Severity Metrics

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Learning Objectives

- Understand the purpose and use of severity metrics in an incident learning system
- Review examples of severity metrics that have been used in different systems, focusing on those in recent AAPM reports
- Understand the issues and options associated with assigning severity scores to near misses
- Practice applying the severity metrics used in the AAPM/ASTRO RO-ILS system

Why use severity metrics?

- Prioritize: help decide which events to focus on first
- Characterize: describe the frequency of different event severities
- Track: identify changes in event characteristics over time

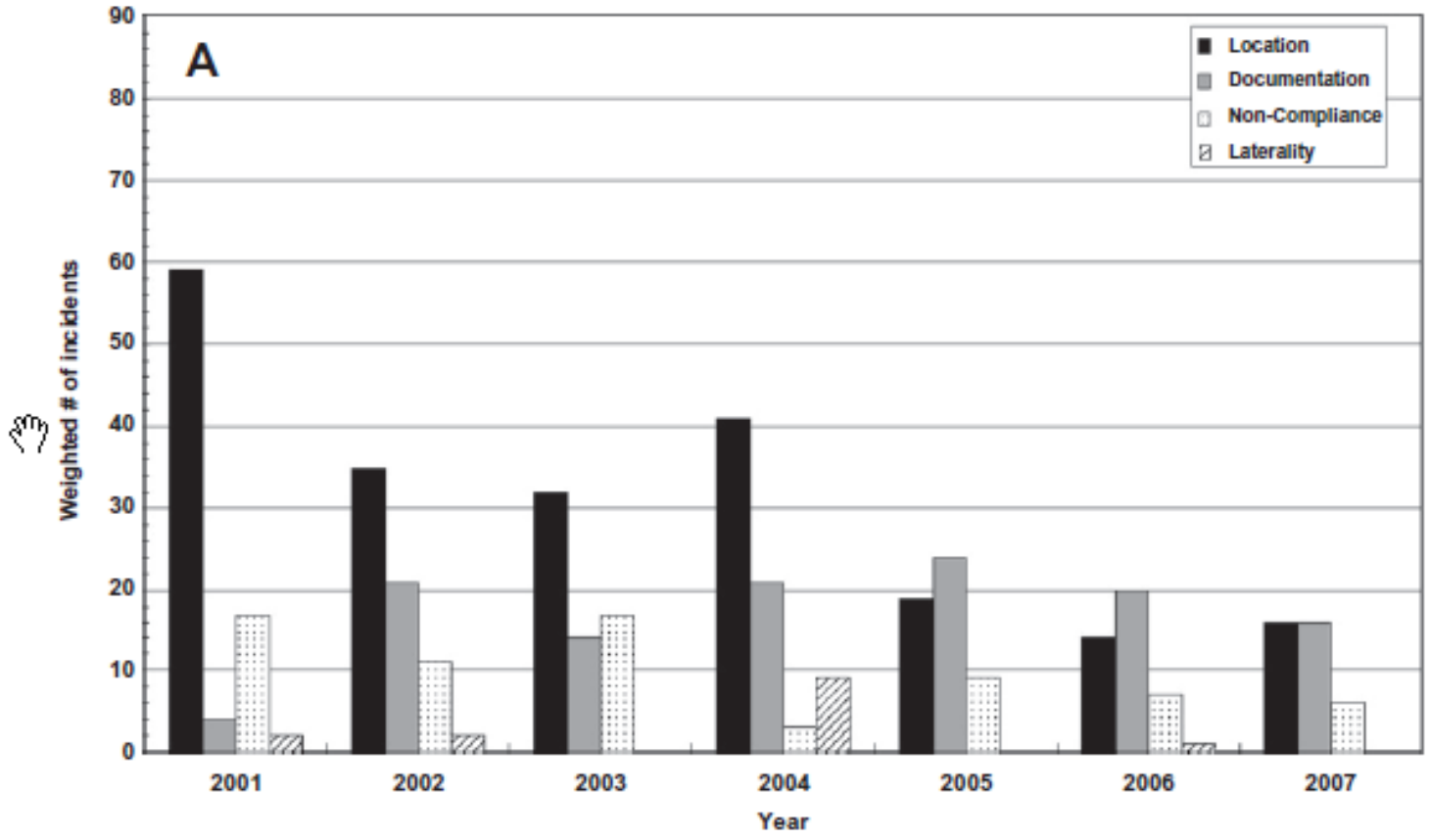
Bissonnette 2010:
1063 events at PMH over 7 yrs

Clinical impact scale

Level	Description	Score
Near miss	Caught and remedied before reaching the patient	0
None	Reached the patient; no harm	1
Minor	Reached the patient; corrected; no harm	2
Moderate	Reached the patient; correction needed; potential harm	3
Severe	Serious, undesirable, permanent unexpected outcome; dose discrepancy at least 25%	4

J.-P. Bissonnette, G. Medlam / Radiotherapy and Oncology 96 (2010) 139–144

PMH: Severity-weighted frequency of incidents over time



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To think about …

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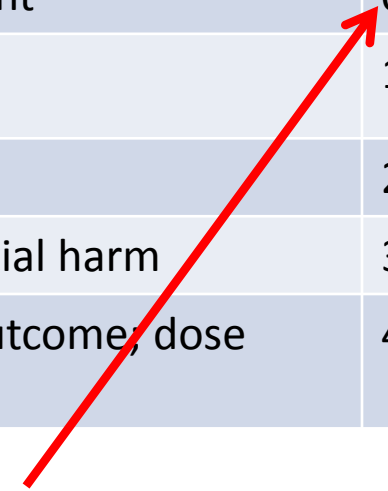

- Should a “near miss” score “0”?
  - Depends on the purpose and process
  - Want to describe what has happened to patients?
    - No harm, no foul
  - Want to characterize potential failures?
    - Assume it reached the patient

To think about …

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- How many grades are needed?
- How to describe them?

Terezakis 2013: 4407 events from Hopkins and Washington U over 4 yrs

- Analyzed using validated French Nuclear Safety Authority scale

Level	Description	Harm
0	Event with no consequences	None
1	Dosimetric but no clinical consequences	Minimal
2	Actual or potential alteration of organ or function	Moderate
3	Severe alteration of one or more organs or functions	Significant
4	Life-threatening; disabling complication or sequela	Severe
5	Death	Death

Terezakis et al.
Volume 85 • Number 4 • 2013
International Journal of Radiation Oncology • Biology • Physics
Analysis of radiation oncology incident reports for a national reporting system

Terezakis 2013: 4407 events from Hopkins and Washington U over 4 yrs

- 34% had potential for clinical consequences
- 3.4% were graded "2" or higher, i.e. at least moderate (potential) harm (149 events)
- 1.2% would considered to be of interest to a national event reporting system (79 events)

- [Note: in a robust practice improvement reporting system, most "events" are minor and of local interest]

Terezakis et al.
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TG-100 Severity Scale

Level	Description
1	No effect
2	Inconvenience
3	Inconvenience
4	Minor dosimetric error; suboptimal plan or treatment
5	Limited toxicity or tumor underdose
6	Limited toxicity or tumor underdose
7	Potentially serious toxicity or tumor underdose
8	Potentially serious toxicity or tumor underdose
9	Possible very serious toxicity or tumor underdose
10	Catastrophic

Part of FMEA: Occurrence, Severity, Detectability; each level has different O, D values;
Note: O and D are quantitative; S is qualitative

Ford 2012: AAPM Taxonomy Report

Consensus recommendations for incident learning database structures in radiation oncology

E. C. Ford, L. Fong de Los Santos, T. Pawlicki, S. Sutlief, and P. Dunscombe

Citation: Medical Physics **39**, 7272 (2012); doi: 10.1118/1.4764914
View online: http://dx.doi.org/10.1118/1.4764914

Considered many examples of severity scales and provides a consensus recommendation

Taxonomy: Medical Severity Scale

Score	Consequences (actual or predicted)
0	No harm
1	Temporary side effects – intervention not indicated
2	Temporary side effects – intervention indicated
3/4	Temporary side effects – major treatment/hospitalization
5/6	Permanent major disability (or grade 1/2 permanent toxicity)
7	Permanent major disability (or grade 3/4 permanent toxicity)
8/9	Life threatening – intervention essential. Possible recurrence due to underdose
10	Premature death

Note: near miss events should be assigned the estimated harm that would have occurred had the incident reached the patient.

Taxonomy: Dosimetric Scale

Score	Consequences (actual or predicted)
…	Not applicable
1/2	<5% absolute dose deviation from the total prescription for any structure
3/4	>5%-10% absolute dose deviation from the total prescription for any structure
5/6	>10%-25% absolute dose deviation from the total prescription for any structure
7/8	>25%-100% absolute dose deviation from the total prescription for any structure
9/10	>100% absolute dose deviation from the total prescription for any structure

Note: near miss events should be assigned the dosimetric effect that would have occurred had the incident reached the patient.

RO-ILS: Toxicity Scale

Consequences (actual or predicted)
Report not patient related
This incident refers to a latent error or condition
None or mild. Asymptomatic or mild symptoms; clinical or diagnostic observation only; intervention not indicated
Moderate. Minimal, local or non-invasive intervention indicated. Activities of daily living beyond self care (shopping, laundry, driving) may be limited.
Severe or medically significant, but not immediately life threatening. Hospitalization or prolongation of hospitalization indicated; disabling or limiting self-care activities of daily living (bathing, feeding, toileting, …)
Life-threatening consequences – urgent intervention indicated. Possible recurrence due to underdose
Premature death

Note: near miss events should be assigned the estimated harm that would have occurred had the error reached the patient.

RO-ILS: Dosimetric Scale

Description
No dosimetric effect
<5% absolute dose deviation from the total prescription for any structure
>5%-25% absolute dose deviation from the total prescription for any structure
>25%-100% absolute dose deviation from the total prescription for any structure
>100% absolute dose deviation from the total prescription for any structure

Note: near miss events should be assigned the dosimetric effect that would have occurred had the error reached the patient.

In practice: setting priorities

- How have people with incident learning systems decided which reports to delve into first?
  - Examples from E Ford, D Brown, …
- Initial RO-ILS experience: majority of reports do not have toxicity or dosimetry scale data entered

Developing RO-ILS priority scale
(from U of Washington, E. Ford)

Score	Harm	Criteria
1	None	Event does not pose downstream risk in workflow Event is not related to patient safety or quality of treatment
2	Mild	Event may enhance the risk of other downstream errors Event may cause emotional distress or inconvenience but no other clinical impact
3	Moderate	Event enhances the risk of other critical downstream errors Temporary pain or discomfort to patient Deviations from best practice, but with no obvious clinical impact
4	Severe	Limited barriers to prevention of problem Event with potential clinical impact that is non-critical
5	Critical	Extremely limited barriers to prevention of problem Event with potentially critical clinical impact

Mayo Arizona: adapted FMEA formalism applied to reported events

Score	Probability of Recurring	Dose difference	Detection
1	Remote	<5%	Found on routine application of first safety barrier
2	Low	>5%-10%	Found on exemplary application of first safety barrier
3	Moderate	>10%-25%	Found at first treatment before delivery
4	High	>25%-100%	Found during treatment
5	Certain	>100%	Found after treatment completed

Note: near miss events should be assigned the dosimetric difference that would have occurred had the error reached the patient.

Questions for discussion

- How to decide which reports should be prioritized for internal review?
- What to do with the reports not reviewed?
- How to decide which reports would be of interest externally?

For the purpose of incident learning, a "near miss"

20%	1. Is of no interest; no harm done
20%	2. Seldom provokes an RCA
20%	3. Should be treated as if it reached the patient
20%	
20%	4. Should provoke disciplinary action
	5. Should be treated the same no matter where it was found

For the purpose of incident learning, a "near miss"

- 3. Should be treated as if it reached the patient

Consensus recommendations for incident learning database structures in radiation oncology

E. C. Ford, L. Fong de Los Santos, T. Pawlicki, S. Sutlief, and P. Dunscombe

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The most common number of levels used in severity scales is

20%	1. 0 – no one uses them
20%	2. 2-3
20%	3. 4-7
20%	4. 10
20%	5. >10

The most common number of levels used in severity scales is

- 3. 4-7

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A patient with left breast cancer has her right breast simulated for treatment; this is found at planning. For the purpose of incident learning, the severity of this incident is:

20%	1. No harm
20%	2. Mild
20%	3. Moderate
20%	4. Severe
20%	5. Life-threatening

Wrong breast simulated

- 5. Life-threatening

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Mayo Arizona: adapted FMEA formalism applied to reported events

Score	Dose difference to target or organ or Potential harm*		Probability of Recurring	Detection
1	<5%	None	Remote (~0.01%)	Found on routine application of first safety barrier
2	>5%-10%	Minor	Low (~0.1%)	Found on exemplary application of first safety barrier
3	>10%-25%	Moderate	Moderate (~1%)	Found at first treatment before delivery
4	>25%-100%	Significant	High (~5%)	Found during treatment
5	>100%	Severe	Certain (>5%)	Found after treatment completed

Assign the dosimetric difference that would have occurred had the error reached the patient. *Harm scale follows Terezakis, et al.

Score is three digit number

- 100's digit: dose difference or harm
- 10's digit: probability of recurrence
- 1's digit: when detected
- Example:
  - 30% dose difference (4)
  - Might occur in 1 of similar cases (3)
  - Found at first session before treatment (3)
  - Score: 433

Why not multiply?

- See Problems with Risk Priority Numbers by Donald Wheeler http://www.qualitydigest.com/inside/quality-insider-article/problems-risk-priority-numbers.html

"both serious and trivial problems have the same RPN value, and where some trivial problems end up with larger RPN values than other, more serious, problems. This is why any attempt to use RPN values is an exercise in absurdity. Their use in the same room with a mathematician will tend to produce a spontaneous explosion. They are utter and complete nonsense."

(Thanks to Brett Miller for showing me this article.)