



Patient Event Database

Promises and Challenges

Bruce Thomadsen, PhD

Advisory Committee on the Medical Uses
of Isotopes

Radiotherapy Database Needs

1. Consolidation of event databases
 - Obviously to reduce redundant effort.
 - To increase information on events.
 - To facilitate research on prevention.
 - To get a better estimate of numbers
2. A unified taxonomy

Radiotherapy Database Needs

- Require cooperation among groups
- Experts who have worked on database taxonomies.
- A poor taxonomy, such as used in *all* the existing databases *greatly* reduces the utility of the data.
- There is a multi-institutional group working on this now, but unofficial

Radiotherapy Database Needs

3. A carefully crafted, smart data entry method designed by experts AND users. (Nothing kills a reporting system faster than a bad interface.)
4. Carefully chosen data
 - Many types of information are necessary to address problems.

Nuclear Regulatory Commission Database

- For looking at things that the regulators need.
- Entered by the NRC investigator, who often does not understand the clinical or physical aspects of the case well.
- The licensee may not be completely forthcoming.

Where is NMED Lacking?

- All of the procedural information is in the free text, which is not useful, is incomplete and often inaccurate.
- There is little information on the case and confounding circumstances.
- There *is* the general description of the type of treatment approach (e.g. HDR afterloader.)

Radiotherapy Database Needs

5. Regulations that allow and require reporting.
 - Currently, most states have laws that prohibit release of any information on events that will have a RCA performed, which would be many events that should be entered into this database.

Radiotherapy Database Needs

6. Incentive.

- The airlines crafted a method to exempt from discipline those involved in incidents and hazardous activities *if* they report to the database immediately.
- This worked very well and improved safety greatly.

Incentive

- The incentives are absences of punishment.
- This would take a change in culture among regulatory bodies preferring patient safety to punishment.

Conclusion

- Radiotherapy needs a discipline-wide, consolidated reporting system.
- The system needs a carefully drafted taxonomy and data-entry methodology.
- The regulatory culture needs to shift focus from punishing errors to making radiotherapy safer.

Acronyms

HDR – High Dose Rate

NMED – Nuclear Materials Events
Database

NRC – Nuclear Regulatory
Commission

RCA – Root Cause Analysis