RCA²: Improving Root Cause Analyses and Actions to Prevent Harm

March 23, 2017

James P. Bagian, MD, PE
Director, Center for Healthcare Engineering & Patient Safety
Professor, Engineering and Anesthesiology
University of Michigan
jbagian@umich.edu
Learning Objectives

Upon completing this session, attendees will be able to:

- Identify methodologies and techniques leading to more effective and efficient RCAs
- List tools to improve the process of completing RCAs to increase patient safety
- Identify and demonstrate tools that assist management in the evaluation process
- To have a clear and credible report that identifies root causes and suggests strong, viable improvement strategies
Why This? Why Now?

- Same patient safety problems recur
- Root Cause Analysis has been used with highly variable success
  - Lack of standardized approach
  - Failure to identify systems level causes
  - Superficial solutions/countermeasures
  - Poor implementation of solutions
  - Lack of follow-up
Why This? Why Now?

- RCA has been advocated for >15 years with highly variable success
- Need to get real improvement
- New approach needed
- Root Cause Analysis & ACTION (RCA²)
NPSF Initiative – RCA²

- Standardize Process
- Risk-based rather than severity-based
- Systems-based approach
- Goal is real ACTION & Improvement
- Sustainable results
RCA² Elements

- Risk-based prioritization
- Non-punitive
- Timing & Team Membership
- Determination of
  - What Happened?
  - Why It Happened?
  - What Actions to Prevent Future Occurrence?
- Formulation and Implementation of Stronger Actions
- Follow-up – Measurement
- Sustainment
Risk-Based Prioritization

Why?
- Credibility – Internally and Externally
- Shared Mental Model
- Best Overall Patient Outcomes

How?
- Severity vs Likelihood (Probability)
- Actual vs Potential
- Importance of Close Calls
The Severity Categories and the Probability Categories that are used to develop the Safety Assessment Codes (SACs) for adverse and close calls are presented in the following, and are followed by information on the SAC Matrix.

**SEVERITY CATEGORIES**

1. **Key factors for the severity categories are extent of injury, length of stay, level of care required for remedy, and actual or estimated physical plant costs. These four categories apply to actual adverse events and potential events (close calls). For actual adverse events, assign severity based on the patient's actual condition.**

2. **If the event is a close call, assign severity based on a reasonable "worst case" systems level scenario. NOTE: For example, if you entered a patient's room before they were able to complete a lethal suicide attempt, the event is catastrophic, because the reasonable case is suicide.**

<table>
<thead>
<tr>
<th>Catastrophic</th>
<th>Major</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients with Actual or Potential:</strong></td>
<td>Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission) or any of the following:</td>
</tr>
<tr>
<td></td>
<td>a. Disfigurement</td>
</tr>
<tr>
<td></td>
<td>b. Surgical intervention required</td>
</tr>
<tr>
<td></td>
<td>c. Increased length of stay for three or more patients</td>
</tr>
<tr>
<td></td>
<td>d. Increased level of care for three or more patients</td>
</tr>
<tr>
<td><strong>Visitors:</strong></td>
<td>Hospitalization of one or two visitors</td>
</tr>
<tr>
<td><strong>Staff:</strong></td>
<td>Hospitalization of one or two staff or three or more staff experiencing lost time or restricted duty injuries or illnesses</td>
</tr>
<tr>
<td><strong>Equipment or facility:</strong></td>
<td>Damage equal to or more than $100,000**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Moderate</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients with Actual or Potential:</strong></td>
<td>No injury, nor increased length of stay nor increased level of care</td>
</tr>
<tr>
<td><strong>Visitors:</strong></td>
<td>Evaluated and no treatment required or refused treatment</td>
</tr>
<tr>
<td><strong>Staff:</strong></td>
<td>First aid treatment only with no lost time, nor restricted duty injuries nor illnesses</td>
</tr>
<tr>
<td><strong>Equipment or facility:</strong></td>
<td>Damage less than $10,000 or loss of any utility without adverse patient outcome (e.g., power, natural gas, electricity, water, communications, transport, heat and/or air conditioning)**</td>
</tr>
</tbody>
</table>

---

*Title 29 Code of Federal Regulations (CFR) 1960.70 and 1904.8 requires each Federal agency to notify the Occupational Safety and Health Administration (OSHA) within 8 hours of a work-related incident that results in the death of an employee or the in-patient hospitalization of three or more employees. Volunteers are considered to be non-compensated employees.*
2. PROBABILITY CATEGORIES  
   a. Like the severity categories, the probability categories apply to actual adverse events and close calls.

   b. In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs at your facility. Sometimes the data will be easily available because they are routinely tracked (e.g., falls with injury, Adverse Drug Events (ADEs)). Sometimes, getting a feel for the probability of events that are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess. Like the severity categories, the probability categories apply to actual adverse events and close calls.

   (1) **Frequent** – Likely to occur immediately or within a short period (may happen several times in 1 year).

   (2) **Occasional** – Probably will occur (may happen several times in 1 to 2 years).

   (3) **Uncommon** – Possible to occur (may happen sometime in 2 to 5 years).

   (4) **Remote** – Unlikely to occur (may happen sometime in 5 to 30 years).

3. How the Safety Assessment Codes (SAC) Matrix Looks

<table>
<thead>
<tr>
<th>Probability and Severity</th>
<th>Catastrophic</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequent</strong></td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Occasional</strong></td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Uncommon</strong></td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Remote</strong></td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

4. How the SAC Matrix Works. When a severity category is paired with a probability category for either an actual event or close call, a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk) results. These ranks, or SACs, can then be used for doing comparative analysis and for deciding who needs to be notified about the event.
Pacemaker Example
Pacemaker

- Pacemaker failed to generate a pacing pulse
- Repeated attempts to pace failed
- Turning off and on did not clear failure
- Happened previously – approx. q9months
<table>
<thead>
<tr>
<th>Safety Assessment Code (SAC)</th>
</tr>
</thead>
</table>

### Catastrophic

<table>
<thead>
<tr>
<th>Impact on Patient or Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death of a patient or permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission) or any of the following:</td>
</tr>
<tr>
<td>Disfigurement</td>
</tr>
<tr>
<td>Surgical intervention required</td>
</tr>
<tr>
<td>Increased length of stay for 3 or more patients</td>
</tr>
<tr>
<td>Increased level of care for 3 or more patients</td>
</tr>
</tbody>
</table>

### Visitors
- Hospitalization of 1 or 2 visitors

### Moderate

<table>
<thead>
<tr>
<th>Impact on Patient or Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased level of care for 1 or 2 patients</td>
</tr>
</tbody>
</table>

### Minor

<table>
<thead>
<tr>
<th>Impact on Patient or Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor injuries or illnesses</td>
</tr>
</tbody>
</table>

### Frequency & Probability

<table>
<thead>
<tr>
<th>Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
</tr>
<tr>
<td>Occasional</td>
</tr>
<tr>
<td>Uncommon</td>
</tr>
<tr>
<td>Remote</td>
</tr>
</tbody>
</table>

### Severity & Probability

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

### Table

<table>
<thead>
<tr>
<th></th>
<th>Minor</th>
<th>Moderate</th>
<th>Major</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

---

- **Visitors**: A death or a hospitalization of 1 or 2 patients.
- **Staff**: Medical expenses, lost time or restricted duty injuries or illnesses for 1 or 2 staff members, hospitalization.
- **Equipment or Facility**: Damage more than $10,000 but less than $100,000.
- **Fire**: Incipient stage or smaller.
Non-Punitive

- Why?
- Transparent and Explicit Criteria
- Concept of Blameworthiness/Just Culture
- NOT BLAMELESS!!!
Timing

- Having an established RCA\textsuperscript{2} team in place or mechanism to convene one quickly allows for a rapid appropriate response. Be prepared.
- The patient is the first priority
  - Medical care and treatment
  - Disclosure to the patient and family
- Make the environment safe
- Preserve evidence
  - Sequester medical equipment
  - Find out what has occurred
Timing

– Needs to be appropriately resourced. A commitment to the RCA\(^2\) process.
– Review process should begin within 72 hours. Completed within 30-45 days.
– Scheduled meetings in place. 1½ to 2 hours for each meeting.
– RCA process takes more than 1 meeting.
– Requires team member work between meetings.
Team Membership
Team Membership

– Fundamental knowledge of subject area and RCA process.
– Conflict of interest minimized – should not include those that are part of event.
– Consider limited membership: 4-6 team members.
– Team Leader: Experienced and skilled
The Role of Patient / Family

- Patient representative should be considered
- Involved patient / family has role...but not on team
- Issues to consider
  - Ability and willingness to participate
  - Psychological and legal barriers
Flow Diagramming
(Event Story Map)
Why Use Flow Diagramming?

– Ensures the team has a common understanding of the adverse event
– Permits the team to conduct a gap analysis
– Provides a platform to build upon
– Can act as a road map for the analysis
Event Story Map

- Chronological order
- Include primary events, facts, vulnerabilities, pertinent negatives
- Compare what happened to what should have happened
- Identify where barriers exist or are needed
- ESM may serve as final report when combined with root cause/contributing factors, actions & outcome measures
How Is It Constructed?

– Build the flow diagram using post-it notes and an easel
– Stick with the known facts
– Start with the known facts chronologically construct what happened
Needs

• Identify team questions
• Review and add Triggering Questions
• Identify who needs to be interviewed
Triggering Questions
Triggering Questions* (TQ)

TQ.1 Was communication (verbal or written) between staff or between organizational layers a factor in this adverse event?

TQ.2 Was equipment/automation available to support the work processes? If no, is it needed? If yes, did its design contribute to the adverse event?

TQ.3 Were the equipment, automation, and physical environment properly maintained?

TQ.4 Did the design or configuration of the physical environment contribute to the adverse event?

TQ.5 Was lighting adequate to complete the task(s)?

TQ.6 Were there continuous or intermittent distractions (i.e., audible, physical, or visual) that may have contributed to this adverse event?

TQ.7 Was workload, scheduling, and/or fatigue an issue?

TQ.8 Was the number of staff and supervision of staff adequate?

TQ.9 Did staff have the proper level of knowledge/training to perform their duties (i.e. was competency an issue)?

TQ.10 Is there a mechanism in place to assure that staff is competent to perform their required duties?

TQ.11 Did the policies and standard operating procedures adequately address the tasks being completed and were they communicated to the staff?

TQ.12 Are there new barriers needed, or existing barriers that require reinforcement, to prevent this adverse event from reoccurring? Note: Barriers protect patients from adverse events and can be physical (e.g., negative/positive pressure rooms) or procedural (e.g., timeout prior to surgery).

*Rephrase the Triggering Questions to fit the specific situation being investigated.
### Create an Interview Plan – the WHAT

<table>
<thead>
<tr>
<th>Team Questions</th>
<th>Surgical Resident</th>
<th>Surgical Faculty</th>
<th>Circulating Nurse &amp; Relief</th>
<th>Scrub Nurse &amp; Relief</th>
<th>Scrub Tech &amp; Relief</th>
<th>Anesthesia Resident</th>
<th>OR Manager</th>
<th>Floor RN on Unit</th>
<th>RN Supervisor on Unit</th>
<th>OR Biomedical Engineer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 2, 3, 7, 11, 14</td>
<td>1, 2, 3, 7, 11, 14</td>
<td>3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13</td>
<td>3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13</td>
<td>3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13</td>
<td>3</td>
<td>2, 3, 13</td>
<td>14</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triggering Questions</td>
<td>1, 6, 7, 11</td>
<td>1, 6, 7, 11</td>
<td>1, 2, 3, 4, 5, 6, 7, 8, 9, 11</td>
<td>1, 2, 3, 4, 5, 6, 7, 8, 9, 11</td>
<td>1, 2, 3, 4, 5, 6, 7, 8, 9, 11</td>
<td>2, 3, 7, 8, 9, 10, 11</td>
<td>7, 8, 9, 10, 11</td>
<td>2, 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Needs

Divide work among team members
Conduct interviews
Review documents
Complete Event Story Map
Interviewing
Interviewing

– RCA² Appendix 3 provides Tips for the Interviewing Process

– Requires Preparation and Thought by RCA² team

– Experienced Interviewers can be invaluable, it is a skill

  – “Just the Facts”

  – Be a Good Listener
Causation
Causation Determination

– Systems-based approach
– Human Factors Engineering techniques
– Timeline – graphical representation
– Triggering Questions
– Interviews: staff, patients, others
– Literature
– Past experience
– Event Story Map ➔ Cause & Effect Diag.
When to Use Cause and Effect Diagramming

- After the Event Story Map is Completed
- Before the Root Cause Contributing Factors are Identified
Cause & Effect Diagram – the WHY

Start with Problem Statement

Identify at least one action and several conditions

*Actions are momentary and fleeting*

*Conditions exist over time*

Complete diagram by answering “caused by” question
Actions: Momentary, fleeting
Conditions: Exist overtime
Primary causes: Without these present, event would not have happened
“5 Rules” of Causation

1. Show cause and effect
2. Use specific and accurate descriptors; avoid vague and negative words
3. Human errors must have a preceding cause
4. Violations of policy are not root causes
5. Failure to act is only causal when there is a pre-existing duty to act.
5 Rules of Causation

• Why use the 5 Rules?
  – Assist us in avoiding typical reactions to error (blame and train)
  – Leads to deeper analysis and effective (stronger) interventions
  – Address why something occurred, not who is responsible
  – Make sure focus on process and system vulnerabilities, not individuals

Adapted for patient safety by the VA NCPS from work done by David Marx in aviation industry
### Tips for writing RCCFs:

<table>
<thead>
<tr>
<th></th>
<th>“Cause”</th>
<th>Something Leads to something Which increases the likelihood that the adverse will occur</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>“Cause”</td>
<td>Something</td>
</tr>
<tr>
<td>2</td>
<td>“Effect”</td>
<td>Leads to something</td>
</tr>
<tr>
<td>3</td>
<td>“Event”</td>
<td>Which increases the likelihood that the adverse will occur</td>
</tr>
</tbody>
</table>

A high volume of activity and noise in the ED led to the resident being distracted when entering medication orders which increased the likelihood that the wrong dose would be ordered.
5 Rules of Causation

Rule 1. Clearly show the “cause and effect” relationship.

– INCORRECT: A resident was fatigued.

– CORRECT: Residents are scheduled 80 hours per week, which led to increased levels of fatigue, increasing the likelihood that dosing instructions would be misread.
Rule 2. Use specific and accurate descriptors for what occurred, rather than negative and vague words.

Avoid negative descriptors such as:

- “Poor”
- “Inadequate”
- “Wrong”
- “Bad”
- “Failed”
- “Careless”
5 Rules of Causation

Rule 2 example

– INCORRECT: The poorly written manual.....

– CORRECT: The pumps user manual had 8 point font and no illustrations; as a result nursing staff rarely used it, increasing the likelihood that the pump would be programmed incorrectly.
5 Rules of Causation

Rule 3. Human Errors must have a preceding cause


Human error is not the cause of failure, it is the effect or symptom of deeper trouble in a system

Human errors are the starting point for an investigation
5 Rules of Causation

Rule 3 example

– INCORRECT: The resident selected the wrong dose which led to the patient being overdosed

  **Cause**

– CORRECT: Drugs in Computerized Physician Order Entry (CPOE) system are presented to the user without sufficient space between the different doses on the screen, increasing the likelihood that the wrong dose could be selected, which led to the patient being overdosed. **Effect**
5 Rules of Causation

Rule 4. Violations of procedure are not root causes, but must have a preceding cause

- INCORRECT: The techs did not follow the procedure for CT scans which led to the patient receiving an air bolus from an empty syringe, resulting in a fatal air embolism.

- CORRECT: Noise and confusion in the prep area, coupled with production pressures increased the likelihood that steps in the CT scan protocol would be missed, resulting in the injection of an air embolism from using an empty syringe.
Rule 5. Failure to act is only causal when there is a pre-existing duty to act.

- INCORRECT: The nurse did not check for STAT orders every half hour, which led to a delay in the start of anticoagulation therapy, increasing the likelihood of a blood clot.

- CORRECT: The absence of an assignment for designated RNs to check orders at specified times increased the likelihood that STAT orders would be missed or delayed, which led to a delay in therapy.
Root Cause/Contributing Factors

• Address system vulnerabilities identified in Event Story Map and/or Cause and Effect diagram

• Must meet the 5 Rules of Causation
  – Focus on system issues not individuals
  – Convey need to approving official
Review of the “5 Rules”

1. Show cause and effect
2. Use specific and accurate descriptors; avoid vague and negative words
3. Human errors must have a preceding cause
4. Violations of policy are not root causes
5. Failure to act is only causal when there is a pre-existing duty to act.
Every RCA2 report **must have** at least one RCCF statement.

<table>
<thead>
<tr>
<th>Root Cause/Contributing Factor (RCCF) Statement #1:</th>
<th></th>
</tr>
</thead>
</table>
Pacemaker Example
Causation(s)

1. Lack of familiarity with the failure modes and associated corrective actions of the pacemaker and its documentation (cause) resulted in the inability of the care providers to be able to restore the pacemaker to proper operation (effect) delaying care to the patient with potentially catastrophic results (event).
2. The pacemaker design (cause) permitted a keyboard input during the startup period to result in a malfunction rendering the pacemaker unusable (effect) depriving the patient of care with potentially catastrophic results (event).
Actions
Actions

• *The* most important step
  – Aim
    – Prevent recurrence
    – Reduce risk of recurrence
      » Probability and/or severity
  – Ensure each action coupled to cause
  – Use action hierarchy
    – Focus on strength of action
  – No censorship!
Human Factors Engineering and “Actions”

– Warnings and labels (watch out!)
– Training (don’t do that)
– Procedure changes (work around that)
– Interlock, lock-in, lock-out, etc (let me design it so you can not do that – forcing functions)
– Is there one right action???
<table>
<thead>
<tr>
<th>Stronger Actions</th>
<th>Action Category</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Architectural physical plant changes</td>
<td>Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.</td>
<td></td>
</tr>
<tr>
<td>New devices with usability testing</td>
<td>Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.</td>
<td></td>
</tr>
<tr>
<td>Engineering control (forcing function)</td>
<td>Eliminate the use of universal adaptors and peripheral devices for medical equipment and using tubing and connectors that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).</td>
<td></td>
</tr>
<tr>
<td>Simplify process</td>
<td>Remove unnecessary steps in a process.</td>
<td></td>
</tr>
<tr>
<td>Standardize on equipment or process</td>
<td>Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.</td>
<td></td>
</tr>
<tr>
<td>Tangible involvement by leadership</td>
<td>Participate in unit patient safety evaluations and interact with staff; support the RCA² process; purchase needed equipment; ensure staffing and workload are balanced.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intermediate Actions</th>
<th>Redundancy</th>
<th>Use two RNs to independently calculate high-risk medication dosages.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase in staffing/decrease in workload</td>
<td>Make float staff available to assist when workloads peak during the day.</td>
<td></td>
</tr>
<tr>
<td>Software enhancements, modifications</td>
<td>Use computer alerts for drug-drug interactions.</td>
<td></td>
</tr>
<tr>
<td>Eliminate/reduce distractions</td>
<td>Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.</td>
<td></td>
</tr>
<tr>
<td>Education using simulation-based training, with periodic refresher sessions and observations</td>
<td>Conduct patient handoffs in a simulation lab/environment, with after action critiques and debriefing.</td>
<td></td>
</tr>
<tr>
<td>Checklist/cognitive aids</td>
<td>Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiberoptic endoscopes.</td>
<td></td>
</tr>
<tr>
<td>Eliminate look and sound-alikes</td>
<td>Do not store look-alikes next to one another in the unit medication room.</td>
<td></td>
</tr>
<tr>
<td>Standardized communication tools</td>
<td>Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.</td>
<td></td>
</tr>
<tr>
<td>Enhanced documentation, communication</td>
<td>Highlight medication name and dose on IV bags.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weaker Actions</th>
<th>Double checks</th>
<th>One person calculates dosage, another person reviews their calculation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warnings</td>
<td>Add audible alarms or caution labels</td>
<td></td>
</tr>
<tr>
<td>New procedure/memorandum/policy</td>
<td>Remember to check IV sites every 2 hours</td>
<td></td>
</tr>
<tr>
<td>Training</td>
<td>Demonstrate the hard-to-use defibrillator with hidden door during an in-service training.</td>
<td></td>
</tr>
</tbody>
</table>
Pacemaker
Example
Corrective Action(s)

1. Immediately label all pacemakers to indicate remedy for pacemaker malfunction so that knowledge or referral to the instruction manual is unnecessary.
WARNING: If error code 0004 appears immediately release battery door. REMOVE battery until error message clears. REINSTALL battery
Corrective Action(s)

2. Change software in pacemaker so that the keyboard is not active during the vulnerable start up period where pacemaker malfunction can be introduced
“Strength of Actions”

- **Warnings and labels** (watch out!)
- **Training** (don’t do that)
- **Procedure changes** (work around that)
- **Interlock, lock-in, lock-out**, etc (let me design it so you can not do that – forcing functions)
- Seldom just one right action

Weak

Stronger
Measuring Effectiveness
We Manage What We Measure
Actions Without Measure Cannot Show Success
Measuring Effectiveness

- Must Address the Causation Statement
- Measurement Doesn’t Have to be Complicated
- Make the Measures Specific and Understood
Measuring Effectiveness

• Accountability is Key
  ▪ A specific person
  ▪ By a date certain

• Know what will be measured, how it will be measured, by whom it will be measured, and date it will be measured.
Determine the Outcomes You Want to Achieve

- **Process Measures** - focus on how well and how often intervention(s) are carried out.
- **Outcome Measures** – what will occur because the designed and selected interventions are performed.
- **Clinical Outcomes** - clinical results that you will see as a result of the selected interventions.
Measuring Effectiveness

• Examples

  – Process Measure
    – 85% of staff will be compliant with the established patient rounding process within 4 weeks of training and implementation

  – Outcome Measure
    – There will be 25% fewer falls in the 3rd quarter, when compared to the 1st quarter of the calendar year.
Pacemaker Example
### Root Cause/Contributing Factor (RCCF) Statement #1:

| Lack of familiarity with failure modes and assoc. corrective actions of pacemaker and its documentation resulted in the inability of care providers to be able to restore the pacemaker to proper operation and thus delayed care to the patient with potentially catastrophic results. |

### Action 1.

| Immediately label all pacemakers to indicate remedy for pacemaker malfunction so that knowledge or referral to the instruction manual is unnecessary. |

| Completion Date: | 24 hrs after transmission of the requirement |

| Responsible Person: | Chief of Clinical Engineering |

### Outcome Measure 1. (Each Outcome Measure needs to include: what will be measured; how long it will be measured; and the expected level of compliance.)

| All Pacemakers will be confirmed to have the appropriate labeling in place |

| Measure Date: | 48 hrs after transmission of requirement to label pacemakers |

| Responsible Person: | Chief of Patient Safety |

| Was the Compliance Level Met? | Y/N |

| Management Concurs with this Action and Outcome Measure | Y/N |

| If No, why not? |  |

<p>| Is the identification of another action required? | Y/N |</p>
<table>
<thead>
<tr>
<th>Root Cause/Contributing Factor (RCCF) Statement #2:</th>
<th>Pacemaker design that permitted keyboard input during vulnerable start up period resulted in malfunction that made pacemaker unusable and deprived patient of care with potentially catastrophic results.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action 2.</td>
<td>Change software in pacemaker so that the keyboard is not active during the vulnerable start up period where pacemaker malfunction can be introduced</td>
</tr>
<tr>
<td>Completion Date:</td>
<td>6 months from issuance of action</td>
</tr>
<tr>
<td>Responsible Person:</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>Outcome Measure 2. (Each Outcome Measure needs to include: what will be measured; how long it will be measured; and the expected level of compliance.)</td>
<td>Pacemaker will be unable to placed in the Error 0004 condition</td>
</tr>
<tr>
<td>Measure Date:</td>
<td>7 months from the issuance of action</td>
</tr>
<tr>
<td>Responsible Person:</td>
<td>Chief of Clinical Engineering</td>
</tr>
<tr>
<td>Was the Compliance Level Met?</td>
<td>Y/N</td>
</tr>
<tr>
<td>Management Concurs with this Action and Outcome Measure</td>
<td>Y/N</td>
</tr>
<tr>
<td>If No, why not?</td>
<td></td>
</tr>
<tr>
<td>Is the identification of another action required?</td>
<td>Y/N</td>
</tr>
</tbody>
</table>
Measuring Effectiveness

• Provide Feedback on Results
  – To Leadership
  – To Staff
  – To Patients and Families

• Celebrate Wins!

• Maintain the Gain - Sustainment
Measuring Effectiveness

• Need to Know
  – Has there been compliance with the Action Items?
  – Were Action Items Effective?
  – Is further Corrective Action Needed?
  – Should there be a different approach?
Leadership & Boards
Leadership & Boards

• Leadership support **critical** to success
  – Who?
    • CEO and Board
  – What?
    • Approval of actions
    • Rationale for actions not approved
    • Considering organization-wide applicability
  – How?
    • Assess actions against Hierarchy
    • Be cognizant of “red flags”
Warning Signs of an Ineffective RCA²

- Contributing factors absent or lack supporting data or information.
- Human error identified as causing the event.
- Causal statements do not comply with Five Rules of Causation (Appendix 6).
- No stronger or intermediate strength actions are identified.
- No corrective actions are identified, or the corrective actions do not address identified system vulnerabilities.
- Action follow-up is assigned to a group and not to an individual.
- Actions do not have completion dates or meaningful measures.
- The event review took longer than 45 days to complete.
- There is little confidence that corrective action will significantly reduce the risk of future occurrences of similar events.
Summary

- Active leadership participation
- Blameworthy Definition
- Transparent Risk-Based Prioritization
- Timeliness
- Team Composition
- Tools: Triggering Questions, Five Rules of Causation, Action Hierarchy, etc.
- Feedback
Download the full PDF report for free at:

www.npsf.org/RCA2