Infection-Related Root Cause Analysis
Denise Murphy, RN, MPH, CIC
A Webber Training Teleclass

Objectives
- Be able to define and identify Sentinel Events (SE)
- Have an understanding of the steps involved in a Root Cause Analysis (RCA) process
- Compare steps in SE and outbreak investigations, and performance improvement methodology
- Discuss one example of infection-related RCA

I'd like to acknowledge...
The infection control, patient safety, performance improvement & risk management experts that I have learned from, especially those who were kind enough to allow me to blend their ideas or slides with mine:
- Jan McDonald & Teresa Garrison from the Center for Healthcare Quality and Effectiveness and the ICHE Consortium, BJIC Health Care.
- Pat Matt, Jeanne Zack and Trish Hill, HEIC and PI, Barnes-Jewish Hospital
- Janet Frain, Gigi Dash and Marie Kasai, APIC Board
- Linda Goss, Ruth Carrico, Infection Control Dept, University of Kentucky Medical Center
And of course, the Academy

What is Root Cause Analysis?
- A process for identifying the basic or causal factors that underlie variation in performance.
- This process should be used to identify risk that led to a sentinel event (SE)

What is a Sentinel Event?
- “An unexpected occurrence involving death or serious physical or psychological injury or risk thereof.”

Examples of Sentinel Events
- Death resulting from a medication error or other treatment related error
- Suicide of a patient in a setting where they receive around-the-clock care
- Surgery on the wrong patient or body part regardless of the magnitude of the operation
- Hemolytic transfusion reaction involving the administration of incompatible blood or blood products
- Infection-related death or permanent disability
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**JCAHO - Categories of reported SE**

<table>
<thead>
<tr>
<th>Event</th>
<th>#SE</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient suicide</td>
<td>382</td>
<td>15%</td>
</tr>
<tr>
<td>Op/post-op</td>
<td>330</td>
<td>12.9</td>
</tr>
<tr>
<td>Wrong-site surgery</td>
<td>310</td>
<td>12.1</td>
</tr>
<tr>
<td>Medication error</td>
<td>291</td>
<td>11.4</td>
</tr>
<tr>
<td>Delay in treatment</td>
<td>172</td>
<td>6.7%</td>
</tr>
<tr>
<td>Restraint death/injury</td>
<td>172</td>
<td>4.4%</td>
</tr>
<tr>
<td>Patient fall</td>
<td>114</td>
<td>4.5%</td>
</tr>
<tr>
<td>Assault/rape/homicide</td>
<td>89</td>
<td>3.5%</td>
</tr>
<tr>
<td>Transfusion error</td>
<td>73</td>
<td>2.9%</td>
</tr>
<tr>
<td>Perinatal death</td>
<td>71</td>
<td>2.8%</td>
</tr>
<tr>
<td>Patient on floor</td>
<td>48</td>
<td>1.9%</td>
</tr>
<tr>
<td>Fire</td>
<td>45</td>
<td>1.8%</td>
</tr>
<tr>
<td>Anesthesia event</td>
<td>38</td>
<td>1.5%</td>
</tr>
<tr>
<td>Med equipment</td>
<td>33</td>
<td>1.3%</td>
</tr>
<tr>
<td>Vent death/injury</td>
<td>39</td>
<td>1.5%</td>
</tr>
<tr>
<td>Maternal death</td>
<td>31</td>
<td>1.2%</td>
</tr>
<tr>
<td>Infant abduction</td>
<td>19</td>
<td>0.7%</td>
</tr>
<tr>
<td>Transfer death</td>
<td>10</td>
<td>0.7%</td>
</tr>
<tr>
<td>Other</td>
<td>297</td>
<td>11.6%</td>
</tr>
</tbody>
</table>

**Sentinel Event Outcomes**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>#SE</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient death</td>
<td>2,000</td>
<td>75%</td>
</tr>
<tr>
<td>Loss of Function</td>
<td>268</td>
<td>10%</td>
</tr>
<tr>
<td>Other</td>
<td>399</td>
<td>15%</td>
</tr>
<tr>
<td>Total patients impacted</td>
<td>2,667</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Settings**

**Root Causes**

<table>
<thead>
<tr>
<th>Event</th>
<th>#SE</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>BJH 2003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication</td>
<td>9</td>
<td>100%</td>
</tr>
<tr>
<td>Orientation/teaching</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staffing levels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Availability of info</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competency/understanding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedural compliance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical environment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organization culture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alarm systems</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Most Common Root Causes of Medical Errors:**

1. Communication problems
2. Inadequate information flow
3. Human problems
4. Patient-related issues
5. Organizational transfer of knowledge
6. Staffing patterns/work flow
7. Technical failures
8. Inadequate policies and procedures
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JCAHO 2004 Patient Safety Goal #7

- Comply with current CDC hand hygiene guidelines
- Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a healthcare-acquired infection

What are the issues ICPs need to address?

- Issue 1:
  - "Unanticipated death" or "permanent loss of function" related to HAI is grossly underreported
  - ANY unanticipated death or permanent loss of function should always be considered a sentinel event
- Issue 2:
  - All SE should be investigated
  - SE are investigated using root cause analysis (RCA)
  - Hence, National Patient Safety Goal #7: "All unanticipated deaths or permanent disability related to nosocomial infections should be handled as a sentinel event"
- Issue 3:
  - All reporting of SE to JCAHO is "voluntary"...but JCAHO does encourage reporting
  - WHY? RCA results in identifying risk factors
- Issue 4:
  - NPSG #7 requires 100% compliance
  - Interpretation: You don't have to report them all, you do have to investigate them all, so you better know how to find them!

Why the Focus Now?

- Institute of Medicine report on the Quality of Healthcare in America (1999)
  - In 1997 more Americans died because of medical error than because of auto accidents (43,458), breast cancer (42,297), or AIDS (16,516).
- The Harvard Medical Practice Study (1984)*
  - 98,609 adverse events, 27,179 of which were due to negligence
  - 2,550 suffered permanent total disability
  - 13,451 died, at least in part as a result of the adverse event
- The Colorado and Utah Study (1992)
  - In 1992, an estimated 5,614 adverse events occurred in Utah and 11,578 in Colorado.
  - In-patients only*

Proportion of Adverse Events

<table>
<thead>
<tr>
<th>Harvard Medical Practice Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-surgical</td>
</tr>
<tr>
<td>25%</td>
</tr>
</tbody>
</table>

Why include IC in NPSG?

- CDC estimates 2 million patients/year are infected
- Approximately 90,000 die (1 death every 6 minutes)
- Cost over $4.5 billion
- 250,000 central venous catheter-related bloodstream (CRBSI)/year
  - Attributable mortality 12%-25%
  - $25,000 per episode

Thanks Teresa

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What do ICPs bring to the RCA process?

- Ability to investigate outbreaks and identify risk factors associated with infectious events
- Data collection, organization, analysis
- Familiarity with use of standards and prevention guidelines
- Experience in literature search
- Working with multidisciplinary teams

What happens once the ICP identifies a SE?

- A credible root cause analysis has to be completed within 45 days of the event occurring.
- The Joint Commission has created a framework to use to make sure all elements are addressed.
- A multidisciplinary team should tackle each of these content areas to help identify contributing factors, identify root cause, and put effective control measures in place to reduce the risk of recurrence.
- Include Risk Mgt. & Performance Improvement experts!

Source: *Framework for Investigating Infection-related Sentinel Events www.apic.org

Identifying HAI-related Sentinel Events

- Work with medical records dept. to identify all deaths
- Compare hospital deaths with your HAI database to identify potential HAI-related deaths
- Work with hospital epidemiologist or ICC chair to review chart; determine if death or disability is “unanticipated”
- Know expected mortality rate associated with type of infection
  - e.g., patients with VAP have a highly anticipated mortality rate (up to 60%); may be hard to consider VAP death as unanticipated
  - patients having elective surgery with few risk factors for SSI are not expected to die of SSI-related infection
- Unanticipated deaths should be considered SE and must be investigated

SEE ALGORITHM

Steps in Root Cause Analysis

WE NEVER MAKE MISTAKES IN OUR CLINIC, MR. SMITH!
MY NAME IS KRASCHINSKY!
### Step One: Organize a Team

- Leader(s) lay the groundwork
  - Identification and reduction of risks
  - Processes not individuals – blame
- Multidisciplinary – (10 or less)
  - May include ad hoc members

### Step Two: Define the Problem

- **First Team Meeting**
  - Establish ground rules
    - Decision making
    - Attendance
    - Meeting schedule
    - Opportunity to speak
    - Disagreements
    - Assignments

### Step Three: Study the Problem

- Collect information related to the event or possible event
  - Witness statements of those directly & indirectly involved
  - Observations
  - Physical evidence (purulent secretions at CVC insertion site)
  - Documentary evidence (“pus noted at insertion site” in progress note)
Step 4: Determine What Happened

- Flowchart the sequence of the event
  - First, chart the actual sequence of events
  - Then flowchart the ideal sequence of events (highlight the differences)
  - Flowchart the steps in the policy/procedure
  - Compare the gaps

Create a timeline of the events

<table>
<thead>
<tr>
<th>TIME</th>
<th>EVENTS</th>
<th>ACTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/1/04</td>
<td>Patient underwent CABG surgery CVC placed in PACU</td>
<td>Patient transferred to CTICU</td>
</tr>
<tr>
<td>4/2/04</td>
<td>CVC functioning, site looks clean, no S&amp;S infection</td>
<td>ICU RN pulled line out prior to transfer to step down unit. Pus noted at insertion site. Antibiotics started 0620.</td>
</tr>
<tr>
<td>4/3/04</td>
<td>Patient transferred to step down unit at 1800</td>
<td>Attending notified, blood cultures ordered and drawn at 0540. Antibiotics started 0620.</td>
</tr>
<tr>
<td>4/4/04</td>
<td>Pt. developed fever and shaking chills at 0600</td>
<td>Code called 0606</td>
</tr>
<tr>
<td></td>
<td>Nurse found patient unresponsive, no pulse or respirations at 0655</td>
<td>Code called 0606</td>
</tr>
<tr>
<td></td>
<td>Patient expired 0800</td>
<td>Code called 0606</td>
</tr>
</tbody>
</table>

Step 5: Identify Contributing Process Factors

- Why did the event occur?
  - Which processes were involved in the event or could have lead to the event? (brainstorming, affinity diagrams)
  - What are the steps in the process as designed? (flowchart of policy/procedure)
  - Which steps may have contributed to the event?

Continue asking why the event occurred?

- What is currently done to prevent failure at this step? (fault tree analysis)
- Was it done? (barrier analysis)
- If not, why?
- What additional services/departments are effected?
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Step 6: Identify Other Contributing Factors

- Minimal Scope of Root Cause Analysis for Specific Types of Sentinel Events (see next slide)

SAMPLE:
FISHBONE DIAGRAM
Sharps Injury in OR

Step 6: Identify Other Contributing Factors

Step 7: Measure - Collect & Assess Data

(Proximate and Underlying Causes)
- Baseline data – is this a one time event or a trend?
- Measure a process or step in a process
- Assess effectiveness of improvement interventions
- Measurements should be rate-based
  » % central lines placed in femoral sites
  » CVC-BSI/1,000 line days in CTICU
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Step 8:
Design and Implement Interim Changes

- Fix low hanging fruit

- Create a timeline, Gantt chart or implementation tree to help the team & administration view key steps and time frames needed to complete each step

Example Gantt Chart

<table>
<thead>
<tr>
<th>ID</th>
<th>Task Name</th>
<th>Start</th>
<th>Finish</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Fix the overhead light to maintain position</td>
<td>Feb 2002</td>
<td>Mar 2002</td>
<td>3/3</td>
</tr>
<tr>
<td>2</td>
<td>Analyze current data for BSE in the OR</td>
<td>2/15/2002</td>
<td>2/31/2002</td>
<td>1/2w</td>
</tr>
<tr>
<td>3</td>
<td>Determine data to be collected, when &amp; by whom?</td>
<td>2/28/2002</td>
<td>3/1/2002</td>
<td>1/2w</td>
</tr>
<tr>
<td>5</td>
<td>Review data collection re: use of tool</td>
<td>4/1/2002</td>
<td>4/7/2002</td>
<td>4/6w</td>
</tr>
<tr>
<td>6</td>
<td>Data collection</td>
<td>4/12/2002</td>
<td>4/30/2002</td>
<td>1/4w</td>
</tr>
<tr>
<td>7</td>
<td>Data Analysis</td>
<td>4/12/2002</td>
<td>5/5/2002</td>
<td>4.6w</td>
</tr>
<tr>
<td>8</td>
<td>Review findings with the team</td>
<td>5/1/2002</td>
<td>5/5/2002</td>
<td>4/6w</td>
</tr>
</tbody>
</table>

Step 9: Identify Which Systems Are Involved

The Root Causes

- Identify the underlying causes for the proximate causes (using BSE example)
  - Why did the nurse wait to report the sharps injury until the end of the shift?
  - Why did the nurse not know a sharp was being handed to her?
  - Why hadn’t the nurse completed orientation?

The Root Causes

- May involve multiple causes
- Drill down using the flowcharts, fishbone, barrier analysis, FMEA or fault tree analysis
- May include factors beyond the organizations control (e.g., nursing shortage)

The Root Causes

<table>
<thead>
<tr>
<th>Proximate Cause</th>
<th>Underlying Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delay in reporting needle stick until the end of the shift</td>
<td>RN hadn’t completed last two weeks of orientation &amp; was unfamiliar with the policy re: reporting BSE immediately</td>
</tr>
<tr>
<td>Lack of clear communication when passing sharp</td>
<td>Physicians not trained on policy to 1st announce intent to pass sharp</td>
</tr>
</tbody>
</table>

Five Rules of Causation*
("Adapted from David Marx")

1 - Causal statements must clearly show the "cause and effect" relationship.
2 - Negative descriptors (e.g., poorly, inadequate) are not used in causal statements.
3 - Each human error must have a preceding cause.
4 - Each procedural deviation must have a preceding cause.
5 - Failure to act is only causal when there was a pre-existing duty to act.

http://www.patientsafety.gov/causation.html

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Step 10: Prune the List of Root Causes

Ask three questions to each cause

- Would the problem have occurred if Cause #1 had not been present?
- Will the problem recur due to the same causal factor if Cause #1 is corrected or eliminated?
- Will correction or elimination of Cause #1 lead to similar events?

If answer is NO, you have the root cause; if answer is YES, you have contributing cause.

Step 11: Confirm Root Causes

- Literature review
  - Risk – reduction strategies
    - System approach - do not blame individual (s)
    - Each stage of system development
  - Error prevention strategies
    - Systems should be designed to absorb errors
    - Look to “mistake-proof” when possible

Step 12: Explore & Identify Risk-Reduction Strategies

- Failure Mode & Effect Analysis (FMEA)
  - Look at the steps in the process
  - Flow chart the process, predict where risk or “failure modes” exist and redesign process to eliminate risk
- Determine the severity of potential cause
  - Catastrophic – death, suicide, rape,
  - Major - permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement
  - Moderate – increased length of stay
  - Minor – near miss

What is Failure Mode & Effect Analysis (FMEA)?

- “A prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome.
- “A systematic approach to identify and prevent product and process problems before they occur.”

FMEA

- Determine the probability of the potential cause or risk
  - Frequent - Likely to occur immediately or within a short period
  - Occasional - Probably will occur (may happen several times in 1 to 2 years)
  - Uncommon - Possible to occur (may happen sometime in 2 to 5 years)
  - Remote - Unlikely to occur (may happen sometime in 5 to 30 years)
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Failure Mode & Effect Analysis
Hazard Scoring Matrix

<table>
<thead>
<tr>
<th>Probability</th>
<th>Catastrophic</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>16</td>
<td>12</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Occasional</td>
<td>12</td>
<td>9</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Uncommon</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Remote</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

12
- Design a system to absorb errors
- Standardize procedures
  - Reduce variation
- Training & re-training
  - Competency assessments
- Create a safe reporting environment

Step 13: Formulate Improvement Actions
- Directed at processes
- Tools
  - Brainstorming
  - Flowchart
  - Cause & effect diagram (Fishbone)

Step 14: Evaluate Proposed Improvements
- Rank the ideas based on the criteria
  - Individuals rank each idea best to worst (1-5)
  - Then consolidate into team ranking
- Are improvement actions objective and measurable?
- Ensure team reaches consensus
- May rank according to multiple criteria
  - Cost, risk, implementation time, etc.
- Each selected improvement action should:
  - Address a root cause
  - Offer a long-term solution to the problem
  - Offer more positive then negative impact on other processes (no negative ripple effect)
  - Objective and measurable
  - Defined implementation time
  - Have assigned accountability

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Step 15: Design Improvements

- What?
  - Determine scope of actions
- How?
  - Sequence of events
  - Measurement – quantitative
- When?
  - Timeline for implementation
- Who?
  - Who owns the process – initially & eventually
- Where?
  - Clarify where each action will be implemented

Step 16: Ensure Acceptability of Action Plan

- Acceptable to the Joint Commission if:
  - Focuses primarily on systems and processes, not individual performance
  - Identifies who is responsible for implementation
  - Identifies when actions will be implemented (including pilots)
  - Identifies how the actions will be evaluated (measurement)

Step 17: Implement the Improvement Plan

- Scientific Method
  - Plan, test, study, implement
- PDSA
  - Plan, Do, Study, Act

Step 18: Develop Measures of Effectiveness & Ensure Their Success

- Collect Data
  - Team is responsible for measurement
    - Bring in organization experts (RM, PI, QI, Analyst) to design
    - Is software available?
    - Information management resources

Step 19: Evaluate Implementation Efforts

- Data analysis & presentation
  - Internal comparisons – before & after
    - Run chart, control chart, histogram
  - External comparisons – benchmarking
  - Practice guidelines/parameters
  - Performance targets, specifications or thresholds
    - NNIS, other professional organizations

Step 20: Take Additional Steps

- If meeting goals —
  - Communicate the results
  - Revise processes or procedures
  - Complete training related to new policies, processes, procedures, documentation tools, etc.
  - Plan for continued monitoring
  - Roll out improvements to other areas
    - Radiology
    - Laboratory
If NOT meeting goals —
- Ask if improvement was fully implemented
- Leadership involvement - sponsorship
- Communication gaps
- Confirm the root causes
- Identify risk reduction strategy
- Plan for continued monitoring
- Roll out improvements to other areas
- Radiology
- Laboratory

Step 21: Communicate the Results

- Communication is key THROUGHOUT the RCA process
  - Sponsorship
  - Departments/services impacted by changes (proposed changes)
  - New or revised policies
  - Celebrations/recognition for team

Joint Commission Resources
  > SE Policies & Procedures
  > Root Cause Analysis Matrix
  > Sentinel Event Statistics
  > Glossary
  > Links to other sites
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Joint Commission Resources

This publication is intended to help healthcare organizations improve processes and procedures in order to avoid critical errors. The first 12 chapters are organized according to the sentinel events most frequently reported to the Joint Commission.

Patient Safety Resources

  - The National Center for Patient Safety (NCPS) homepage
  - David Marx’s Rules of Causation
- http://www.patientsafety.gov/HFMEA.html
  - Failure Mode and Effects Analysis course online & PowerPoint presentation
- http://www.ahrq.gov/HFMEA.html
  - National Patient Safety Goals
  - Sample FMEAs

www.qualityhealthcare.org
or IHI.org

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<table>
<thead>
<tr>
<th>Other 2005 Teleclasses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>April 14</strong> - Disinfectants and Environmental Impact, with Dr. Franz Daschner</td>
</tr>
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| **April 19** - Methods for Testing Hand Disinfectants, with Dr. Manfred Rotter  
  Sponsored by Deb Medical Hand Hygiene  www.deb.co.uk |
| **April 21** - Creutzfeldt-Jakob Disease: Recommendations for Disinfection and Sterilization, with Dr. William Rutala |
| **April 28** - Overcoming the Resistance of Biofilms, with Dr. Peter Gilbert  
  Sponsored by Virox Technologies Inc.  www.virox.com |

For more information, refer to www.webbertraining.com/schedule.cfm

Questions? Contact Paul Webber paul@webbertraining.com