

Incidence Reporting and learning: The benefits and possibilities for achieving the common goal

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Disclosures



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Sciences

I am a professor at the University of Wisconsin-Madison.

I am also the president of the non-profit Center for the Assessment of Radiological Sciences, a 501(c)(3) non-profit Patient Safety Organization listed with the Agency for Healthcare Research and Quality and dedicated to improving the safety and quality of radiotherapy. I receive no remuneration from CARS.

Learning Objectives

- To understand the valuable role that incident reporting serves
- To understand the reasons to participate in incident reporting
- To understand features of the Patient Safety Act that benefit safety and quality by supporting incident reporting
- To understand the limitations of incident reporting systems

Failure

Despite best efforts, a practice is likely to fail to accomplish the desired goal some time.

- *Failure* – not achieving the desired end or goal.
- *Incident* – a situation or actions that could have resulted, or did result, in unnecessary harm to a patient, staff or other person.
- *Event* – an incident that affected a patient, staff or other person.
- *Near event, close call, good catch* – an incident that had no affect on any person. Sometimes referred to as a *near miss*.

The Valuable Role of Incident Reporting

Keeping track of failures is useful:

- To establish statistics for benchmarking
 - How good are things going now
 - How effective have corrective actions been
- To identify hazardous procedures or activities
- To provide feedback to reporters

Reporting Systems

- Can be local
 - Important to identify problem areas
 - Applies to how practices are performed at the institution
 - Can lead to local improvements
- Can be national or international
 - While procedures are not necessarily performed the same, large amounts of data can be gathered
 - Can identify general aspects of healthcare to look at carefully

Reporting Systems for Radiotherapy

- Joint Commission for Sentinel Events- only **very** serious events
- Regulatory bodies
 - NRC – Nuclear Materials Event Database (NMED) – Serious radioactive materials events, entered by NRC investigators
 - CRCPD – Serious radiological events, entered by states investigators
- Issues
 - A regulator point of view
 - Limited searchability
 - Limited access

Reporting Systems for Radiotherapy

- FDA
 - Voluntary for users; mandatory for manufacturers
 - Only for equipment
 - No feedback
- Voluntary, international, anonymous
 - IAEA Safety in Radiation Oncology – SAFRON
 - Radiation Oncology Safety Information System – ROSIS, replaced with Radiation Oncology Safety Education Information System - ROSEIS
 - No feedback
 - Very poor data

Reasons to Participate in Incident Reporting

- In addition to the values in slide 5, for you, uncovering weaknesses in your system you would not see looking at a single event.
- For the community
 - Sharing your experiences can help others prevent similar failures,
 - Just as with a single facility, the community reports can uncover common issues.

Reasons Facilities do not Participate in Community Reporting Systems

- Bother
- Fear of release of unflattering information to the public through hacks, slips or, most importantly, *legal discovery!*

The Congressional Fix

Patient Safety and Quality Improvement Act, 2005

- Established Patient Safety Organizations (PSO) listed by Agency for Healthcare Research and Quality.
- The mission of the PSOs is to work with clients to improve their safety and quality.
- Information given to or received from a PSO is protected from discovery...with some limitations.

Patient Safety Act Confidentiality

- Several court cases have been seen challenges to the discovery shield around PSOs.
- In short, all but one have either decided for PSO confidentiality or ended with no decision.
- There is clearer demarcation on what information is NOT shielded:
 - Any information in the patient's chart
 - Any information required to be reported to regulatory or accreditation bodies
 - Information that can be found through other sources

Shielded Information

Most importantly,

- Answers to questions from the PSO,
 - Causal analysis of an event performed by a PSO,
- are shielded.

Note that none of the reporting systems we considered before are PSOs.

Radiotherapy PSOs

There are two. One is:

- Radiation Oncology – Incident Learning System (RO-ILS)
 - Operated by Clarity PSO
 - Funded by ASTRO and AAPM
 - Free to clients
 - All root-cause analysis performed by the client and information entered by client
 - Analysis of aggregated data by a committee of ASTRO and AAPM
 - Data kept by Clarity and not accessible to researchers

Radiotherapy PSOs

The other is:

- Center for the Assessment of Radiological Sciences (CARS) PSO
 - Operated by CARS PSO, a non-profit
 - Funded by small fees from clients
 - All root-cause analysis performed by CARS and information entered by CARS with the client on a video call
 - Analysis of aggregated data by CARS
 - Open to researchers

Limitations on Learning from Incident Reporting Systems

- For those run by regulatory bodies:

- Inspectors writing the narratives often do not understand the procedures,
- Inspectors may have a bias to find violations,
- Facility staff may not be forthcoming with information on failures to inspectors,
- The narrative entered is second or third hand information,
- The reports often are hard to understand and have important information missing,
- Access to the data may be prohibited,
- The inspectors are not experts in causal analysis.

Richardson S, Thomadsen B. Limitations in learning: How treatment verifications fail and what to do about it? *Brachytherapy* 18: 7-15; 2018.

Causal Analysis

This last point is very important on many levels.

- In a study of events reported to the NRC, Ostrom et al. found that the facilities' root-cause analyses almost always only found very superficial causes and did not look for systemic problems.
- They also found that the corrective actions were narrow and would only protect from an identical event.
- We have found that RCA has a very long learning curve and if not performed by analysts with a lot of experience usually is wrong.
- Analyses based on aggregated data from system with the causes and remediations determined by facilities may give incorrect conclusions.

Ostrom, L. T., P. Rathbun, R. Cumberlin, J. Horton, R. Gastorf, and T. J. Leahy. 1996. Lessons learned from investigations of therapy misadministration events. *Int J Radiat Oncol Biol Phys* 34 (1):227-34.

Limitations on Learning from Incident Reporting Systems

- For the anonymous systems or those that cannot validate analyses:

- The reporters writing the narratives often do not understand what the important information to convey is,
- The reporters' writing skill is often poor,
- The information cannot be validated or corrected by the system,
- Data in the forms is usually partially missing,
- Access to the data may be prohibited,
- The reporters are not experts in causal analysis.

Richardson S, Thomadsen B. Limitations in learning: How treatment verifications fail and what to do about it? *Brachytherapy* 18: 7-15; 2018.

Last Comments on Reporting Systems

- Capturing near events is more valuable than events because you can find barriers that work to prevent an event.
- Complete and clean data is essential to aggregate analysis.
- Events are always have multiple causes.
- This has been a VERY short discussion. There is a lot of science and work behind a good reporting system that we have not mentioned.

Summary

- Incident reporting help identify underlying causes that can lead to failures in a facility.
- Aggregated data from reporting systems can point to procedures with high risk.
- Participating with a PSO provides help to improve safety and keeps analysis data protected from discovery.
- Conclusions drawn from aggregated data that has not been validated can lead to erroneous conclusions.
