Ethics and the Reporting Adverse Events in the Healthcare Environment

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Definitions

“Adverse Event”
- An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.

“Near Miss”
- An event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.
“Medical Error”

- An adverse event or near miss that is preventable with the current state of medical knowledge.

“Sentinel Event”

- Term used by the Joint Commission defined as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.

**Sentinel Event**

- Serious injury specifically includes loss of limb or function.
- "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
- Such events are called "sentinel" because they signal the need for immediate investigation and response.
Medical Error Classification

How Bad Is It?
2010 ANNUAL SENTINEL EVENT SUMMARY REPORT

Sentinel Events

- Nevada now has the “Sentinel Events Registry” database.
- On 1/19/11, 119 medical facilities (including 59 hospitals) were sent a form to fill out that asked:
  A) Total # and types of sentinel events
  B) A copy of the facility patient safety plan
  C) A summary of membership & activities of patient safety committee.
## Nevada Sentinel Events

### Table 1 -- sentinel event type totals from the 2015 sentinel event report summary form

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication error</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Accidental drug overdose</td>
<td>2</td>
<td>0.5%</td>
</tr>
<tr>
<td>Accessory -- attempted</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Accessory -- attempted</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Retained foreign object</td>
<td>5</td>
<td>1.2%</td>
</tr>
<tr>
<td>Suicide</td>
<td>10</td>
<td>2.4%</td>
</tr>
<tr>
<td>Suicide -- attempted</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Transfusion</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Treatment delay</td>
<td>3</td>
<td>0.7%</td>
</tr>
<tr>
<td>Treatment error</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Wrong patient/hospital procedure</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Wrong drug/hospital procedure</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Total</td>
<td>811</td>
<td>100%</td>
</tr>
</tbody>
</table>

## How Bad Is It??

PENNSYLVANIA
PATIENT SAFETY
AUTHORITY
2011 ANNUAL REPORT
Pennsylvania

Table 1. Number of reports submitted to PA-PSRS, by facility type

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Harms</th>
<th>No Harms</th>
<th>NH HAI</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Hospital</td>
<td>5,708</td>
<td>108,651</td>
<td>294,570</td>
<td></td>
</tr>
<tr>
<td>Other Hospital</td>
<td>816</td>
<td>26,758</td>
<td>29,515</td>
<td></td>
</tr>
<tr>
<td>Ambulatory Surgery</td>
<td>1,424</td>
<td>3,513</td>
<td>4,937</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>55</td>
<td>1,396</td>
<td>294</td>
<td></td>
</tr>
<tr>
<td>Nursing Homes</td>
<td>32,761</td>
<td>32,761</td>
<td>65,522</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>8,045</td>
<td>220,790</td>
<td>228,835</td>
<td></td>
</tr>
</tbody>
</table>

(Reports submitted in 2011)

Table 4. Reports by Event Type and Submission Type for 2011

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Serious Events</th>
<th>Incidents</th>
<th>Number of Reports</th>
<th>% of Type</th>
<th>% of Total</th>
<th>Number of Reports</th>
<th>% of Type</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Errors</td>
<td>226</td>
<td>3</td>
<td>44,740</td>
<td>3%</td>
<td>1.9%</td>
<td>44,740</td>
<td>3%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Adverse Drug Reaction</td>
<td>269</td>
<td>3</td>
<td>4,827</td>
<td>0.6%</td>
<td>0.2%</td>
<td>4,827</td>
<td>0.6%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Equipment / Supplies</td>
<td>63</td>
<td>1</td>
<td>4,287</td>
<td>0.1%</td>
<td>0.0%</td>
<td>4,287</td>
<td>0.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Falls</td>
<td>2,210</td>
<td>3</td>
<td>34,430</td>
<td>15%</td>
<td>7.6%</td>
<td>34,430</td>
<td>15%</td>
<td>7.6%</td>
</tr>
<tr>
<td>Errors Related to Proac</td>
<td>719</td>
<td>1</td>
<td>47,366</td>
<td>8%</td>
<td>10.7%</td>
<td>47,366</td>
<td>8%</td>
<td>10.7%</td>
</tr>
<tr>
<td>Complications of Proac</td>
<td>3,000</td>
<td>12</td>
<td>29,485</td>
<td>1%</td>
<td>7.3%</td>
<td>29,485</td>
<td>1%</td>
<td>7.3%</td>
</tr>
<tr>
<td>Transfusion</td>
<td>27</td>
<td>1</td>
<td>2,079</td>
<td>1%</td>
<td>0.4%</td>
<td>2,079</td>
<td>1%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Skin Integrity</td>
<td>848</td>
<td>2</td>
<td>34,594</td>
<td>10%</td>
<td>7.7%</td>
<td>34,594</td>
<td>10%</td>
<td>7.7%</td>
</tr>
<tr>
<td>Other / Unclassifiable</td>
<td>818</td>
<td>4</td>
<td>18,485</td>
<td>5%</td>
<td>4.0%</td>
<td>18,485</td>
<td>5%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Total</td>
<td>8,045</td>
<td>100</td>
<td>220,790</td>
<td>100%</td>
<td>100%</td>
<td>220,790</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

\[
8,045 / 228,835 = 3.5\%
\]
### Table 4. Reports by Event Type and Submission Type for 2011

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Serious Events</th>
<th>Incidents</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Errors</td>
<td>402</td>
<td>64,760</td>
<td>44,964</td>
</tr>
<tr>
<td>Adverse Drug Reactions (not a medication error)</td>
<td>260</td>
<td>94</td>
<td>2,687</td>
</tr>
<tr>
<td>Equipment/Supplies</td>
<td>426</td>
<td>0</td>
<td>4,224</td>
</tr>
<tr>
<td>Falls</td>
<td>1,215</td>
<td>10</td>
<td>36,845</td>
</tr>
<tr>
<td>Errors Related to Procedure/Treatment/Test</td>
<td>115</td>
<td>0</td>
<td>6,374</td>
</tr>
<tr>
<td>Complications of Procedure/Treatment/Test</td>
<td>3,155</td>
<td>88</td>
<td>39,428</td>
</tr>
<tr>
<td>Transfusions</td>
<td>37</td>
<td>0</td>
<td>3,235</td>
</tr>
<tr>
<td>Skin Integrity</td>
<td>30</td>
<td>0</td>
<td>30,946</td>
</tr>
<tr>
<td>Other/Miscellaneous</td>
<td>818</td>
<td>10</td>
<td>18,416</td>
</tr>
<tr>
<td>Total</td>
<td>8,045</td>
<td>100</td>
<td>229,825</td>
</tr>
</tbody>
</table>

### Table 5. Reports by Event Type and Level of Patient Harm (2011)

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Unhailed Conditions</th>
<th>Event No. %</th>
<th>Fatal Event No. %</th>
<th>Death Event No. %</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Errors</td>
<td>2,248</td>
<td>1%</td>
<td>22%</td>
<td>22%</td>
<td>44,964</td>
</tr>
<tr>
<td>Adverse Drug Reactions</td>
<td>50</td>
<td>0.2%</td>
<td>2%</td>
<td>2%</td>
<td>1,497</td>
</tr>
<tr>
<td>Equipment/Supplies</td>
<td>539</td>
<td>2.2%</td>
<td>2%</td>
<td>2%</td>
<td>4,224</td>
</tr>
<tr>
<td>Falls</td>
<td>424</td>
<td>2%</td>
<td>18%</td>
<td>18%</td>
<td>39,428</td>
</tr>
<tr>
<td>Errors Related to Procedure/Treatment/Test</td>
<td>3,589</td>
<td>19%</td>
<td>22%</td>
<td>9%</td>
<td>6,374</td>
</tr>
<tr>
<td>Complications of Procedure/Treatment/Test</td>
<td>3,234</td>
<td>12%</td>
<td>14%</td>
<td>9%</td>
<td>39,428</td>
</tr>
<tr>
<td>Injuries</td>
<td>399</td>
<td>1%</td>
<td>7%</td>
<td>0%</td>
<td>3,235</td>
</tr>
<tr>
<td>Skin Integrity</td>
<td>1,851</td>
<td>13%</td>
<td>2%</td>
<td>0%</td>
<td>30,946</td>
</tr>
<tr>
<td>Other/Miscellaneous</td>
<td>818</td>
<td>10%</td>
<td>0%</td>
<td>0%</td>
<td>18,416</td>
</tr>
<tr>
<td>Total</td>
<td>22,779</td>
<td>13%</td>
<td>1%</td>
<td>0%</td>
<td>229,825</td>
</tr>
</tbody>
</table>

### Medical Equipment-related Events Reviewed by The Joint Commission

[Diagram showing data on medical equipment-related events reviewed by the Joint Commission]

Sentinel Events Reviewed by Joint Commission 1995-2011
How Does Respiratory Care Contribute To Medical Errors?

Sentinel Events Reviewed by Joint Commission 1995-2011

How Does Respiratory Care Contribute To Medical Errors?

History of Medical Errors Involving Respiratory Care

Medical Errors & Respiratory Care

Child killed in MRI machine by oxygen canister

VALHALLA, N.Y. (AP) — A 6-year-old boy having an MRI exam was killed when the machine’s powerful magnet caused a metal oxygen canister to fly across the room and hit him in the head.
I’v Never Made A Medical Error…
Have You EVER...
1. Administered a medication that was already D/C’d?
2. Turned off a patient’s nasal cannula during a nebulizer tx and then didn’t turn it back on?
3. Forgotten to treat a patient ordered for therapy??
4. Drawn an ABG on the wrong patient?
5. Entered the wrong settings on a ventilator patient or forgotten to set an alarm?

I Always Report A Medical Error When I Witness One….
Have You EVER...
1. Entered a patient’s room to find their nasal cannula connected to a flowmeter that’s not turned on?
2. Checked a ventilator and found that the alarms were not set or not set correctly?
3. Found a ventilator patient with an MDI adaptor inserted proximal to an HME?

Why Do ALL Errors & Near Misses Need To Be Reported?
• If errors or near misses are not reported, there is the root causes of these events will never be investigated since no one will know they are causing a problem.
• If the root causes continue to exist, the potential for another event that becomes a sentinel event remains in place.
• Many of the today’s healthcare policies are a direct result of errors or near misses that lead to the discovery of an important root cause which lead to a policy change.
Is it Ethical To Report Someone Else?

- Many people struggle with the idea of reporting a friend and/or co-worker’s error or a near miss that resulted from their action (or lack of action).
- Fear of penalty from employer to their friend/co-worker.
- Fear of retribution from employer or friend/co-worker.

The Human Element In Event Reporting

- If it didn’t happen, then it doesn’t need to be reported….it didn’t happen (near miss).
- Acceptable complication
- Fear of reprisal from:
  - Supervisor / Administration (makes them look bad)
  - Co-workers
  - Licensure Board

Cultural Issues In Event Reporting

- Work overload in healthcare
- Frustration with organization
- Fear of lost income
- “Long timers” perspective
- Punitive perspective from within
- A society that values retribution?
Human Elements...Cultural Issues... Why Bother Reporting?

- TWA Flight 514 crashed on approach to Dulles airport near Washington, D.C. killing all 85 passengers and 7 crew.
- Investigation of crash found that the pilot misunderstood an ambiguous response from the Dulles air traffic controllers, and that earlier another airline had told its pilots, but not other airlines, about a similar near miss.
- Crash lead to Aviation Safety Reporting System (ASRS). The rate of fatal accidents has dropped approximately 65%.

Is it Ethical To Report Someone Else?

- Any member of the healthcare team has the ethical responsibility to report errors, near misses and adverse events.
- Most healthcare facilities have a “Code of Ethics”.
- Healthcare workers must overcome the forces that make it difficult to report events (human, cultural, and self-imposed).

Making It Easier To Report Events and Near Misses

- In 2002, Pennsylvania enacted a new malpractice law (Act 13) in an effort to fight the growing problem of malpractice insurance.
- Act 13 included two major components:
  1. Malpractice reform processes
  2. Patient Safety section
Patient Safety Authority (PSA)

- State run agency created by Act 13
- Hospitals must report ALL serious events and "incidents" (near miss) to the PSA within 24 hours. PSA may also receive information from anonymous callers who are given legally protection by provisions in Act 13.
- The PSA develops recommendations for specific hospitals or all hospitals concerning "immediate changes that can be instituted to reduce serious events and incidents".

Patient Safety Authority (PSA)

- PSA cannot enforce recommendations but the Department of Health has authority to do so.
- Hospitals are now required by law to *notify patients of a serious event* within seven days of that event. A "serious event" is an event or situation which produces either: (1) a death or (2) compromises patient safety *and* (i) results in an unanticipated injury (ii) which requires additional healthcare.

Patient Safety Authority (PSA)

- Hospitals must have a Patient Safety Plan and part of the plan must include a Patient Safety Committee and a Patient Safety Officer must be identified.
- A 24 hour reporting mechanism must be in place to allow hospital employees to report serious events and incidents (can be a hotline but this is not required).
Act 13 – Reporting, Reporting, Reporting!

1. Healthcare workers must report serious events and incidents to the hospital. Section 308(a).

2. The hospital must report serious events to the PSA within 24 hours of confirmation of the occurrence. Section 313(a).

3. The hospital has to report serious events to the patient within 7 days. Section 308(b).

4. Physicians have to report all notices of lawsuits (e.g., complaints) to the State Licensing Board. Section 903.

Act 13 – Reporting, Reporting, Reporting!

5. The hospital has to report "infrastructure failures" to the DOH within 24 hours of confirmation of occurrence. An infrastructure failure refers to a failure of structures related to the physical plant. Section 313(c).

6. The hospital has to report licensed personnel to their respective State Licensing Board if it discovers that the individual should have reported a serious event but did not. Section 314(e).

How Does This Effect Respiratory Therapists?

- Not only do RTs have an ethical responsibility to report serious events and near misses, they have a LEGAL responsibility to do so.

- Note that hospitals are required, by law, to "Report licensed personnel to their respective State Licensing Board if it discovers that the individual should have reported a serious event but did not."

Tom Lamphere BS, RRT, RPFT
Scenario

- A respiratory therapist enters a patient’s room to deliver a regularly scheduled Duoneb treatment. The therapist notes that the patient is somewhat dyspnic and obtains pulse oximetry which reveals an SaO2 of 85%.
- The therapist administers the nebulizer treatment and while connecting the nebulizer tubing, notes that the flowmeter connected to the patient’s nasal cannula is shut off. The patient is ordered for O2 at 2 lpm.

Scenario

- What is the ethical responsibility of the healthcare workers involved in the case?
- Despite the fact that the patient did not suffer any permanent adverse effect from the lack of oxygen, the therapist has the ethical responsibility to report it via an internal incident report.
- The hospital’s policy will also require reporting of the event. Failure to follow policy can lead to termination from employment.
- Should the patient be told?

Scenario

- At 1300 hours, a mechanically ventilated patient is transported to the Radiology department for a CT Scan. Upon return from the study, the patient is reconnected back to their ventilator. A short time later, the patient goes into cardiac arrest and dies.
- While doing CPR, it is noted that the patient’s ventilator is in the “Stand By” mode. Upon further investigation of the internal ventilator log, it is found that the ventilator was never changed out of the Stand By mode since it was changed at the time of transport for the CT scan at 1300 hours.
Scenario

- What is the ethical responsibility of the healthcare workers involved in the case?
- What is the legal responsibility for the licensed healthcare workers involved in the case?
- What is the legal responsibility for the hospital?

Scenario

- What is the ethical responsibility of the healthcare workers involved in the case?
  - Whoever discovers that the ventilator was not changed out of the "stand by" mode has the ethical responsibility to report that information. Keeping it to themselves may mask any number of problems that could lead to a repeat of the event (i.e. equipment problem, lack of familiarity with policy & procedures, etc.)

Scenario

- What is the legal responsibility for the licensed healthcare workers involved in the case?
  - Whoever discovers that the ventilator was not changed out of the "stand by" mode has the LEGAL responsibility to report that information to the hospital administration. Failure to report the event can lead to disciplinary action by the licensing board up to and including revoking the worker’s license.
Scenario

- What is the legal responsibility for the hospital?
- Must report the incident to JCAHO
- Must report the incident to PSA
- Must report the incident to DOH
- Must report the incident to the patient’s family
- If it is found that a licensed healthcare worker did not report the incident, the hospital must report it to the employee’s licensing board.

Where Does JCAHO Fit In??

- Many of the requirements created by Act 13 are duplicates of requirements from the Joint Commission. However, there are some differences (definitions, reporting requirements, etc.) and it can be challenging for hospitals to keep everything straight.
- Therefore….

Be Nice To Your Patient Safety Officer!

What do you mean JCAHO’s here and the DOH is on it’s way?????
Do I Have To Report EVERY Error or Near Miss?

YES!

THANKS!!!