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 Thomassen
- Standardizing Incident Reporting in the VA Medical System - Jatinder Palta

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

Incident Reporting

- Why?
  - Known knowns
    - 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)

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.
Incident Reporting Systems

- Henry Ford Cancer Institute – In-house
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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)

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<tbody>
<tr>
<td>From Date</td>
<td>To Date</td>
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Analyst's Form (1-4)

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<tbody>
<tr>
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Work Product (1-4)

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 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.

How is the information reviewed?
- All reports are reviewed by a 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.

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.

Growth trajectory:

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

Examples from Quarterly Reports: CBCT Issues

2015 Q3
CASE 1: INCOMPLETE VERTEBRAL BODY TREATED
A patient was being treated with a fractional dose of 10.5 gray (Gy) for 5 fractions for the palliation of bone metastases in the thoracic vertebra (T4) spine. The incorrect vertebral body was treated for 2 of the 5 fractions. Cone-beam computed tomography (CBCT) was used to perform the alignment. The automatically generated alignment algorithms looked onto the incorrect vertebral body, thus resulting in a large shift of the patient. This incident was discussed at the final fraction when the treating radiation oncologist noted the discrepancy.

2015 Q2
Event: The following event description (slightly edited for clarity) illustrates incorrect treatment situations that can occur. A patient’s right treatment position was off by 5 cm superior-inferior (super- in) for 1 fraction. The error was discovered during the weekly physics review as the physicist noted the limitations of the CBCT for extracranial. The treating physician was notified that CBCT was not used for setup confirmation for that treatment fraction, 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 when appropriate. This may aid in reducing confusion. One vendor supplies a “regional” view to specify the superior-inferior extent of the set. Another vendor has predefined settings ranging up to 20 cm in this dimension.
• Other centers have begun using kilovoltage (kV) or megavoltage (MV) phase images to verify alignment in addition to cone-beam CT. These phase 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.