Root Cause Analysis (RCA) Instructions

Purpose: To provide guidance in conducting a Root Cause Analysis for a Patient Safety Event, and to identify potential opportunities for improvement.

Who should use this document? Hospital risk managers and patient safety specialists assigned to the particular event

How to use this document:

- 1st Meeting: Goal to initiate meeting within 72 hours of event submission. Identify team members. Complete Step 1. Make investigation assignments (policies, publications, research, interviews). Plan who will draft Steps 2 – 8.
- 2nd Meeting: Goal to hold meeting within 14 days of event submission. Review investigation findings. Identify contributing factors, vulnerabilities. Complete Steps 2 – 8. Discuss potential actions. Plan to draft Steps 9 – 10.
- 3rd Meeting: Goal to hold meeting within 28 days of event submission. Finalize action plan and measures. Each identified cause/contributing factor should have at least one action. Each identified action must have a process or outcome measure. Complete Steps 9 – 10.

Step 1: Assemble a team to review the patient safety event

Team composition should vary based upon the event. Designate an Executive Leader and process owner of the RCA.

Step 2: Describe what happened

Provide a clear, thorough and objective explanation of what happened. Reconstruct the timeline.

Step 3. Immediate/Remedial Actions.

Record any actions immediately taken to mitigate harm. Document details regarding process owners, and when the actions were started and/or stopped. Revisit and update this section throughout the RCA meetings.

Step 4. Disclosure.

Provide relevant details of the disclosure process. Continue to update this section throughout the RCA process.

Step 5. Investigation approach.

Note which methods/tools are being used as a part of this investigation.

Step 6. Why did it happen?

Review the event summary and consider what factors contributed to the event happening. There are commonly multiple system factors that contribute to an event. Sample 1 provides examples of possible contributing factors.

Indicate whether each identified root cause, contributing factor, or incidental finding is an opportunity for improvement.

This review process may identify additional factors, or incidental findings, that increase the risk of a patient safety event.

Step 7. Literature search.

Record any research the team conducted regarding this investigation.

Step 8. Conclusion.

Discuss the final findings of the investigation. Discuss causality and how the root causes resulted in the final outcome.

Step 9. How could we fix the defects

Identify corrective actions for each identified root cause, contributing factor, or incidental finding. Carefully consider the type of action and the potential impact of the action to reduce the risk of the event recurring.

Aim to prioritize stronger actions, but note that weak actions may sometimes be the only option. If weak actions are necessary, consider pairing them with stronger actions to support a greater impact.

Step 10. Develop recommended action plan

List prioritized actions to mitigate each causal or incidental factor.Sample 2 provides types of interventions and examples. In prioritizing the action plan, consider impact and feasibility of each recommended action. Prioritize actions with a high potential to reduce or eliminate future events, and that are feasible to implement. Each action requires an appropriate leader, measures and methods for evaluation, and follow-up dates to evaluate progress.

ROOT CAUSE ANALYSIS REPORT

Privileged and Confidential Medical Review Document

SAFE #:

RCA Completed By:

Date of Incident		**Date Reported**	
Entity		**Event Type**	
Location		**Event Severity (MERP)**	
Patient Name		**MRN**	
Keywords/ short phrase to describe event:			

#	RCA Meeting Date	Activities Completed
1		☐ Identify team members (Step 1) ☐ Make investigation Assignments ☐ Other:
2		☐ Review and approve investigation findings (Steps 2 – 8) ☐ Make Action Plan Assignments ☐ Other:
3		☐ Review and approve Action Plan (Steps 9 – 10) ☐ Identify presenter for PSC: ☐ Other:

Step 1. Assemble a team. Include team members with insights into what happened in the specific incident. It is also frequently helpful to include others who were not directly involved with the event, but may have expertise in relevant areas.

RCA Team Members

Facilitator		**Risk (Core)**	
Executive Sponsor		**Nursing (Core)**	
Subject Matter Expert		**MD (Core)**	
Subject Matter Expert		**Quality (Core)**	
Unit Representative		**Pharmacy (Core)**	
Unit Representative		**Unit Representative**	

Step 2. What happened? Provide a clear, thorough, and objective explanation of what happened. Presenting in a timeline is frequently helpful.

Timeline. Please describe, in detail, the timeline of the event as it occurred.

Date	Time	Details	Notes/Comments	Source

Step 3. Immediate/Remedial Actions. Discuss any immediate actions taken to mitigate harm. Include details regarding decision making on starting and stopping actions, and who the action owners were.

Action	Purpose	Start Date	Stop Date

Step 4. Disclosure. Please provide the following details:

Date of Disclosure	
Who performed the disclosure?	
Who received the disclosure?	
What was disclosed?	

Step 5. Investigation approach.

☐ Interviews ☐ Demo ☐ Photos ☐ 5 Whys

☐ Team Meeting ☐ Tour ☐ Referred to Peer Review ☐ Ishikawa (Fishbone)

☐ Affinity Diagram ☐ Case/Physician Review

Step 6. Why did it happen? List the root causes and contributing factors that contributed to the event as well as incidental findings. Then, indicate which of these are targets for improvement.

Category	Root Cause, Contributing Factor, or Incidental Finding	Target ✓
Communication		
Communication breakdown between and among teams including handoffs and transitions		
Information availability or presentation		
Misinterpretation of information		
Language or literacy		
Environment		
Space availability, design		
Attributes (e.g. noise, lighting, flooring)		
Condition (e.g. maintenance, housekeeping)		
Equipment / Device / Supply		
Availability of equipment, device, or supplies		
Condition of equipment, device, or supplies		
Malfunction or misuse of equipment, device, supply		
Missing or confusing labels or instructions		
Health information technology issues		
Alarms silenced, disabled, or overridden		
Task / Process		
Workflow inefficient or overly complex		
Interruptions, lack of decision support		
Missing or ineffective quality/safety checks		
Staff Performance		
Fatigue, inattention, distraction, workload		
Staff knowledge deficit or competency		
Criminal or intentionally unsafe act		
Teamwork		
Lack of shared understanding, disruptive behavior		
Lack of empowerment		
Failure to engage patient		
Management / Supervision		
Disruptive or intimidating behaviors		
Staff training		
Inadequate or confusing rules/ policies/ procedure		
Failure to provide appropriate staffing or correct a known problem		

Failure to provide necessary information or training		

Step 7. Literature search. Please include any evidence-based best practices, journal articles, policies, procedures, regulatory guidelines, or protocols that may be relevant to the event.

Step 8. Conclusion. Discuss any root causes, who did what because why? Discuss any collateral processes, determined ultimate cause of death, etc.

Identified Root Causes.

Problem #1:	
Why?	
Why?	
Why?	
Why?	

Problem #2:	
Why?	
Why?	
Why?	
Why?	

Problem #3:	
Why?	
Why?	

Why?	
Why?	
Problem #4:	
Why?	
Why?	
Why?	
Why?	

Problem #5:	
Why?	
Why?	
Why?	
Why?	

Step 9. How could we fix the defects? For each root cause, contributing factor or incidental finding that will be targeted, identify and prioritize potential corrective actions. The RCA instructions provide examples. **Aim for the strongest action possible, but note that sometimes a weak action is the only option.**

Category	Strength	Potential Corrective Action
Communication		
Increase non-standard communication	Weak	
Communicate risk in a memorandum	Weak	
Standardize communication tools	Medium	
Environment		
Eliminate/reduce distractions	Medium	
Use differentiation	Medium	
Change architecture/physical plant	Strong	
Tools		
Add warning	Weak	
Modify software	Medium	
Standardize equipment with same usability level	Medium	
New device with usability testing	Strong	
Add forcing function/engineering control to equipment	Strong	
Process		
Write a new policy/procedure	Weak	
Add non-independent check to process	Weak	
Add checklist/cognitive aids into process	Medium	
Add independent check to process	Medium	
Remove unnecessary steps to simplify process	Strong	
Standardize process	Strong	
Education		
One time, didactic training	Weak	
Simulation-based training, with periodic refresher sessions and observations	Medium	
Periodic didactic training	Medium	
People		
Change the number of available staff	Medium	
Organization		
Audit and feedback	Medium	
Substantial involvement by leadership	Strong	

Step 10. What will we do to address the defects and how will we know it worked? List what you will do, who will lead the intervention, when you anticipate implementing the intervention, how you will measure if the action worked, and when the group will follow up on the action.

Corrective Action	Person Responsible	Planned Implementation Date	Measure of Success	Follow up Date

Sample 1. Root Cause Examples

Category	Example
Communication	
Communication breakdown between and among teams including handoffs and transitions	Change in resuscitation status not communicated to next shift.
Information availability or presentation	Emergent radiographic finding not communicated to clinicians.
Misinterpretation of information	Provider misinterpreted lab results and administered medication that was not indicated per lab values
Language or literacy	Language barrier; patient did not speak English.
Environment	
Space availability, design	Patient room not visible from the nurse's station.
Attributes (e.g. noise, lighting, flooring)	Low lights contributed to misidentification of medication
Condition (e.g. maintenance, housekeeping)	Room not cleaned overnight, resulting in delayed morning procedure.
Equipment / Device / Supply	
Availability of equipment, device, or supplies	Only 1 CO_2 detector on unit, not available when needed for a procedure.
Condition of equipment, device, or supplies	8 of 20 mattresses on unit found to be contaminated with infectious material
Malfunction or misuse of equipment, device, supply	Medication pump did not infuse as programmed.
Missing or confusing labels or instructions	Equipment instructions not clearly posted by the patient's bed.
Health information technology issues	EMR alert failed to perform as designed.
Alarm fatigue, alarms silenced, disabled, or overridden	Medical staff overwhelmed with excessive alarms on unit
Task / Process	
Workflow inefficient or overly complex	STAT test results delayed 5+ hours
Interruptions, lack of decision support	Call to order not completed before incision due to shift change and change between outgoing RN and incoming RN.
Missing or ineffective quality/safety checks	Medication stored outside of Omnicell, thus Pharmacy is not alerted when medication is low or out of stock.
Staff Performance	
Fatigue, inattention, distraction, workload	After working a double shift, a fatigued staff member incorrectly calculated medication dose.
Staff knowledge deficit or competency	New team member not competent in unit procedures.
Criminal or intentionally unsafe act	Staff diversion of medication
Teamwork	
Lack of shared understanding, disruptive behavior	Staff did not consider following up on a result to be part of their job.
Lack of empowerment	Staff was not comfortable expressing his/her concern regarding high dose.
Failure to engage patient	Patient procedure done based on incorrect armband due to multiple failures to verify identification information
Management / Supervision	
Disruptive or intimidating behaviors	One clinician yelling at another in OR
Inadequate or confusing rules/ policies/ procedure	No consistent dress code policy
Failure to provide appropriate staffing or correct a known problem	Chronic short staffing resulting in team members covering twice their normal number of patients on weekends.
Failure to provide necessary information or training	Personnel not trained in new test ordering procedure.

Sample 2. Strength of Interventions*

Strength	Subcategory	Example
Communication		
Weak	Increase non-standard communication	
Weak	Communicate risk in a memorandum	Remember to check IV sites every 2 hours
Medium	Standardize communication tools	Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format
Environment		
Medium	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distraction for nurses when programming medication pumps
Medium	Use differentiation	Do not store look-alikes next to one another in the unit medication room
Strong	Change architecture/physical plant	Replace revolving doors with powered sliding doors to reduce patient falls, reduce ambient noise to reduce distraction
Tools		
Weak	Add warning	add visual or audible warning (e.g. EMR alerts for drug-drug interactions, telemetry alarms, medication warning labels)
Medium	Modify software	Align EMR software to reflect desired behaviors/processes (e.g. only order high risk medications using specific order sets)
Medium	Standardize equipment with same usability level	Standardize the make and model of medication pumps used throughout the system
Strong	New device with usability testing	Perform test of outpatient glucose meters and test strips and select the most appropriate for the patient population being served
Strong	Add forcing function/engineering control to equipment	Use tubing/fittings that can only be connected the correct way (e.g. IV tubing connectors that cannot be connected to sequential compression devices)
Process		
Weak	Write a new policy/procedure	
Weak	Add non-independent check to process	One nurse calculates a high risk medication dosage and another nurse reviews their calculations
Medium	Add checklist/cognitive aids into process	Use pre-induction and pre-induction checklists in operating rooms. Use a checklist when re-processing flexible fiberoptic endoscopes
Medium	Add independent check to process	2 RNs independently calculate high risk medication dosages and then compare results
Strong	Remove unnecessary steps to simplify process	Remove unnecessary steps in a process
Strong	Standardize process	Standardize the use of bar coding for medication administration
Education		
Weak	One time, didactic training	Demonstrate correct usage of hard-to-use medical equipment
Medium	Simulation-based training, with periodic refresher sessions and observations	Conduct patient handoffs in a simulation labs/environment, with after-action critiques and debriefing
Medium	Periodic didactic training	Annual on-line training for re-credentialing
People		
Medium	Add to the number of available staff	Make float staff available to assist when workloads peak during the day
Organization		
Medium	Audit and feedback	
Strong	Substantial involvement by leadership	Participate in unit patient safety evaluations and interact with staff; purchase needed equipment, ensure staffing and workload are balanced

***Please note: Sometimes a weaker action is the only option.**