

**Therapy Symposium: You Too Can Create Great Incident Reports**

Moderator: Jennifer Johnson

- **An Overview of Incident Reporting** - Brett Miller
- **Essential Elements of Incident Narratives** - Bruce Thomadsen
- **Standardizing Incident Reporting in the VA Medical System** - Jatinder Palta

Therapy Symposium: You Too Can Create Great Incident Reports

**An Overview of Incident Reporting**

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**Disclosures**

- Henry Ford Health System has a research and site visit agreements with Varian Medical Systems.
- Board member of Center for Assessment of Radiological Sciences (CARS)
- Henry Ford is a member of RO-ILS
- Member the AAPM working group on RO-ILS

**Outline**

- Introduction – A Culture of Patient Safety
- Incident Reporting
  - HFHS – In-house
  - Center for the Assessment of Radiological Sciences (CARS)
  - Radiation Oncology Incident Reporting System (RO-ILS)
- Summary

**Culture of Patient Safety: What we need to do**

- Start at the top
- Work as a Team
- Accountability not blame
- Policies and Procedures
- Measurement of Quality

**Culture of Patient Safety**

- **Start at the top**
  - Every process needs a leader who must lead by example
  - Everyone, including the leader, must look at their work with a critical eye
- Work as a Team
- Accountability not blame
- Policies and Procedures
- Measurement of Quality

## Culture of Patient Safety

- Start at the top
- **Work as a Team**
  - Therapist, Dosimetrist, Physicist, Physician, Nurse IT Professionals, Administrators
  - Remove Hierarchy
  - Anyone on the team can prevent an error
  - Everyone member of the team needs to have the appropriate tools, training and time to do their job correctly
  - Communication; Flow of Information
- Accountability not blame
- Policies and Procedures
- Measurement of Quality



## Culture of Patient Safety

- Start at the top
- Work as a Team
- **Accountability not blame**
  - Talk about errors as a learning experience
  - Must be a non-punitive, nurturing environment
- Policies and Procedures
- Measurement of Quality



## Culture of Patient Safety

- Start at the top
- Work as a Team
- Accountability not blame
- **Policies and Procedures**
  - Clear, consistent and thorough
  - Willingness to delay a treatment if not safe
  - Continually updated and modified with feedback from staff and monitoring of variance
  - Review of incidents when policies are not followed
- Measurement of Quality



## Culture of Patient Safety

- Start at the top
- Work as a Team
- Accountability not blame
- Policies and Procedures
- **Measurement of Quality**
  - Error Analysis and Variance Reporting
  - Key Quality Indicators, FMEA



## Incident Reporting

- Why?
  - Known knows
    - Output at the time of morning QA
    - Results of patient specific quality assurance
  - Known unknowns
    - Output at the time of treatment
    - Will the patient move during treatment



## Unknown unknowns?

- NYT articles
- International publications
  - “Radiotherapy Risk Profile” by WHO
  - “Lessons Learned from Accidental Exposures in Radiotherapy” by IAEA
- Vendor Customer Technical Bulletins
- Incident Learning



### Incident Reporting Systems

- Henry Ford Cancer Institute – In-house
- Center for the Assessment of Radiological Sciences (CARS)
- Radiation Oncology Incident Learning System (RO-ILS)



Henry Ford Hospital  
Department of Radiation Oncology  
Process Improvement Form

Location of occurrence: [dropdown] Category of Report: [dropdown]

Date: [MM/DD/YYYY] Report creator: [Mike Best] Patient Physician: [dropdown]

Patient MRN: [input] Patient Last Name: [input] Patient First Name: [input]

Occurred at: [dropdown] Other specify: [input]

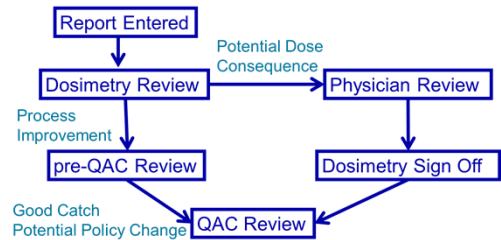
Discovered by: [dropdown] Other specify: [input]

Description: [dropdown menu with options: Treatment Log, Transport Initial Check, Table Off, Transport Final Check, Imaging, Physics Initial Check, Physics Weekly Check, Physics, Dosimetry, Self Audit, Chart Rounds, Physician, Naming, Other]

Send email notification of this report creation [checkbox]



### Incident Reporting System - Workflow



### QAC Review

- Reports submitted at any of our 5 sites via the intra-department website.
- Reviewed by leads (physician, physicist and therapist) at each site.
  - Keeps leaders informed
  - Distributes workload
  - Allows for information gathering prior to QAC meeting
- Reviewed on a monthly basis by QAC.



### QAC Review

- Review Selected Incident Reports
- Review Statistics Looking for Trends
  - By site
  - By category
- Identify "Good Catches"
- Discuss Policy Updates
- Open Discussion
- Monitors compliance with regulatory and accrediting organizations



### Incident Reporting Systems

- Henry Ford Cancer Institute – In-house
- Center for the Assessment of Radiological Sciences (CARS)
- Radiation Oncology Incident Learning System (RO-ILS)

### The Center for the Assessment of Radiological Sciences (CARS)

- CARS's incident reporting system was developed in spring 2012.
- CARS is a Patient Safety Organization listed with AHRQ.
- Went live for reporting September 2013, the first radiotherapy incident reporting system!
- Reporting software used in VA.

### More About CARS

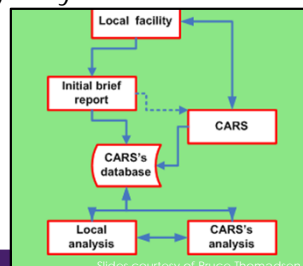
- CARS also has equipment-problem reporting.
- CARS is run by radiotherapy physicists experienced in systems engineering and system engineers experienced in analyzing radiotherapy problems.
- Panel of experts (physicians, etc.)

### CARS's Philosophy

- Help improve radiotherapy quality and safety working with practitioners and manufacturers.
- We work with clients during reporting and analysis of incidents.
- We work with clients to develop corrective actions that will work in their setting and to develop prospective QM.

### CARS' Radiotherapy Incident Reporting and Analysis System

1. Facility files very short notice.
2. CARS calls back; completes form during call.
3. Analyzes and discusses action options



### Advantages of the CARS Approach

- All incidents go into database – avoids some selection bias.
- All fields completed and correct – avoids data-entry fatigue (a very real problem) and omission of items not understood (some examples follow).
- Root-cause analysis done by professionals who understand both the analysis and radiotherapy – RCA has a long learning curve.
- We work with clients on process maps, FMEA and QM development.
- Clients are supported

### More about the CARS System

- System serves as the local database.
  - All data from a facility's reports searchable to facility
  - Only anonymized data searchable to others
- Anyone can view the anonymized data.
- For incidents with equipment, we contact vendor for solutions.
- We also have an equipment reporting system

### Dissemination to Community

CARS will be issuing:

- Alerts for immediate hazards,
- Bulletins for important notices,
- Periodic reports on findings,
- Through e-mail to clients, messages to list servers, letters to professional newsletters.

### Filing a Report (1-3)

Patient Treatment Information	
Disease being treated	The primary disease being treated.
Disease stage	The stage of the disease at the time of the incident.
Treatment Modality	The radiation therapy modality used or planned to be used at the time of the incident.
Incident type	Actual event or good catch.
Number of fractions delivered incorrectly	The number of radiation treatment fractions delivered incorrectly.
Intended treatment site	Intended anatomical site of treatment. For multiple sites include the most appropriate site.
Treatment intent	Immediate intent of radiation treatment.
Total prescribed dose	Total prescribed radiation dose for the full treatment being delivered at the time of the incident.
Dose per fraction	Total dose divided by number of fractions at the time of the incident.

### Analyst's Form (1-4)

Patient Treatment Information	
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### Work Product (1-4)

**Incident description**

**By Client**

Patient was scheduled for HDR at 4:30 pm. At 1:30 pm, a physicist walked through the nursing area and saw the patient on the exam table, being moved to a stretcher. The physicist realized the patient was here early for treatment, and that the HDR unit QA had not been completed. The physicist asked the 2nd physicist to assist with the applicator placement verification sim, and went to the HDR unit to perform the daily QA. The patient had already been moved to the sim table and been scanned by the time the 2nd physicist arrived. Marker strands had not been treated into the IMRT applicators, although the physician said he could easily see what he needed to see without them. The sim was completed by the sim therapist. The patient was moved to the holding area for approximately 10 minutes while the HDR daily QA was completed. The patient was then treated without incident. Investigation afterward showed that the patient had been called to come in early for treatment as she was the only patient on the physician's schedule that afternoon. However, no therapy or physics staff had been notified of the change. The therapist who performed the placement verification had never done one before and was the only therapist in the simulator. Applicators were verified by labels during hook-up to the HDR unit instead of during the sim process.

**Incident Analysis**

**By CARS Analyst**

This event presented several opportunities to turn into an actual event. Changing the scheduled treatment time without checking, or even notifying the staff involved, placed the patient at risk first by having the simulation performed by a therapist who had not performed such a procedure before. This therapist did omit the step of insertion of the marker strands, that, fortunately, was recoverable during treatment planning. Also, the applicator would normally have been identified at the simulation, but that step was omitted and pushed to the time of hook-up to the treatment unit, leaving less opportunity for recovery should an error have been detected. There also was only one therapist available for the simulation, contrary to the facility's policy of having two in attendance. The second source of risk was the rushing required of the physicist performing the treatment unit QA and the additional stress under which the staff was placed.

The cause of this incident was lack of planning to see if the staff could accommodate the schedule change and lack of communication about the change. While the staffing in the department may be adequate for routine operations, another cause of the incident is that the staffing level cannot handle unexpected changes. A lack of a strong safety culture underlies the planning and communication problems.

### Corrective Actions

- The analyst makes recommendations.
- Then there is a discussion with the facility.
  - One recommendation to address a problem may be right for one facility but unworkable at another.
  - The discussion finds a solution with a high probability of working at that facility.
  - Sometimes, however, the only real solution may not be good news to the facility.
- The final agreed-upon remedial action is in the report.

### Device Reporting 1

Report a Problem with a Radiotherapy Device

Please fill in appropriate spaces and check all items that apply to this incident. Fields marked with \* are mandatory.

**Report Details**

Date of report/m/d/yyyy\*  The date that the report is logged.

Date modified\*  The date that the report was last modified.

Device type\*  Choose the type of radiotherapy device.

Device Name  Choose the name of the radiotherapy device.

Problem Classification\*  Physics modeling  
 Dose calculation / accuracy  
 Dose display  
 Dose evaluation  
 Other  
 Choose the problem classification.

AAPM 2017 hadsen

### Device Reporting 2

Description of the issue\*

Consequences of the issue\*

AAPM 2017 Bruce Thomadsen

## Device Database

- The device database alerts CARS to problems that we should discuss with a vendor.
- It can help if someone has a problem or question that may be answered in the database.
- The database can be helpful if someone is looking to buy equipment.

## Incident Reporting System

- Henry Ford Cancer Institute – In-house
- Center for the Assessment of Radiological Sciences (CARS)
- Radiation Oncology Incident Learning System (RO-ILS)

## RO-ILS basics

- **RO-ILS:** Radiation Oncology Incident Learning System®
- ASTRO initiative, AAPM co-sponsors
- Run through Clarity PSO
  - “PSO” = Patient Safety Organization
  - Web-based, no IT support needed
  - No charge to users; but need to sign contract
  - Data is protected by law

## How are events entered?

- Report form jointly designed 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

**What is being reported?**  
 Incident that reached the patient. A safety event that reached the patient, with or without harm.

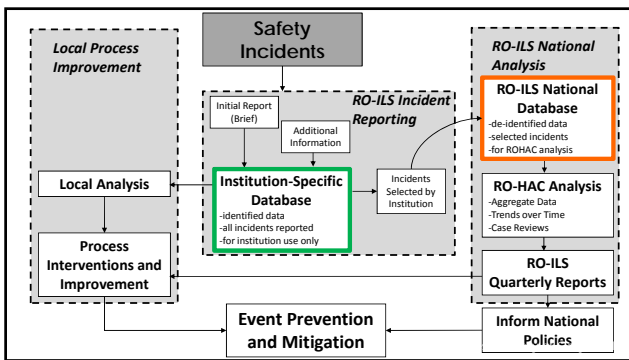
**Narrative: (Briefly describe the event that occurred or the unsafe condition, 4000 character limit)**  
 (Patient with lung tumor was being treated on the boost. Image guidance was being used, based on bony anatomy. For one fraction, the therapists aligned to one vertebral body inferior to the actual isocenter. This was found after the treatment when the therapists reviewed the images again.)

**How was the event discovered?**  
 Therapists were uncomfortable with the setup and reviewed the KV images after the treatment.

**Actual workflow step was the event first discovered?**  
 Select all that apply:  
 Patient Assessment, Imaging for RT Planning, Simulation, Treatment Planning, Pre-Treatment Review and Verification, Treatment Delivery, On-Treatment Quality Management, Post-Treatment Completion, Equipment and Software Quality Management, Incident and Software Quality Management

How is the information reviewed?

- All reports are reviewed by team of 12 RadOnc professionals – MDs, Physicists, etc.
  - Radiation Oncology Health Advisory Council (RO-HAC)
- Reports summarizing the most useful findings are done quarterly and transmitted to users



RO-ILS Status as of Feb 8, 2017

- Signed contracts: 122 practices representing 269\* facilities
- 29 pending representing 51 facilities
- 3153\* reports uploaded to national
  - Doubled since March, 2016
- 9 Quarterly Reports issued
  - Link on AAPM and ASTRO home page

Growth trajectory

Date	# Reports in System	Average submissions/month
July, 2014	175	baseline
June, 2015	700	48
May, 2016	1775	90
December, 2016	2681	129

How are the events analyzed?

- After anonymization by Clarity PSO, all events are reviewed by ROHAC
- Events are prioritized automatically so that ROHAC sees the most important events first
  - 5 priority levels

- Highest priority – treatment events
  - Significant dose deviation to target or critical structure, or
  - Multiple patients effected
  - Multiple fractions to same patient
  - SRS or SBRT
- Lowest priority – non-safety, operational events

## Quarterly Report example

## Examples from Quarterly Reports: CBCT Issues

### 2015 Q3

#### 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.

### 2015 Q2

**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 and procedures* should be clear regarding the actions to take when large shifts are indicated from image-guided radiation therapy (IGRT) imaging. In this case, the shift was 3 cm and was indicative of a problem. Some centers have adopted policies that require a secondary verification of patient setup when the shifts are larger than a specified amount.
- *Use a cone-beam CT setting that captures a larger extent of anatomy where appropriate.* This may aid in reducing confusion. One vendor supplies a "topogram" to specify the superior-inferior extent of the scan. Another vendor has predefined settings ranging up to 26 cm in this dimension.
- *Other centers have begun using kilovoltage (kV) or megavoltage (MV) planar images to verify alignment* in addition to cone-beam CT. These planar images can show a larger extent of anatomy and reduce the likelihood of aligning to a wrong vertebral body.

## Summary

- CARS
  - Individualized discussion, analysis and feedback from a multidisciplinary panel of experts
  - Access to all reports, anyone can view the anonymized data
  - Equipment Issue Reporting System
  - Cost for participation

## Summary

- RO-ILS
  - Backed by ASTRO and AAPM
  - Quarterly analysis and newsletter from a multidisciplinary panel of experts
  - Newsletter available to everyone
  - No cost for participation



## Thank You

- Special Thanks to:
  - Dr. Ben Movsas, Chairman, Department of Radiation Oncology, HFHS
  - Dr. Indrin Chetty, Physics Division Lead, HFHS
  - Dr. Bruce Thomadsen
  - Dr. Gary Ezzell

## Why Report Incidents?

- Unknown knowns – bonus slide
  - Psychoanalytic philosopher [Slavoj Žižek](#) says that beyond these three categories there is a fourth, the unknown known, that which we intentionally refuse to acknowledge that we know.
- I haven't planned an HDR prostate in 1 years...
- My son knows he has homework but plays his video games.