

Integrating Sentinel Event Analysis Into Your Infection Control Practice

Association for Professionals in Infection Control and Epidemiology

Developers: Janet Frain, Denise Murphy, Georgia Dash and Marie Kassai

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What is a sentinel event?

The JCAHO defines a sentinel event as “an unexpected occurrence involving death or serious physical or psychological injury.” Serious injury specifically includes loss of limb or function. The JCAHO further prescribes a list of “reviewable” sentinel events as

- Unexpected deaths
- Unanticipated major loss of function
- Infant abduction
- Infant discharged to wrong family
- Rape
- Hemolytic transfusion reaction
- Surgery on the wrong patient or body part
- Patient suicide

The facility can certainly determine other types of events for which a root cause analysis (RCA) is an appropriate investigative and problem-resolution tool.

What is the relevance to your practice as an ICP?

ICPs actively involved in surveillance activities would most likely identify unexpected deaths or unanticipated major loss of function due to infection as a potential sentinel event. Some of these cases are clearly identifiable but, unfortunately, many are not. Each case has to be evaluated individually. Use the help of your internal resources to make this determination. The requirement to perform RCA's has been in place for four years. Each facility has a department or person who is responsible for “managing” this process. Collaboration with an Infectious Diseases expert, your Administrator and Medical Staff leadership will be valuable resources to you.

What skills do I have to contribute to this process?

The ICP is an extremely valuable member of the patient care team. Your experience with outbreak management and ability to identify infectious events, evaluate likely sources for infection, recognize standards that help prevent transmission or development of an infection, and analyze medical literature make you an excellent resource to the team.

What happens once the ICP identifies a sentinel event?

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 (Attachment A). The 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.

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How does a root cause analysis differ from an epidemiologic investigation?

This document presents an excellent crosswalk for a comparison of the two methodologies (Attachment B). There are many similarities in the two processes. A root cause analysis focuses on individual events based on patient outcome. The process we are most used to using for an epidemiologic investigation typically looks at clusters of infections or individual cases of epidemiologic importance. It is not fully dependent on patient outcome.

What is my job in a root cause analysis?

The ICP can participate either as the team leader or a team member. If the ICP accepts the role of Team Leader, it is important to remember that you are there primarily as a content expert. Carefully listening as participants describe the processes leading to the untoward event is an important skill. You know what the Infection Control standards are; therefore, you are the person most qualified to identify gaps or compliance issues.

Other team members would include front-line staff most involved in the process, an Infectious Diseases physician and other appropriate members of the medical staff. It's important to remember that these may be very emotionally charged meetings, so the ICP as a Team Leader should know techniques for "de-fusing" sensitive situations.

Warning: It is not unusual for clinicians to debate the clinical management or specific aspects of the case. For example, did the patient die from the infection or was the cardiac status so fragile that the patient would have expired anyway? While this level of review is important, the peer review committee may be the more appropriate setting for a decision. The root cause analysis focuses on *systems* and *processes*. The Team Leader and/or facilitator must skillfully bring the group back to this focus.

In addition, it is important that the message be delivered very early on in the meeting that ALL participants are on equal footing and everyone should contribute. For many groups, this will be the first time physicians and staff have actually sat in the same room to analyze an event.

What does success look like?

A credible and successful RCA identifies all the elements that contributed to an event, develops action plans to prevent recurrence and ensures that those actions are completed. A very important component of a RCA is thorough review of the literature; to ensure that action plans are based on best practices and appropriate standards.

As labor-intensive as an RCA is, it is never a waste of time!

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Attachment A

Level of Analysis		Questions	Findings
What happened?	Sentinel Event	What are the details of the event? (Brief description)	What type of infection did the patient have that caused the death or permanent loss of function?
		When did the event occur? (Date, day of week, time)	
		What area/service was impacted?	Surgery? ICU? Pulmonary Services? Transplant unit?
Why did it happen?	The process or activity in which the event occurred.	What are the steps in the process, as designed? (A flow diagram may be helpful here)	Sterilization process? Skin preparation process? Prophylactic antibiotic administration? Environmental cleaning? The process should be flowcharted "as is," so critical steps can be identified.
What were the most proximate factors? (Typically "special cause" variation)		What steps were involved in (contributed to) the event?	Were instruments cleaned adequately before putting in the sterilizer? Was the cycle allowed to complete? Was the skin prep rushed because everyone was in a hurry to start the case? Was the antibiotic given at the right time pre-op (or at all)? Analyze the flowchart and determine the gaps.
	Human factors	What human factors were relevant to the outcome?	Did staff feel pressured to get the job done quickly? Were critical steps missed because they thought they weren't important? Have shortcuts been built into the system? Participants have to be painfully honest without fear of retribution!
	Equipment factors	How did the equipment performance affect the outcome?	Was the appropriate preventive maintenance done? Was the staff oriented appropriately to equipment? Types of equipment may be autoclaves, sterilizers, ventilators, all types of tubing's connected to the patient, etc
	Controllable environmental factors	What factors directly affected the outcome?	Was the staff in a hurry? Is clean equipment stored near contaminated equipment? Does the staff have what they need when they need it? Were there distractions that interrupted the process? Is the area they are working in conducive to the process?
	Uncontrollable external factors	Are they truly beyond the organization's control?	Are there productivity standards for MDs that force them to hurry through processes?
	Other	Are there any other factors that have directly influenced this outcome?	This is the time for the group to brainstorm other systems or processes that they feel contributed to the outcome
		What other areas or services are impacted	

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Level of Analysis		Questions	Findings
Why did that happen? What systems and processes underlie those proximate factors? (Common cause variation here may lead to special cause variation in dependent processes)	Human Resources issues	To what degree is staff properly qualified and currently competent for their responsibilities?	<p>Is the right skill level person performing the function? Is orientation adequate? Have the staff demonstrated competency on the equipment they are using? Has competency with the process been demonstrated? Are the learning needs of the individual taken into consideration when training/orienting new employees?</p> <p>This is the time to ask all relevant questions about adequate education and training for the process.</p>
		How did actual staffing compare with ideal levels?	<p>Was the department running short that day? Did the therapists have time to do their rounds? Were tubing changes let go due to inadequate staff? Are there enough people to do the job?</p> <p>Ideal staffing levels are difficult to determine. Comparison with industry standards, if available, can be helpful.</p>
		What are the plans for dealing with contingencies that would tend to reduce effective staffing levels?	<p>What does the department do if they are "short-staffed" for the day? Who prioritizes?</p> <p>What realistic options for replacement personnel are available to the manager?</p>
		To what degree is staff performance in the operant process(es) addressed?	<p>How do we know the staff is competent to do the procedure? Is there adequate supervision? Are the staff allowed to find creative shortcuts?</p> <p>Does staff understand their role in reducing infectious complications as part of the process they work in?</p>
		How can orientation and in-service training be improved?	<p>Brainstorm and listen carefully to the front-line caregiver that knows best what will and will not work. Once an event of this nature occurs, staff really think about their role and what could be done better. They don't want a repeat incident!</p>
	Information management issues	To what degree is all necessary information available when needed? Accurate? Complete? Unambiguous?	<p>Are there procedures available to the staff? What information about the patient was passed on in report? Any critical information omitted? Did the therapist know they had to see the patient? Is the procedure for sterile dressing changes complete? Did the pre-op nurse know the pre-op antibiotic had not been given?</p> <p>This information can be found in documents, on-line, direct communications, shift reports, etc</p>

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Level of Analysis		Questions	Findings
		To what degree is communication among participants adequate?	Was the technician comfortable telling the physician that the skin prep was not complete? That the equipment had been rushed through the sterilization process? This is a critical question when doing a root cause analysis – communication breakdown has been the root cause in many events
	Environmental management issues	To what degree was the physical environment appropriate for the processes being carried out?	Is the staff member able to work uninterrupted? Is the sink placed in such a way that it makes hand washing cumbersome? Are fans blowing through dirty work areas? Is the ventilator equipment stored appropriately? Are the surgical supplies in a clean, dry area, away from contamination? This sometimes requires a site visit by the team to the area in question.
		What systems are in place to identify environmental risks?	Does the hospital have a process for content experts to make assessments of environmental risks? Is the ICP a welcome visitor in Surgery? Are the issues identified acted upon and is there accountability?
		What emergency and failure-mode responses have been planned and tested?	The group can brainstorm all potential failure modes associated with the process and determine what interventions would be most helpful to prevent that potential failure mode? This is a very labor-intensive process.
	Leadership issues: - Corporate culture	To what degree is the culture conducive to risk identification and reduction?	Is the staff comfortable in reporting risks? Is their manager responsive? Does the staff know what to do if no action is taken? Asking this question may reveal some serious systems issues or management issues that leadership should be aware of and must act on.
	- Encouragement of communication	What are the barriers to communication of potential risk factors?	Is the manager available to the staff? Are all opinions respected, regardless of skill level? Processes may need to be developed to allow free and open communication
	- Clear communication of priorities	To what degree is the prevention of adverse outcomes communicated as a high priority? How?	Has the staff been educated on patient safety and prevention of adverse outcomes? Do they understand the rationale for each step in a process to reduce risk of infectious outcomes? Does the Environmental Services employee understand how critical their role is in infection prevention and control? How is the department-specific orientation to infection prevention and control communicated to the staff?
	Uncontrollable factors	What can be done to protect against the effects of these uncontrollable factors?	Brainstorm with the group.

- For each of the findings identified in the analysis as needing an action, indicate the planned action expected, implementation date and associated measure of effectiveness. OR. ...
- If after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rationale for not taking action at this time.
- Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action.
- Consider whether pilot testing of a planned improvement should be conducted.

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- Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented.

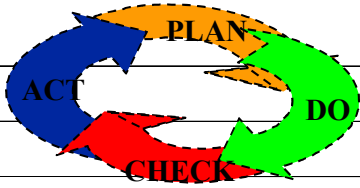
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Attachment B

FOCUS-PDCA	Steps in Preparing for a Root Cause Analysis		Outbreak Investigation
F ind An Opportunity 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 for 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 person, place, time (line list)
	Step 7	Measure – Collect and Assess Data on Proximate and Underlying Causes	7. Generate tentative hypothesis
	Step 8	Design and Implement Interim Changes	8. Test hypothesis
	Step 9	Identify Which Systems Are Involved – Root Causes	9. Institute additional studies
	Step 10	Prune the List of Root Causes	10. Implement interventions
	Step 11	Confirm Root Causes	11. Communicate findings
S elect the improvement solution P lan the Improvement	Step 12	Explore and Identify Risk Reduction Strategies	12. Move to process improvement!
	Step 13	Formulate Improvement Actions	
	Step 14	Evaluate Proposed Improvement Actions	
	Step 15	Design Improvements	
D o the Improvement and Collect Data	Step 16	Ensure Acceptability of the Action Plan	
	Step 17	Implement the Improvement Plan	
C heck and Study the Results	Step 18	Develop Measures of Effectiveness and Ensure Their Success	
	Step 19	Evaluate Implementation of Improvement Efforts	
A ct and Hold the Gain	Step 20	Take Additional Action	
	Step 21	Communicate the Results	

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Attachment C

Scenario One

A 73-year-old male was admitted with aortic stenosis. The patient also had diabetes mellitus. He underwent an aortic valve replacement. He had an uneventful recovery and was ready for discharge nine days post-op.

On the day of discharge, the staff RN was removing the saline lock from the right forearm. The nurse noticed a small, reddened area around the site. The nurse reported the findings to the physician, who ordered wet soaks, but did not delay the discharge. The patient's temperature was 99.4°F. This was not reported to the physician.

Twenty-four hours after discharge, the patient was readmitted with a temperature of 103°F and was acutely ill. Cultures from the saline lock site, spinal fluid, blood, urine, and sputum were all positive for *Staph aureus*. The patient expired.

Would this be considered a sentinel event?

While the risk of any operative procedure certainly includes infection, this patient's infection and death were *most likely* not related to his surgical procedure. He had a very normal post-operative course. There appeared to be an infection starting at his IV site that was left untreated. While we cannot say with 100% certainty that the true source of infection was the IV site, it did appear this was the proximate cause of his ultimate demise.

A root cause analysis in this unexpected death would analyze several systems issues:

- What is the policy for changing saline locks? What are the assessment expectations if the saline lock is not changed?
- Does this nursing unit have a policy that all patients on their unit will have a saline lock, regardless of the patient condition?
- Were the nurses doing the assessment competent in assessment and maintenance of IV saline locks?
- Was the appropriate information communicated to the physician?
- Were the staffing levels appropriate for the needs of the patients on this unit? Did the nurses feel rushed to discharge a patient?
- Were there other factors that could have potentially diverted the nurse from conveying all necessary information to the physician prior to discharge?
- Should the physician have delayed discharge? Were there external factors influencing the surgeon's decision to discharge (monitoring of LOS by the MD group for example)

Typically, several systems issues will be identified that will result in a plan of action. In this case, it may be policy and procedures changes, staff competency assessment, and peer review.

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Scenario Two

A 24-year-old mother underwent a c/section for fetal distress at 32 weeks. The infant weighed 4lbs 3 oz. at birth but appeared to be in no acute distress. The infant was admitted to the Neonatal ICU for close observation. The infant progressed well and did not require intubation, intravenous lines or any invasive procedures.

As is the policy in this facility, the mother was instructed to pump her breasts for feedings. She used the new electronic breast pump that was stored at the nurse's station on the Post Partum unit. The mother elected to go home without her baby on day four to care for her other children at home. When she came back to the hospital, she continued to use the breast pump from Post Partum.

The infant gained weight and was scheduled for discharge. The evening before discharge, the infant became irritable and had episodes of bradycardia. The neonatologist on call immediately ordered blood cultures and empiric antibiotics. The blood cultures were positive for *Pseudomonas aeruginosa*. Despite aggressive therapy by the physicians, the baby expired.

Would this be considered a sentinel event?

This infant, while certainly pre-term, experienced a very uneventful hospital stay. While the infant was housed in the NICU, he did not have any of the invasive procedures that the ICP would normally associate with a stay in that unit. The infant was scheduled for discharge and had an abrupt change in condition that resulted in death. This would be considered a sentinel event.

A root cause analysis in this unexpected death would analyze several systems issues:

- What is the policy for cleaning and storing the electronic breast pumps?
- Did the mother receive any education on hand hygiene, cleaning her breasts prior to pumping and ascertaining that the breast pump was cleaning?
- Was the nurse competent in maternal-child care, including instruction for breast-feeding?
- The pump was new – was everyone on the unit oriented to that pump and how to use it?
- How was the breast milk stored?
- What education had the staff nurses in the NICU received on hand hygiene?
- What was the census in the NICU? Was there adequate staffing?
- Were there adequate safeguards in place to make sure the infant got the correct mother's milk?

The risk in this setting would be to only focus on the issue of the breast pump. Experienced ICP's realize that many factors could have contributed to this infection. Continually asking "Why" will ultimately get to root cause.

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Scenario Three

A nine-year-old child was admitted to the Pediatric Unit with acute lymphocytic leukemia. This was a new diagnosis for this patient. Following six weeks of chemotherapy in the hospital, her immune system became extremely compromised. She was maintained in an isolation room for the last three weeks of therapy as her white count had dropped to very low levels.

During week six in the hospital, the child spiked a fever to 104°F and became tachycardic. She complained of a new onset of pain in her head. This was reported to the oncologist immediately and cultures were obtained from blood, nasopharynx and spinal fluid. The spinal fluid and NP cultures grew *Aspergillus fumigatus*. Despite aggressive treatment, the child was taken to the operating room for removal of her left eye and cheekbone to prevent further damage from the *Aspergillus*. She was ultimately discharged home.

Would this be considered a sentinel event?

Some ICPs would argue that infections of this nature are a rare but well-known complication of this diagnosis and treatment regimen. This could be considered permanent loss of function. Many safeguards were probably put in place to prevent this tragic outcome. This event would warrant intense analysis at a minimum.

An intense analysis (or perhaps root cause analysis) could analyze several systems issues:

- What engineering controls are in place to prevent acquisition of *Aspergillus*? Were the engineers adequately oriented and trained in the role of environmental pathogens for this patient population?
- What education and training did the nurses receive for this high-risk patient population? How are new employees oriented?
- What is the staffing ratio for these children? Do the assignments require nurses or other members of the health care team to care for children with infection as well as these immune suppressed children?
- What equipment was involved in the care of this patient? Any system breakdowns in cleaning processes?
- Is the medical staff working with these patients educated on appropriate barrier precautions and hand hygiene?
- Was there any construction going on in or around the facility?
- Were the parents taught about hand hygiene?

Because the ICP comes armed with the knowledge of microorganisms and how they are introduced or spread, the ICPs knowledge will be invaluable in reviewing the systems issues associated with this type of event.

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