Infection-Related Root Cause Analysis: A Primer for the ICP

Denise Murphy, RN, MPH, CIC Chief Patient Safety and Quality Officer

> Hosted by Paul Webber paul@webbertraining.com

www.webbertraining.com

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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



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 Mc Donald & Teresa Garrison from the Center for Healthcare Quality and Effectiveness and the ICHE Consortium, BJC Health Care.
 Pat Matt, Jeanne Zack and Trish Hill, HEIC and PI, Barnes-Jewish Hospital

Pat Matt, Jeanne Zack and Trish Hill, HEIC and PI, Barnes-Jewish Hospital
 Janet Frain, Gigi Dash and Marie Kasai, APIC Board

And of course, the Academy



Linda Goss, Ruth Carrico, Infection Control Dept, University of Kentucky Medical Center N.

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

Patient suicide Op/post-op Wrong-site surgery Medication error Delay in treatment <i>Restraint death/injury</i> Patient fall Assault/rape/homicide Transfusion error Perinatal death	382 330 310 291 172 113 114 89 73 71	15% 12.9 12.1% 11.4% 6.7% 4.4% 4.5% 3.5% 2.9% 2.8%	Patient elopement Fire Anesthesia event Med equipment Vent death/injury Maternal death Infant abduction Transfer death Other	49 45 38 33 39 31 19 18 297	1.9% 1.8% 1.5% 1.3% 1.2% 0.7% 0.7% 11.6%
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Sentinel Event Outcomes	#	%
Patient death	2,000	75%
Loss of Function	268	10%
Other	399	15%
otal patients impacted	2,667	100%









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 <u>unanticipated</u> 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 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 	;
Thar	nks Teresa

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





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

1

- May be a new or already existing team
 - Individuals closest to the event
 - Individuals critical to implementation of recommendations
 - A respected & credible leader
 - Individuals with diverse knowledge base
 (& PI experience)
 - Be sensitive to clinician's needs/fears

1 ■ First Team Meeting ■ Establish ground rules ■ Decision making ■ Attendance ■ Meeting schedule ■ Opportunity to speak ■ Disagreements ■ Assignments

Step Two: Define the Problem

- Describe what happened
 - Focus on what happened not why it happened
 - $\ensuremath{\,^{\ensuremath{\scriptscriptstyle \neg}}}$ Verbalize accurately and succinctly
 - ☞ "Mrs. Jones was a 55 y/o pt. who underwent elective CABG procedure. She had a cardiac arrest and died on her third post-op day. No signs of SSI. Sepsis was found confirmed by blood cultures and autopsy. Central line sepsis suspected."

Step 3: Study the Problem

- Collect information related to the event or possible event
 - Witness statements of those directly & indirectly involved
 - **7 Observations**
 - Physical evidence (purulent secretions at CVC insertion site)
 - Documentary evidence ("pus noted at insertion site" in progress note)

3

- Information format
 - Written documentation
 - ↗ Audiotape
 - Photographs
 - > Videotape (may be intimidating)





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?















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
 - R CVC-BSI/1,000 line days in CTICU

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

Step 8:

Design and Implement Interim Changes

Example Gantt Chart

ID	Took Nama	Start	Finish	Duration	Feb 2002 Mar 2002 Apr 2002
U	Task hame				3/3 4/7 5/5
1	Fix the overhead light to maintain position	2/6/2002	2/6/2002	.2w	
2	Analyze current data for BSE in the OR	2/13/2002	2/21/2002	1.4w	
3	Determine data to be collected, when & by whom?	2/21/2002	2/28/2002	1.2w	
4	Develop data collection tool	3/1/2002	3/8/2002	1.2w	
5	Instruct data collectors re: use of tool	3/18/2002	3/20/2002	.6w	•
6	Data collection	3/20/2002	4/19/2002	4.6w	
7	Data Analysis	4/22/2002	4/30/2002	1.4w	
8	Review findings with the team	5/1/2002	5/1/2002	.2w	1

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?

9

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)

Proximate Cause	Underlying Cause
Delay in reporting needle stick until the end of the shift	RN hadn't completed last two weeks of orientation & was unfamiliar with the policy re: reporting BSE immediately
Lack of clear communication when passing sharp	Physicians not trained on policy to 1st announce intent to pass sharp

9

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 preexisting duty to act.

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

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)

 n 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."

12

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)

	Fallu	Hazard S	coring	Matrix	SIS	
	Severity					
P		Catastrophic	Major	Moderate	Minor	
ĝ.	Frequent	16	12	8	4	
abi	Occasional	12	9	6	3	
Ϊţ	Uncommon	Jncommon 8		4	2	
	Remote	4	3	2	2	

12

- Design a system to absorb errors
- Standardize procedures
 Reduce variation
- Training & re-training

 [¬] Competency assessments
- Create a safe reporting environment



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.

14

- Each selected improvement action should:
 - Address a root cause

 - Offer more positive then negative impact on other processes (no negative ripple effect)
 - > Objective and measurable
 - Defined implementation time
 - > Have assigned accountability

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
- Restauration External comparisons benchmarking
- Practice guidelines/parameters
- Performance targets, specifications or thresholds
 - NNIS, other professional organizations

Step 20: Take Additional Steps

If meeting goals —

- **7** Communicate the results
- **7** 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

20

- If NOT meeting goals
 - Ask if improvement was fully implemented
 Leadership involvement sponsorship
 - Communication gaps

 - Identify risk reduction strategy
 - Plan for continued monitoring
 - - Radiology
 - Laboratory

Step 21: Communicate the Results

- Communication is key THROUGHOUT the RCA process

 - Departments/services impacted by changes (proposed changes)
 - **7** New or revised policies
 - Provide the second s



FOCUS-PDCA F ind an opportunity	Steps in P	Outbreak Investigation		
O rganize a Team	Step 1	Organize a Team	1. Confirm existence of outbreak	
	Step 2	Define the Problem	2. Confirm diagnosis of cases	
C larify the current process	Step 3	Study the Problem	3. Prepare or investigation	
	Step 4	Determine What Happened	4. Create case definition	
U nderstand variation	Step 5	Identify Contributing Process Factors	5. Search for additional cases	
	Step 6	Identify Other Contributing Factors	6. Characterize epidemic by	
	Step 7	Measure – Collect and Assess Data on Proximate and Underlying Causes	person, place, time (line list)	
	Step 8	Design and Implement Interim Changes	7. Generate tentative hypothesis	
	Step 9	Identify Which Systems Are Involved – Root Causes	8. Test hypothesis	
	Step 10	Prune the List of Root Causes	9. Institute additional studies	
	Step 11	Confirm Root Causes	10. limplement interventions	
S elect the improvement solution	Step 12	Explore and Identify Risk Reduction Strategies	11. Communicate findings	
P lan the improvement	Step 13	Formulate Improvement Actions	12. Move to process improvement!	
	Step 14	Evaluate Proposed Improvement Actions		
	Step 15	Design Improvements		
	Step 16	Ensure Acceptability of the Action Plan		
D o the improvement; and collect data	Step 17	Implement the Improvement Plan	PLAN	
C heck and study the results	Step 18	Develop Measures of Effectiveness and Ensure Their Success	ACT	
	Step 19	Evaluate Implementation of Improvement Efforts	CHECK	
A ct and hold the gain	Step 20	Take Additional Action	enter	
	Step 21	Communicate the Results		

Joint Commission Resources

- http://www.jcaho.org/sentinel/sentevnt_frm.html
 - **SE Policies & Procedures**
 - Root Cause Analysis Matrix
 - > Sentinel Event Statistics

 - Inks to other sites

Joint Commission Resources

This publication is to provide health care organizations with the "how to" of conducting a root cause analysis.

Describes "how to" conduct each of the twenty-one steps.



Joint Commission Resources

This publication is intended to help health care 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

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









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Questions? Contact Paul Webber paul@webbertraining.com