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

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Disclosures
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.

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**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

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**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

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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

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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 a 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

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
  • 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.


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.


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.

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.