LEARNING FROM EACH OTHER

A Report on RO-ILS
November 2017

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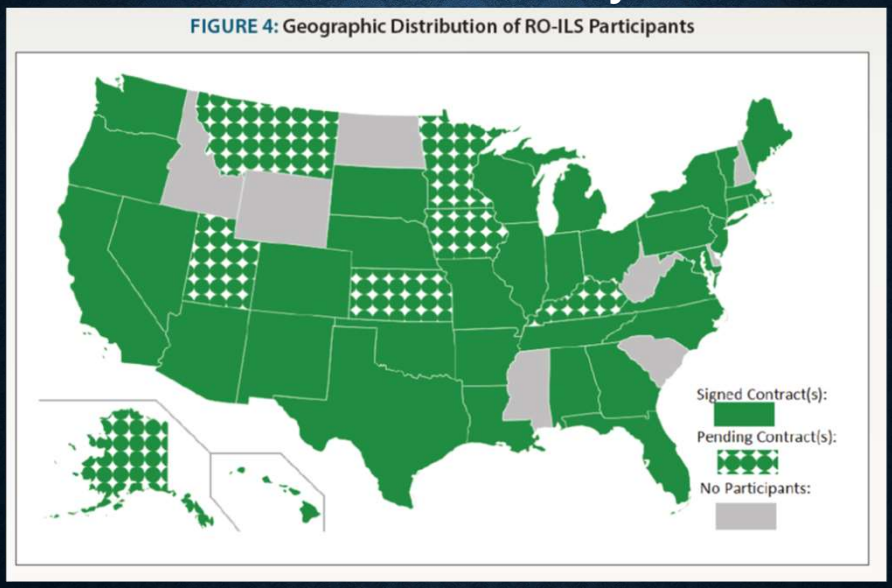
- One of the most basic dictionary definitions of culture is "the set of shared attitudes, values, goals, and practices that characterizes an institution or organization" (Merriam-Webster n.d.).

RO • ILS

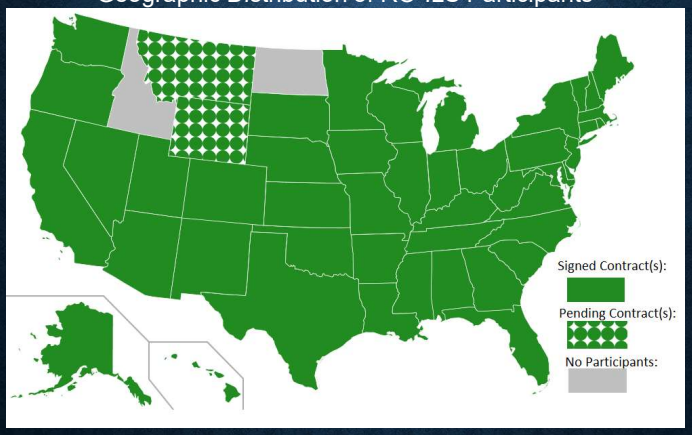
- RO-ILS: Radiation Oncology Incident Learning System®
- A system to facilitate safer and higher quality care in radiation oncology at no cost to providers or facilities.
- The only medical specialty society - sponsored radiation oncology incident learning system.

States Involved in RO-ILS June 2017

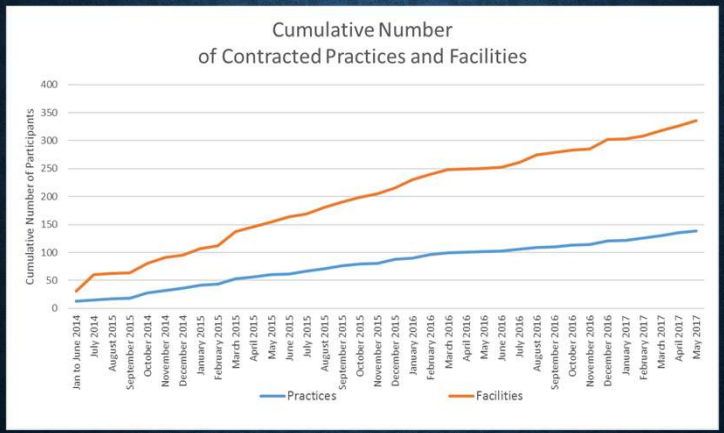


States Involved in ROILS October 2017

Geographic Distribution of RO-ILS Participants



PARTICIPATING FACILITIES



338 Facilities

139 Contracts 42 Pending Contracts

June 2017

astro.org/roils

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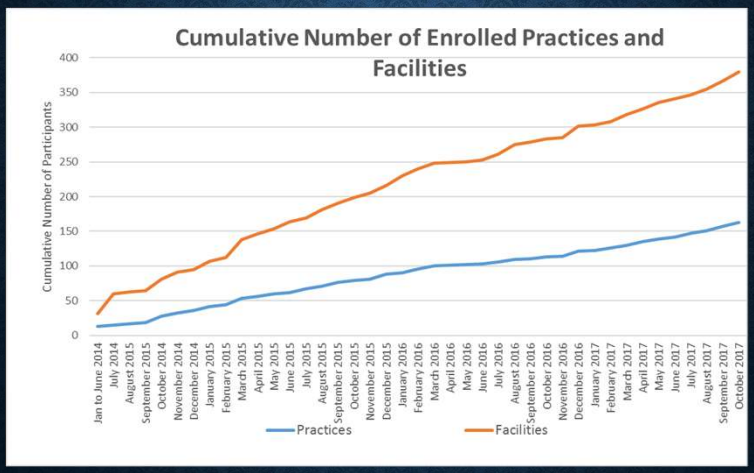
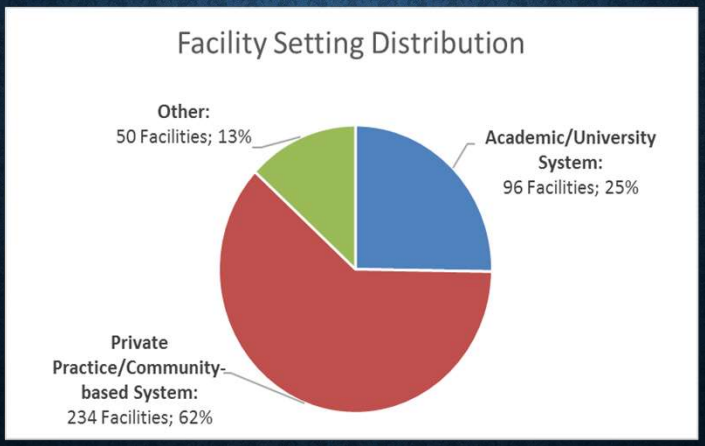


380 Facilities
October 2017

163 Practices

62% PRIVATE PRACTICE Or COMMUNITY HOSPITALS



RO-ILS

- ASTRO initiative, AAPM co-sponsors
- Run through Clarity PSO
- Web-based, no IT support needed
- No charge to users; but need to sign contract
- Data (PSWP)is protected by law
  - PSWP - Patient Safety Work Product (US Patient Safety & Quality Improvement Act of 2005)

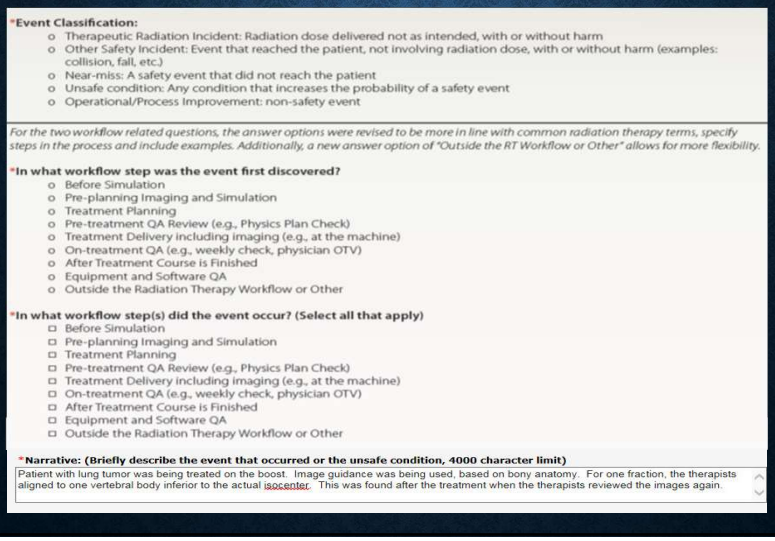
WHAT IS A PSO?

- "PSO" = Patient Safety Organization
- They serve as independent, external experts.
- They assist providers in collection and analyzing patient data that a provider **voluntarily chooses** to report on a local, regional and national level.
- With the large number of events collected they develop insights into the root causes of patient safety events .

ROILS REPORTING DESIGN

- Form was jointly developed by ASTRO, AAPM, Clarity
- Can serve as a facility's only Incident Learning System (ILS)
- Two-step reporting process
  - Initial report by front-line user (brief)
  - Additional data added after internal review

REPORT INCLUDES NARRATIVE DESCRIPTIONS AND DATA ELEMENTS THAT CAN BE SELECTED AND COMPILED FOR ANALYSIS



***Event Classification:**
- o Therapeutic Radiation Incident: Radiation dose delivered not as intended, with or without harm
- o Other Safety Incident: Event that reached the patient, not involving radiation dose, with or without harm (examples: collision, fall, etc.)
- o Near-miss: A safety event that did not reach the patient
- o Unsafe condition: Any condition that increases the probability of a safety event
- o Operational/Process Improvement: non-safety event

For the two workflow related questions, the answer options were revised to be more in line with common radiation therapy terms, specify steps in the process and include examples. Additionally, a new answer option of "Outside the RT Workflow or Other" allows for more flexibility.

***In what workflow step was the event first discovered?**
- o Before Simulation
- o Pre-planning Imaging and Simulation
- o Treatment Planning
- o Pre-treatment QA Review (e.g., Physics Plan Check)
- o Treatment Delivery including imaging (e.g., at the machine)
- o On-treatment QA (e.g., weekly check, physician OTV)
- o After Treatment Course is Finished
- o Equipment and Software QA
- o Outside the Radiation Therapy Workflow or Other

***In what workflow step(s) did the event occur? (Select all that apply)**
- ☐ Before Simulation
- ☐ Pre-planning Imaging and Simulation
- ☐ Treatment Planning
- ☐ Pre-treatment QA Review (e.g., Physics Plan Check)
- ☐ Treatment Delivery including imaging (e.g., at the machine)
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- ☐ After Treatment Course is Finished
- ☐ Equipment and Software QA
- ☐ Outside the Radiation Therapy Workflow or Other

***Narrative: (Briefly describe the event that occurred or the unsafe condition, 4000 character limit)**

Patient with lung tumor was being treated on the boost. Image guidance was being used, based on bony anatomy. For one fraction, the therapists aligned to one vertebral body inferior to the actual isocenter. This was found after the treatment when the therapists reviewed the images again.

REPORT REVIEW

- All reports are reviewed by team of 12 RadOnc professionals –
  - Radiation Oncology Health Advisory Council (RO-HAC)
- Reports summarize the most useful findings
- Reports are done quarterly and transmitted to users
  - 12 Quarterly Reports sent to users since inception
- https://www.astro.org/RO-ILS-Education.aspx

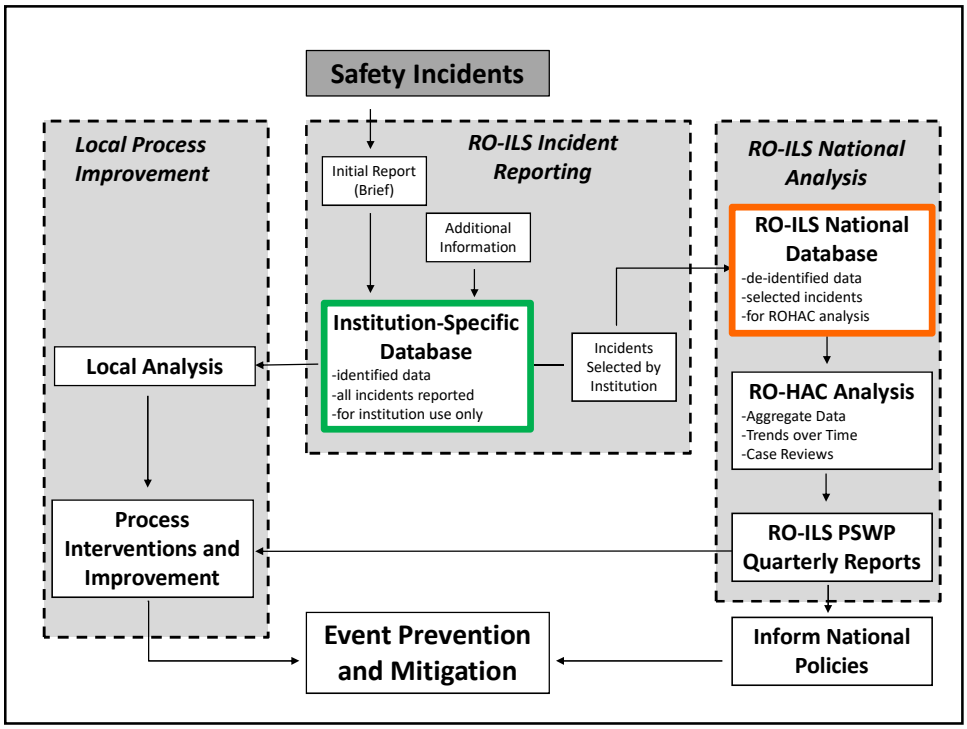
RADIATION ONCOLOGY HEALTH ADVISORY COUNCIL

THE TEAM
RO-HAC

- Robert Alan Burns, RT
- Bhisham Chera, MD
- Adam Dicker MD PhD
- Gary A. Ezzell PhD
- Eric Ford PhD
- Erin Heuser, MBOE, BSRT (R)(T)
- David Hooped MD
- Theresa M. Kwiatkowski BS, RT(T), CMD, FAAMD ☺
- Louis Potters, MD, FACR, FASTRO
- Taleah Tatum, MHA, RT(T)
- Lakshmi Santanam, PhD
- Sheri Weintraub, MS, DABR

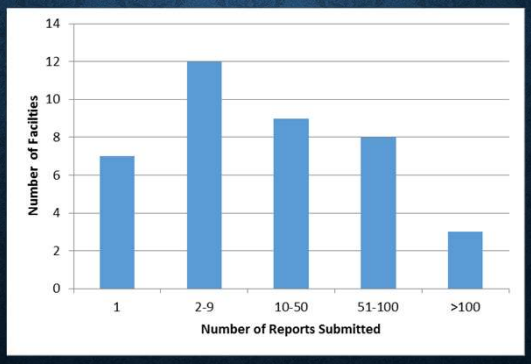
The Clarity Group

- Heather DeMoss RN BSN
- Tom Pitrowski RN MSN
- Emily Sanscrainte
- Cindy Tomlinson MPP

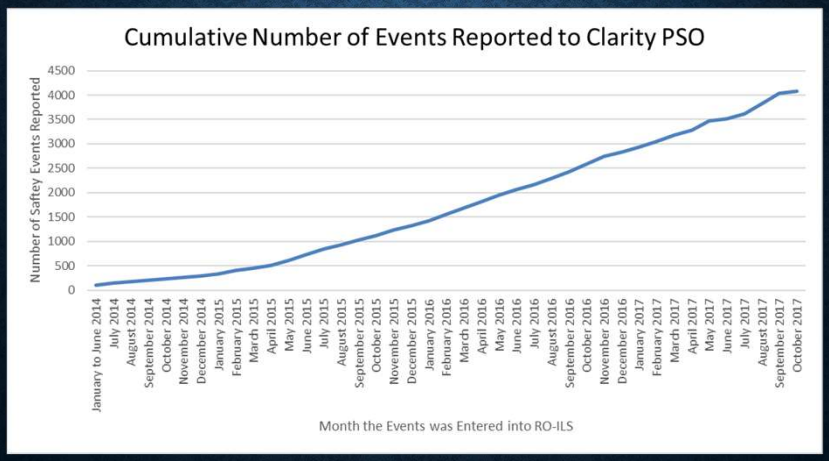


HOW IS ROILS BEING USED?

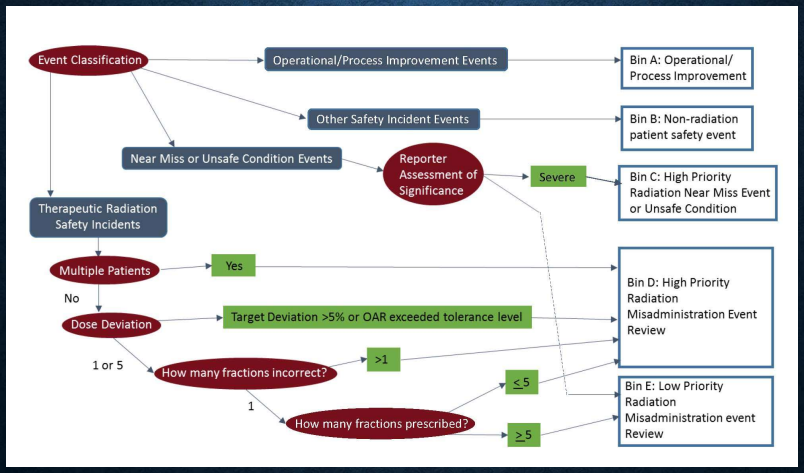
- Some users report a few safety events
- Some use it as a comprehensive practice improvement system



GROWTH CURVE OF EVENTS REPORTED TO PSO



EVENT ASSESSMENT PROCESS

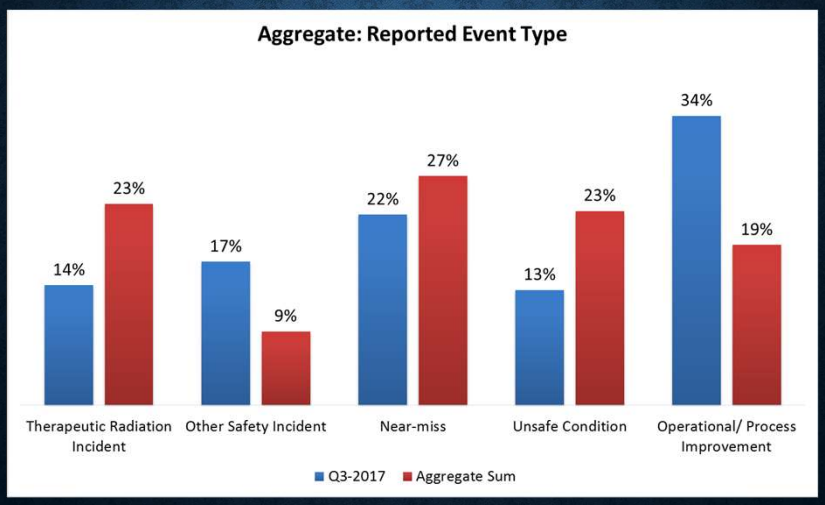


RO-ILS DATABASE LANDSCAPE OCTOBER 2017

Reported Events 4057

- Near Miss 1082
- Therapeutic Radiation Incidents 951
- Unsafe Conditions 918
- Operational/Process Improvement 757
- Other Safety Incidents 349

RO-ILS DATABASE LANDSCAPE OCTOBER 2017



TRIAGE SCALABILITY PROCESS

Near Miss Severity Index	Criteria	Representative Event Example
1	• Event does not pose downstream risk in workflow.	• Suggestion to add all phone numbers for weekend call team to department intranet. Phone numbers were scattered in multiple locations.
(No Potential Harm)	• Event is not related to patient Safety or quality of treatment.	• Treatment plan documentation was incorrect for billing purposes. Dosimetrist was called to edit documentation.
2	• Events may enhance the risk of downstream errors.	• Late planning volumes given to dosimetry, led to rushed planning and checks. Therapists could not fully complete film day checklist and physics check was preformed after hours.
(Mild Potential Harm)	• Event may cause emotional distress or inconvenience to the patient with no clinical impact.	• Patient was not instructed to arrive early for placement of an IV for simulation. Patient had to wait for IV to be placed. Extra time put the simulation room behind schedule, delaying patients, and leading to rushed therapists.
		• Patient treatment time was changed. Patient was not notified and arrived several hours before scheduled time.
3	• Event enhances the risk of other critical downstream errors.	• Incorrect headrest used for one fraction, leading to suboptimal patient positioning.
(Moderate Potential Harm)	• Temporary pain or discomfort of patient.	• Offsite physician was scheduled for image guidance check. Patient was delayed on the treatment table for 20 minutes in pain until another physician was located to approve IGRT imaging.
	• Deviations from best practices, with no obvious clinical impact.	• Patient treatment delayed two days due to miscommunication regarding treatment planning.

TRIAGE SCALABILITY PROCESS

4	• Limited barriers to prevention of problems.	• Linear accelerator backup jaws were not fully pushed back behind the multileaf collimator during planning. Dose to surrounding tissue would have been increased by 3%. Caught on pretreatment physics check.
(Severe Potential Harm)	• Event with potential clinical impact that is non critical.	• Patient's immobilization device deflated during treatment, requiring resimulation and replanning during the treatment course. The patient missed a treatment.
5	• Extremely limited barriers to the prevention of the problem.	• Patient receiving palliation treatment in one fraction, was repositioned several times due to setup errors. Patient was almost treated with the incorrect SSD.
(Critical Potential Harm)	• Event with potential critical clinical impact.	• Patient was set up and filmed to the incorrect extremity. Identified prior to beam on.
		• Patient receiving repeated radiation, had volumes contoured on previous data set, which were submitted to dosimetry for planning. Identified on pre treatment imaging.

WHAT HAVE WE SEEN THAT IS *INTERESTING*?

- Looking at 297 events ranked 4 or 5 out of 1296 (18%)

Reached the patient (R)	123	53%
Near miss (N)	105	45%
Unsafe condition (U)	4	2%

HOW WERE THESE EVENTS *CAUGHT*?

	All	R	N or U
Physicist review	30	11	19
RTT review	34	9	25
IGRT	13	2	11
Dosimetrist review	2	0	2
Chart Rounds	3	3	0
Daily QA device	2	2	0
In vivo dosimetry	1	1	0

HOW WERE THESE EVENTS *MISSED*?

	All	R	N or U
Physicist second check	74	32	42
IGRT failed to catch	9	9	0

Keywords	All	R	N or U
Rx, plan mismatch	44	18	26
Shifts	31	13	18
Plan quality	26	12	14
Communication	19	14	5
Human data transfer	14	14	0
Gating	12	10	2
Laterality	11	1	10
Previous treatment	10	5	5
Emergent treatment	5	3	2
Haste	2	1	1

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FAILURE MODE: APPROVED PLAN ≠ INTENT

Approved plan not equal to intent	22
MD gave incorrect instruction	4
Plan did not match Rx	11
Planner wrote the Rx for MD to approve	7

MD GAVE INCORRECT INSTRUCTION

- "SBRT" prescribed 4 Gy x 4 instead of intended 12 Gy x 4
  - Planner and second checker did not question.
  - Found at weekly physics check.
- "SBRT" prescribed 5 Gy x 6 instead of intended 6 Gy x 5
  - Questioned by plan checker

PLAN DID NOT MATCH RX; NOT RECOGNIZED AT TIME OF APPROVAL

- 11 cases; 7 reached the patient
  - 3: Original targets were not planned
    - 2 not found by pre treatment physics check
  - 8: Dose/fraction mis-match
    - 7 not found by physics checker
    - 3 found by RTT

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  - 8: dose/fraction mis-match
    - 7 not found by physics checker
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How can we prevent this?
Can this be automated?

PLANNER WROTE THE RX FOR MD APPROVAL

- 3 cases in which this was specifically written out; 3 others in which it was implied
  - 5 involve dose/fraction
    - 6.0 Gy/fx intended > 2.0 Gy/fx planned
    - 2.67Gy/fx intended > 1.8 Gy/fx planned
    - 2.40Gy/fx intended > 2.0 Gy/fx planned
    - 2.0 Gy/fx intended > 2.2 Gy/fx planned
    - 1.80Gy/fx intended > 2.0 Gy/fx planned
  - Supraclavicular field included in breast treatment in error

"12 IN 2"

The patient was to receive radiation therapy to his right shoulder for his painful bone metastasis. The dosimetrist received a verbal order from the Radiation Oncologist for a dose of "12 in 2".
The dosimetrist wrote the written directive for 6 treatments of 200cGy each for a total of 1200cGy.
The written directive was then approved by the Radiation Oncologist. The physicians intent was 2 treatments of 600cGy/fx for a total of 1200 cGy.
Found at chart rounds. The patient had already received 2 fractions at 200cGy each.
The Radiation Oncologist decided to give one additional treatment of 600cGy and finish his course of treatment.

HOW CAN WE PREVENT THIS?

- Inaccurate, incorrect or incomplete prescriptions have been an increasing problem.
- Pathways include :
  - Miscommunication from physician.
  - Failure to execute the plan intended.
- Release of ASTRO's White Paper on Standardizing Dose Prescriptions creates a consistent format that can reduce some prescription errors.

How missed	All	R	N or U
Physicist missed	74	32	42
IGRT failed to catch	9	9	0

CBCT ISSUES

CASE 1: INCORRECT VERTEBRAL BODY TREATED

A patient was being treated with a fractionated dose of 4.0 gray (Gy) for 5 fractions for the palliation of bone metastasis in the thoracic-lumbar (T-L) spine. The incorrect vertebral body was treated for 2 of the 5 fractions. Cone-beam computed tomography (CT) was used to perform the alignment. The automatic image alignment algorithm locked onto the incorrect vertebral body, thus resulting in a large shift of the patient. The incident was discovered on the third fraction when the treating radiation therapists noted the discrepancy.

Event: The following event description (slightly edited for clarity) illustrates incorrect isocenter situations that can occur. A patient's thigh treatment position was off by 5 cm superior-inferior (sup-inf) for 1 fraction. This was discovered during the weekly physics review as the physicist reviewed the limitations of the CBCT for extremities. The attending physician was notified that CBCT was not valid for sup-inf positioning of the thigh treatment region, and orthogonal images were suggested for the remainder of the patient's treatments.

RECOMMENDATIONS …

- Policies & Procedures should be clear when large shifts are indicated from IGRT imaging.
  - Some centers have adopted policies that require a second verification when shifts are larger than a specific amount.
- Use CBCT settings that capture a larger extent of anatomy.
  - Vendors differ in their settings:
    - "Topogram" to specify Sup/Inf borders
    - Predefined settings ranging up to 26cm.
- Use of KV or MV films to verify alignment in addition to CBCT. These images show a larger extent of anatomy.

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30 SHIFT EVENTS

- 9 had shift *values* transcribed incorrectly
- 4 had shift *directions* transcribed incorrectly

- 6 were caught by physics
- 13 were missed by physics
- 13 reached the patient

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How can we automate this?

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LATERALITY EVENTS

- Most were documentation errors: the correct side is being treated but the wrong side is written.
- Not all:
  - "Patient's case was reviewed in weekly Peer Review Radiosurgery/SBRT conference. After reviewing the diagnostic images, it appears that the target was delineated on the wrong side."

WHERE ARE EVENTS HAPPENING? WHERE ARE THEY BEING DETECTED?

	Occurred	Detected
Patient Assessment	2	0
Imaging for Planning	5	3
Treatment Planning	135	16
Pre-treatment Review and Verification	2	46
Treatment Delivery	76	104
On-Treatment Quality Management	1	52
Post-treatment Completion	0	8
Equipment and Software Quality Management	11	3

LESSONS ABOUT RO-ILS

- Patterns can direct attention
  - Failure modes
  - Safety barriers that worked or didn't
  - Opportunities for improvement

IMPROVEMENTS COMPLETED

- Data Element Revisions:
  - Removal of inconsistent and non-critical data elements, resulting In fewer overall questions.
  - Development of new sophisticated branching logic to display only relevant questions and reduce the total number of questions, especially for those events that did not reach the patient.
  - Requiring certain questions be answered in order to facilitate through and complete analysis.
- Slide set template created for local quarterly report discussions

ISSUES SO FAR …

- Many reports are too sparse to be useful to outsiders
  - "Patient was treated 3.0 cm to the right of the planned isocenter for one fraction."
  - No indication of how, why
- As more reports come in, it became harder for the team to do the reviews.

IMPROVEMENTS ON THE WAY SPARSE REPORTS

- RO-HAC is working on a Rapid Review Process with a User Guide to help explain …
  - What is needed in a narrative
  - How to classify events

"Shift instructions were incorrect: 0.9 cm anterior instead of posterior. Found at initial IGRT and corrected" *Near-miss or Reached the patient?*

"Rx and sim order for right leg, but sim and plan done for left. Left was correct, documentation was wrong" *Near-miss or Unsafe condition?*

IMPROVEMENTS ON THE WAY

- Mapping process is being developed so that existing systems can send selected events to RO-ILS

HOW TO BEGIN

- Go to astro.org/roils
  - Download the Participation Guide
  - Review the helpful FAQs
  - Questions? Email roils@astro.org

RO-ILS RADIATION ONCOLOGY® INCIDENT LEARNING SYSTEM
Sponsored by ASTRO and AAPM

LET'S DO SOME SAMS AND THEN ASK YOURSELF…

- How could RO-ILS be helpful to you?
- What do you want to see from the system?

RO-ILS …

1. Requires purchasing software
2. Requires a contract to be signed
3. Requires AAMD Membership
4. Directly connects to your EMR
5. Requires an annual fee

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RO-ILS went live in June, 2014. By October, 2017, the number of reports entered was ?

1. 10-50
2. 100>250
3. 500-750
4. 750>1000
5. 1000>4500

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4. 750>1000
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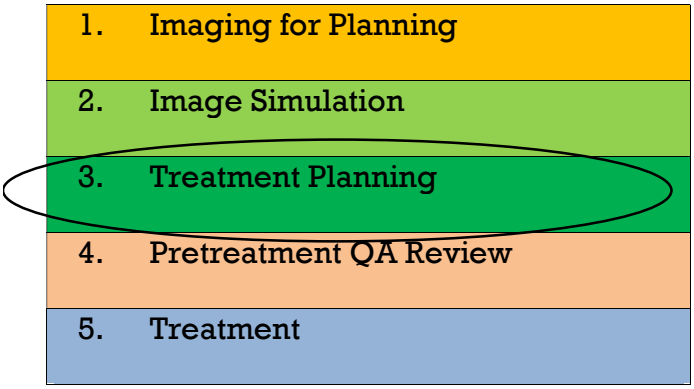
RO-ILS Quarterly Reports on ASTRO website:
https://www.astro.org/Clinical-Practice/Patient-Safety/ROILS/Index.aspx

The workflow step most commonly identified as the source of the reported event is?

1. Imaging for Planning
2. Image Simulation
3. Treatment Planning
4. Pretreatment QA Review
5. Treatment

The workflow step most commonly identified as the source of the reported event is?



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SAFETY CULTURE

- One of the most basic dictionary definitions of culture is "the set of shared attitudes, values, goals, and practices that characterizes an institution or organization" (Merriam-Webster n.d.).
- Within this definition, how would leadership characterize the culture of your organization and your department?
- How would frontline staff characterize the culture?

THANK YOU!

- A special thanks to Gary A. Ezzell PhD