Root Cause Analysis

What Are the Risk Exposures?

Root cause analysis (RCA) is a process that retrospectively reviews a high-severity event or near miss. The purpose of an RCA is to identify and understand the underlying causes and variations that contributed to the event. This identification assists in effectively determining risk reduction and treatment methods to avoid the recurrence of such an event in the future. An RCA focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in an organization's processes, identifying potential improvements in those processes or systems that would assist in decreasing the likelihood of high-severity events or near misses occurring in the future.

The RCA methodology is based on the philosophy that problems are best solved by attempting to correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms. By directing corrective measures at root causes, it is expected that the likelihood of problem recurrence by a single intervention is not always possible. Thus, RCA is often considered to be an iterative process and is frequently viewed as a tool of continuous improvement.

RCA is not a single, sharply defined methodology. Instead, there are many different tools, processes, and philosophies for RCA. Primarily, five types of RCA emerge; they are classified into their basic fields of origin:

- **Production-based** – Originated in the field of quality control for industrial manufacturing.
- **Process-based** – Followed from production-based RCA, but expanded to include business processes.
- **Failure-based** – Rooted in the practice of failure analysis used in maintenance and engineering.
- **Safety-based** – Descended from the fields of accident analysis and occupational safety and health.
- **Systems-based** – Emerged as an integrated combination of the schools, along with ideas taken from the fields of change management, risk management, and systems analysis.[1]

The systems-based RCA will be the focus of this chapter.

When Is This a Risk Issue?

Unlike failure mode and effects analysis (FMEA), which proactively seeks to identify and eliminate potential failures, the RCA process, at least initially, is a reactive method of problem detection and problem-solving. This means that the analysis is done after an event has occurred. However, after acquiring expertise in RCA, it too becomes a proactive method in that an RCA is able to forecast the possibility of an event even before it occurs.

Updated: April 2019

It is important to note that although The Joint Commission is likely the impetus behind the introduction of RCA activities into healthcare institutions in the context of acquiring and maintaining accreditation status, its inherent value to all hospital facilities cannot be overstated. The RCA is a basic feature of high-reliability learning organizations. An RCA can effectively transform an organization's culture from one of blame to one of safety, where variation is minimized and problem-solving and risk avoidance are maximized.

On June 16, 2015, the National Patient Safety Foundation (NPSF) released a new methodology for conducting root cause analyses, *RCA*[2] *– Improving Root Cause Analyses and Actions to Prevent Patient Harm*. Since that time, The Joint Commission, the Institute for Healthcare Improvement (IHI), the Institute for Safe Medication Practices (ISMP), and many other professional healthcare organizations have endorsed RCA[2] as the preferred method for conducting a root cause analysis.[2]

The Joint Commission's Requirements

The Joint Commission is heralded for its accomplishments in patient safety initiatives and "raising the bar." The discussion and recommendations that follow focus on The Joint Commission's requirements and terminology. While The Joint Commission previously referred specifically to conducting a root cause analysis in response to a sentinel event, as of January 1, 2015, The Joint Commission has changed to using a broader term – *comprehensive systematic analysis*. An RCA would suffice as a type of comprehensive systematic analysis.

While hospitals are not required to report any patient safety event that meets The Joint Commission's definition of a sentinel event to The Joint Commission, they are strongly encouraged to do so.[3] The Joint Commission may also learn of the occurrence of a sentinel event through other avenues, such as through a media report, directly from a patient or family members, from a hospital surveyor, or from an individual hospital employee.[4]

Self-reporting a sentinel event is not required, and there is no difference in the expected response, time frames, or review procedures whether the hospital voluntarily reports the event or The Joint Commission becomes aware of the event by some other means.[5] The organization is required to submit or otherwise make available to The Joint Commission an acceptable comprehensive systematic analysis (e.g., an RCA) and action plan within 45 business days of the event or of becoming aware of the event.

State Reporting

Many states now require hospitals to report adverse events and the resulting RCA and corrective action plan to a state agency. Twenty-six states and the District of Columbia have hospital reporting requirements.[6] It is prudent for hospital leaders in these states to be aware of the types of events that require reporting and the information that must be reported. In many cases, the RCA conducted to meet accreditation requirements may meet state requirements for analyzing the event and creating an action plan.

Patient Safety Organizations

Under the Patient Safety and Quality Improvement Act of 2005, hospitals have the option to voluntarily report medical errors, near misses, and other patient safety events to a certified patient safety organization (PSO) on a privileged and confidential basis. The purpose of this federal program is to improve patient safety nationally by collecting patient safety data for aggregation and analysis and to provide healthcare providers with guidance on how to minimize risks in the delivery of patient care.[7]

Benefits to contracting with a PSO include receiving event data analysis and feedback on patient safety initiatives. While the obvious benefit is improved patient safety, enhanced confidentiality protection is another attractive feature of contracting with a PSO. Organizations reviewing options for contracting with a PSO should become familiar with the confidentiality provisions and limitations.

Information obtained during an RCA may be "patient safety work product" for submission to a PSO. The information may also be shared with an accreditation organization and maintains its confidentiality protection under federal law if one of the two following stipulations is met:

- Identified providers must agree to the disclosure.
- Provider identifiers are eliminated from the information.[8]

Conducting an RCA

Blameworthy Events

It is inappropriate for RCA processes to be used to focus on the performance of individual healthcare workers. Instead, it seeks to discover the systems-level causes for adverse events.[9] Some adverse events are blameworthy, and the organization must identify which actions or inactions fall into this category. A common definition of blameworthy events includes those that are the result of criminal acts, patient abuse, alcohol or substance abuse on the part of the provider, or acts defined by the organization as being intentionally or deliberately unsafe.[10] RCA^2 is not the appropriate approach to use to analyze blameworthy events.

Risk-Based Prioritization – The new RCA^2 versus the historic RCA

An RCA^2 prioritization that is explicit and risk-based is superior to one that takes a harm-based approach, as is seen with the historic RCA approach. A harm-based approach requires that an event cause patient harm before an RCA is warranted.[11] Alternatively, RCA^2 provides a risk-based prioritization tool *The Safety Assessment Code (SAC) Matrix*. The SAC uses four severity categories: catastrophic, major, moderate, and minor, along with four probability categories—frequent, occasional, uncommon, and remote—to determine when an RCA^2 is warranted.[12] This risk-based system prioritizes hazards and vulnerabilities that may not yet have caused harm so that these hazards and vulnerabilities can then be mitigated or eliminated before harm occurs. Therefore, near-miss situations should be evaluated using the SAC.

Timing

The RCA^2 process should be initiated as soon as possible, preferably within 72 hours following

the event in order to capture event details while they are still fresh in the minds of those involved.[13]

Team Membership
Several meetings will be required to complete the RCA[2] process. Meetings are typically between 1.5 to 2 hours in length, with work required by individual members prior to and between meetings to complete interviews or locate and review publications and documents.[14]

The size of the RCA[2] review teams should be limited to four to six members.[15] Review teams with more members will use more person-hours to complete the review and make scheduling team meetings most difficult.[16]

Teams should include both a subject matter expert as well as someone who is familiar with the RCA[2] process but has no familiarity with the event under review.[17] Typically a subject matter expert is a frontline staff member from the department where the event occurred. The facility risk manager or patient safety officer is often the RCA process expert. Importantly:

> Managers and supervisors may serve as team members provided the event did not occur in their area of responsibility and their subordinates are not team members. This avoids the possibility of subordinates censoring themselves if their supervisor or manager is present, thus inhibiting free and open communication.[18]

A significant change from previous way of thinking in the historic RCA is presented in RCA[2]:

> Individuals who were involved in the event *should not* [italics added] be on the team because they may feel guilty and insist on corrective measures that are above and beyond what is prudent, or they may steer the team away from their role in the event and activities that contributed to the event. It may also be hard for other team members to ask difficult questions and have frank discussions with these individuals present in the room. These same reasons apply to having patients or family members who were involved in the event serve on RCA[2] teams. However, it is certainly appropriate and usually vital that involved individuals (staff, patients, family members) should be interviewed by the team, in order to understand what happened and to solicit feedback on potential corrective actions.[19]

Individuals who were involved in the event should be interviewed by one or more team members. Patients and/or the patient's family, as appropriate, should be among those interviewed unless they decline. Interviewing the patient and/or family will provide a more complete understanding of the circumstances surrounding the event under consideration.[20]

Follow-up Activity
For accredited organizations, a sentinel event measure of success (SE MOS) process may be used to document follow-up activity. The SE MOS generally consists of numerical data related to monitoring outcomes that show whether the actions taken were effective in meeting the intended

performance improving goal and that the improvements are sustained. The SE MOS is due to The Joint Commission on a mutually agreed-upon date after the root cause analysis and action plan are accepted.[21]

How Can I Reduce Risk?

Understand The Joint Commission's Requirements	

Understand requirements	• Understand that all accredited organizations are expected to identify all sentinel events occurring in the organization.
	• Respond to all sentinel events by conducting a thorough and credible comprehensive systematic analysis and developing an action plan within 45 business days of the event or becoming aware of an event.[22]
	• Implement the action plan, evaluate the effectiveness of the actions, and provide measures of success to the Joint Commission on a mutually agreed upon date.[23]
	• Understand that The Joint Commission defines a sentinel events as follows:
	  ○ A sentinel event is a 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 any of the following:
	  ▪ Death.
	  ▪ Permanent harm.
	  ▪ Severe temporary harm:
	  • *Severe temporary harm* is critical, potentially life-threatening harm lasting a for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.
	  ○ An event is also considered sentinel if it is one of the following:
	  ▪ Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED).
	  ▪ Unanticipated death of a full-term infant.

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- Discharge of an infant to the wrong family.
- Abduction of any patient receiving care, treatment, and services.
- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient.
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, RH, other blood groups).
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on-site at the hospital.
    - Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated on the premises of the hospital, including oral, vaginal, or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ, or object. One or more of the following must be present to determine that it is a sentinel event:
        - Any staff-witnessed sexual contact as described above.
        - Admission by the perpetrator that sexual contact, as described above, occurred on the premises.
        - Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact.
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioners, visitor, or vendor while on-site at the hospital.
- Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure.

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- Invasive procedures, including surgery, on the wrong patient, at the wrong site, or that is the wrong procedure, are reviewable under the policy regardless of the type of the procedure or the magnitude of the outcome.

- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery.
  - "After surgery" is defined as any time after the completion of final skin closure, even if the patient is still in the procedural area or in the operating room under anesthesia. This definition is based on the premise that a failure to identify and correct an unintended retention of a foreign object prior to that point in the procedure represents a system failure, which requires analysis and redesign. It also places the patient at additional risk by extending the surgical procedure and time under anesthesia. If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter).
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care.
  - *Fire* is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion

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process that results in smoldering condition (no flame) is still classified as fire. Source: National Fire Protection Association.

- Any intrapartum (related to the birth process) maternal death.
- Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying conditions) when it reaches a patient and results in any of the following:
  - Permanent harm or severe temporary harm.
    - *Severe maternal morbidity* is defined by the American College of Obstetrics and Gynecology, the US Center for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hrs.), that requires the transfusion of 4 or more units of blood products (fresh frozen plasma, packed red blood cells, whole blood, platelets) and/or admission to the intensive care unit (ICU). Facilities are strongly encouraged to review all cases of severe maternal morbidity for learning and improvement. *Admission to the ICU* is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support. Ongoing vigilance to better identify patients at risk—and timely implementation of clinical intervention consistent with evidence-based guidelines—are important steps in the ongoing provision of safe and reliable care. Appropriate systems improvements can be informed by identifying occurrences of maternal morbidity, reviewing the cases, and analyzing the findings.[24]

Be thorough and credible

- Ensure that a comprehensive systematic analysis is *thorough* and *credible* and that the action plan is acceptable.[25]
- Include the following in the comprehensive systematic analysis to be *thorough*:

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- The analysis asks a series of "why" questions until it identifies the systemic causal factors associated with each step in the sequence that led to the sentinel event.
- The analysis focuses on systems and processes, not solely on individual performance.
- A determination of the human and other factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence.
- The analysis of the underlying systems and processes through the series of "why" questions determines where redesign might reduce risk.
- An inquiry into all areas appropriate to the specific type of event.
- An identification of risk points and their potential contributions to this type of event.
- A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.[26]

- Include the following in the comprehensive systematic analysis to be *credible*:
  - Participation by a process owner who is not a member of the response team; typically, this is a senior leader of the hospital or a designee. A senior leader is not necessarily required to be actively involved in the day-to-day work of the comprehensive systematic analysis team. However, the team should report to the senior leader or designee, and he or she should be involved in deciding or approving the actions the hospital will take as a result of the comprehensive systematic analysis.
  - Each action recommended by a review team should be approved or disapproved, preferably by the CEO or alternatively by another relevant member of top management. If an action is disapproved, the reasons for its disapproval should be shared with the comprehensive systematic analysis and action team so that the constraint can be understood and another developed by the team to replace it if the systems vulnerability is not otherwise effectively addressed in the action plan.[27]

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- Include patients, family members, or patient representatives (when appropriate), to ensure that the facts are thoroughly understood.
- Participation by individuals most closely involved in the processes and systems under review.
- Internal consistency (that is, nothing is contradictory or leaves questions unanswered).
- An explanation for any findings of "not applicable" or "no problem."
- A bibliography of any relevant literature.[28]

- Understand that an Action Plan is considered acceptable if it:
  - Identifies and implements actions to eliminate or control systems hazards or vulnerabilities.
  - It is recommended but not required that review teams should attempt to identify actions that are likely to reduce the risk or prevent the event from recurring and if that is not possible, reduce the severity or consequences if it should recur.
  - It is recommended that the review team use a tool that will assist in identifying stronger actions that provide effective and sustained system improvement. A tool such as the Action Hierarchy can help organizations evaluate the strength of the corrective actions identified in their comprehensive systematic analysis. The U.S. Department of Veterans Affairs National Center for Patient Safety developed this tool in 2001. An example of the Action Hierarchy tool is available at https://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf.[29]

Understand Cause and Effect Analysis

Understand analysis

- Use the five rules of causation to help RCA team members identify and understand human biases that can impair an investigation into the root cause, which may be viewed on the US Department of Veterans Affairs website: https://www.patientsafety.va.gov/professionals/publications/glossary.asp.

Understand Cause and Effect Analysis

- Recognize that the description of the event should explain the link between the bad outcome and the root cause.
- Ensure that each member of the team has a clear understanding of this relationship.
- Be clear in statements of findings and avoid inflammatory statements, such as stating that something was "poorly written."[30]
- Determine why the human error was a factor that led to the outcome.
- Identify a corresponding cause for every human error identified.[31]
- Understand why a deviation from the procedure, such as a workaround or not fulfilling all the procedure's steps, led to a problem.
- Examine the standards, guidelines, and protocols of practice to determine if there was a preexisting duty to act.

Sample tool

- ***RCA Brainstorming Tool and Cause and Effect Analysis - SAMPLE*** is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.

Follow the Steps for Conducting an RCA

Follow steps

- Ensure that each step of the RCA process is documented.
- Arrange documentation in a binder with the following tabs:
  - Investigation Notes.
  - Team Agendas, Meeting Minutes, and Educational Materials.
  - Analytical Tools.
  - Policies/Procedures.
  - Literature Review.
  - Best Practices.
  - Action Plan.
  - Audit Results.
  - Evaluation of Effectiveness.

Follow the Steps for Conducting an RCA	
Sample tool	• ***Serious Adverse Event Reporting Investigation and Conducting RCA – SAMPLE*** is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.
Identify and classify events	• Understand that some events are inappropriate for RCA review. • Look for underlying systems-level causations for performance issues. • Define blameworthy actions and inactions that will be handled or dealt with using administrative or human resource systems.
Use risk-based prioritization	• Use a risk-based RCA prioritization system rather than one focused on a patient's harm or injury. • Understand that the risk-based system prioritizes hazards and vulnerabilities that may not yet have caused harm.
Initiate process	• Initiate the RCA^2 process as soon as possible, preferably within 72 hours following the event. • Limit RCA^2 review team to four to six members. • Include a subject matter expert on the team, as well as someone who is familiar with the RCA^2 process but not familiar with the event process being reviewed. • Do not include individuals who were involved in the event on the team. • Interview individuals who were involved with the event, including the patient and/or the patient's family members, as appropriate.
Sample tool	• ***First Team Meeting Agenda – SAMPLE*** is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.

Complete review process	• Understand that the RCA^2 review process includes the following steps:
	  ○ Describe the event using a chronological flow diagram or timeline.
	  ○ Identify gaps in knowledge about the event.
	  ○ Visit the location of the event to obtain firsthand knowledge about the workspace and environment.

Follow the Steps for Conducting an RCA

- Evaluate equipment or products that were involved.
- Identify team-generated questions that need to be answered.
- Use triggering questions and team-generated open-ended questions that can broaden the scope of the review by adding additional areas of inquiry.
- Identify staff members who may have answers to the questions and conduct interviews of involved parties, including staff members and affected patients.
- Include patients, family members, or a patient representative, as appropriate, to ensure a thorough understanding of the facts.
- Identify internal documents to review (e.g., policies, procedures, medical records, maintenance records).
- Identify pertinent external documents or recommended practices to review (e.g., peer reviewed publications, manufacturers' literature, equipment manuals, professional organization guidance and publications).
- Identify and acquire appropriate expertise to understand the event under review. This may require interactions with internal and external sources of expertise (e.g., manufacturers, vendors, professional organizations, regulatory organizations).
- Enhance the flow diagram or timeline to reflect the final understanding of events and where hazards or system vulnerabilities are located.
- Provide feedback to the involved staff and patients, as well as feedback to the organization as a whole.

- Understand that RCA[2] methodology includes a comprehensive list of triggering questions categorized into the following areas:
  - Communication.
  - Training.
  - Fatigue/scheduling.
  - Environment/equipment.
  - Rules/policies/procedures.
  - Barriers.[32]

Follow the Steps for Conducting an RCA	

Implement action plan	• Analyze the impact of the proposed actions.
	• Utilize Dr. Alan Card's proposal that there are three types of controls or actions with three levels of impact:[33]
	  ○ Administrative (low impact – all still require people to do, understand, and know about the changes and choose to follow them):
	  ▪ Revised policies or procedures.
	  ▪ Checklists.
	  ▪ Double-checks.
	  ▪ Training and retraining.
	  ○ Design (medium impact – there remain situations when the design controls might be bypassed):
	  ▪ Physical barriers.
	  ▪ Automation/forcing functions.
	  ▪ Non-interchangeable connectors.
	  ○ Elimination (high impact – there Is no longer an opportunity to make an error if the service or product no longer exists in the organization):
	  ▪ Program or service discontinuation.
	  ▪ Product substitution.
	  ▪ Procedure discontinuation.[34]

Measure and assess	• Set a date to audit and monitor the implemented performance improvement activities. • Verify that the implemented measures have had the desired impact and prevented a recurrence.
Sample tool	• ***RCA Action Impact Analysis Tool – SAMPLE*** is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.
Report outcomes	• Report activities and outcomes to the quality oversight committee and the governing body.

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