Preparing our Hospitals for Clinical Alarm Safety

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Lean Six Sigma Master Black Belt

Objectives: at the end of the session the participant will be able to explain:

- How to perform a FMEA
- When to perform a FMEA
- How to document and analyze the results of a FMEA
- How to perform a RCA
- When to perform a RCA
- How to document and analyze the results of a RCA
- How to prepare for NPSG 06.01.01 on Clinical Alarm Safety
Failure Mode and Effects Analysis (FMEA)

- Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change.

Steps in the FMEA process

- Failure modes
  - What could go wrong?
- Failure causes
  - Why would the failure happen?
- Failure effects
  - What would the consequences be of each failure?
Steps in the FMEA process

- Select a process to evaluate
- Recruit a multidisciplinary team
- Have team list all the steps in the process
- List failure modes and causes
- For each failure assign an Risk Priority Number (RPN)
- Evaluate the results
- Use RPNs to plan improvement efforts
  - Reduce harm
  - Evaluate potential impact
  - Monitor and track improvement over time

When to perform a FMEA?

- To identify and eliminate concerns early in the development of a process or new service delivery
- To examine a process prospectively for possible ways in which failure can occur, and then
- To redesign the processes so that the new model eliminates the possibility of failure
### Example of a FMEA

<table>
<thead>
<tr>
<th>Process</th>
<th>Potential Failure Modes</th>
<th>Effects of Failure Occurring</th>
<th>Severity Ranking</th>
<th>Detection Ranking</th>
<th>Root Causes</th>
<th>Strategies for Improvement</th>
</tr>
</thead>
</table>
| Remove drug from Omnicell   | 1. wrong drug selected on screen  
2. med is not there  
3. wrong strength  
4. wrong form of drug  
5. Omnicell fails  
6. wrong drug taken out | 1. med error  
2. delay in administering  
3. med error  
4. med error  
5. delay in administering  
6. med error | 3  | 2  | 2  | 1. malfunctioning Omnicell  
2. operator error  
3. pharmacy error | 1. report technical problems immediately  
2. provide education to users  
3. track errors |
| Take drug to room and use beside computer | 1. lose power  
2. wrong room  
3. lose drug  
4. distraction | 1. delay  
2. med error  
3. delay or med error  
4. med error | 3  | 2  | 2  | 1. IT difficulties  
2. nurse error  
3. equipment malfunction  
4. nurse distraction | 1. report IT problems immediately  
2. minimize nurse distractions during process |
For a quick RCA use 5 Why’s

- Comes from Toyota Lean methodology
- Question-asking method used to explore the cause/effect relationships underlying a particular problem
- Goal is to determine the root cause of a defect or problem

5 Why’s

- Five iterations is generally enough to reach a root cause
- The real root cause should point to a process
- The process is not working well or the process does not exist
- Nothing magical about 5, could be less, could be more
- Keep asking why until root cause is determined
Example of 5 why’s

- Why is a patient’s intravenous run rate wrong?
  - The previous nurse didn’t change the run rate.

- Why didn’t the previous nurse change the rate?
  - The doctor’s order had gone to the pharmacy and the medication administration record (MAR) was not updated.

- Why wasn’t the MAR updated?
  - The MAR is updated only once per day.

- Why is the MAR updated only once per day?
  - The hospital has chosen to use oral instructions for updates that happen more frequently.

- Why are oral instructions used?
  - The process was constructed a decade ago, when medication orders changed less frequently due to longer lengths of stay.

5 WHY’S TOOL

Problem statement: (One sentence description of event)

WHY?
WHY?
WHY?
WHY?
WHY?

To validate Root Cause(s) ask the following:
If you removed this Root Cause, would this event have been prevented?
**Root Cause Analysis**

- A process for identifying the factors that underlie variation in performance, including the occurrence of a possible sentinel event
- Focuses primarily on systems and processes, not on individual performance
- Identifies potential improvements that will prevent recurrence
- The product of the RCA process is an action plan that identifies the strategies that we intend to implement in order to reduce the risk of similar events occurring in the future.

**When to use RCA**

- To analyze serious adverse events
- As an error analysis tool
- To identify underlying problems that increase the likelihood of errors while avoiding the trap of focusing on mistakes by individuals
- To identify both
  - active errors (errors occurring at the point of interface between humans and a complex system) and
  - latent errors (the hidden problems within health care systems that contribute to adverse events).
RCA is a tool that helps to understand:

- What happened?
- How did it happen?
- Why did it happen?
- What can be done to prevent it from happening again?

Sources of information for RCA

- Incident report
  - A single report or aggregate
- Near Misses/Close calls
- Medication error
- Customer complaint
- Employee complaint
- Facility incident
Basic steps of RCA

1. Gather the facts using a timeline and interviews
2. Understand what happened
3. Identify root causes
4. Develop a Risk Reduction Plan
5. Evaluate effectiveness of actions

Root Cause Analysis

<table>
<thead>
<tr>
<th>Categories</th>
<th>Issues/Findings</th>
<th>Information Source Assessment – Multitude Used</th>
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</thead>
<tbody>
<tr>
<td>Patient Care Processes</td>
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<td>Human Resource Factors</td>
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<td>Environmental Management</td>
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<td>Equipment</td>
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<td>Information Management</td>
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<td>Policies &amp; Procedures</td>
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<td>Leadership</td>
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<td>Communication</td>
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<td>Patient Factors</td>
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<td>External Factors-Controllable</td>
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<tr>
<td>External Factors-Uncontrollable</td>
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</table>
Pennsylvania Patient Safety Reporting System (PA-PSRS)

- June 2004 to October 2006
- 328 alarm-related reports submitted
- 277 reports detectable by doing a FMEA
- 3 resulted in patient death

During chart check, found orders for telemetry, but monitor was never placed. Patient admitted at 3:00 p.m. and placed on monitor at 2:30 a.m.
Telemetry-monitored patient with history of a fall, who arrested. Resuscitation efforts were not successful. After the arrest, it was noted that the monitor was not recording for approximately one hour prior to arrest.

Female patient admitted to observation for chest pain, unknown etiology. Went to a medical unit and was to be placed on telemetry monitoring. Monitor was placed on patient; however, the unit was not turned on in the intensive care unit where the actual monitoring is viewed. It was discovered approximately 10 hours later.
Monitor tech was doing wave review and noted patient had frequent pauses but did not alarm. Checked arrhythmia alarms and noticed pause alarm turned off, also noted heart rate turned down to 37.

Upon making rounds, physician interrogated the stored alarms and found patient had a 4.2-second pause that was not picked up for 3 shifts after initial event occurred. Patient scheduled for permanent pacemaker.
Telemetry monitor found to be on standby at 11:09 p.m. Had been on standby since 11:09 a.m.

Patient said that his telemetry monitor came off the leads during the night. No one reapplied it, so he took the monitor off and laid it on the shelf next to his bed. This was reported to doctor, covering for another doctor.
When patient was transferred to another room at 3:58 p.m., the patient was not moved on the telemetry computer. Two days later discovered at 8:00 a.m. Telemetry was placed on wrong patient.

Two-bed room. Both patients being monitored on telemetry. This patient was assigned and connected to monitor. However, incorrect monitor number entered into telemetry system for this patient. As a result, two patients (same room) assigned same number. Both patients had same number transcribed onto telemetry strips. Several shifts lapsed prior to error being noted . . .
Patient entered into telemetry system under the wrong name. Patient having episodes of tachycardia. Telemetry strips were labeled with wrong patient name.

Initial printout for telemetry received Monday at 12:17 a.m. Since 11:00 p.m. Sunday, this patient has been hooked up to telemetry but no reading. Nurse on unit was called and confirmed patient was hooked to telemetry, but when box was checked the battery was placed incorrectly.
Patient admitted via the emergency room. Telemetry pack applied in ER and patient transferred to PCU bed A. The patient received was to be placed in bed B, patient identified and paperwork corrected on admission. At 3:30 a.m., the patient in bed B has a bradycardic episode. Staff identified that the telemetry packs were not corrected on admission and rate reported was on patient in bed A.

Patient arrived on unit at 1:10 p.m., was connected to telemetry unit as ordered, no battery inserted. Battery inserted at 2:45 when recognized by telemetry tech. Patient not monitored on telemetry for approximately 1.5 hrs.
9 categories of telemetry issues

1. Telemetry received not connected to patient, delayed in connecting, or taken off without orders
2. Telemetry data not received or recorded at central station
3. Telemetry data inaccurate or patients transceivers switched
4. Battery issues
5. Leads off
6. Lacking communication between providers

9 categories of telemetry issues (cont’d)

7. Alarm limits changed, turned off, or alarm volume turned down or off
8. Telemetry in standby mode
9. Delayed clinical response to clinical condition
RCA from PA-PSRS

- Patient misidentification
- Human/equipment error
- Alarm condition not detected
- Alarm condition not detected by ecg-qualified staff
- Ecg-qualified staff not available
- Detection of alarm condition delayed
- Verification of alarm condition delayed
- Locating patient delayed
- Intervention for alarm condition delayed

For further information

- IHI Institute for Healthcare Improvement
- ECRI Institute
- AHRQ
- AAMI
- Patient Safety organizations for Pennsylvania, Minnesota, and North Dakota