Incident Learning Systems in Radiation Therapy

SAMs Session

AAPM 2014 Spring Clinical Meeting, Denver, CO
Sunday 7:30-9:30 am
March 16, 2014
Disclosures

- Debbie Gilley
  - None
- Gary Ezzell
  - None
- Eric Ford
  - R18 HS22244-01
Incident Learning

Aviation

Nuclear power

Manufacturing

Healthcare
Incident Learning: Why Participate?

✓ “Each department should have a department-wide review committee which monitors quality problems, near-misses and errors.”

✓ “Employees should be encouraged to report both errors and near-misses.”

Safety is No Accident, Zietman et al. 2012
Incident Learning: Why Participate?

• **ASTRO report 2012**
  Safety is No Accident: A Framework for Quality Radiation Oncology and Care. Zeitman A, Palta J, Steinberg M. ASTRO; 2012

• **AAPM white-paper 2012**

• **ASTRO safety white-papers**

• **ASRT safety white-paper**
Incident Learning: Why Participate?

A key component of practice accreditation

Standard 7: Culture of Safety

The radiation oncology practice (ROP) fosters a culture of safety in which all team members participate in assuring safety; the practice capitalizes on opportunities to improve safety; and no reprisals are taken for staff that report safety concerns.
Quality and Outcomes in RO

Seriously non-compliant (12% of plans)

Peters et al. JCO, 28(18), 2996, 2010
Protocol deviations and overall survival

**Trial**
- RTOG 73-01
- SWOG 7628
- POG 9031
- SIOP/UKCCSG PNET-3
- TROG 02.02
- RTOG 97-04
- COMBINED

**Hazard ratio associated with radiotherapy deviations**

HR = 1.74
95% CI = 1.28 to 2.35

More reports = Safer

NUMBER OF REPORTS vs. NUMER of patient safety incidents
$R^2 = 0.33 \; p<0.001$

Mardon et al. AHRQ, J Patient Saf, 6, 226-232, 2010
Incident Learning: Why Participate?

- Data linking treatment quality to patient outcomes
- Recommended at the society level
- Data suggests more reports = safer
The following sources recommend incident learning for near-miss events:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Source</th>
</tr>
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<tbody>
<tr>
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REFERENCE: Safety is No Accident, Zietman et al. 2012
Outcomes data indicate that patient survival is associated with:

| 20% | 1. Academic vs. non-academic center |
| 20% | 2. Plan quality |
| 20% | 3. Use of image-guidance |
| 20% | 4. Volumes of patients treated |
| 20% | 5. Board certification of medical physicist |
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<td>2. More handoffs</td>
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<tr>
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<td>3. More safety incident reports</td>
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<td>4. More complex technology</td>
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REFERENCE: Mardon et al., J Patient Saf, 6, 226-232, 2010
Objectives:
What you will learn in this session

• Definitions of key terms
• Requirements and recommendations for reporting
• Key aspects of a new national incident learning system
• The value of incident learning through example
Outline

• Debbie Gilley, MPA, AAPM
  – Incident learning – What is incident learning?
• Gary Ezzell, PhD, Mayo Clinic, Arizona
  – The ASTRO/AAPM Radiation Oncology-ILS
• Eric Ford, PhD, University of Washington
  – Examples of incident learning – Wrong isocenter
Incident Learning in Radiation Oncology: An Update

What is incident learning?

Debbie Gilley
AAPM
Patient Safety

Patient safety: the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of health care.

National Institute of Health, US National Patient Safety Foundation
Definitions

- Medical Error
- Reportable Medical Error or Event
- Near Miss
- Unsafe Practices
Medical Error

A preventable event that may cause or lead to patient harm while under the care of a professional health care provider.

Agency for Healthcare Research and Quality (AHRQ) common formats, 2014
Reportable Medical Event

• Established by regulatory authority.
• Establishes a threshold for reporting based on what was prescribed in the written directive and what was given or based on the outcome of the event.
• Does not reflect patient harm but a variance in the actual activity versus the planned activity.
Near Miss

Any event that could have had an adverse patient consequence but did not, and was indistinguishable from a full-fledged adverse event in all but outcome.

National Institute of Health
Unsafe Condition

Any circumstances that increase the probability of a patient safety event.

Agency for Healthcare Research and Quality (AHRQ) common formats, 2014
Scope of Medical Errors in the United States
US Medical Errors

- Third leading cause of death
- 440,000 Americans are dying annually from preventable hospital errors
- Of the 2,539 general hospitals issued a Hospital Safety Score, 813 earned an "A," 661 earned a "B," 893 earned a "C," 15 earned a "D," 22 earned an "F"

US Radiation Related Medical Events

US NRC NMED 2012 Report to Congress

*Radioactive Materials

<table>
<thead>
<tr>
<th>Isotope</th>
<th>Number of Reports</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yttrium-90</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Iridium-192 (HDR)</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Iodine-131</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Iodine-125</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td>Palladium-103</td>
<td>2</td>
<td>35</td>
</tr>
</tbody>
</table>

19 reports
## US Radiation Therapy Data

**Conference of Radiation Control Program Directors (CRCPD)**

Presentation on May 20, 2013 given by J. Elee, CRCPD

Linear Accelerators

63 events reported from 26 states

<table>
<thead>
<tr>
<th>Types of Medical Events</th>
<th>Number of Medical Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong patient</td>
<td>10</td>
</tr>
<tr>
<td>Wrong anatomical treatment site</td>
<td>25</td>
</tr>
<tr>
<td>Weekly does greater than 30 or prescribed dose</td>
<td>6</td>
</tr>
<tr>
<td>Total dose greater than 20% of the prescribed dose</td>
<td>6</td>
</tr>
<tr>
<td>Single fraction dose was greater than 50% of the prescribed dose</td>
<td>6</td>
</tr>
<tr>
<td>Unintended overdose to normal tissue</td>
<td>9</td>
</tr>
<tr>
<td>Geographical miss</td>
<td>1</td>
</tr>
</tbody>
</table>
US Food and Drug Administration
Manufacturer and User Facility Device Experience
Mandatory for manufacturers, voluntary for users
2013

<table>
<thead>
<tr>
<th>Linear Accelerators Types of Report</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>3</td>
</tr>
<tr>
<td>Injury</td>
<td>8</td>
</tr>
<tr>
<td>Malfunction</td>
<td>46</td>
</tr>
</tbody>
</table>
No comprehensive reporting system in the US
What is the Value of Reporting Errors

• Reporting systems can provide warnings.
• Reporting systems can identify important problems.
• Reporting systems can provide some understanding of causes.
• Reporting systems can be used to raise awareness.
What is the Value of Reporting Errors

• Identify strength and weakness in patient safety.
• Identify basic details of the event.
• Purpose should be to learn from the incidents and near misses (counting incidents is of no value).

British Medical Journal, 2007 January 13; 334(7584): 51
Types of Reporting Systems

- Institutional Reporting System
  - Facility Based
  - Department Specific
- National Required
- National Voluntary
- International Voluntary
- International Required
Institutional Reporting Systems

Types

- Facility Based
- Department Specific

- Many varieties, using many different formats.
- Most designed to address patient falls and medication errors.
- Not able to benchmarked with other like institutions.
- Information is not shared outside of the organization.
- Usually not evidenced based but more of a reporting system (hospital grading).
Regulatory Required Reporting

- US NRC Nuclear Materials Event Database (NMED) Includes activities with fuel processing and nuclear reactors
- US FDA MAUDE required for manufacturers
- State Regulations (26 states have reporting requirements for medical radiation events)
National Voluntary System

The RO-ILS mission 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.

RO-ILS is the only medical-specialty-sponsored radiation oncology PSO. Data collected from RO-ILS will educate the radiation oncology community on how to improve safety and patient care.

For more information, visit: www.astro.org/ROILS
Email: ROILS@astro.org
SAFRON

Safety in Radiation Oncology (SAFRON) is an IAEA-developed user system for improving the safety and quality of care in radiation therapy through sharing of knowledge.

- SAFRON collaborates with other reporting systems, and currently contains incident information gathered by the IAEA, ROSIS, French Nuclear Regulatory Authority and individual clinics. Clearinghouse for international sharing.
- SAFRON has over 1200 incidents and near misses events in its database
- SAFRON is non-punitive, anonymous, and voluntary
- SAFRON is a comprehensive source of information for radiation safety related events
- SAFRON includes information on a wide variety of published scientific journals and incident reports

RPOP.IAEA.org
Safety Reporting and Learning System for Radiotherapy

SAFRON is voluntary and aims to enable global shared learning from safety related events and safety analysis in order to improve the safe planning and delivery of radiotherapy. SAFRON is provided by the IAEA.

Featured Incident Reports

- Incorrect calibration of machine output
  Electron beams of 7 and 11 MeV were calibrated incorrectly, resulting in underdosage of 17-18%. On the same machine, a photon beam was calibrated incorrectly, resulting in overdosage of 5%. In...

- Misapplication of distance correction
  An institution treated most patients with a constant source-skin distance (SSD) technique, although some patients were treated with a constant source-axis distance (SAD) or isocentric technique....

Featured Documents & Links

- Task Group 142 report: Quality assurance of medical accelerators
  This is an AAPM report on quality assurance of medical accelerators. It provides the reader with information on up-to-date recommendations of Table II of the AAPM TG-40 report on quality assurance...

- Acceptance Testing and Commissioning of Linear Accelerators
  This Report gives guidance for the acceptance testing and commissioning of radiotherapy linear accelerators and comprises a comprehensive account, including some of the most recent clinical...
• Requires reporting and investigation of medical errors.
• Significant for most of the world.
• The European Basic Safety Standards also adopted similar language for EU.
Other Incident Reporting Systems
Incident Learning Systems

• Demographics of the event or near miss
• Narrative of the event
• Conclusions for the cause of the event
• Corrected actions to prevent the reoccurrence of the event
• Easy to complete
• Can measure activities over time (improvements)
• Can be benchmarked to other organizations based on size and complexity (industry standards)
• Uses common nomenclature and format (process steps)
• Information can be shared with others
The following is an example of an incident reporting system required by regulations:

<table>
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REFERENCE: CFR Title 21
Characteristics of a good incident learning system include which of the following?

- A. Incident demographics
- B. Patient Identification
- C. Description of the event
- D. Potential causes of the event
- E. Proposed corrective actions to prevent reoccurrence

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<th>Option</th>
<th>Percentage</th>
<th>Correct Answer</th>
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<td>1. B, C, and E</td>
<td>20%</td>
<td>1</td>
</tr>
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<td>2. All are correct</td>
<td>20%</td>
<td>2</td>
</tr>
<tr>
<td>3. A, C, E</td>
<td>20%</td>
<td>3</td>
</tr>
<tr>
<td>4. A, C, D, E</td>
<td>20%</td>
<td>4</td>
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20%  4. A, C, D, E
20%  5. A,B,C,E

REFERENCE: IAEA
US federal regulations require that the following type of medical error be reported:

| 20% | 1. Any error that harms a patient |
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REFERENCE: CFR Title 21
Incident Learning in Radiation Oncology: An Update

RO-ILS from AAPM and ASTRO

Gary Ezzell, PhD
Mayo Clinic, Arizona
Motivation for a shared system

• Learn from each other
  – Equipment “oddities”
  – Unanticipated failure modes
  – Best practices

• Why this structure?
  – Authorized by federal statute that provides protection against litigation prompted by shared information
  – Can be used as the local incident learning system as well as input to the national system
Mission Statement

Facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure non-punitive environment.
The Patient Safety and Quality Improvement Act of 2005

- Patient Safety and Quality Improvement Act of 2005 (PSQIA)
  - Signed into law July 29, 2005
  - Allowed for the creation of Patient Safety Organizations (PSOs)

- Impetus for the Act
  - Healthcare providers *fear* discoverability and liability
  - Variation in State-to-State protections
    - *Limited* in scope
    - *Not* necessarily the *same* for *all healthcare providers*
  - *No* existing *federal protections*
  - *Data* reported within an organization is *insufficient*, viewed in *isolation* and *not* in a *standard format*
What is a PSO?

- A PSO is an entity (listed by AHRQ) that allows providers to:
  - Participate in patient safety activities and share sensitive information relating to patient safety events without fear of liability
- The work done by/with providers within the confines of a PSO:
  - Fosters a culture of safety in a safe environment
  - Provides a better way to share and learn about quality and safety of healthcare delivery
How are adverse event data protected now?

• Medical Studies Acts
  – State specific acts to protect information collected for quality assurance purposes
  – Largely written to protect hospitals and the peer review process
  – Differ from state to state and generally do not cover the work of physicians in private practice or clinics not owned by a hospital

• Attorney – client privilege (work product)
  – Tied to a specific case or claim where the physician, clinic or hospital may be/are named defendants in a lawsuit
New Protection Afforded by PSQIA

- Patient Safety Work Product
  - Any data, reports, records, memoranda, analyses (such as Root Cause Analyses), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;

And that:

- Are ‘assembled or developed’ by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a Patient Safety Evaluation System

PSES: Patient Safety Evaluation System
(Provider & PSO Specific Process)
### What protections are afforded by working with a PSO?

<table>
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<tr>
<th>Privileged and not subject to:</th>
<th>Confidential and not disclosed...except in:</th>
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<tr>
<td>– Subpoena or order</td>
<td>– Criminal proceedings</td>
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<td>– Provider authorization</td>
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<td>– Freedom of Information Act</td>
<td>– Non-identifiable data</td>
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<td>– Legal or administrative proceedings including those against a provider</td>
<td>– Law enforcement</td>
</tr>
<tr>
<td>– Disciplinary proceeding of a professional disciplinary body</td>
<td>– FDA reporting</td>
</tr>
<tr>
<td></td>
<td>– Patient safety activities</td>
</tr>
<tr>
<td></td>
<td>– Business operations</td>
</tr>
<tr>
<td></td>
<td>– Equitable relief</td>
</tr>
<tr>
<td></td>
<td>– Research sanctioned by Secretary</td>
</tr>
<tr>
<td></td>
<td>– Voluntary disclosure to an accrediting body</td>
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Federal Pre-emption of State Laws to Level the Playing Field in Terms of Reporting of Near misses and Events in a Protected Space
Radiation Oncology- Incident Learning System (RO-ILS)


• Comprised of:
  
  – An electronic web-based reporting system to report events within the practice or department
  
  – A process the national level to receive, review and digest reports and inform the community
The Basics of how the Radiation Oncology Community can participate in the RO-ILS

- Radiation Oncology Department / Clinic joins RO-ILS
- Training on Reporting Templates provided; Procedures for Data Collection Determined
- Radiation Oncology Department / Clinic determine who may enter event data
- Practice Review of Data; Decision on what events will be sent to the PSO made by clinicians
- Clarity PSO working with the Radiation Oncology -Healthcare Advisory Council analyzes national data submitted as PSWP and returns recommendations & learnings to the Radiation Oncology Community
Chronology – Commitments

• National Incident Learning System is part of AAPM and ASTRO strategic plans
  – Subsequent to the 2010 meeting on safety in radiation therapy

• Partnership proposed at meeting of ASTRO and AAPM leadership in March, 2012

• Approved in principle by both governing boards during summer, 2012
Basic data flow

- Each facility will enter local events
  - Can analyze and report locally
  - Decide which events to upload to national

- National group will analyze and report to community
Basic flow – Local

• First report is brief, could be done by “anyone”

• Follow-up information will then be added by facility’s designees
  – Uses AAPM taxonomy
3 types of events to be reported

- **Incident** that reached the patient with or without harm
- **Near-miss event** that did not reach the patient
- **Unsafe condition** that increases the probability of an event
Example event – wrong site near-miss

- Patient with sarcoma of left calf
- CT sim feet first for treatment feet first; MD not present; temporary marks on left leg
- On treatment planning computer, MD sets isocenter and draws fields on wrong leg, not realizing the left/right reversal on the screen
- Plan is done, approved, and passes physics check
- Error caught by therapists at first treatment day – saw that Rx was for left leg but fields on right leg
Initial report

*Location:
Location 1

*Sub Location:
Sub Location 1

*Event Type:
External Beam

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

*Likelihood of incident being harmful to the patient:
- Unlikely to be harmful
- Likely to be harmful

*Narrative: (Briefly describe the event that occurred or the unsafe condition, 4000 character limit)
Patient with sarcoma of left calf had CT Sim done feet first. On treatment planning computer, clinician set the isocenter and drew field shape on wrong leg. Plan done and approved; physics check completed. At first setup, therapists noted that Rx was for left

*Patient's Age:
18-64 years

*Patient's Gender:
- Female
- Male
- Unknown, N/A
Initial report

Patient’s Medical Record Number (MRN):

Patient’s First Name:

Patient’s Last Name:

Reporter’s Name:

Reporter’s Role:
Physicist

*Date/Time of Report:
07/11/2013 6:47 PM

[Save] [Reset] [Cancel]
Follow-up to be added later

• Add information
• Classify event
• Identify contributing causes
• Record corrective actions
Short Description of Event: (200 character limit)
Near-miss: wrong leg set up for treatment

Which of the following best characterizes the event or condition?

- Desired Procedure Inadvertently Omitted
- Wrong Anatomical Treatment Site
- Wrong Dose to All or Part of the Tumor or Normal Tissue
- Wrong Laterality
- Wrong Patient Treated
- Wrong Procedure Done to the Patient
- Wrong Treatment Modality
- Not Sure How to Characterize This Event or Condition

Supplemental Information/Additional Follow-up to Event:
- Patient with sarcoma of the left calf.
- CT simulation performed with scan feet first (to accommodate treatment feet-first)
- Temporary alignment marks are set at the time of sim. Patient is released.
- Clinician sets the isocenter and draws blocks for involved fields, accidentally placing it on the right calf.

Dosimetric severity scale:
- 100 percent absolute dose deviation from the total prescription for any structure

What is the clinically observed toxicity?
- No harm

What is the potential future toxicity?
- Life threatening, intervention essential. Possible recurrence due to underdose.

Name of person who discovered the event:

Role of person who discovered the event:
- Radiation Therapist

*When was the event or condition discovered?
- At first treatment

*At first treatment, when was the event or condition discovered?
- Before treatment initiation
Portion of therapy at time of discovery:

Treatment Equipment: (if applicable)
  Lookup

Treatment Planning System: (if applicable)
  Lookup

Information System (if applicable):
  Lookup

Record and verify system manufacturer:

Third-party ancillary device manufacturer:

What changes, if any, has the facility made in response to the report?
  Add Comment

Please comment on your experience with any changes made in response to the report:
  Add Comment

Do you want to report this event to the PSO?
  ○ Yes  ○ No
Option: add contributing factors

Would you like to identify contributing factors to any errors in the care delivery process?
- Yes  - No

At what point in the care delivery process did the error occur?
- Treatment Planning

Select one or several places where error(s) were made during Treatment Planning:
- Registration of image sets
- Delineation of Target(s)
- Delineation of Organs-at-Risk
- Preliminary prescription parameters, constraints and Technique (i.e. physician intent)
- Physics consult
- Isocenter definition
- Dose distribution optimization
- Dose distribution calculation
- Primary evaluation of treatment plan by physicist
- Primary evaluation of treatment plan by physician
- Iteration of treatment plan
- Set up for image-guidance/motion management
- Final plan and prescription approval by physician
- Plan information transfer to radiation oncology inform
- Scheduling treatment session(s)
- Image Import
- Other

Unsafe Acts:
- Unintended action - Attention failure
- Intended violation - Routine
- Unintended action - Memory failure
- Intended violation - Exceptional
- Unintended action - Mistakes
What to report to the national ILS?

*Events of possible general interest*

- Events for which there was no safety barrier
  - i.e. “Here is a failure mode we never thought of”

- Events which passed through at least one barrier – indicating need for better systems
  - i.e. “This got through the plan check and made it to the machine”

- Events involving equipment performance or communication between equipment
What will happen to the data in the national system?

• Protected from legal discovery

• Analyzed by...
  – Patient Safety Organization (PSO) staff
  – Subject matter experts: Radiation Oncology Healthcare Advisory Council

• Summarized for reports back to participants and community at large
Initial “RO-HAC”

- Adam Dicker, MD, PhD
  Jefferson Medical College of Thomas Jefferson University
- Gary Ezzell, PhD
  Mayo Clinic Arizona
- Eric Ford, PhD
  University of Washington
- Benedick A. Fraass, PhD
  Cedars-Sinai Medical Center
- David J. Hoopes, MD
  David Grant Medical Center
- Theresa Kwiatkowski, CMD, RT
  Rochester General Hospital
- Kathy Lash, RT
  University of Michigan
- Gregory Patton, MD, MBA, MS
  Compass Oncology
What will be the outcome?

• Reports
  – Anonymized descriptions of interesting events
  – Aggregated information about common types of events
    • Vendor–specific
    • Frequent factors

• Improved practices

• Improved equipment

• Improved safety
Which property applies to the availability of information in the patient safety work product uploaded into RO-ILS:

<table>
<thead>
<tr>
<th></th>
<th>Percentage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20%</td>
<td>Subject to Freedom of Information Act request</td>
</tr>
<tr>
<td>2</td>
<td>20%</td>
<td>Subject to subpoena</td>
</tr>
<tr>
<td>3</td>
<td>20%</td>
<td>Commonly demanded by an accrediting body</td>
</tr>
<tr>
<td>4</td>
<td>20%</td>
<td>Privileged and confidential</td>
</tr>
<tr>
<td>5</td>
<td>20%</td>
<td>Part of the patient’s medical record</td>
</tr>
</tbody>
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1. Subject to Freedom of Information Act request
2. Subject to subpoena
3. Commonly demanded by an accrediting body
4. Privileged and confidential
5. Part of the patient’s medical record

Participation in the RO-ILS system requires which of the following:

1. A contract with the PSO (20%)
2. Web-based sign-up (20%)
3. Willingness to forego mandatory reporting (20%)
4. Internal IT support (20%)
5. Membership in AAPM or ASTRO (20%)
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Incident Learning in Radiation Oncology: An Update

Examples in Incident Learning

Eric Ford, PhD
University of Washington, Seattle
Incident Reporting: UWMC Experience

Number of Reports

Examples in Incident Learning

- Wrong CT scan used for planning
- Wrong MR fusion images loaded for contouring
- Wrong vertebral body treated
- Confusing policy for online imaging
- Patients not taking oral chemo at the correct time
Example Incidents

• Many flavors of incident are possible.
• We will focus on several examples of wrong isocenter treated or almost treated.
• The statement of incident (e.g. “wrong vertebral body treated”) is almost meaningless.
• Real meaning comes from exploring and addressing the causal factors at work.
Wrong Isocenter
Wrong Isocenter: Case #1

- 3 cm shift (wrong isocenter) noted on day 1 films
- Patient shifted. Correct treatment delivered
- Near miss
Identify Isocenter on Sim CT
• Place isocenter in treatment planning system
• Place isocenter in treatment planning system
Wrong Mark Identified
Wrong Mark Identified

BB (correct)

Drain site (incorrect)
Wrong Mark Identified

AP BB →

wire

drain site

Identified
Wrong Isocenter
Mark Correct Isocenter

AP BB ➔

drain site wire

original iso from sim

new iso after Fx
Wrong Isocenter: Case #1

Contributing Factors

• Multiple features to be marked (unusual)
• Drain site marker similar to a BB
• Dosimetrist was confused but no follow-up
• No double check of CT localization
Wrong Isocenter: Case #1

Possible Solutions

• Sim staff to add POI in planning system
Wrong Isocenter: Case #1

Possible Solutions

• Sim staff to add POI in planning system

• Increase communication about unusual situations
Wrong Isocenter: Case #1

Possible Solutions

• Sim staff to add POI in planning system
• Increase communication about unusual situations
• Physics check of CT localization
Wrong Isocenter: Case #1

Possible Solutions

• Sim staff to add POI in planning system
• Increase communication about unusual situations
• Physics check of CT localization
• Plastic washer for drain sites
Wrong Isocenter: Case #1

Possible Solutions

- Sim staff to add POI in planning system
- Increase communication about unusual situations
- Physics check of CT localization
- Plastic washer for drain sites
- Replace BBs with a different type of marker
Arguments Against Incident Learning

1. The patient was treated correctly. Why do you need an extensive investigation? No harm, no foul.
2. This was a perfect storm.
3. This will be caught on cone-beam CT.
4. This will be caught on port films.
Swiss Cheese Model of Accidents

ERROR

Planning

Plan Check

Port Films

PATIENT
Wrong Isocenter: Case #2

- Patient present for R neck Tx. Previous RT.
- CT sim, isocenter marked.
- Dosimetrist picks prior CT instead of current CT.
- On first Tx: IGRT indicates 2 cm shift.
- RTT discusses with dosimetrist. Standard fractionation. MD not present.
- Elect to treat.
- Dosimetrist discusses with colleague and finds the error.
- Correction made for next treatment.
Select Correct CT Scan

Multiple CT scans
Check for Correct CT Scan

Patient Name: 
Patient ID: 
Plan Name: L5–S2
Trial Name: L... Approved
Revision: R04.P03.D03
Lock Status: The plan was locked by 

Plan Setup

Primary Data Set Name: 
Primary Data Set Dimensions: 232 slices, 512 x 512 pixels
CT to Density Table Name: CT Sim Aug05
Patient Position: On back (supine)
Body Board Angle: None
Couch: Removed at Y = −10.29

Number of Photon Beams: 2
Number of Stereo Beams: 0
Number of Electron Beams: 0
Number of Brachy Sources: 0

Outside Patient Air Threshold: 0.60 g/cm³

Dose Grid Geometry

<table>
<thead>
<tr>
<th>Lateral</th>
<th>Ant-Post</th>
<th>Sup-Inf</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.400</td>
<td>0.400</td>
<td>0.400</td>
<td>cm</td>
</tr>
<tr>
<td>119</td>
<td>97</td>
<td>109</td>
<td>cm</td>
</tr>
<tr>
<td>-23.415</td>
<td>-22.922</td>
<td>-18.840</td>
<td>cm</td>
</tr>
</tbody>
</table>

Top Slice of CT Extended: 0.00 cm
Bottom Slice of CT Extended: 0.00 cm

Region of Interest Density Overrides: R01

PT firstname, lastname
Wrong Isocenter: Case #2

Possible Solutions

• Include date in the name of the scan
• Greater awareness during physics checks
Wrong Isocenter: Case #2

Possible Solutions

• Include date in the name of the scan
• Greater awareness during physics checks
• Introduce error checks into software
• Vendors: please help!
Which of the following is the best error-proofing intervention?:

1. Greater awareness during physics checks
2. Implement staff continuing education
3. Email daily reminders to check work
4. Purchase a new device for IMRT QA
5. Automatic software check for correct CT
Which of the following is the best error-proofing intervention?:

1. Greater awareness during physics checks
2. Implement staff continuing education
3. Email daily reminders to check work
4. Purchase a new device for IMRT QA
5. Automatic software check for correct CT

REFERENCE: *Quality and Safety in Radiotherapy, AAPM Summer School 2013, Eds. Thomadsen et al. Medical Physics Monograph 36, Chapter 5*
Incident Learning in Radiation Oncology: An Update

Incident Learning ... Examples from SAFRON

Debbie Gilley
AAPM
Why Safety Reporting and Learning?

France 2007 (1-year period)

USA 2009 (5-year period)

Radiation Errors Reported in Missouri
By WALT BOGDANICH and REBECCA R. RUIZ
Published: February 24, 2010

A hospital in Missouri said Wednesday that it had overirradiated 76 patients, the vast majority with brain cancer, during a five-year period because powerful new radiation equipment had been set up incorrectly even with a representative of the manufacturer watching as it was done.

From: W. Bogdanich, N.Y.Times, USA

SIMILAR ACCIDENTS:
- Commissioning of stereotactic equipment
- Detector used for measuring in the smallest fields was too large
- Overdose to 200 patients as a result

From: S. Derreumaux, IRSN, France

« Farmer » chamber : 0,65 cm³
« Pinpoint » chamber : 0,03 cm³
Why Safety Reporting and Learning?

SIMILAR ACCIDENTS:
- Linac field opening set too large when using stereotactic collimator mounted on linac
- Large volumes outside target were given very high absorbed dose

From: W. Bogdanich, N.Y.Times, USA
### What phase in the process is the incident associated with?

<table>
<thead>
<tr>
<th>Phase</th>
<th>Number of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-clinical phase</td>
<td>1</td>
</tr>
<tr>
<td>Pre treatment phase</td>
<td>34</td>
</tr>
<tr>
<td>Treatment Phase</td>
<td>42</td>
</tr>
</tbody>
</table>

### Who discovered the incident

<table>
<thead>
<tr>
<th>Role</th>
<th>Number of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncologist</td>
<td>3</td>
</tr>
<tr>
<td>Medical Physicists</td>
<td>4</td>
</tr>
<tr>
<td>Therapists on the treatment unit</td>
<td>41</td>
</tr>
<tr>
<td>Simulation staff</td>
<td>5</td>
</tr>
<tr>
<td>No information provided</td>
<td>24</td>
</tr>
</tbody>
</table>
## Medical Events and Near Misses

### ISOCENTER

<table>
<thead>
<tr>
<th>How was it discovered? (Barriers)</th>
<th>Number of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chart checks</td>
<td>13</td>
</tr>
<tr>
<td>In vivo Dosimetry</td>
<td>1</td>
</tr>
<tr>
<td>Portal Imaging</td>
<td>13</td>
</tr>
<tr>
<td>Clinical review</td>
<td>0</td>
</tr>
<tr>
<td>Found at the time of patients first treatment</td>
<td>18</td>
</tr>
<tr>
<td>Found at a later stage of the treatment</td>
<td>8</td>
</tr>
<tr>
<td>No information provided</td>
<td>14</td>
</tr>
</tbody>
</table>
Medical Events and Near Misses

ISOCENTER

What can we learn from this information?

Pre-treatment Phase Commissioning Error

ERROR in treatment planning adding a correction factor to the isocenter plans
when it was already incorporated into the treatment planning calculations

More than 1045 patients affected

Serious

Corrective actions

Additional Training

Improve procedures

Improved quality assurance procedures

Justification for independent verification of calibrations
Medical Events and Near Misses

Consistent themes in the cause of the incident or near miss:
- Communication hand-off
- Lack of procedures
- Not following procedures
- Not adequately trained

<table>
<thead>
<tr>
<th>Pre-treatment Phase</th>
<th>Number of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioning and immobilization</td>
<td>3</td>
</tr>
<tr>
<td>Simulation, imaging and volume determination</td>
<td>12</td>
</tr>
<tr>
<td>Treatment planning</td>
<td>15</td>
</tr>
<tr>
<td>Treatment information transfer</td>
<td>4</td>
</tr>
<tr>
<td>Pre treatment patient preparation</td>
<td>4</td>
</tr>
<tr>
<td>Not specified</td>
<td>6</td>
</tr>
</tbody>
</table>
Medical Events and Near Misses

ISOCENTER

What can we learn from this information?

Treatment planning incidents

Corrective actions

Additional Training
Improve procedures
Improved quality assurance procedures
Justification for independent verification of calibrations
Medical Events and Near Misses

What can we learn from this information?

Causality
Lack of training
Lack or poor communication
Lack of procedures to address the issue
Radiation Oncology team not following procedures
Set up sheet or checklist inadequate or not followed
No procedure in place to address variance in patient set up from standard practices
Human error*
What can we learn from this information?

Corrective Actions

The need for constant training and education
The need for continuous improvement through updated policies and procedures
The need for an effective safety culture
The need for effective communications
Errors in calibration of small fields have been reported in which 2 countries?

1. Germany and Switzerland
2. Germany and France
3. United States and Germany
4. United States and France
5. United States and Switzerland
Errors in calibration of small fields have been reported in which 2 countries?

<table>
<thead>
<tr>
<th>Rank</th>
<th>Percentage</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20%</td>
<td>Germany and Switzerland</td>
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<td>20%</td>
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<td>United States and Germany</td>
</tr>
<tr>
<td>4</td>
<td>20%</td>
<td>United States and France</td>
</tr>
<tr>
<td>5</td>
<td>20%</td>
<td>United States and Switzerland</td>
</tr>
</tbody>
</table>

REFERENCE: S. Derreumaux, IRSN, France; W. Bogdanich, N.Y. Times, USA, 2010
Conclusions

1. Incident reporting improves safety and quality
2. We are supposed to be doing it!
3. The RO-ILS will provide an established and protected means of doing this
4. Sharing information on root causes and error-proofing