Oncology information system-derived indicators of safety-critical events in radiation oncology

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DISCLOSURES

> P.E. Hartvigson – nothing to disclose
> M.F. Gensheimer – nothing to disclose
> K. Evans – nothing to disclose
> J.C. Carlson – nothing to disclose
> E.C. Ford – nothing to disclose
OUTLINE

> Quality & Safety in Radiation Oncology
> Continuous Safety Improvement
> Trigger Indicators
> Trigger Indicators in Radiation Oncology
LEARNING OBJECTIVES

> What are trigger indicators

> How triggers are used to identify safety events

> How a trigger indicator tool could be used by dosimetrists
QUALITY AND SAFETY

> Radiation is important

– Approx. 50% of all cancer patients will receive radiotherapy
QUALITY AND SAFETY

Help more people

Complex TPS Technology
High Risk Patients
Advanced treatment technique
Higher doses
Challenging Anatomy
Reirradiations
QUALITY AND SAFETY

Harm more people

- Complex TPS Technology
- High Risk Patients
- Advanced treatment technique
- Higher doses
- Challenging Anatomy
- Reirradiations
Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH  JAN. 23, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.
Heinrich, HW. *Industrial accident prevention: a scientific approach*, 1st Ed., 1931

**Heinrich 300-29-1 Model**

- **300** Near Misses
- **29** Minor Injuries
- **1** Major Injury
QUALITY AND SAFETY

> Reason’s Swiss Cheese Model

Providing radiotherapy to patients: A complex process
 QUALITY AND SAFETY

*EBRT process map exhibiting 269 process nodes.

QUALITY AND SAFETY

*EBRT process map exhibiting 269 process nodes.

QUALITY AND SAFETY

> Safety and Quality concerns are not unique to radiation medicine

• Institute of Medicine, 1999
• Estimated 98,000 preventable medical error deaths per year

QUALITY AND SAFETY

> Quality health care

— Safe  — Timely
— Effective  — Efficient
— Patient-centered  — Equitable

QUALITY AND SAFETY

HOW DO WE MAKE RADIATION THERAPY SAFER?

This new document is designed to address the specific requirements of a contemporary radiation oncology facility in terms of structure, personnel and technical process in order to ensure a safe environment for the delivery of radiation therapy. It was developed through collaboration between all of the major societies in the field representing physicians, medical physicists, radiation therapists, medical dosimetrists, nurses and administrators. It explicitly sets a high bar below which no radiation oncology facility should operate, and it foresees that the bar will be raised further in the years ahead.

American Society for Radiation Oncology. 2012.
QUALITY AND SAFETY

Figure 3.1B. Collaborative Model

COLLABORATIVE MODEL

CLINIC

- Integrating facilitators of quality/safety into routine workflow; (e.g., peer review, checklists, standardization, lean assessments)

- Supports/celebrates quality/safety initiative

- Nurtures culture of safety

- Empowers others to improve processes

Departmental Leadership, QA Committee (proactive)

American Society for Radiation Oncology. 2012.
QUALITY AND SAFETY

Figure 3.1B. Collaborative Model

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Incident Learning System!
CONTINUOUS SAFETY IMPROVEMENT

> Incident Learning System (ILS)
  > Proactive process
  > Purpose:
    > Learn from errors
    > Encourage high volume reporting

> Ultimate goal is to improve the system to prevent patient safety events
> ILS differs from many traditional incident reporting systems
  – Reactive process
  – Only include patient safety events
  – Punitive
ILS available on every desktop computer in the department.

High volume reporting: 1.2 ILS entries per treatment course.

Continuous Safety Improvement
CONTINUOUS SAFETY IMPROVEMENT

WE REPORT EVERYTHING

– Pt not called/notified of appt change
– Hospital Transport late
– DRR not associated with a beam
– Incorrect initial localization of CT data
– Isopair fields created for wrong LINAC
– DRR set on CT origin or Calc Point instead of Isocenter
> WE REPORT EVERYTHING

Learn from whoopsies to prevent whoppers
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.
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- FREE mechanism for shared learning in secure and non-punitive environment established 2011

- Contribute to national database while receiving national level and practice specific reports

- https://www.astro.org/ROILS
Dosimetrists report approximately 1/3 of all events submitted.
Another example of a near miss that occurred during treatment planning.
• Patient with metastatic melanoma undergoing Tx to R hilar mass
• 600 cGy x 5
• Physicist notes wrong isocenter on plan check
Centroid point (Incorrect)

Isocenter point (Correct)
AP setup

Plan Summary Sheet

**Isocenter**

Centroid Calc Pt

Position patient such that lasers line up with patient marks.
Move the laser LEFT 0.75 cm (looking from foot of table.)
Move the table DOWN 0.73 cm.
Move the table OUT (away from the gantry) 0.06 cm.
Big effect (SBRT/small fields)

- PTV Intended
- With shift

Dose (cGy) vs. Volume graph.
> Safety Culture

– The collective values, attitudes, perceptions, competencies and patterns of behaviors that demonstrate a commitment to health and safety management.

CONTINUOUS SAFETY IMPROVEMENT

> Key Features

– Acknowledgement of high-risk nature of an organizations’ activities and determination to achieve consistently safe operations

– Blame-free environment where individuals report errors or near-misses without fear of reprimand or punishment

– Encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems

– Organizational commitment to resources to address safety concerns

https://psnet.ahrq.gov/primers/primer/5/safety-culture
CONTINUOUS SAFETY IMPROVEMENT

Safety Culture

Patient Safety, Quality Care

Incident Learning System
CONTINUOUS SAFETY IMPROVEMENT

> Incident Learning Systems (ILS)
  - Encourage culture of safety
  - Facilitate learning from errors
  - Generate data that can be followed and measured
Central problem of ILS

— **PEOPLE**
  — Depend on people recognizing safety events
  — Depend on people reporting safety events
  — Events go undetected and unreported
  — Variable ILS results across institutions
> Safety events have root causes and risk factors
Safety events leave traces or ‘triggers’ in record

TRIGGER INDICATORS

Root Cause 1

Risk Factor A

Risk Factor B

Safety Event

Trigger 1

Trigger 2

Trigger 3
“Trigger” method first developed by Classen et al.

- Custom software developed to interface with hospital records

Goal:

- Automate detection of adverse drug events (ADEs) and compare to rate of voluntary reporting

TRIGGER INDICATORS

Triggers examples

- Diphenhydramine Rx
- Naloxone Rx
- High serum drug levels
- Leukopenia
- Antidiarrheal medication Rx

- Pruritis
- Nausea and/or rash
- Confusion/lethargy

Records flagged for triggers manually verified by a pharmacist to verify ADE

Monitored records of all patients over 18 months:
- 36,653 pts
- 731 ADEs total were identified in 648 pts

### TRIGGER INDICATORS

<table>
<thead>
<tr>
<th>Automated triggers</th>
<th>Voluntary reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>631 of 731 ADEs</td>
<td>92 of 731 ADEs</td>
</tr>
</tbody>
</table>

> Most common types of medications involved with ADEs were pain medications, anti-infectives, and cardiovascular medications.

> Triggers may help capture adverse events that would otherwise go unreported

> Could this be applied to Radiation Oncology?
EXAMPLE:

- Pediatric patient receiving craniospinal irradiation under anesthesia
- MD fussing with plan leaves errant MLC on PA field
- Caught by Therapist after port film obtained, field corrected, filmed, treated
TRIGGERS & RADIATION
ONCOLOGY
TRIGGERS & RADIATION ONCOLOGY

MLC error

- Pediatric Pt
- Technical Error
- Missed on Review
- Extra port film
- Hidden field
- Rejected port film
> Triggers may help capture adverse events that would otherwise go unreported

> Could this be applied to Radiation Oncology?
> How might this look or work?
OUR GOAL:

- Create a universal, objective, fully automated tool that uses prospective data to identify safety events.
> FIRST STEP:

– Develop a set of radiation oncology triggers high grade near miss safety events that can be assessed in an automated fashion
### METHODS & MATERIALS:

<table>
<thead>
<tr>
<th>10 Triggers Queried</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missed fraction(s)</td>
</tr>
<tr>
<td>New fields after RT start</td>
</tr>
<tr>
<td>New Rad Rx</td>
</tr>
<tr>
<td>2 or more Physics QA documents</td>
</tr>
<tr>
<td>Physics QA document after RT start</td>
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</tbody>
</table>
> Queried oncology information system over 4 year period to identify treatment courses with triggers

> Queried ILS over same 4 year period linking reported safety events with their respective treatment courses
> End point: Odds of high risk near miss event in patients with vs. without trigger
  
  – P-values calculated using chi-squared test
> RESULTS:

– 3,313 treatment courses over the 4 year period

– 3,917 safety event entries in ILS over same 4 year period

– Approximately 12% of the 3,313 treatment courses had a high grade near miss safety events
Statistically significant

Triggers

- New fields after treatment start
- New Rad Rx
- 2 or more Physics QA documents
- Physics documents after course start
- Missed fraction(s)
- Hidden fields
- Delayed first fraction
- Rejected port films
- Voided plan
- No Physics QA document

Strong trend
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Odds ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>New fields after course start</td>
<td>2.27 (1.73-2.96)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>New radiation prescription</td>
<td>2.35 (1.69-3.22)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Two or more physics docs.</td>
<td>2.04 (1.62-2.56)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Physics doc. after start of treatment</td>
<td>2.14 (1.62-2.80)</td>
<td>&lt;0.001</td>
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<tr>
<td>Missed fractions</td>
<td>1.42 (1.04-1.91)</td>
<td>0.02</td>
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<tr>
<td>Hidden fields</td>
<td>1.23 (0.98-1.55)</td>
<td>0.07</td>
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<tr>
<td>Delayed first fraction</td>
<td>0.74 (0.32-1.47)</td>
<td>0.47</td>
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<tr>
<td>Rejected port films</td>
<td>1.30 (0.90-1.83)</td>
<td>0.16</td>
</tr>
<tr>
<td>Voided plan</td>
<td>1.76 (0.78-3.60)</td>
<td>0.16</td>
</tr>
<tr>
<td>No physics doc.</td>
<td>0.90 (0.63-1.26)</td>
<td>0.60</td>
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</table>
> INTERIM CONCLUSION: (further research is ongoing)

- 5 statistically significant triggers that could be used in a fully automated universal trigger tool for radiation oncology departments.
Incident learning systems are critical to patient safety

*You can begin now with ROILS*

- Highly variable across institutions
- Safety events may go undetected and/or unreported
CONCLUSION

> An effective trigger tool could estimate the prevalence of high risk safety events in an unbiased, automated manner across institutions

– May reveal occult patterns of root causes and risk factors

– Could be used to objectively compare safety across departments with variable ILS quality and content
CONCLUSION

> We are working on further refinement of trigger tool

> Dosimetrists – who are at the center of the highly complex system of radiotherapy – are poised to make a big impact on radiation safety
CONCLUSION

> Future:
  
  — What would real-world clinical application look like?

  — Automated trigger tool specific for Radiation Oncology used by Dosimetrist
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