Root Cause Analysis
Going from Who to Why

Tammy Lundstrom, MD, JD

SVP, System Chief Medical Officer

Trinity Health

Livonia, MI

SHEA
The Society for Healthcare
Epidemiology of America

CDC

Financial Disclosure

Tammy Lundstrom, MD, JD
Trinity Health

Nothing to disclose.

Learning Objectives:

▸ Determine criteria for performance of RCA

▸ Recognize elements of RCA and infrastructure

▸ Recognize critical steps in performance of RCA

▸ Evaluate how program fits into strategic plan

▸ Review basic concepts

Sentinel Event Definition

▸ Patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in:

  ▸ Death

  ▸ Permanent harm

  ▸ Severe temporary harm (potentially life threatening, limited time, no permanent residual, requires a higher level of care, procedure, treatment)

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Sentinel Event (continued)

▸ Suicide in 24 hr care setting or within 72 hours of discharge

▸ Unanticipated death of full-term infant

▸ Discharge of infant to the wrong family

▸ Abduction of any patient receiving care, treatment, services

▸ Elopement from 24 hr care setting

▸ Hemolytic transfusion reaction involving major blood group incompatibilities

▸ **Surgical and invasive procedures on the wrong patient, wrong site or wrong procedure**

▸ **Unintended retention of a foreign object in a patient after surgery/procedure**

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Sentinel Event (continued)

▸ Prolonged fluoroscopy/radiotherapy to wrong site/radiotherapy dose >25% above planned

▸ **Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of care**

▸ **Any intrapartum (related to the birth process) maternal death or severe maternal morbidity ($\geq$ 4 units blood products or ICU admission)**

Appropriate Hospital Response

▶ Stabilize patient and disclose event to patient and family

▶ Provide support to family AND staff involved

▶ Notify Hospital Leadership

▶ Immediate investigation (72 hours)

▶ Completion of comprehensive systematic analysis for identifying causal and contributory factors (Root Cause Analysis)

▶ Corrective actions taken (timeline for implementation)

▶ Systemic improvement

Patient Safety Event

▸ An event, incident, or condition that **could have resulted** or did result in harm to a patient

▸ Adverse Event= harm to the patient; may or may not result from an error; still requires investigation and corrective action according to hospital policy (Intense Analysis)

▸ No-harm event= reaches patient but doesn't cause harm

▸ Close call (Near miss)=patient safety event that did not reach the patient

▸ Hazardous condition= circumstance (other than patient's own disease process) that increases the probability of an adverse event

So……………

▸ **ALL** Sentinel events are patient safety events, but **NOT ALL** patient safety events are sentinel events

▸ As part of a comprehensive safety program, no-harm events, close calls and hazardous conditions still need to be tracked and trended- trends may trigger pro-active corrective action (ex: FMEA)

What is required?

▸ Prioritize the events, hazards and vulnerabilities in the system

▸ Understand **what** happened

▸ Understand **why** it happened

▸ Take positive **action to prevent** it from happening again

▸ Measure actions to demonstrate success (**fix it**)

▸ The goal is **NOT** to focus on or address individual performance

What is a Root Cause Analysis?

▸ Highly structured series of questions

▸ Purpose: to find the underlying cause for the event; to identify system vulnerabilities so they can be eliminated or mitigated

▸ Oversimplification: implies single cause
   ▸ Usually a chain of events with a wide variety of contributing factors

▸ Use incident to identify process inadequacies that need correction

Moving From RCA to RCA Squared

- Root cause analysis has had inconsistent success at improving safety

- RCA squared = root cause analysis and actions

  - Focus on measuring improvements to assure corrections improve safety

  - Analyze RCA to assure strong actions to prevent future error included (more later)

  - Assure RCA is through and credible

  National Patient Safety Foundation (NPSF)

  RCA2 Improving Root Cause Analysis and Actions to Prevent Harm (www.npsf.org)

Immediate Actions After an Event

▸ Take care of the patient

▸ Document what happened in the record

▸ Disclose what is known to the patient/family

▸ Secure /sequester equipment

▸ Begin gathering relevant information

▸ Identify team members

Conducting a RCA

▸ Should be conducted as soon as possible following an event (within 72 hours)

▸ Team members (4-6) need to include:

  ▸ process expert

  ▸ team leader/team facilitator

  ▸ subject matter experts

  ▸ risk management

  ▸ **senior executive**

  ▸ trainees (ACGME)

  ▸ Do **NOT** include those involved in the actual event in the team (they are interviewed by a trained interviewee)

Why is it no longer recommended to include those on the sharp end of an adverse event?

▸ They may feel guilty

▸ They may insist on corrective measures that are above and beyond what is prudent

▸ They may steer the team away from their role in the activities that contributed to the event

▸ However, they should be made aware of actions taken to prevent future events

Sequence of Events

- Step 1: Map out process as it actually happened in the particular event.
  - Sequence of events – chronological flow
    - What happened?

Address the following categories of potential issues:

▸ Physical assessment process

▸ Care planning process

▸ Staffing levels

▸ Orientation and training

▸ Competency/credentialing

Address the following categories of potential issues:

▸ Behavioral assessment

▸ Patient identification process

▸ Patient observation procedures

▸ Communication with patient/family

▸ Security

▸ Control of medications/storage/access

Address the following categories of potential issues:

▸ Supervision of staff
▸ Communication
▸ Availability of information
▸ Adequacy of technological support
▸ Equipment maintenance/management

RCA versus FMEA

	RCA	FMEA
MODE	REACTIVE	PROACTIVE
Process flow	Chronological : what happened	Process: Actual versus ideal
Goal	Revise process after event for future prevention	Revise process based on risk/severity/ probability for future prevention
Measure success	Yes	Yes

How will your Root Cause Analysis be evaluated

To be complete, your root cause analysis must be:

‣ Thorough

‣ Credible

‣ Acceptable (Action Plan)

Thorough

- Analysis repeatedly asks "why" (5 times) until causal factors are identified

- Analysis focuses on systems and processes (not individuals)

- Human and other factors most directly associated with event and processes and systems related to its occurrence are identified

- Analysis determines where redesign of systems and processes might reduce risk

- Inquires into all areas (categories) appropriate to the specific event

- Identify risk points and their contribution

- Determine potential areas to improve processes or systems OR that no improvement opportunities exists

Credible

- Include participation by a process owner who is not a member of the response team (sr. executive or designee)
- Include individuals most closely associated with processes under review
- Be internally consistent (no obvious questions unanswered)
- Provide and explanation for all findings of "not applicable"

Acceptable (Action Plan)

▸ Identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking changes

▸ For EACH improvement action, identifies:

  ▸ **Who** is responsible for implementation
  ▸ **What** will be changed
  ▸ **When** the action will be implemented
  ▸ **How** the effectiveness of the actions will be evaluated (measurement)
  ▸ **How** actions will be sustained

Stronger actions

▸ Architectural/physical plant changes
▸ New devices with usability testing
▸ Engineering control (forcing function)
▸ Simplify process
▸ Standardize on equipment or process
▸ Tangible involvement by leadership

Intermediate actions

▸ Redundancy

▸ Increase staffing/decrease workload

▸ Software enhancements/modifications

▸ Eliminate/reduce distractions

▸ Educate using simulation-based training with refreshers and observations

▸ Checklist/cognitive aids

▸ Eliminate look-alike-sound-alike

▸ Standardize communication tools

▸ Enhanced documentation/communication

Weaker actions

▸ Double checks
▸ Warnings
▸ New procedure/policy
▸ Training/education

Measure of Success

- ▶ Define Numerator/denominator
- ▶ Define audit methodology
  - ▸ What will be audited
  - ▸ How many
  - ▸ Frequency
  - ▸ How audit charts/patients to be selected (random sample, etc.)
- ▶ Define goal (90-100% for most)

- ▶ MAKE THE OWNER THE PROCESS OWNER NOT INFECTION CONTROL OR QUALITY

Warning signs of an Ineffective RCA

▸ No contributing factors identified, or contributing factor lack supporting data or information

▸ One or more individuals are identified as causing the event; causal factors point to human error or blame

▸ No stronger or intermediate strength actions are identified

▸ Causal statements do not comply with the five rules of causation

Warning signs of an Ineffective RCA

▸ No corrective actions are identified, or corrective actions do not address the system vulnerabilities

▸ Action follow up is assigned to a group or committee, not an individual

▸ Actions do not have completion dates or meaningful outcome or process measures

▸ The event took longer than 45 days to complete

▸ There is little confidence that implementing and sustaining corrective actions will significantly reduce the risk of future events

Measuring the Effectiveness and Sustainability of the RCA Process

▸ Percent of contributing factors that do not meet the five rules of causation

▸ Percent of RCA with at least one strong or intermediate action

▸ Percent of total actions that are strong or intermediate

▸ Percent of actions that are completed on time

▸ Percent of total actions completed

Measuring the Effectiveness and Sustainability of the RCA Process

- Audits or checks that independently verify that hazard mitigations has been sustained over time

- Staff and patient satisfaction with RCA process

- Response to AHRQ survey questions pertinent to the RCA review process

- Percent of RCA results presented to the Board

Conclusions and and Take Aways

▸ Leadership support

▸ Start asap after the event

▸ Support the staff

▸ Keeping digging until you get to the root cause

▸ Assure actions are in strong and intermediate categories