Using Event Reporting to Improve Patient Safety

SAMs Session

AAPM 2015 Spring Clinical Meeting, St. Louis, MO
Sunday 7:30-9:30 am
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Using Event Reporting to Improve Patient Safety

Case Studies

Susan Richardson, PhD
Swedish Cancer Center
Seattle, WA
Case Study List

1. Radiopharmaceutical (NRC)
2. HDR (NRC)
3. Software (my institution)
4. Communication (ROILS)
5. Contouring (ROILS)
Recalling your regs...

- NRC collects reports from medical byproduct use:
  - Radiopharmaceutical
  - HDR (Ir-192)
  - Cobalt delivery (e.g. GammaKnife)
- ROILS collects ALL incidents
- These two things are not mutually exclusive
Example Case 1A: Radiopharmaceutical

Problem: Patient pregnant during ablative therapy

- On Dec 11th, 2014, patient received thyroid ablation therapy (97mCi of I-131)
- On Dec 29th, patient reported to medical center that she was pregnant on day of treatment (4 weeks)
- Calculated dose to uterus 20.4 rad
- Reportable event – unintended exposure

Cause: Unknown/unconfirmed pregnancy
Example Case 1A: Radiopharmaceutical

Corrective Actions

• Review counseling/consent with patient
• Possible RX of birth control or alternate means for patients of child-bearing age

Lessons learned

• You can’t control the patient!
Example Case 1A: Radiopharmaceutical

- 6 cases of unintended exposure to the fetus
  - In 4 of those, the patient tested negative directly before treatment
- In 2 cases, the patient was already pregnant
  - one was approximately 6 months along when she received her therapy

**Table 1** Summary of events reported from January 1, 2009 to December 31, 2010

<table>
<thead>
<tr>
<th>Type of dose delivery</th>
<th>Type of error</th>
<th>Isotope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma Knife (13)</td>
<td>Wrong site (7)</td>
<td>Co-60 (7)</td>
</tr>
<tr>
<td></td>
<td>Wrong dose (5)</td>
<td>Co-60 (5)</td>
</tr>
<tr>
<td></td>
<td>Unintended exposure (1)</td>
<td>Co-60 (1)</td>
</tr>
<tr>
<td>RP (34)</td>
<td>Wrong site (2)</td>
<td>I-125 (1)</td>
</tr>
<tr>
<td></td>
<td>Wrong dose (22)</td>
<td>I-131 (9)</td>
</tr>
<tr>
<td></td>
<td>Unintended exposure (8)</td>
<td>I-131 (8)</td>
</tr>
<tr>
<td></td>
<td>Other (2)</td>
<td>P-32 (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Y-90 (1)</td>
</tr>
</tbody>
</table>

Example Case 1B: Radiopharmaceutical

Problem: Wrong patient administered therapy

- Dec 17, 2014- patient received 150 mCi instead of prescribed 30 mCi

- Cause: the patient was misidentified
Example Case 1B: Radiopharmaceutical

Corrective Actions
- JCAHO time out training – 2 identifiers
- Two individuals read vial/activity

Lessons learned
- Patients can (and will) have the same name
- Labels can be switched even from vendor! Buyer beware.
Radiopharmaceutical examples

- Five cases involved the wrong dose of radiation being administered to an I-131 ablation patient.
  - Switched vials
  - Ordered wrong dose

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I Cannot get left!

“Hey look kids, there's Big Ben, and there's Parliament... again.”
What to learn

• Never get comfortable
• Some factors are beyond control
• Mistakes differ depending on workload
  – Few patients
    • What are we supposed to do?
    • Lack of knowledge, practice
  – Many patients
    • Switching of vials
    • Confusing prescriptions
    • Communication transfer/split shift work
• What can we do about it?
Example Case 2A: HDR

Problem: Patient received overdose during HDR brachytherapy treatment

- Dec 2, 2014, patient received Ir-192 HDR brachytherapy treatment to the vaginal cuff with a single channel cylinder
- Prescription: 3 cm cylinder, 400cGy. Treated: 5 cm cylinder, 700cGy
- Cause: the next patient’s plan was being reviewed on the workstation, that plan initiated/treated
- Cause (2): Patient’s identification was not verified
Example Case 2A: HDR

Corrective Actions
• Identify patient
• Appropriate time out can include dose and applicator
• Engage other people on your team

Lessons learned
• Working ahead can get you in trouble!
• Don’t multi-task
  – At least in highly dangerous situations
Example 2B: HDR

Problem: Stuck HDR source/unintended exposure

- Staff performing daily QA on HDR after loader when source became stuck in the ‘safe’ position
- When vendor RSO attempted to free source, it because stuck in unshielded position
- Service manager used hand crank used to return source to normal positioning.
- RSO received approximately 9mR, manager received 27mR.
Example 2B: HDR

Problem: Stuck HDR source/unintended exposure

• Cause:
  – Service Engineer had just performed the routine source exchange
    • failed to perform or performed incorrectly one step*
    • Source became stuck
    • Physicist is “blind” to this procedure
  – Engineer received retraining from company*

*Per telephone conversation with company representative
Example Case 2B: HDR

Corrective Actions
• Test your equipment regularly, thoroughly, excessively (?)..

Lessons learned
• Don’t assume things will work because a vendor touched it last
Example Case 3: Software/Hardware

**URGENT FIELD SAFETY NOTICE**

Date: 21 November 2014
Attention: TomoTherapy® System Medical Physicist
Affected Product: Software versions 2.0.1/2.0.2/2.0.3 (Hi-Art 5.0.1/5.0.2/5.0.3)

Accuray has become aware of a potential safety issue related to the TomoTherapy® Treatment System caused by a failure to monitor the jaw position after a jaw error occurs. This may result in an incorrect jaw position during treatment, without generating a system interruption.

Please review the following information with all applicable members of your staff.

**Description of the Issue**
Example Case 3: Software/Hardware

• “On rare occasions, a jaw communication issue may occur and the jaws will not perform any further planned movement.”
Example Case 3: Software/Hardware

• A communications issue causes the jaw monitoring system to stop monitoring the jaw position. The jaws will then remain stationary for the remainder of the procedure.

• Upon investigation of our machine log files, Accuray determined that this had occurred during the treatment of one of our patients for one of her 5 beams

• Only occurred on 1 fraction out of 28
Example Case 3: Software/Hardware

• the effected field was essentially a PAB field treating the elective nodal region of a breast patient.
• The offset was luckily only 1 cm from where it should be.
• 40% underdose for that particular beam
What to learn?

• Software not infallible
• IMRT QA does not catch everything*
• Daily monitoring of MLCs, delivery, etc important
Example Case 4: Communication

Problem: Miscommunication about physician intent & fractionation scheme

- Patient receiving IMRT treatment
- Physician intends a simultaneous integrated boost ("dose painting") and indicates this in prescription
- Treatment planner does not notice this
Example Case 4: Communication
Example Case 4: Communication

<table>
<thead>
<tr>
<th>Site</th>
<th>Technique</th>
<th>Modality</th>
<th>Act</th>
<th>Rx</th>
<th>Dose</th>
<th>Pattern</th>
<th>Rx Dose</th>
<th>Total Cum</th>
</tr>
</thead>
<tbody>
<tr>
<td>L parietal</td>
<td>IMRT</td>
<td>x10</td>
<td>30</td>
<td>200 cGy</td>
<td>Daily</td>
<td></td>
<td>6,000 cGy</td>
<td></td>
</tr>
</tbody>
</table>

Dx: 2 - Left *Brain, NOS

View Fractions: By Course
Number Fractions: By Course

Pattern: Dose painting. PTV1=54 Gy, PTV2=60 Gy

Radiation Rx is View Only

Comment:
Example Case 4: Communication

Comment: Dose painting. PTV1=54 Gy, PTV2=60 Gy
Example Case 4: Communication

Problem: Miscommunication about physician intent & fractionation scheme

- Patient is planned to 60Gy only
  - no dose painting
- Plan approved by physician
- Plan approved by physicist
- Treatment begins
Example Case 4: Communication

Problem: Miscommunication about physician intent & fractionation scheme

- On 3rd treatment fraction physicist notes the discrepancy on a weekly physics chart check
Example Case 4: Communication

Lessons learned

• Communication is essential
• Software design does not promote optimal communications in this case
• Multiple missed opportunities (QA barriers)
Example Case 4: Communication

Corrective Actions

• Clinic uses a physics checklist for new plans
• Checklist modified to include checking the MD notes section of the prescription
Example Case 5: Contouring

Problem: Plan performed on the wrong set of contours

• Patient receiving IMRT for rectal cancer.
• 180x25 followed by 180x3 boost
Example Case 5: Contouring
Example Case 5: Contouring

• Resident contours targets and normal tissues in TPS (Pinnacle). Makes “PTV45” and “PTV50”
• Sends study to MIM. (Standard practice).
• Attending reviews contours in MIM, modifies them, deletes resident contours and sends back to TPS
Example Case 5: Contouring

- TPS now has two sets of contours:
  "PTV45", "PTV50" (resident)
  And "PTV45_1", "PTV50_1" (attending)
- Treatment planner picks up the case
- Deletes "PTV45_1" and "PTV50_1" volumes
- Plans the case
Example Case 5: Contouring

- While reviewing final plan in TPS, attending notes that nodal volumes should extend ~4 cm superiorly.
- Plan modified and treated as intended.
Example Case 5: Contouring

Problem: Plan performed on the wrong set of contours

Lessons learned

• Multiple hand-offs (and multiple software packages) can contribute to error

• Residents now label contours with their initials
Example Case 5: Contouring

Problem: Plan performed on the wrong set of contours

Corrective Actions

- Residents now label contours with their initials
- Standardized nomenclature can help! (TG262)
Where in the process? Adverse events

- [Link](http://www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf)
Where in the process? Near Misses
Causes: Linac based errors in NY

<table>
<thead>
<tr>
<th>Cause and contributing factors and staff involved</th>
<th>Frequency of occurrence (%) (N=228)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate QA (Failure to follow policy and procedures)</td>
<td>145 (63.6%)</td>
</tr>
<tr>
<td>Documentation/communication error (includes verbal, hardcopy and data flow)</td>
<td>53 (23.2%)</td>
</tr>
<tr>
<td>Inadequate policy and procedures (lack of established QA protocols)</td>
<td>35 (15.4%)</td>
</tr>
<tr>
<td>Equipment malfunction</td>
<td>17 (7.5%)</td>
</tr>
<tr>
<td>Inadequate training</td>
<td>2 (0.9%)</td>
</tr>
<tr>
<td>Staff shortage</td>
<td>4 (1.8%)</td>
</tr>
<tr>
<td>Physics/dosimetry error</td>
<td>62 (27.2%)</td>
</tr>
<tr>
<td>Therapist error</td>
<td>193 (84.6%)</td>
</tr>
<tr>
<td>Radiation oncologist error</td>
<td>28 (12.3%)</td>
</tr>
</tbody>
</table>

*Note: Cause/Contributing Factors add up to more than 228 events and percentages add up to >100% because QA practice has redundancy. Most often, multiple failures result in an event.*

Databases/Resources

• NRC – Nuclear Material Events Database (nrc.gov database)
• [http://www.othea.net/](http://www.othea.net/) (European incident database)
• [http://cars-ps.org/](http://cars-ps.org/) (Radiotherapy Incident and Analysis System)
• ROILS – Astro.org
• S Richardson. A two year review of recent NRC events – What errors occur in the modern brachytherapy era? PRO 2012.
100+ Virtual library presentations!
If a medical event is reported to the NRC or state:

1. It cannot be entered in to RO-ILS
2. The data entered must be exactly the same to the NRC or state
3. It can also be entered into RO-ILS but should be de-identified
4. The NRC will automatically send it to RO-ILS
5. Only near misses are reported to RO-ILS, not actual events
Incidents that can be submitted to RO-ILS include:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>1. Only those due to reports from manufacturers (e.g. customer technical bulletins)</td>
</tr>
<tr>
<td>20%</td>
<td>2. Only due to errors involving human factors engineering</td>
</tr>
<tr>
<td>20%</td>
<td>3. Only involving external beam incidents</td>
</tr>
<tr>
<td>20%</td>
<td>4. Only involving brachytherapy</td>
</tr>
<tr>
<td></td>
<td>5. Any event involving radiation therapy (near miss or actual events)</td>
</tr>
</tbody>
</table>
The NRC collects information regarding what types of events?

1. Only those due to reports from manufacturers (e.g. customer technical bulletins)
2. Only medical events involving external beam incidents
3. Near misses and medical events involving brachytherapy
4. Only medical events involving medical byproduct use
5. Any event involving radiation therapy (near miss or actual events)