Error and Near-Miss Reporting in Radiotherapy

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Outline

• Introduction
• Reporting infrastructure
• Organizational culture
• Errors and near-misses
• Reporting systems
• Feedback mechanisms
• Lessons learned
Errors in Radiation Therapy

- Staff and public exposures
- Misadministrations
  - Underdose
  - Overdose
  - Anatomical misses
- Magnitude
  - From few percent to lethal doses
  - From couple of millimeters to complete misses
- Regulatory
  - Nuclear Regulatory Commission
  - Errors that do not necessarily affect patients but have regulatory/legal consequences
- Sources
  - Staff
  - Software
  - Hardware
- Random
  - Affect one to few patients
- Systematic
  - Affect hundreds of patients
  - Potentially in a short period
Background

Global Problem

• “…it calls into question the integrity of hospital systems and their ability to pick up errors and the capability to make sustainable changes.”

• Sir Liam Donaldson, Chief Medical Officer, Department of Health


WORLD ALLIANCE FOR PATIENT SAFETY

WHO DRAFT GUIDELINES FOR ADVERSE EVENT REPORTING AND LEARNING SYSTEMS

FROM INFORMATION TO ACTION
Error Reporting

• We are not airline industry nor nuclear power
• Perfection in complex systems across hundreds of diverse clinics is impossible
• Reporting systems for sake of reporting alone are a great way to squander resources and demoralize staff
• Error reporting as a part of broader process improvement efforts can be very valuable
Event Reporting

• Mandatory (statutory)
  – Reporting required by law
  – NRC in U.S.
  – State requirements
  – Mainly concentrated on well defined treatment delivery errors
  – Guidelines for near-miss reporting typically not provided

• Voluntary
  – Mainly at institutional level
  – Some states in the U.S. have voluntary reporting systems – utility for radiation therapy not clear
  – Errors and near misses tracked
Voluntary Reporting
Dependent on Many Factors

- Culture
- Reporting guidelines
- Reporting system
- Competence to interpret reported data
- Willingness to implement, when necessary, significant changes based on collected data and subsequent analyses
- Ability to share the collected data and provide feedback
Lessons Learned I  
Naming a Voluntary Reporting System

• We often name our homegrown software by what it does
• Our brand new web-based system, back in 2007, was named “Process Improvement Logs”
• Our staff provided a nickname

“E-Snitch”
Organizational Culture

• “Shared values (what is important) and beliefs (how things work) that interact with an organization’s structures and control systems to produce behavioural norms (the way we do things around here).” *Uttal, B.*, *Fortune*. 17 October 1983.

• Safety culture
  – Reporting culture
  – Just culture
## Organizational Cultures

<table>
<thead>
<tr>
<th>Pathological Culture</th>
<th>Bureaucratic Culture</th>
<th>Generative Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not want to know</td>
<td>May not find out</td>
<td>Actively seek it</td>
</tr>
<tr>
<td>Messengers (whistle blowers) are “shot”</td>
<td>Messengers are listened to if they arrive</td>
<td>Messengers are trained and rewarded</td>
</tr>
<tr>
<td>Responsibility is shirked</td>
<td>Responsibility is compartmentalized</td>
<td>Responsibility is shared</td>
</tr>
<tr>
<td>Failure is punished or concealed</td>
<td>Failures lead to local repairs</td>
<td>Failures lead to far reaching reforms</td>
</tr>
<tr>
<td>New ideas are actively discouraged</td>
<td>New ideas often present problems</td>
<td>New ideas are welcomed</td>
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</table>

Reporting Culture

- Indemnity against disciplinarily proceedings and retribution
- Confidentiality
- To the extent practical, separation of those collecting the event data from those with the authority to impose disciplinary actions
- An efficient method for event submission
- A rapid, intelligent, and broadly available method for feedback to the reporting community
Just Culture
Acceptable and Unacceptable Actions

• Vast majority of errors is due to factors and actions where attribution of blame is not appropriate nor useful

• Rarely events are due to unacceptable actions:
  – Recklessness
  – Negligent or malevolent behavior

• The line between these can be thin and the tendency is to attribute errors to acceptable actions

• It is operationally impossible to give a blanket immunity which would include unacceptable actions
Errors and Near Misses

• Error
  - “The failure of planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).”

*Institute of Medicine. To Err is Human: Building a Safer Health System, 2000.*
Errors and Near Misses

- Near Misses
  - Near Hits
  - Free Lessons
  - Close Calls
  - Near Collisions
Small to Sentinel Events

“We know that single events are rare, but we do not know how small events can become chained together so that they result in a disastrous outcome. In the absence of this understanding, people must wait until some crisis actually occurs before they can diagnose a problem, rather than be in a position to detect a potential problem before it emerges. To anticipate and forestall disasters is to understand regulations in the ways small events can combine to have disproportionally large effects.”

K.E. Weick, “The vulnerable system: an analysis of the Tenerife air disaster” in P.J. Forst et al/ Reframing Organizational Culture
Error Process

- Errors are product of a chain of causes
What to Report/Track

• Explicit events — frequent events
• Random events
• Actual errors
• Potential errors (near misses)
Reporting process

• **Statutory reporting**
  – Which agencies should receive reports
  – Which errors are subject to reporting
  – Do near misses have reporting mandates
  – Reporting process

• **Voluntary reporting**
  – Which errors/near misses to report
  – Reporting process
  – What should be provided in the report
  – Feedback mechanism
Taxonomy and Event Classification

- Event reporting should enable process improvement
- This requires efficient processing and analysis of data
- Submitted events must be classified and organized
- Enables efficient processing, analysis, and communication of data and trends
Taxonomy and Event Classification

- Organized data can provide insight in system weaknesses and opportunities for improvement
- Submitted number of events alone are not an indicator as it is difficult to differentiate between increased problems and improved reporting culture
Reporting Systems

• **Paper**
  - Single form or set of multiple forms
  - Well defined submission and routing process
  - Manual processing and data extraction

• **Electronic**
  - Desktop or web-based applications
  - Commercial and home grown (rad-onc specific)
  - Automatic processing and data mining
  - ROSIS - [http://www.clin.radfys.lu.se/default.asp](http://www.clin.radfys.lu.se/default.asp)
System Acceptance

Paper

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<th>Jul-00</th>
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Legend:
- Dark blue bars represent the number of reported events for each quarter from April 2000 to January 2007.

No reported events in the first quarter of 2000.
System Acceptance
Voluntary Web-based

Events Reported

No. of events Reported

Month

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<th>Jul-07</th>
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Feedback Mechanisms

• Feedback process often stated as a prerequisite
• Feedback can be provided as individual correspondence or by demonstrating sustainable changes
• A combination of the above two methods is likely the best solution
• Need a method to deal with anonymous submissions
Data Collection, Standardization, and Benchmarking

Each clinic with its own independent database and varied software

Centralized Database

Manufacturers  Regulatory Agencies  Professional Societies
Conclusions

• Sustainable data collection possible
• Need to collect broader parameters to determine failure triggers
• Need resources to process events and follow up on effects of implemented changes
• Electronic reporting and standardized classification could facilitate benchmarking among institutions
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