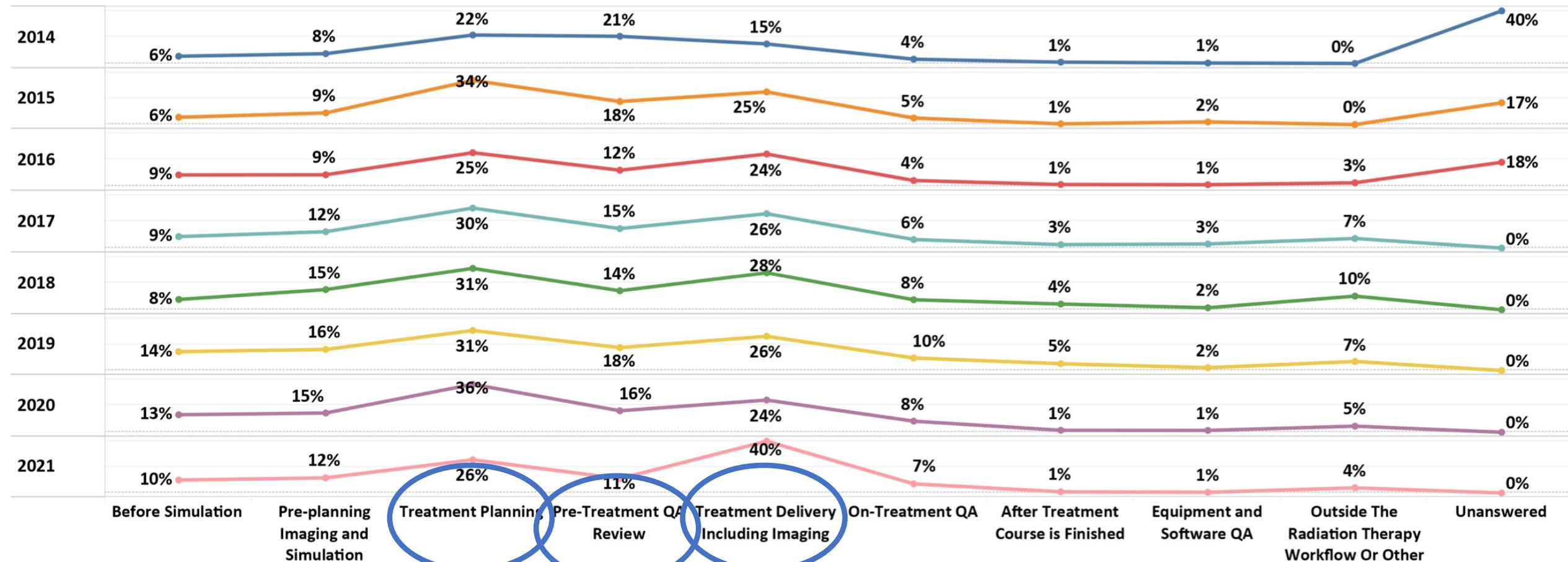
Aggregate: Event Classification



This graph depicts the distribution of data for data element #104 (*Event_Classification*) on a bi-annual basis. The “Operational/Process Improvement” answer option became available in the Q3 2016 data element update.

■ Therapeutic Radiation Incident
 ■ Other Safety Incident
 ■ Near-miss
 ■ Unsafe condition
 ■ Operational/Process Improvement

Aggregate: Workflow Step(s) Where Event Occurred



Possibilities

- ***First, let's consider interpretation 1: More events are happening at treatment delivery, fewer events at other workflow steps.***
- Positive: with the rise of new equipment like surface guided radiation therapy (SGRT), practices may be better able to detect errors occurring during treatment that were otherwise opaque before. As treatment planning can be done remotely, this may have altered the work environment for dosimetrists towards less interruptions
- Negative: Multiple waves of COVID-19 in 2021 left many practices with significant numbers of staff out at one time for various reasons (e.g., personal, family illness, quarantine).

Possibilities

- ***Now, let's consider interpretation 2: The number of events happening at treatment delivery is stable, but there are other confounding factors that skew the data.***
- Estimates are that voluntary reporting only accounts for approximately 10% of the events that actually occur
- With so many constraints on their time, in the second year of the pandemic, incident learning may have become a lower priority. RO-ILS recommends reporting any error that passes through the first checkpoint, regardless of whether it reaches the patient or is caught further downstream at a later safety check. However, we know not all practices are able to do this and that not all staff work in a culture of safety that supports this.

RO-ILS: Dream versus Reality

- Dream: We don't have to learn about errors from lawsuits, private conversations, and/or hearsay



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CLARITY
PSO
A Patient Safety Organization

RO-ILS SAFETY NOTICE:
SRS HETEROGENEITY CORRECTION

During the review of events reported to RO-ILS, the Radiation Oncology Healthcare Advisory Council (RO-HAC) may identify an event worthy of escalated status and determine that a Safety Notice is warranted. A RO-ILS Safety Notice communicates RO-ILS findings that may be novel to the community, of higher clinical significance, and/or deserve more prompt review. RO-HAC determined that the following event warranted a

RO-ILS: Dream versus Reality

- **Dream = Reality:** We don't have to learn about errors from lawsuits, private conversations, and/or hearsay

A radiation oncology practice purchased a new linac and upgraded their existing intracranial stereotactic radiosurgery (SRS) program. A qualified medical physicist commissioned the replacement SRS program that included new hardware and software.

The immobilization system for this new SRS program included a substantial base plate and accessories, which the physicist(s) decided to contour in order to account for this new density device in the beam path. Given the amount of air within the mask, the result was a long physical pathlength but relatively short effective pathlength used in the dose calculations.

Physics staff assumed that heterogeneity corrections were accounted for in the new planning software, but they were not. This incorrect utilization of the software resulted in a ~10% deviation in dose for patients treated before the miscalculation was discovered and corrected.

RO-ILS: Dream versus Reality

- Dream: RO-ILS can advocate for users to implement safest practices and software/hardware at the vendor level

RO-ILS: Dream versus Reality

RO•ILS

- **Dream = Reality:** RO-ILS can advocate for users to implement safest practices and software/hardware at the vendor level

Winter 2021
Industry Webinar

RO-ILS: Radiation Oncology Incident Learning System®

Uploading Incorrect CT: Opportunities

- Warnings for starting contours/plans on CTs which are more than X days old (e.g., 10 days).(has been implemented)
- Warnings for starting to plan on a CT which has a previous Tx plan associated with it.
- Customer settings allowing rules for which CT will be used for planning, e.g.
 - IF 4DCT, MIP and Average present, contour should be created on MIP and dose calculated on Average.

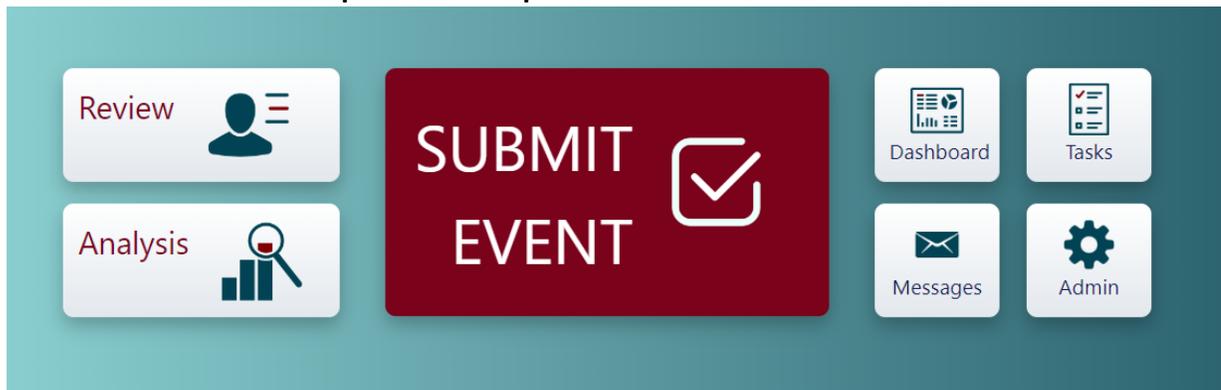
RO-ILS: Dream versus Reality

- Dream: Radiation oncology practice have an easy-to-use tool to aggregate their errors and learn from them.



RO-ILS: Dream versus Reality

- **Dream = Reality:** Radiation oncology practice have a easy-to-use tool to aggregate their errors and learn from them.
 - Anonymous Reporting, Pre-set, interactive graphs, report development capacities

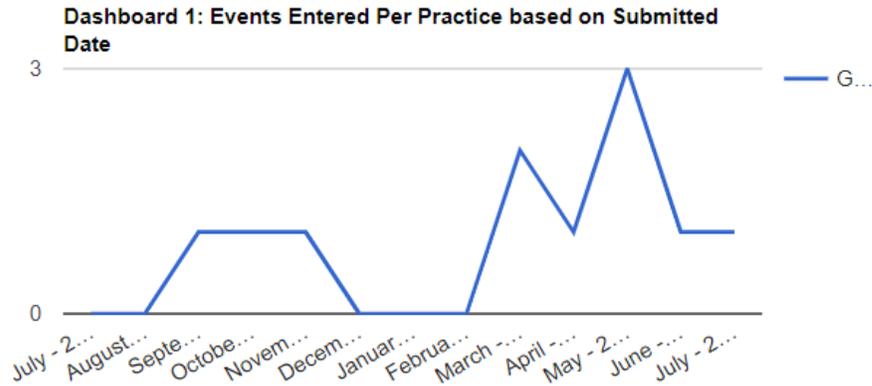


RO-ILS: Dream versus Reality

Dashboard

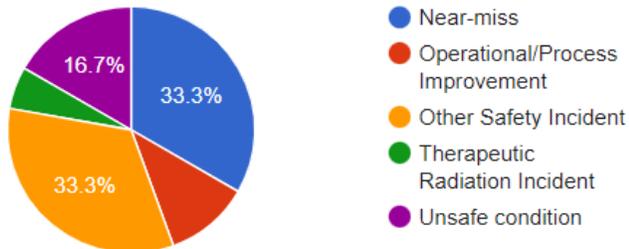
 Refresh Data

The most recent 1 Years by Month



The most recent 1 Years

Dashboard 3: Event Classification of All Entered Events



- Home
- Time Frame
- Forms
- Event Type
- Primary Locations
- Secondary Locations
- Result Set
- Sorting
- Columns
- Filter
- Export To Excel
- Export To PDF
- Graphing
- Create Saved Template
- Create Scheduled Report

Name of Report:

Description:

Start Date:

Time Period:

Monthly

Weekly

Monthly

Yearly

Day

How Often? month(s)

Who to Notify:

Demo Test, Demo General, Demo Group, Clarity

Save

Clear

RO-ILS: Dream versus Reality

- **Dream = Reality:** Radiation oncology practice have an easy-to-use tool to aggregate their errors and learn from them.
 - Data is protected.
 - Opportunity to interact with a PSO, safety experts, and other quality/safety-minded individuals across the country.
 - Data can help improve the field of radiation oncology.





Incident Learning Cycle



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