AAPM 2013: Safety Improvement through Incident Learning
E. Ford, G. Ezzell, A. Dicker, T. Piotrowski

This handout is intended as supplementary material for the educational session noted above. Presentation material and slides are available through the AAPM website.

Introduction: Incident learning is a key tool for improving the quality and safety of procedures. At its most fundamental level, incident learning is method to systematically capture information on incidents and near-misses and learn from them to improve the quality and safety of treatments. This session will describe basic concepts in incident learning with a practical focus for the clinical medical physicist working in the radiation oncology setting.

Background: Numerous studies have appeared over the years highlighting the need for incident learning in radiation oncology (1-11). The value of incident learning has been demonstrated through large hospital survey databases (12) and also anecdotally through demonstration of safety impact in radiation oncology (13). Recent interest in incident learning in radiation oncology can be traced back to a conference in June 2010 in Miami sponsored by AAPM and ASTRO (14). This conference, entitled “Safety in Radiation Therapy: A Call to Action”, considered numerous issues related to patient safety. One of the key recommendations from this meeting was that “Error reporting systems should be developed in radiation therapy” (14). Following the meeting in Miami the AAPM embarked on a study to develop technical recommendations for incident reporting in radiation oncology. This work was performed by the AAPM Work Group on Prevention of Errors chaired by one of us (EF) and culminated in the publication in December 2012 of a study entitled “Consensus recommendations for incident learning database structures in radiation oncology” (15). The study had numerous contributors from various societies and the final document was approved by AAPM, the American Society of Therapeutic Radiation and Oncology (ASTRO), and the Society of Radiation Oncology Administrators (SROA).

Definitions: First some definitions of terms. These appear in the WGPE white paper and are consistent with the definitions from the National Patient Safety Foundation.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error</td>
<td>Failure to complete a planned action as intended or the use of an incorrect plan of action to achieve a given aim</td>
</tr>
<tr>
<td>Incident</td>
<td>An unwanted or unexpected change from a normal system behavior which causes or has the potential to cause an adverse effect to persons or equipment</td>
</tr>
<tr>
<td>Near-miss</td>
<td>An event or situation that could have resulted in an accident, injury, or illness but did not either by chance or through timely intervention. Also known as a close call, good catch or near hit</td>
</tr>
</tbody>
</table>

Here we refer to the process as “incident learning” rather than “incident reporting” to highlight the entire learning process, i.e. the feedback loop of reporting an incident and then analyzing it for salient detail and developing interventions to prevent it from happening again. We also avoid the term “error reporting” or “error learning” since it is often not errors themselves that are reported, but rather the consequences of those errors.
**Society recommendations**: Several documents, approved at the society level, now call for the use of incident learning to improve safety.

<table>
<thead>
<tr>
<th>Study</th>
<th>Statement</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASTRO “Safety is No Accident”</td>
<td>“Employees should be encouraged to report both errors and near-misses (errors that almost happen).” A quality assurance committee “should ensure that a mechanism for reporting and monitoring errors and near-misses is in place.”</td>
<td>16</td>
</tr>
<tr>
<td>ASTRO White paper on safety in IMRT</td>
<td>“To improve error prevention and remediation of events (any unplanned/undocumented deviation from the department’s standard process or the patient’s expected treatment), the team should discuss potential and actual sources of errors and document all events that occur.”</td>
<td>17</td>
</tr>
<tr>
<td>ASTRO White paper on safety in IGRT</td>
<td>“Establish a reporting mechanism for IGRT-related variances in the radiation treatment process.”</td>
<td>18</td>
</tr>
<tr>
<td>AAPM WGPE White paper on incident learning</td>
<td>“Discipline-specific incident learning systems would significantly improve the practice of radiation oncology.”</td>
<td>15</td>
</tr>
<tr>
<td>UK Toward Safer Radiotherapy</td>
<td>“Each radiotherapy center must operate a quality system, which should ensure best practice is maintained by applying lessons learnt from radiotherapy incidents and near misses from other departments as well as in-house.”</td>
<td>19</td>
</tr>
</tbody>
</table>

**Harm vs. Near-miss and Reporting Volumes**: It must be recognized that most incidents encountered in the course of daily operations are near-misses, i.e. events or situations that do not result in patient harm. Incident learning should include these events as well. If near-miss events are included, the volume of information collected can be quite large even within a single clinic. The study by Mutic et al., for example, noted an incident report rate of 1 per 1.6 patients treated (3). This would translate into approximately 26 reports per month for a clinic treating 500 patients per year.

**A National Incident Learning System**: The concepts behind incident learning apply both at the departmental level (i.e. incident learning within a given clinic) and on the larger level nationally or even internationally. The international voluntary reporting system ROSIS has existed for years (9, 10). More recently there has been a call to develop a system for the United States with the goal of facilitating information flow and learning between departments. Such a system is now being developed by AAPM and ASTRO under the mechanism of a Patient Safety Organization (PSO). The PSO system was established by the US Congress as part of the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41). It provides privilege and confidentiality protection to encourage reporting. PSOs are widely used in other areas of medicine. The details of the Radiation Oncology PSO system will be described in more detail in the presentation by an expert in this area.
Learning Points: The process of incident learning is complex. The presentations will explore the following topics in more depth.

- What is the proven value of incident learning?
- What are the key elements of a departmental incident learning system?
- What are typical hurdles to implementation and continued use?
- How should such a system be structured at the institutional level and what types of incidents can be expected?
- What is the value of participating in a national Radiation Oncology Incident Learning System?
- How can my clinic participate in the national Radiation Oncology Incident Learning System?

References

Safety Improvement through Incident Learning

Education Session

WE-F-WAB-1 Wednesday 3:00PM - 3:50PM
Room: Wabash Ballroom
AAPM 2013 Annual Meeting Education Session August 7, 2013
Mistakes and errors are inevitable

We all have some methods for learning from our own mistakes

We do a poor job of learning from other departments’ mistakes

A national system to share that knowledge
Outline

• Adam Dicker, MD PhD, Thomas Jefferson University
  – Quality/safety and outcomes
• Eric Ford, PhD, University of Washington
  – Incident learning within an institution
• Anna Marie Hajek, President & CEO, Clarity Group Inc.
  – Patient Safety Organizations
• Todd Pawlicki, PhD, University of California, San Diego
  Gary Ezzell, PhD, Mayo Clinic, Arizona
  – The ASTRO/AAPM Radiation Oncology-ILS
Quality and Clinical Outcome

Implications of prospective clinical trials and credentialing

Adam P. Dicker, M.D., Ph.D.

Department of Radiation Oncology
Jefferson Medical College of Thomas Jefferson University
Philadelphia, PA, USA

AAPM 2013 Annual Meeting Education Session August 7, 2013
Clinical Investigation


Yaacov Richard Lawrence, M.R.C.P., Michal A. Whiton, M.D., Zvi Symon, M.D., Evan J. Wuthrick, M.D., Laura Doyle, M.S., Amy S. Harrison, M.S., and Adam P. Dicker, M.D., Ph.D.

*Department of Radiation Oncology, Jefferson Medical College of Thomas Jefferson University, Philadelphia, Pennsylvania; †Department of Radiation Oncology, Sheba Medical Center, Tel HaShomer, Israel; ‡Sackler School of Medicine, Tel Aviv University, Israel; ††Department of Radiation Oncology, Skagit Valley Hospital Regional Cancer Care Center, Mt. Vernon, Washington; and †‡Department of Radiation Oncology, Ohio State University, Columbus, Ohio
Radiotherapy Protocol Deviations are Associated with Inferior Clinical Outcomes: A Meta-analysis of Cooperative Group Clinical Trials

Nitin Ohri\textsuperscript{1}, Xinglei Shen\textsuperscript{2}, Adam Dicker, Laura Doyle, Amy Harrison, Timothy Showalter\textsuperscript{3}

Thomas Jefferson University

\textsuperscript{1} – Current affiliation: Albert Einstein College of Medicine
\textsuperscript{2} – Current affiliation: University of Kansas Medical Center
\textsuperscript{3} – Current affiliation: University of Virginia
Methods – Data Extraction

• Primary outcome – overall survival
• Secondary outcomes – local control, event-free survival, etc.
• Hazard ratios (HRs) for time-to-event outcomes were extracted directly from the original studies or were estimated indirectly by reading off survival curves (Parmar et al, Statistics in Medicine, 1998)

<table>
<thead>
<tr>
<th>Trial Name</th>
<th>Disease</th>
<th>Definition of RT Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>RTOG 73-01</td>
<td>Non-small cell lung cancer</td>
<td>“Major” Variation: Recalculated dose variation &gt; 10%, no margin on primary target, or partial treatment of elective target</td>
</tr>
<tr>
<td>SWOG 7628</td>
<td>Small cell lung cancer</td>
<td>“Major” Variation: Incorrect dose, ≥ 5% underdosing of involved target, ≥ 10% underdosing of elective target, ≥ 10% overdosing of critical normal structure, etc.</td>
</tr>
<tr>
<td>POG 8346</td>
<td>Ewing’s Sarcoma</td>
<td>“Minor” or “Major” Deviation: &lt; 2 cm margin or &gt; 5% deviation from the recommended dose</td>
</tr>
<tr>
<td>SFOP.TC 94</td>
<td>Medulloblastoma</td>
<td>“Minor” or “Major” Deviation: ≤ 5 mm margin (cranial fields) or ≤ 10 mm margin (spinal fields)</td>
</tr>
<tr>
<td>POG 9031</td>
<td>Medulloblastoma</td>
<td>“Major” Deviation: ≥ 10% underdosing of brain, posterior fossa, or spine</td>
</tr>
<tr>
<td>SIOP/UKCC PNET-3</td>
<td>Supratentorial PNET</td>
<td>Deviation: &lt; 3 mm margin (cribriform fossa) or &lt;8 mm margin (skull base)</td>
</tr>
<tr>
<td>TROG 02.02</td>
<td>Head and neck cancer</td>
<td>“Deficiencies predicted to have a major adverse impact on tumor control”</td>
</tr>
<tr>
<td>RTOG 97-04</td>
<td>Pancreatic adenocarcinoma</td>
<td>“Less than per protocol”: numerous criteria regarding field sizes, borders, etc.</td>
</tr>
<tr>
<td>Trial Name</td>
<td># of Patients without RT Deviation (%)</td>
<td># of Patients with RT Deviation (%)</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>RTOG 73-01</td>
<td>277 (92%)</td>
<td>24 (8%)</td>
</tr>
<tr>
<td>SWOG 7628</td>
<td>96 (69%)</td>
<td>44 (31%)</td>
</tr>
<tr>
<td>POG 8346</td>
<td>52 (79%)</td>
<td>14 (21%)</td>
</tr>
<tr>
<td>SFOP.TC 94</td>
<td>49 (29%)</td>
<td>120 (71%)</td>
</tr>
<tr>
<td>POG 9031</td>
<td>69 (43%)</td>
<td>91 (57%)</td>
</tr>
<tr>
<td>SIOP/UKCC PNET-3</td>
<td>28 (67%)</td>
<td>14 (33%)</td>
</tr>
<tr>
<td>TROG 02.02</td>
<td>723 (88%)</td>
<td>97 (12%)</td>
</tr>
<tr>
<td>RTOG 97-04</td>
<td>216 (52%)</td>
<td>200 (48%)</td>
</tr>
</tbody>
</table>
Forest plot of hazard ratios: the association between radiotherapy protocol deviations and overall survival


HR = 1.74
95% CI = 1.28 to 2.35
p < 0.001
Systematic review

QA makes a clinical trial stronger: Evidence-based medicine in radiation therapy

Damien C. Weber a,e,*, Milan Tomsej b, Christos Melidis c, Coen W. Hurkmans d,e

a Geneva University Hospital, Switzerland; b CHU Charleroi; c EORTC HQ, Brussels, Belgium; d Catharina Hospital, Eindhoven, The Netherlands; e EORTC Radiation Oncology Group, Brussels, Belgium
Definition of deviation not always consistent

Table 1
Dosimetric definitions of major deviations for QART performed in prospective trials.

<table>
<thead>
<tr>
<th>Study [ref]</th>
<th>Years of randomization</th>
<th>Major deviations (tumor)</th>
<th>Major deviations (normal tissues)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HD 7 [9]</td>
<td>1994–1998</td>
<td>• Total dose &lt;90% or &gt;110% of the prescribed dose</td>
<td>ND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Dose administered too slowly</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Technical deficiency</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 90%-Isodose surface not encompassing the planning target volume</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Total delivered dose of ±10% of the prescribed randomized dose</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Overall treatment time exceeding the normal treatment time by 10%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 90% isodose-surface not covering the target volume</td>
<td></td>
</tr>
<tr>
<td>RTOG 9704 [1]</td>
<td>1998–2002</td>
<td>• Dose delivered not within ±10% of the prescribed dose</td>
<td></td>
</tr>
<tr>
<td>RTOG 0022 [8]</td>
<td>2001–2005</td>
<td>• The prescription criteria for PTV66 are not met: 60 Gy isodose does not cover &gt;90% of PTV66. Also the 72.6 Gy isodose surface covers &gt;25% of PTV66. The prescription criteria for PTV60 and PTV54 are not met: 47-Gy isodose surface does not cover &gt;99% of PTV54 and the 54-Gy isodose surface does not cover &gt;90% of PTV54. The 52-Gy isodose surface does not cover &gt;90% of PTV60 and the 72.6-Gy isodose covers &gt;20% PTV54 and PTV60.</td>
<td>• Contoured gross tumor volume &gt;5 cm greater than the actual tumor size on the basis of diagnostic imaging. • The use of block margins &gt;5 cm. • 60% of both parotid glands receive &gt;30 Gy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Gross disease treated &lt;66.6 Gy</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• D10% &lt;66.5 Gy or &gt;75 Gy (PTV)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: ND: not defined.
# Deviations have a huge impact on clinical outcome

Results of QART assessment with patient outcome in prospective clinical trials.

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of QA</th>
<th>Number of cases evaluated n (%)</th>
<th>Minor deviations n (%)</th>
<th>Major deviations n (%)</th>
<th>Technical issues with QA review n (%)</th>
<th>Impact on clinical outcome</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HD-4</td>
<td>R</td>
<td>385 (91.0)</td>
<td>-</td>
<td>141 (36.7)</td>
<td>9 (2.1)</td>
<td>7-year RFS with D: 72% vs. 7-year RFS without D: 80%</td>
<td>0.004</td>
</tr>
<tr>
<td>EORTC 20884</td>
<td>R</td>
<td>135 (88.8)</td>
<td>-</td>
<td>63 (46.7)</td>
<td>46 (30.3)</td>
<td>5-year RFS with D: 90% vs. 5-year RFS without D: 84%</td>
<td>0.31</td>
</tr>
<tr>
<td>RTOG 0611</td>
<td>P</td>
<td>NS</td>
<td>-</td>
<td>13 (8.4)</td>
<td>NS</td>
<td>Grade G1 &amp; G2 toxicity with D: 95% vs. Grade G1 &amp; G2 toxicity without D: 95%</td>
<td>0.05</td>
</tr>
<tr>
<td>RTOG 9704</td>
<td>R</td>
<td>416 (92.2)</td>
<td>-</td>
<td>200 (48.0)**</td>
<td>14/35 (40.0)</td>
<td>mOS with D: 1.46 yo vs. mOS without D: 1.74 yo</td>
<td>0.008</td>
</tr>
<tr>
<td>RTOG 0022</td>
<td>D</td>
<td>57 (97.0)</td>
<td>47 (89.0)</td>
<td>8 (11.0)</td>
<td>14/87 (12.1)</td>
<td>LRF with major D: 50% vs. LRF with no major D: 6%</td>
<td>0.04</td>
</tr>
<tr>
<td>TROG 0202</td>
<td>P&amp;R</td>
<td>687 (80.5)</td>
<td>-</td>
<td>97 (11.8)</td>
<td>33/820 (4.0)</td>
<td>OS with major D: 70% vs.</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Abbreviations: R, retrospective; P, prospective; LRF, local-regional failure; D, deviations; mOS, median overall survival; RFS, relapse-free survival. *P* values <0.05 are considered significant.
RT quality does impact on outcome when RT is combined with drugs

Designed to provide 90% power to detect a 10% difference (70% vs 60%) in 2-year overall survival rate

Sample Size = 861 Patients
“It is sobering to note that the value of good radiotherapy is substantially greater than the incremental gains that have been achieved with new drugs and/or biologicals.”

Impact of Radiotherapy on outcome

Primary Endpoint

Planned Secondary Analysis

Overall Survival by Arm (%)

Time Since Random Assignment (years)

Percent Surviving

Time Since End of RT (years)

Compliant ab initio
Made compliant
No major TCP impact
Major TCP impact

Courtesy of David Followill, PhD
Non-Credentialed Protocols are associated with more protocol violations

<table>
<thead>
<tr>
<th>Study</th>
<th>Major Deviations</th>
<th>Minor Deviations</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOG 0184</td>
<td>44 (7%)</td>
<td>114 (17%)</td>
<td>654</td>
</tr>
<tr>
<td>GOG 0122</td>
<td>29 (15%)</td>
<td>37 (19%)</td>
<td>197</td>
</tr>
<tr>
<td>NSABP B14</td>
<td>135 (9%)</td>
<td>214 (15%)</td>
<td>1460</td>
</tr>
<tr>
<td>NSABP R01</td>
<td>72 (44%)</td>
<td>0</td>
<td>163</td>
</tr>
<tr>
<td>RTOG 9001</td>
<td>43 (14%)</td>
<td>76 (24%)</td>
<td>315</td>
</tr>
<tr>
<td>RTOG 9003</td>
<td>75 (7%)</td>
<td>188 (18%)</td>
<td>1073</td>
</tr>
</tbody>
</table>
# Credentialing lower deviations

<table>
<thead>
<tr>
<th>Study</th>
<th>Disease Site</th>
<th>Major Deviations</th>
<th>Minor Deviations</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMS</td>
<td>Eye</td>
<td>43 (5%)</td>
<td>47 (3.6%)</td>
<td>1166</td>
</tr>
<tr>
<td>GOG 165</td>
<td>Cervix</td>
<td>0</td>
<td>15 (21%)</td>
<td>70</td>
</tr>
<tr>
<td>RTOG 95-17 HDR &amp; LDR</td>
<td>Breast</td>
<td>0</td>
<td>4 (4%)</td>
<td>100</td>
</tr>
<tr>
<td>RTOG 0019 LDR</td>
<td>Prostate</td>
<td>0</td>
<td>6 (5%)</td>
<td>117</td>
</tr>
<tr>
<td>NSABP B39/RTOG 0413</td>
<td>3D MultiCatheter</td>
<td>3 (0.3%)</td>
<td>121 (10%)</td>
<td>1171</td>
</tr>
<tr>
<td></td>
<td>MammoSite</td>
<td>0</td>
<td>42 (12%)</td>
<td>348</td>
</tr>
<tr>
<td></td>
<td>3D MammoSite</td>
<td>0</td>
<td>8 (9%)</td>
<td>93</td>
</tr>
</tbody>
</table>

Courtesy of David Followill, PhD
Institution results do not always agree with phantom results

Comparison between institution’s plan and delivered dose

<table>
<thead>
<tr>
<th>Phantom</th>
<th>H&amp;N</th>
<th>Prostate</th>
<th>Spine</th>
<th>Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irradiations</td>
<td>1368</td>
<td>419</td>
<td>176</td>
<td>664</td>
</tr>
<tr>
<td>Pass</td>
<td>1135 (83%)</td>
<td>359 (86%)</td>
<td>119 (68%)</td>
<td>535 (81%)</td>
</tr>
<tr>
<td>Fail</td>
<td>233</td>
<td>61</td>
<td>57</td>
<td>129</td>
</tr>
<tr>
<td>Criteria</td>
<td>7%/4 mm</td>
<td>7%/4 mm</td>
<td>5%/3 mm</td>
<td>5%/5 mm</td>
</tr>
</tbody>
</table>

Courtesy of David Followill, PhD
Summary

• QA data from prospective clinical trials demonstrates that non-adherence to protocol-specified RT requirements are frequent.

• Failure to adhere to protocol RT guidelines is associated with reduced survival, reduced local control and potentially increased toxicity.
Questions and Implications

• How should quality assurance measures be incorporated into clinical practice and clinical trials?

• What does this imply for patients who receive radiotherapy “off study”?

• What are the implications for standards of quality assurance and patient safety?

• What should be the standard of care
Safety Improvement through Incident Learning

Experience with Incident Learning at the Clinical and Institutional Level

Eric Ford, PhD
University of Washington, Seattle

AAPM 2013 Annual Meeting Education Session August 7, 2013
SAFETY IS NO ACCIDENT
A FRAMEWORK FOR
QUALITY RADIATION
ONCOLOGY AND CARE

DEVELOPED AND ENDORSED BY:
American Association of Medical Dosimetrists (AAMD)
American Association of Physicists in Medicine (AAPM)
American Board of Radiology (ABR)
American Brachytherapy Society (ABS)
American College of Radiology (ACR)
American College of Radiation Oncology (ACRO)
American Radium Society (ARS)
American Society for Radiation Oncology (ASTRO)
American Society for Radiologic Technologists (ASRT)
Association of Free-Standing Radiation Oncology Centers (AFROC)
Society of Chairs of Academic Radiation Oncology Programs (SCAROP)
Society for Radiation Oncology Administrators (SROA)

Zietman et al. 2012
“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.”
The Call for Incident Learning

• 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
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
Example event – wrong site near-miss
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
Resulting Quality Improvement

• Radioopaque marker to prevent R/L reversal
• Improving safety barriers
  – E.g. physicist and therapist checklists
• Training and education
  – Education module for incoming residents
Institutional Studies of Incident Learning

- Clark et al., Patient safety improvement in radiation treatment through five years of incident learning, Prac Rad Onc (2012)
- Ford et al., Prevention of a wrong-location misadministration through the use of an intradepartmental incident learning system, Med Phys, 39, 6968- (2012)
- Bissonnette and Medlam, Trend analysis of radiation therapy incidents over seven years, Radiother Oncol, 96, 139–144 (2010)
- Clark et al., The management of radiation treatment error through incident learning, Radiother Oncol, 95, 344–349 (2010)
Event (error and near-miss) reporting and learning system for process improvement in radiation oncology

Sasa Mutic, a) R. Scott Brame, Swetha Oddiraju, Parag Parikh, Melisa A. Westfall, Merilee L. Hopkins, Angel D. Medina, Jonathan C. Daniele, Jeff M. Michalski, Issam M. El Naqa, and Daniel A. Low
Department of Radiation Oncology, Mallinckrodt Institute of Radiology, Washington University School of Medicine, 4921 Parkview Place, St. Louis, Missouri 63110

Bin Wu
Department of Industrial and Manufacturing Systems, Engineering University of Missouri, E3437 Thomas and Nell Laffer Hall, Columbia, Missouri 65211

Med. Phys. 37 (9), September 2010

III. RESULTS

III.A. Reporting statistics

Figure 5 shows the number of events for each quarter from August 2007 through July 2009. An average of 342 events was reported per quarter, or approximately 0.6 events per treated patient. While this seems like a large number, it is important to note that the faculty and staff are encouraged to

Medical Physics, Vol. 37, No. 9, September 2010
Major Accident

Minor Injury

Near Miss

Bad Practices

Vast majority of incidents

Heinrich’s Triangle

Heinrich, HW. Industrial accident prevention: a scientific approach, 1st Ed., 1931
Incident Learning

CLINIC A
Only reportable events
Hospital PSN
< 1 / year

CLINIC B
Encouraged to submit everything
Paper forms
10 / year

CLINIC C
Almost all staff participate
Electronic
10 / week
More reports = Safer

![Graph showing scatter plot of PSI composite versus HSOPS composite average (N = 179).](image)

**FIGURE 1.** Scatter plot of PSI composite versus HSOPS composite average (N = 179).

Mardon et al. AHRQ, J Patient Saf, 6, 226-232, 2010

**NUMBER OF REPORTS vs. NUMER of patient safety incidents**

$R^2 = -0.33 \quad p<0.001$
Incident Reporting: Usage

Kusano et al. 2013
Incident Reporting: Usage

Mean Severity Score

Month since Feb 2012

$p < 0.01$

Kusano et al. 2013
Summary: Incident Learning at the Institutional Level

- Called for by numerous authoritative bodies
- Valuable source of information for QI
- Volume (experience) is crucial
- Value of a national system will depend on good incident learning conducted at the institutional level
Safety Improvement through Incident Learning

The ASTRO/AAPM Radiation Oncology – Incident Learning System

Anna Marie Hajek
President & CEO
Clarity Group, Inc.

AAPM 2013 Annual Meeting Education Session August 7, 2013
Medical Physicists can create a reporting culture to sustain continuous safety improvement ...

...Within a protected space created by the PSQIA/PSO Structure

The Basis of the Radiation Oncology – Incident Learning System (RO-ILS)
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

PSOs are the learning labs for healthcare providers where event analysis and recommendations for positive and sustainable change can be made and shared broadly to improve overall 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 PSES for reporting to a PSO, and such documentation includes the date the information entered the PSES; or
  – Are developed by a PSO for the conduct of patient safety activities; or
  – Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES

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

- Privileged and not subject to:
  - Subpoena or order
  - Discovery
  - Freedom of Information Act
  - Legal or administrative proceedings including those against a provider
  - Disciplinary proceeding of a professional disciplinary body

- Confidential and not disclosed...except in:
  - Criminal proceedings
  - Provider authorization
  - Non-identifiable data
  - Law enforcement
  - FDA reporting
  - Patient safety activities
  - Business operations
  - Equitable relief
  - Research sanctioned by Secretary
  - Voluntary disclosure to an accrediting body

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)

• Designed by ASTRO-AAPM to address the need expressed by the Radiation Oncology community for a national database to support healthcare quality and patient safety of patients served

• Comprised of:
  – An electronic web-based reporting system to report events within the practice or department
  – Contracting with a PSO that receives that information in a protected space and provides reports and resources back to the Radiation Oncology community to achieve the goal of enhanced safety

Goal: National standardized data collection specific to the needs of the Radiation Oncology community sent to a protected space for learning without fear of litigation
The Development Chronology of RO-ILS

- **2010**: Early discussions led to:
  - Safety is No Accident: A Framework for Quality Radiation Oncology and Care. Zeitman A, Palta J, Steinberg M. ASTRO; 2012

- **2011**: ASTRO Membership Survey: 85% of Radiation Oncologists and 94% of Medical Physicists would use an ASTRO sponsored confidential reporting system for medical errors and near misses

- **April 2012**: ASTRO RFP for partners to help create the RO-ILS ... Data Collection Tool and PSO (AAPM joined the effort in Summer 2012)

- **February 2013**: Current work
  - ASTRO/AAPM Steering Committee –Clarity / Clarity PSO create reporting templates
    - Electronic web-based tool – accessible in the practice setting
    - Templates based on the work of the Ford, et. al. in the Consensus paper
  - Beta testing of RO-ILS to begin in Summer 2013
  - Preparation for Launch of RO-ILS **First Quarter 2014**
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
Radiation Oncology – Incident Learning System (RO-ILS)

- Voluntary participation
- Currently will be offered to the Radiation Oncology Community at no cost to the participants
- Educational materials are being prepared to help the Radiation Oncology Community make the decision on participation
What other healthcare providers have gained from working with a PSO:

**Awareness in reporting**

![Distribution of Medication Error Types](image)

Outlier: Identification and hand-off process issue

- Incorrect dose: 20.3%
- Incorrect timing: 11.9%
- Incorrect medication: 9.3%
- Incorrect duration: 6.6%
- Incorrect patient: 5.4%
- Incorrect concentration: 2.7%
- Incorrect rate: 2.5%
- Incorrect preparation: 1.7%
- Incorrect route: 1.7%
- Incorrect dosage form: 1.4%

<table>
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<th>Type</th>
<th>Aggregate</th>
<th>HC101</th>
<th>HC102</th>
<th>HC103</th>
<th>HC104</th>
<th>HC105</th>
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</thead>
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<td>20.2%</td>
<td>23.8%</td>
<td>19.0%</td>
<td>29.4%</td>
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<tr>
<td>Incorrect dosage form</td>
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<td>1.0%</td>
<td>0.9%</td>
<td>3.0%</td>
<td>1.2%</td>
</tr>
</tbody>
</table>
What other healthcare providers have gained from working with a PSO?

*Improvements from Reporting*

![Distribution of Harmful Events – Hospital Clients](image)

- Q211: 12.1%
- Q311: 18.2%
- Q411: 16.0%
- Q112: 10.7%
- Q212: 12.7%
- Q312: 11.2%
- Q412: 10.9%

N=10,000 Event-specific Common Format Reports
Safety Improvement through Incident Learning

Progress on the AAPM/ASTRO System

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AAPM 2013 Annual Meeting Education Session August 7, 2013
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
Relationship between organizations

• ASTRO has the contract with the Patient Safety Organization

• AAPM has Memorandum of Understanding with ASTRO (under development)

• Program is jointly sponsored (AAPM/ASTRO)
  – Web links through ASTRO and AAPM websites
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

  - Local facility
  - Initial report (brief)
  - Additional information
  - Local database
  - Send to PSO?
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  Hour: 6  Min: 47  PM
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 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 physicist
- Iteration of treatment plan
- Set up for image-guidance/motion management
- Final plan and prescription approval by physician
- Plan information transfer to radiation oncology information system
- 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 Health Advisory Council

• Summarized for reports back to participants and community at large
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
Questions?

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