HHC
Healthcare Hazard Control

Analysis

Volume 1
Safety and Behavior 2.2.1

Root-Cause Analysis

Abstract: A root-cause analysis (RCA) is a structured, step-by-step investigation of an adverse event or close call that determines what happened, underlying causes, and what can be done to prevent recurrence. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)-accredited healthcare organizations are required to perform an RCA for all sentinel events and to submit the RCA to JCAHO for certain sentinel events. This analysis discusses the elements of a JCAHO-acceptable RCA and action plan for improvement. It outlines five steps organizations should follow to conduct an RCA, based on recommendations from JCAHO, the Department of Veterans Affairs, and other entities. It also provides tips on how to design an action plan based on the results of the RCA and how to measure the success of that action plan.

The provision of safe and effective care in a hospital or other healthcare setting is a complex process that involves not just the individual clinician and patient, but the entire healthcare system in which treatment takes place. In the past, when something went wrong, the tendency was to blame the adverse event on human error—and there is no question that humans are fallible. However, what has sometimes been called a "name, blame, and shame" mentality looks only at the final action that caused the problem and ignores the long series of actions and processes that led to the final action. Moreover, simply "punishing" the individual who made the mistake does not prevent other individuals from making the same mistake in similar circumstances.

Root-cause analysis (RCA) was developed as a structured and process-focused framework to investigate serious accidents in high-risk industries (e.g., aviation, chemical, nuclear).[1] As can be imagined, trying to investigate, for example, why a plane crashed is a complicated undertaking. There are many possible causes (e.g., equipment failure, inadequate pilot training, bad weather) and possible contributing factors (e.g., inappropriate weight load of passengers and cargo, wind shear). Without a structured way to approach the investigation, it would be easy to miss important elements—which would mean the accident could happen again. The RCA technique helps ensure that all possible causes are considered.

In 1997, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) began to require hospitals and other healthcare organizations to use the RCA process to investigate sentinel events. JCAHO defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof." Certain sentinel events, such as a patient suicide, infant or patient abduction, and rape, may involve healthcare safety and security managers when the RCA is conducted.

Some healthcare institutions may also choose to conduct an RCA on events that do not necessarily qualify as a sentinel event. The U.S. Department of Veteran Affairs (VA), for example, requires all its hospitals to perform RCAs for all serious adverse events and "potential" adverse events—sometimes called "near misses" or "close calls."

This Analysis will review RCA techniques. Healthcare safety and security managers can use the information to help identify contributing factors such as human factors, technological failures, and management process failures that are at the root of a particular problem. In some situations, safety and security managers will be members of an interdisciplinary committee assigned to investigate the root causes of an accident.

What Is Root-Cause Analysis?

JCAHO defines RCA as

> a process for identifying the basic or causal factors that underlie variation in performance . . . [it] focuses

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October 2006

> primarily on systems and processes, not on individual performance. It progresses from special causes . . . to common causes in organizational processes . . . and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future.[2]

A "special cause" is a variation in performance (i.e., adverse event or close call) that is the result of specific identifiable causes. A special cause is not inherently present in a system; rather, it is the result of factors that are not part of the system as designed, such as a mechanical malfunction, an intoxicated employee, or a flood. Eliminating a special cause eliminates only that particular abnormal performance; it does not prevent the same cause from recurring. For example, firing an intoxicated employee means only that the individual will not cause a problem in the future; it does not mean that another intoxicated employee could not cause a similar problem. Only addressing the larger issue—problems with personnel screening, staff education, and supervision or information management systems—will prevent future problems with intoxicated employees.[3]

Common-cause variations, on the other hand, are problems that are inherent in the way a process is designed. For example, when a facility examines the time it takes an emergency department (ED) to obtain a routine radiology report, common-cause variations would include the time of day the report was requested and how busy the radiology service is. In other words, the variation in the process for providing reports would result from common causes such as staffing levels or ED census.[4] Thus, through identification of the process or system vulnerability (i.e., a common cause of radiology report delays), the cause can be eliminated through a basic change in the process itself.

What Is a Root Cause?

A root cause is the most basic factor or factors that, if corrected or removed, will reduce the risk or prevent recurrence of a situation. A root cause is the most fundamental reason a failure has occurred.

Although commonly mistaken as a root cause, human error is not an underlying root cause of an event. For example, one poorly conducted RCA examined the death of a patient who had been treated in the ED for 10 hours and then discharged, only to return 5 hours later in acute respiratory distress that led to death. The root cause was found to be "misinterpretation of information" by a well-trained physician who had no previous poor outcomes. Based on the RCA documentation, the ED doctor appeared to have acted in a vacuum, with no other clinicians with whom to consult and no quality oversight system. Clearly, the RCA did not look beyond the "sharp" end (the ED physician) to identify causes that were more deeply embedded in the system. For example, was a policy needed to require a second physician's opinion? Were additional cross-checking measures needed for patients who spend more than a certain period of time in the ED or who receive certain kinds of treatment?[5]

There are usually between four and six root causes for each sentinel event investigated. Even in those rare situations in which the adverse event resulted from an intentional act of an individual, there is usually more than one root cause.

Human Factors

While human error is not a root cause of an event, human factors may be contributors. A human-factors engineering approach looks for systems vulnerabilities.[6] It recognizes that an individual's ability to complete work is influenced by many factors, some of which are not immediately apparent. It looks at the entirety of the environment in which an individual works and takes into account factors such as the physical environment and individual mental characteristics (learning, remembering, and decision making). Other human factors include group dynamics, task complexity, and concurrent tasks.[7]

A human-factors engineering approach recognizes that even the best-trained, most competent individual makes mistakes. For example, even the most experienced and highly trained nurse could mistakenly grab a package labeled VINCRISTINE instead of VINBLASTINE. Redesigning the medication label using selective upper- and lowercase lettering instead of all upper- or lowercase lettering, so that the labels appear as VinCRISTine and VinBLASTine, is one change that would make it far less likely that the nurse would make that mistake.[8]

Ask Why at Least Five Times

An RCA investigation goes backward from the adverse event or near miss and analyzes and reanalyzes all possible process and systemic causes (both direct and indirect) until the root cause of the event is identified. RCA investigators must constantly ask "Why?" In fact, it has been said that "the simplest way to perform root cause analysis is to ask why five times."[9] For example, consider the following questions from a

JCAHO-Reviewable Sentinel Events

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires healthcare facilities to conduct a "thorough and credible" root-cause analysis (RCA) on the following sentinel events and submit their completed RCA to JCAHO (alternatives to submitting the RCA to JCAHO are available):

- Any event that resulted in an unanticipated death or major permanent loss of function,* not related to the natural course of the patient's illness or underlying condition.** Such events could involve
  - — medication errors;
  - — elopement (i.e., unauthorized departure from a round-the-clock care setting);
  - — assaults, homicides, or other crimes;
  - — falls; or
  - — intrapartum maternal deaths.
- Suicide of any individual receiving care, treatment, and services in a staffed round-the-clock care setting or within 72 hours of discharge
- Unanticipated death of a full-term infant
- Abduction of any patient receiving care, treatment, and services
- Infant abduction or discharge to the wrong family
- Rape***
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
- Surgery on the wrong patient or wrong body part#
- Unintended retention of a foreign object (e.g., sponge, forceps) in a patient after surgery or other procedure
- 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

Source: Sentinel events. In: Joint Commission on Accreditation of Healthcare Organizations. *Comprehensive accreditation manual for hospitals.* Oakbrook Terrace (IL): Joint Commission Resources; 2006.

* Major permanent loss of function, as defined by JCAHO, means "sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or lifestyle change. When major permanent loss of function cannot be immediately determined, applicability of the policy is not established until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first."

**If an adverse outcome is associated with the treatment (including "recognized complications") or lack of treatment of a condition or is not clearly and primarily related to the natural course of the patient's illness or underlying condition, it is reviewable. In indeterminate cases, the event will be presumed reviewable, and the organization's response will be reviewed under the sentinel event policy according to the prescribed procedures and time frames, without delay for additional information such as autopsy results.

*** Rape, for these purposes, is defined as unconsensual sexual contact involving a patient and another patient, a staff member, or other perpetrator while the patient is being treated or is otherwise on the premises of the hospital.

All such events are considered reviewable by JCAHO, regardless of the magnitude of the procedure or outcome.

hypothetical medication error investigation (note that the answer to each question raises more questions):

- Why did the patient get the incorrect medicine? *Because the prescription was wrong*.
- Why was the prescription wrong? *Because the doctor made the wrong decision*.
- Why did the doctor make the wrong decision? *Because he did not have complete information in the patient's chart*.
- Why was the patient's chart incomplete? *Because the doctor's assistant had not entered the latest laboratory report*.
- Why had the doctor's assistant failed to chart the latest laboratory report? *Because the lab technician telephoned the results to the receptionist, who forgot to tell the assistant*.

Once the RCA investigators of the medication error answer the "why" questions, it becomes clear that one way to prevent such mistakes in the future would be to develop a system for tracking laboratory reports and a method to improve communication.

JCAHO Requirements

JCAHO standards for improving organization performance require facilities to identify and manage sentinel events. This includes conducting a "thorough and credible" RCA of the event. JCAHO gives facilities leeway to define sentinel events for their purposes, but at minimum, the definition must include those events subject to review under JCAHO's sentinel event policy (see "JCAHO-Reviewable Sentinel Events" for a list of reviewable sentinel events). For "reviewable" sentinel events, the organization must submit its completed

RCA (and an action plan describing how the healthcare organization plans to prevent or reduce the risk that a similar event will occur in the future) to JCAHO within 45 days of its becoming aware of the event.

JCAHO's standard for proactive risk assessment also requires organizations to analyze at least one high-risk process each year based in part on information published by JCAHO about the most frequent sentinel events and risks.[10]

Alternatives to Submitting the RCA to JCAHO

Because many reviewable sentinel events, such as wrong-site surgery or infant abduction, may also put an organization or individual clinician at risk for legal liability and an RCA would most likely contain information that an organization would wish to keep confidential, JCAHO provides organizations four alternatives to submitting the RCA (see "Alternatives to Submitting RCA Documents to JCAHO" for a description of these alternatives). Legal counsel should always be consulted when a sentinel event has occurred to ensure that the RCA process is done in a way that best protects the organization legally. Counsel should provide advice about submitting the RCA and related documents to JCAHO or selecting one of the four alternatives. Review your organization's sentinel event policy to ensure that this area is addressed.

Elements of an Acceptable RCA

JCAHO describes the various elements of an acceptable RCA in its accreditation manual.[11]

JCAHO will consider an RCA to be acceptable for accreditation purposes if it has the following five characteristics:

- It focuses primarily on systems and processes, not individual performance.
- It progresses from special causes in clinical processes to common causes in organizational processes.
- It repeatedly digs deeper by asking "Why?" and, when the question is answered, asks "Why?" again, and so on.
- It identifies changes that could be made in systems and processes—either through redesign or development of new systems or processes—that would reduce the risk of such events occurring in the future.
- It is thorough and credible.

  To be thorough, an RCA must include the following:

  — A determination of the human and other factors most directly associated with the sentinel event

Alternatives to Submitting RCA Documents to JCAHO

Many organizations are concerned that sending their root-cause analysis (RCA) documents to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) may waive their right to claim confidentiality under state law. JCAHO permits healthcare facilities to select one of four alternative approaches to submitting the RCA and action plan to the accrediting organization.

JCAHO must receive the request for the use of one of these approaches within five business days of a healthcare facility self-reporting a reviewable event or the initial communication by JCAHO to the organization that JCAHO has become aware of a reviewable sentinel event. JCAHO will charge the organization to cover the average direct costs associated with the review.

Alternative 1. The organization can bring the RCA and action plan documents to the JCAHO headquarters for review by JCAHO staff and then leave with the documents on the same day.

Alternative 2. A specially trained JCAHO surveyor can come on-site to review the RCA and action plan.

Alternative 3. A specially trained JCAHO surveyor can come on-site to review the RCA and findings, without directly viewing the RCA documents, through a series of interviews and a review of relevant documentation. Relevant documentation includes, at minimum, documentation relevant to the organization's processes for responding to sentinel events, the patient's medical record, and the action plan resulting from the RCA.

Alternative 4. The organization's chief executive officer affirms in writing that the organization meets specified criteria demonstrating the risk of waiving confidentiality protections by sharing its RCA with JCAHO. If the criteria are met, a JCAHO surveyor conducts an on-site visit to conduct a review of the organization's process for responding to sentinel events; to perform a review of relevant organization policies and procedures before and after the review of the sentinel event to demonstrate the adequacy of the organization's response; to perform a standards-based survey that traces a patient's care, treatment, and services; and to evaluate the organization's management functions relevant to the sentinel event under review.

Sources: Sentinel events. In: Joint Commission on Accreditation of Healthcare Organizations. *Comprehensive accreditation manual for hospitals*. Oakbrook Terrace (IL): Joint Commission Resources; 2006; Joint Commission on Accreditation of Healthcare Organizations. Alternatives for sharing sentinel event-related information with the Joint Commission [online]. [cited 2006 Jun 8]. Available from Internet: http://www.jointcommission.org/SentinelEvents/ReportingAlternatives/se_alts.htm.

and the process(es) and systems related to its occurrence

— Analysis of the underlying systems and processes through a series of "Why?" questions to determine where redesign might reduce risk

— An inquiry into all areas listed for minimum requirements for an RCA, if the sentinel event is one for which JCAHO has established minimum requirements (e.g., elopement death, unanticipated death of a full-term infant). (See "Table. JCAHO Root-Cause Analysis Matrix—Minimum Scope of Analysis for Specific Types of Sentinel Events" for the complete list of those categories.)

— Identification of risk points (i.e., those specific places in a process or system that are susceptible to failure or breakdown) 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

To be credible, an RCA must do the following:

— Include participation of the leadership of the organization and of the individuals most closely involved in the processes and systems under review

— Be internally consistent (i.e., must not contradict itself or leave obvious questions unanswered)

— Provide an explanation for all findings of "not applicable" or "no problem"

— Include consideration of any relevant literature

Identifying the root causes of a problem is nothing more than an exercise if there are no recommendations for risk reduction strategies. The final product of an RCA is an action plan that identifies what the organization plans to do to reduce the risk of similar events occurring in the future. According to JCAHO, an action plan will be considered **acceptable** if it identifies changes that can be implemented to reduce risk (or formulates a rationale for not undertaking such changes) and identifies who is responsible for implementing improvement actions, when the actions will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.

How to Conduct an RCA

A book on RCA, published by Joint Commission Resources, describes 21 separate steps to completing a successful RCA. They can be summarized in six "key" steps.[12] Similarly, the Canadian Patient Safety Institute[13] and the VA National Center for Patient Safety (NCPS) have also developed a more simplified series of steps to follow. Based on these three sources, the basic steps of an RCA can be summarized as follows:

1. Create an RCA team.
2. Gather information.
3. Brainstorm.
4. Identify root causes.
5. Design and implement the action plan.

What is most important, however, is not the precise process of completing an RCA, but rather the application of systems analysis to the entire process. Such an approach will root out many causes of an error and not simply blame individual human error.

Step 1: Create an RCA Team

To perform a thorough and effective RCA, healthcare organizations must create an interdisciplinary RCA team whose core members have multiple skill sets and the time to commit to a time-consuming and labor-intensive process. (Team membership, roles, and responsibilities should be set forth in the organization's sentinel event policy.) Not every member of the team needs to be involved in all aspects of the process, but the core members should be. Typically, an RCA team should consist of

- a leader,
- a facilitator,
- individuals knowledgeable about the subject area,
- outside staff or consultants, and
- a senior leader from upper management.[14]

The Leader

The leader—who may also function as the facilitator—is someone with management responsibility who understands and supports RCA. This individual will keep the team focused on the event and provide organizational support to team members. This individual should also have some subject-matter knowledge about the general type of event being investigated.

The Facilitator

The facilitator is a person who has been trained in RCA processes and has hands-on experience in participating in or conducting RCAs or has had sufficient

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Table. JCAHO Root-Cause Analysis Matrix—Minimum Scope of Analysis for Specific Types of Sentinel Events

	Suicide (24 hr care)	Med. Error	Procedural Complication	Wrong-Site Surgery	Treatment Delay	Restraint Death	Elopement Death	Assault/Rape/ Homicide	Transfusion Death	Patient Abduction	Unanticipated Death of Full Term Infant*	Unintended Retention of Foreign Body*	Fall related*
Behavioral assessment process**	X					X	X	X					
Physical assessment process***	X	X*	X	X	X	X	X				X*		X*
Patient identification process		X		X					X				
Patient observation procedures	X				X*	X	X	X	X		X*		X*
Care planning process	X		X			X	X				X*		X*
Continuum of care	X	X*			X	X							X*
Staffing levels	X	X	X	X	X	X	X	X	X	X		X*	X*
Orientation & training of staff	X	X	X	X	X	X	X	X	X	X	X*	X*	X*
Competency assessment/credentialing	X	X	X	X*	X	X	X	X	X	X	X*	X*	X*
Supervision of staff#	X*	X	X		X	X			X			X*	
Communication with patient/family	X	X*		X	X	X	X			X			X*
Communication among staff members	X	X	X	X	X	X	X*	X*	X	X	X*	X*	X*
Availability of information	X	X	X	X	X	X			X		X*		X*
Adequacy of technological support		X	X										
Equipment maintenance/ management		X	X		X*	X					X*		X*
Physical environment##	X	X	X	X*		X*	X	X	X	X			X*
Security systems and processes	X						X	X		X			
Medication management###		X	X		X*				X		X*		X*

* Indicates updates.
** Includes the process for assessing patient's risk to self (and to others, in cases of assault, rape, or homicide where a patient is the assailant).
*** Includes search for contraband.
# Includes supervision of physicians-in-training.
Includes furnishings; hardware (e.g., bars, hooks, rods); lighting; distractions.
Includes selection & procurement, storage, ordering & transcribing, preparing & dispensing, administration, and monitoring.

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(continued from page 5)

mentoring to be confident in his or her ability to lead an RCA. (Often this individual will be a member of the organization's patient safety, quality improvement, or risk management programs. In some instances, this individual may be an outside consultant brought in especially to assist with the RCA.) This individual's role is pivotal in making sure that the RCA process works and that the team does not revert to applying personal biases and blaming individuals. Like the leader, the facilitator keeps the team focused on the event, but the facilitator must also coordinate team meetings, ensure that the organization's RCA policy is followed and that timelines of events are completed, participate in interviews of witnesses, and, possibly, write the final report.

Ideally, a facilitator has expertise in the following areas:

- RCA tools and techniques
- Group dynamics
- Delegation
- Group consensus building

Leaders and facilitators must be prepared to address a common problem for organizations conducting RCA—specifically, some organizations do not take the RCA process seriously enough.[15] The RCA team may come into the process with preconceived notions of what went wrong and will therefore fail to dig deep enough into the underlying systems. The leader and facilitator must be alert to these potential biases and address them.

Individuals Familiar with Event Subject Matter

Team members should include clinical and nonclinical staff with firsthand knowledge of the adverse event under review and/or the internal circumstances (processes and systems) surrounding the event. These team members could include some staff who were involved in the event and several who were not involved but who are knowledgeable about the subject matter.

For example, an adverse event involving a medication error could include pharmacists, biomedical engineers, information technologists, physicians, and nurses. An RCA regarding a suicide might involve housekeeping, security, and physical plant staff.

These team members provide information relevant to the different steps involved in investigating the adverse event, as well as information about the usual policy, processes, and procedures. They should help identify contributing factors and actions relevant to current practice.

Ideally, these team members have the following attributes:

- Extensive knowledge of the subject matter
- Credibility within the organization
- An analytic and open mind
- Interest in performance improvement

Other Staff or Outside Consultants

Other individuals, including outside consultants, can use specific knowledge of equipment or technology to provide additional information on factors that may have contributed to the event. For example, if medical monitoring devices were associated with the event, biomedical engineers not involved in the incident could provide information about how the devices work. Outside consultants may even serve as facilitators.

Senior Leader from Upper Management

RCA sometimes fails because of lack of support from top management**.** Having an individual from the senior leadership participate in the RCA demonstrates that an appropriate level of support exists. For example, a senior manager can ensure that team members are given time away from normal duties to participate in an RCA. Also, this individual ensures that the actions recommended by the RCA action plan are implemented and that the results of the RCA are broadly communicated within the organization. The senior leader can also drive organizational cultural change by making it clear that the organization does not support a culture of blame.

Commitment and Confidentiality

All members of the RCA team must take the investigation seriously and not jump to conclusions about what happened. Core team members must be prepared to spend a lot of time on the investigation, brainstorming any and all possible causes, reviewing the literature, interviewing witnesses, and visiting the scene of the event. They must be prepared to go back to the "apparent" beginnings of systems and processes until they have come to a complete understanding of what happened and why.

All team members must understand and respect the principle of confidentiality. An individual adversely

affected by the event, or his or her family members, may be considering (or may have already filed) a lawsuit. Team members must keep whatever is discovered during the RCA process confidential unless instructed to do otherwise by the healthcare organization's legal counsel. One commonly used approach is to mark all documents created as part of the RCA as "privileged and confidential." Documents prepared under the direction of an attorney may be considered privileged under the attorney work-product privilege. Some state statutes also provide that investigations that are part of the quality management or peer-review process (which could be argued to include the RCA) are also protected from discovery.

Note also that JCAHO specifically states that the RCA and the action plan should not contain the names of caregivers or patients involved in the sentinel event.[16]

Group Process and Procedures

Before beginning to investigate the event, the team needs to set its own ground rules and expectations regarding team members' responsibilities. Again, much of this information should already have been outlined in the organization's sentinel event policy. But because each event investigated can be different, the team needs to give thought to how information will be recorded and where physical evidence can be stored securely. Also, because team members may vary depending on the event being investigated, the team needs to consider such factors as how English-language fluency or power-differential issues within the culture might mean that, for example, team member 1 would better suited to interview staff members A, B and C, while member 4 would be better suited to interview staff members X , Y, and Z.

The team should also create a basic work plan that includes target dates for the major activities discussed below. This is particularly important in the case of a reviewable sentinel event, since the RCA must be submitted to JCAHO within 45 days.

Step 2: Gather Information

The team must collect as much data as possible about the adverse event itself. Data collection (i.e., establishing what happened through witness interviews, document and evidence reviews, and/or field observations) is a key component of any accident analysis process.[17] However, since one of the goals of conducting an RCA is to identify *system* and *process* issues that are the underlying root causes of the adverse event, information must be collected about systems and processes associated with the adverse event—not just information about the event itself.

Establish Initial Understanding

The team should start by defining the issues and setting forth its initial understanding about what happened. This can be done as a flow chart, narrative timeline, or chronological description.

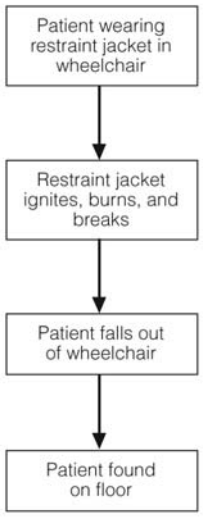
Beginning with the first known fact, the team must proceed chronologically to the actual event and end with the final known event. This may help the team understand where there are gaps in knowledge—in factual knowledge about the adverse event as well as in knowledge about systems and processes.

NCPS gives the following example.[18] A patient in a locked ward is found lying on the floor with third-degree burns on his chest and arms. The patient was last seen asking for a cigarette. A partially burned restraint jacket was found still attached to the patient's wheelchair (see "Figure 1. An Example of an Initial Understanding of an Adverse Event").

Obtain Additional Information

A common problem in RCA is the team's propensity to jump to conclusions before investigating the event. This is not surprising; when looking at something in hindsight, individuals have a tendency to think in

Figure 1. An Example of an Initial Understanding of an Adverse Event



terms of a straight line. But by obtaining more information and using it to revise the team's final understanding, the team will discover many gaps in its initial understanding.

In the scenario of the burned patient, there are still many unknowns. Why was the patient wearing the restraint jacket in the first place? Was the patient at risk of falling out of the wheelchair? If the patient was at risk of falling, why were other restraints not used? Why did the restraint jacket ignite? What was the ignition source? How did the patient get the ignition source? Finding the answers to these and other questions is necessary before the RCA team can completely understand what happened. (How to determine why it happened—the causal sequencing—will be discussed later.)

Witness statements. The team must interview everyone directly associated with the event in private and as soon as possible before memories fade or people unintentionally change their account after hearing gossip or rationalize what happened. (Staff members indirectly involved may be interviewed later in the process to explore possible root causes.) Document all witness statements in writing or using videotape or audiotape. In the rare instances in which an in-person interview is not possible, a telephone interview can be conducted or a witness can be asked to respond to written questions.

The team member or members (some organizations have two team members at each interview) conducting the interviews must be skilled in interviewing and must also be able to put the interviewee at ease. Questions should be open-ended—that is, the questions should require more than just a "yes" or "no" response. Many interviewers write their questions in advance. A skilled interviewer, however, should be able to use the answers to any prepared questions as a springboard for additional follow-up questions.

During the interview, the team members must determine what the witness's role was in the incident and be sure to record the limits of that person's understanding of the event.[19] The interviewers should ask witnesses for the sequence of events they observed and, without interrupting, allow them to describe the events. Next, team members should ask clarifying questions. While other questions will vary depending on the nature of the event being investigated, interviewers should, at minimum, make sure the witnesses are asked the following questions:[20]

- What conditions existed before the event (e.g., physical crowding, rush, shift changes)?
- What procedures and processes were conducted before and during the events? (This will also help identify relevant system and process factors.)
- Who was present, and who was involved? (In addition to helping the team understand who was doing what and when, determining who was present also ensures that all witnesses are identified.)
- What indicated that a problem was occurring?
- How did you respond?

Physical evidence. In many instances, physical evidence could help the team understand what happened. In the example above, the burned restraint jacket and wheelchair would be considered physical evidence. Or if the adverse event involved an anesthesia-related injury that occurred during surgery, the physiologic monitoring equipment, ventilator, and other related equipment should be gathered, examined, and secured.

Because such evidence may also be used in court, members of the RCA team should consult with legal counsel to ensure that the physical evidence is properly secured and that chain-of-custody procedures have been followed. These procedures should be set forth in the organization's sentinel event or adverse event policy. Typically, chain-of-custody procedures require that evidence be labeled with information on the source, location, date and time collected, basic content, and name of the individual collecting it. Once the information is noted, the evidence should be secured in a separate area, if possible.[21]

Also considered part of the collection of physical evidence is a visit by the RCA team to the site of the event. This allows the team to observe what processes and activities are taking place and note relevant physical conditions, including lighting, noise, or crowding. For example, in analyzing an infant abduction, a visit to the nursery at the same time and day of the week that the abduction occurred might reveal to the team how easily security may be breached. Similarly, a visit to the pharmacy storage areas during review of a medication error might reveal that look-alike drugs were stored next to each other in a dimly lighted area. In some instances, the team can further document a site visit by including a drawing or layout of the relevant area.

Documentary evidence. This evidence consists of all relevant records, notes, recordings, device histories, tapes, monitoring readouts, and other materials. While this evidence is also physical (as opposed to verbal statements from witnesses), it is referred to as

"documentary" evidence, since it is often in the form of paper documents. Thus, it would include, for example, the patient record, correspondence and internal communications (e.g., e-mails), relevant organization policies and procedures (e.g., infant abduction policy, patient handoff policies), readouts from patient monitoring devices, and pharmacy records. As with the physical evidence, the RCA team should consult legal counsel to ensure that such evidence is properly protected in order to maintain the confidentiality of the patient and caregivers and to protect documents from legal discovery.

A list of all documentary evidence reviewed should be included when the RCA is complete. (This permits anyone reading the RCA and action plan to see whether all possible factors contributing to an event have been considered.)

Literature review. The team must review the clinical literature to determine whether any national practice standards or evidence-based guidelines exist and, if so, whether they were followed. Similarly, the team should identify and review any reported studies on relevant processes, procedures, medication, or other issues. For example, during an RCA of an infant abduction, one RCA team uncovered 12 recent articles on the topic. Some of the articles showed how would-be abductors often thwart security systems and befriend patients; others described remedies, such as a low-tech card-receipt system to use in the nursery.[22] The literature review will help the team identify root causes as well as identify risk reduction strategies for the action plan.

In addition to listing the documentary evidence, the team should generate a list of all articles reviewed as part of the final RCA. The actual articles can be included with the supporting documents. Although articles pose less of a concern about privilege or confidentiality compared to evidence, legal counsel should always be consulted.

Create Timeline and Ensure Final Understanding

When the RCA team has gathered the information and understands how it fits together, a final timeline should be created. The final timeline can take the form of a flow chart similar to the initial timeline. Once the final timeline is created, the team should ask about the relevance or significance of each event and note the answer on the timeline.

The team must also have a final understanding of the relevant processes (1) as they were designed to be implemented (as specified in written policies and procedures), (2) as they are usually implemented, and (3) as they were implemented when the sentinel event occurred. Without a clear understanding of all the systems and processes involved, the team cannot possibly identify the vulnerabilities of the system or process.

Step 3: Brainstorming

Asking "what" and "why" continually until all possible causes and factors relating to an adverse event have been considered is the very backbone of the RCA. This is the only way the team can identify all the possible risk points in the process (although, as discussed later, not all the risk points identified may have caused or contributed to the event). Unfortunately, according to NCPS, while RCA teams may be able to successfully determine what happened and develop an accurate chronological sequence of events, they often have problems creating a "causal sequencing of events."[23] In other words, they have trouble determining why the event occurred.

JCAHO Minimum Scope of Analysis for Specific Sentinel Events

JCAHO has identified certain specific areas that must be investigated for reviewable sentinel events (see Table). Of these 18 areas, 3 must be investigated for every reviewable sentinel event: competency assessment and credentialing, orientation and training of staff, and communication among staff members. JCAHO identifies communication problems as the most common root cause among all sentinel events investigated between 1995 and 2004, implicated in approximately 65% of sentinel events; training issues are the second most common root cause, implicated in approximately 55% of sentinel events.[24]

Staffing levels must also be investigated for every event, *except* unanticipated death of a full-term infant. On the other hand, a contributing factor such as "adequacy of technical support" needs to be investigated in only two instances—medication errors and procedural complications—and the behavioral assessment process needs to be investigated for suicides, restraint or elopement deaths, and assaults, rapes, or homicides.

Cause-and-Effect Diagrams

Not surprisingly, teams often have difficulty getting down to the root causes. They are usually analyzing a very complicated problem with many possible causes. It is easier to determine the factors closer to the

event—that is, the special causes, or "sharp" end of the system (often human error)—but it may be harder to push the analysis farther back into the "blunt" end of the system. This is why cause-and-effect diagramming is such an essential component of the RCA process. Using a diagram helps the team to brainstorm and to visualize all the different contributing factors and root causes.

Before beginning any diagram, the team must agree on four to six main categories that encompass all possible categories of contributing factors and root causes. This allows the team to focus its brainstorming. In the nonhealthcare setting, investigators often use four categories, sometimes referred to as the "four M's": materials, machines, manpower, and methods.

In the healthcare context, organizations can break down the categories of causes in a variety of ways. Perhaps the most all-encompassing set of general categories, and the set this Analysis uses as its primary focus, has been developed by NCPS. The agency has identified the following six broad categories of causes, also called process variables:

- Communication
- Training
- Fatigue
- Environment and equipment
- Rules, policies, and procedures
- Barriers

Another categorization scheme breaks down causes as follows: human resource system issues, information management systems issues, environmental management systems issues, and leadership issues (e.g., relating to whether a corporate culture of blame or no blame has been established).[25]

Two basic types of cause-and-effect diagrams have proven useful in the RCA context: Ishikawa/fishbone diagrams and tree diagrams.

Ishikawa/Fishbone Diagrams. The Ishikawa diagram, named after the Japanese quality pioneer Kaoru Ishikawa, looks like a fishbone and, appropriately, is also called a fishbone diagram (see "Figure 2. Fishbone Diagram"). It focuses on causes rather than the effect. The basic problem of interest, in this case the sentinel event, is presented at the right of the diagram at the end of the main "bone." As an example, a patient may be mistakenly given morphine instead of hydromorphone; in this case, the event would be "wrong drug administered" if the mistake was caught as soon as it happened. However, if the mistake was not caught in time and the patient ultimately died, the event would be "patient death." The four to six categories of causes that the team has identified are then drawn as ribs off of the main bone. (See Figure 2 for an example.)

Figure 2. Fishbone Diagram

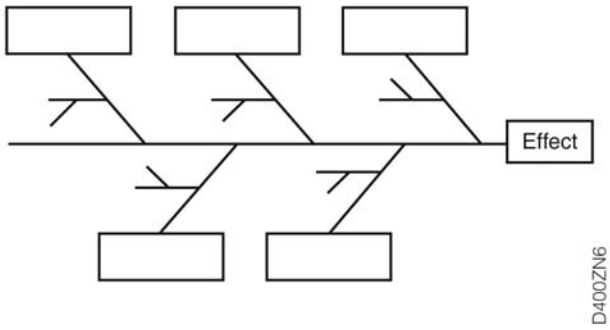
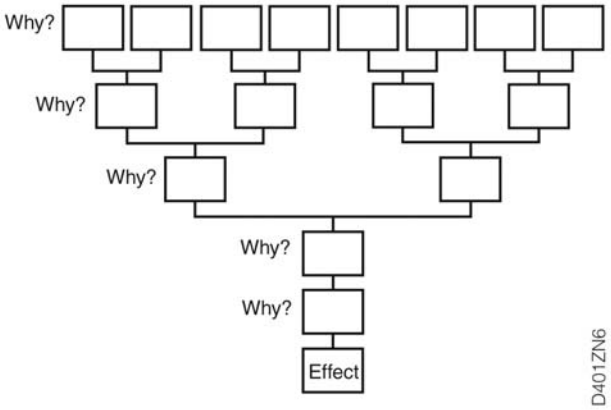


Figure 3. Tree Diagram



NCPS created an exhaustive series of "trigger questions" for each of its six categories that can help the team brainstorm ideas. The answers to these questions should help trigger other ideas. (See "Trigger Questions for a Root-Cause Analysis" for sample questions.)

As the team brainstorms, the facilitator or leader places his or her ideas on one of the ribs. The team should not be concerned if there is disagreement regarding which category is most appropriate for an idea as long as it is put somewhere in the diagram. There will probably be several drafts of the diagram as the team learns more about the factors contributing

to the event. Each iteration should be recorded on paper or via some other recording technique.

Tree Diagrams. The tree diagram resembles a tree with the sentinel event as the trunk (see "Figure 3. Tree Diagram").[26] The tree can be developed through a series of "caused by" and "why" questions, each forming a branch. For example, a medication error was caused by a nurse selecting the wrong medication package. Why? Because the storage area was crowded and dark, the wrong medication was stored next to the correct medication, the nurse was rushed and distracted, and the packaging design looked like the correct medication. Each one of those answers becomes the new "caused by" branch and the question "why" is again asked. This process of developing the tree's branches continues until there are no more "why" questions, knowledge becomes limited, or an issue is outside of the scope of the RCA.[27] For example, look-alike packaging may be one of the root causes relating to many medication errors, but the RCA team cannot redesign the actual packaging (although it can certainly send the manufacturer a letter describing the problem with the design).

The VA "trigger questions" can also be used in tree diagrams to make sure that all areas are considered.

The Five Rules of Causation

It is important to remember that while brainstorming is intended to come up with all *possible* causes and risk points—specific points in a process that are susceptible to failure or system breakdown and that can be eliminated through redesign efforts—not all the risk points and causes will have, in fact, caused or contributed to the adverse event. For example, when investigating a medication error, the RCA team might wonder whether illegible handwriting by the doctor had a role in the problem. Subsequent investigation may determine that illegibility is a problem with other physicians but that this doctor's handwriting was clear. Using handwritten prescriptions would have been identified as a risk point as part of the RCA, but it would not have actually caused the adverse event in this instance.

NCPS has identified five "rules of causation" directly applicable to healthcare.[28] Following these rules when diagramming will help the team to focus on systems and process vulnerabilities rather than individual blame. NCPS has provided examples illustrating the correct and incorrect way to describe events when diagramming.

Rule 1. Clearly show the cause-and-effect relationship. This is the most basic rule. When describing why an event has occurred, show the link between the root cause and the adverse event or close call. Each link should be clear to the RCA team and others. If this root cause/contributing factor is eliminated, it will minimize or prevent future events.[29]

Incorrect: *Resident was fatigued.* This focuses only on the individual and not the wider system. The statement does not describe how and why this led to a slip or mistake. The resident could be fatigued for any number of reasons.

Correct: *Residents are routinely scheduled for 80-hour work weeks; as a result, fatigued residents are more likely to misread instructions, which could lead to an incorrect tube insertion.* Describing the action in this manner helps the team identify the system's vulnerability—overscheduling and resident fatigue—which can be corrected by system redesign.

Rule 2. Use specific and accurate descriptors for what occurred, rather than negative and vague words. Do not use negative descriptors (e.g., poorly, inadequately, haphazardly, improperly, carelessly, complacently) in causal statements. Such words are broad, negative judgments that do little to describe the actual conditions or behaviors that led to the mishap. Instead, provide accurate and clear descriptions.

Incorrect: *The manual was poorly written.* This statement does not identify what was wrong with the manual; therefore, it is difficult to understand what to correct, other than the general need to rewrite the manual.

Correct: *The training manual was not indexed, used a font that was difficult to read, and did not include any technical illustrations; as a result, the manual was rarely used and did not improve performance by the equipment operator.*

Rule 3. Identify the preceding cause, not the human error. Most adverse events involve at least one human error. But as noted earlier, naming and blaming one individual does little to aid the prevention process. Investigate to determine *why* the human error occurred. It can be a system-induced error (e.g., step not included in medical procedure) or an at-risk behavior (e.g., doing task by memory instead of using a checklist). For every human error in the causal chain, there must be a corresponding cause. It is identifying the cause of the human error, not the error itself, that leads to productive prevention strategies.

Incorrect: *The resident manager made a dosage error.*

(continued on page 14)

Trigger Questions for a Root-Cause Analysis

The U.S. Department of Veterans Affairs' National Center for Patient Safety (NCPS) has developed an extensive list of trigger questions to assist with an organization's root-cause analysis. The questions are designed to help the team conducting the root-cause analysis identify potential contributing factors—particularly those that have not yet been considered—for an adverse event. The questions were developed for six broad categories of causes: communication; training; fatigue; environment and equipment; rules, policies, and procedures; and barriers.

Listed below are some of these trigger questions within each of the six categories. The complete list of questions is available online from NCPS at http://www.patientsafety.gov/CogAids/Triage/index.html.

Communication

- Was the patient correctly identified?
- Was information from various patient assessments shared and used by members of the treatment team on a timely basis?
- Was communication between frontline team members adequate?
- Was the correct technical information adequately communicated 24 hours a day to the people who needed it?
- Did the overall culture of the facility encourage or welcome observations, suggestions, or "early warnings" from staff about risky situations and risk reduction?

Training

- Was there a program to identify what is actually needed for training of staff?
- Were the results of training monitored over time?
- Were training programs for staff designed up front with the intent of helping staff perform their tasks without errors?
- Were all staff trained in the use of relevant barriers and controls?

Fatigue/Scheduling

- Were the levels of vibration, noise, or other environmental conditions appropriate?
- Did personnel have adequate sleep?
- Was the environment free of distractions?
- Were there sufficient staff on hand for the workload at the time?
- Was the level of automation appropriate—that is, neither too much nor not enough?

Environment/Equipment

- Was the work area/environment designed to support the function it was being used for?
- Had there been an environmental risk assessment (i.e., safety audit) of the area?
- Was equipment designed to properly accomplish its intended purpose?
- Was there a maintenance program in place to maintain the equipment involved?
- If previous inspections pointed to equipment problems, what corrective actions were implemented and were they effective?
- Was there adequate equipment to perform the work processes?
- Was the equipment designed such that user mistakes would be unlikely to happen?
- Were personnel trained appropriately to operate the equipment involved in the adverse event/close call?

Rules, Policies, and Procedures

- Was there an overall management plan for addressing risk and assigning responsibility for risk?
- Was required care for the patient within the scope of the facility's mission, staff expertise and availability, and technical and support service resources?
- Were the staff who were involved in the adverse event or close call properly qualified and trained to perform their functions?
- Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call?
- Were relevant policies/procedures clear, understandable, and readily available to all staff?

Barriers

- What barriers and controls were involved in this adverse event or close call?
- Were these barriers designed to protect patients, staff, equipment, or environment?
- Were these barriers and controls in place before the event happened?
- Had these barriers and controls been evaluated for reliability?

Source: Department of Veterans Affairs National Center for Patient Safety. Triage cards [online]. [cited 2006 Jul 31]. Available from Internet: http://www.patientsafety.gov/CogAids/Triage/index.html.

(continued from page 12)

Correct: *The lack of automated software to check the dosage limits and absence of cognitive aids on dosing increased the likelihood of this dosing error, which resulted in three times the appropriate level of insulin being ordered and administered.*

Rule 4. Violations of procedure are not root causes; they must have a preceding cause. Procedural violations are like human errors in that they are not directly manageable. They are also like human error in that a poorly conducted RCA often identifies "failure to follow policies" as a root cause. As with human error, simply identifying that someone failed to follow a policy is of little help. What is important is *why* that individual violated the policy. It is the *cause* of the procedural violation that can be managed. For example, if a clinician is violating a procedure because it is the local practice norm, the RCA and action plan must address the incentives that created the norm. If a technician is missing steps in a procedure because he or she is not aware of the formal checklist, the action plan must address education.

Incorrect: *The technician did not follow the procedure for computed axial tomography (CAT) scans.*

Correct: *Noise and confusion in the prep area and production pressures to quickly complete CAT scans increased the probability of missing steps in the CAT scan protocol; this resulted in an air embolism by the inadvertent use of an empty syringe.*

Rule 5. Failure to act is causal only when there was a preexisting duty to act. The purpose of causal investigation is not to simply find ways in which the investigated event would not occur. Rather, the purpose of causal investigation is to find out why this mishap occurred *in the existing system as it is designed today*. For example, a doctor's failure to prescribe a medication is causal only if he or she was required to prescribe the medication. The duty to perform may arise from standards and guidelines for practice or other duties to provide patient care.

Incorrect: *The nurse did not check the stat orders every half hour.*

Correct: *The absence of an established procedure for nurses to check the stat orders on the printer created the vulnerability that urgent orders would not be administered; this resulted in the bolus of antibiotics not being administered.*

Step 4: Identify Root Causes

At this point in the investigation, the team will have identified many possible causes for an event. It is now time to identify which ones are the actual root causes, as opposed to the proximate causes or contributing factors.

A root cause is the most basic factor or factors that, if corrected or removed, will reduce the risk or prevent recurrence of a situation. A root cause is the most fundamental reason a failure has occurred. As noted earlier, human error is not a root cause.

Ask Three Questions

To clarify whether something really is a root cause, consider asking the following three questions (if the answer to any is "no," then the factor is a root cause; if the answer is "yes," then the factor is a contributing cause):[30]

- Would the problem have occurred if this cause had not been present?
- Will the problem recur due to the same causal factor if this cause is corrected or eliminated?
- Will correction or elimination of this cause prevent similar events?

For example, imagine a situation in which a patient at a psychiatric hospital commits suicide.[31] An RCA identifies the following three contributing factors/root causes:

- A suicide risk assessment was not completed when the patient was admitted.
- Staffing levels were lower than usual because two staff members called in sick and replacements could not be found.
- One-on-one continuous supervision of the patient as ordered by the attending psychiatrist was not in place at the time of death because the supervising staff member was taking a lunch break.

In this example, if the staffing levels had been normal that day, and even if the suicide assessment had been completed when the patient was admitted, the suicide might still have occurred. The only way to prevent the suicide would have been to continually supervise the patient as ordered by the psychiatrist. Thus, the last contributing factor is the root cause and the other factors contributed to the death. When the team begins to generate recommendations for the action plan, the team will focus on this root cause.

Root Causes for Three Common Sentinel Events

Restraint Deaths

- Patient assessment factors, such as incomplete medical assessment or incomplete examination of the individual (e.g., failure to identify contraband such as matches)
- Inadequate care planning, such as incomplete consideration of alternatives, use of restraints as punishment, or inappropriate room or unit assignment
- Lack of patient observation procedures or practices
- Staff-related factors, such as insufficient orientation or training, inadequate competency review or credentialing, or insufficient staffing levels
- Equipment-related factors, such as use of split siderails without siderail protectors, use of two-point rather than four-point restraints, use of a high-neck vest, incorrect application of a restraining device, or failure of a monitor or alarm to operate or to be used when appropriate

Inpatient Suicides

- Problems with the environment of care, such as the presence of nonbreakaway bars, rods, or safety rails; lack of testing of breakaway hardware; and inadequate security
- Improper patient assessment methods, such as incomplete suicide assessment at intake, absent or incomplete reassessment, and incomplete examination of the individual (e.g., failure to identify contraband such as matches)
- Staff-related factors, such as insufficient orientation or training, incomplete competency review or credentialing, and inadequate staff levels
- Incomplete or infrequent patient observations
- Information-related factors, such as incomplete communication among caregivers and lack of access to information when needed
- Care planning, such as assignment of the patient to an inappropriate unit or location

Infant Abductions

- Security equipment factors, such as security equipment not being available, operational, or used as intended
- Physical environmental factors, such as the absence of a line of sight to entry points or monitoring of elevator or stairwell access to postpartum and nursery areas
- Inadequate patient education
- Staff-related factors, such as insufficient orientation/training, competency/credentialing issues, and insufficient staffing levels
- Information-management-related factors, such as publishing of birth information in local newspapers, a delay in notification of security when an abduction is suspected, improper communication of relevant information among caregivers, and improper communication among hospital units
- Organization culture factors, such as reluctance to confront unidentified visitors or providers

Sources: Joint Commission on Accreditation of Healthcare Organizations. Preventing restraint deaths. *Sentinel Event Alert* 1998 Nov 18;8; Joint Commission on Accreditation of Healthcare Organizations. Inpatient suicides: recommendations for prevention. *Sentinel Event Alert* 1998 Nov 6;7; Joint Commission on Accreditation of Healthcare Organizations. Infant abductions: preventing future occurrences. *Sentinel Event Alert* 1999 Apr 9;9.

Multiple Root Causes

There is usually more than one root cause for a sentinel event. In fact, JCAHO's sentinel event database identifies between four and six root causes for each sentinel event investigated. (See "Root Causes for Three Common Sentinel Events.")

In many instances, a combination of root causes sets the stage for the adverse event. If an organization eliminates just one of the six root causes, it may have reduced the likelihood of that very specific adverse event occurring again, but other, unaddressed root causes could interact to cause a different but equally adverse event.

For example, imagine investigating a restraint-related patient death and determining that the one and only root cause was unsafe equipment use.[32] Training staff to select safe equipment and use it safely would appear to address the problem. However, what happens a year later when an individual staff member has forgotten how to use a four-point restraint properly? Is there an effective plan for assessing the continued competence of the staff? What happens if restraint is needed when outside agency staff are on the floor? Will they be trained and competent in the safe use of restraints? Do staff know how to consistently observe the patient who has been placed in restraint (i.e., can they detect the result of a mistake in the restraint application or an equipment failure)? If the answer to

any of those questions is "no," another adverse event could occur.

While there are usually several root causes for an adverse event, be careful of identifying too many. An organization that identifies more than six root causes may have too broad a definition of root cause.

Step 5: Design and Implement Action Plan

The RCA team needs to identify risk reduction strategies for all the root causes identified. The recommended actions must be clearly linked to the vulnerabilities they are intended to prevent and be readily understood. Generally, it is usually better to avoid actions that place an additional burden on a person's memory (e.g., training, written policy). However, if there was no previous training or a policy was lacking, such actions are clearly necessary. Ideally, actions should be physical rather than procedural (e.g., use a keypad lock rather than a "Do Not Enter" sign) and permanent rather than temporary. It is also useful to ask all witnesses how they would fix the problem and what has or has not worked before.[33]

Recommended Hierarchy of Actions

NCPS has developed the following recommended hierarchy of actions that can be helpful to the team when it is developing risk reduction strategies:[34]

Stronger Actions

- Implement architectural/physical plant changes (e.g., extra handrails in the bathroom to prevent falls, breakaway fixtures to prevent hanging).[35]
- Conduct usability testing with staff who will be using any new equipment before purchasing.
- Implement engineering controls (e.g., using different-sized line fittings for each medical gas used in the operating room to make it impossible to connect the wrong lines, keeping only the correct dose and strength of medication in a patient's drawer).
- Simplify processes, and remove unnecessary steps (e.g., removing concentrated potassium chloride from patient care areas to ensure that it cannot be administered by intravenous [IV] injection because it is not available for the nurse to select in error).
- Standardize equipment or processes (e.g., limit the number and types of IV pumps, defibrillators, or code carts so that it will be easier for staff to use them, especially under stressful conditions).
- Involve leadership in support of patient safety (e.g., by instituting patient-safety-related individual or team rewards, holding town meetings, or distributing newsletters).

Intermediate Actions

- Increase staffing/decrease workload.
- Add software enhancements/modifications.
- Eliminate/reduce distractions (e.g., prevent interruptions during passing of medications).
- Use checklists/cognitive aids (e.g., laminated card with steps, surgical time-out posters).
- Eliminate look-alike and sound-alike situations (e.g., avoid having two patients with the same name on the same ward, and differentiate them by using an additional identifier; store easily confused IV and irrigation solutions physically apart from each other).
- Read back instructions and orders.
- Enhance documentation/communication.
- Implement redundancy. Systems should have backups, and the backups should have backups (e.g., a second person should check chemotherapy orders).

Weaker Actions

- Double checks
- Warnings and labels (e.g., using brightly colored stickers on the correct IV line, using automatic flags for "panic" lab values)
- New procedure/memorandum/policy
- Training
- Additional study/analysis

What, When, Who, Where, How?

The actual action plan must address the five issues of what, when, who, where, and how with respect to implementing and evaluating the effectiveness of the proposed risk reduction actions.[36]

"What" refers to the specific activities and risk reduction strategies that are being recommended.

"When" refers to the time frame in which the various improvement actions will be implemented. For example, an initial draft of the new process will be developed by W date, a pilot test of the new process will occur by X date, comments and modification suggestions will be submitted by Y date, and organization-wide implementation will occur by Z date.

Resource List

Canadian Patient Safety Institute
Suite 1414
10235 101 Street
Edmonton, AB T5J 3G1
Canada
(780) 409-8090
http://www.patientsafetyinstitute.ca

- Canadian Root Cause Analysis Framework

Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333
(404) 639-3311
http://www.cdc.gov

- Sample Form for Performing a Simple Root Cause Analysis of a Sharps Injury or a Near Miss Event (http://www.cdc.gov/sharpssafety/pdf/AppendixA-9.pdf)

Joint Commission on Accreditation of Healthcare Organizations
One Renaissance Boulevard
Oakbrook Terrace, IL 60181
(630) 792-5000
http://www.jointcommission.org

- Framework for Conducting a Root Cause Analysis
- Root Cause Analysis Matrix
- Sentinel Event Alerts
- Sentinel Event Policy and Procedure
- Tool to Assist Completing the Framework for Conducting a Root Cause Analysis

National Patient Safety Agency
4-8 Maple Street
London W1T 5HD
England
(0207) 927 9500
http://www.npsa.nhs.uk

- Exploring Incidents—Improving Safety: a Guide to Root Cause Analysis from the NPSA (http://www.msnpsa.nhs.uk/rcatoolkit/course/index.htm)

U.S. Department of Veterans Affairs
National Center for Patient Safety
PO Box 486
Ann Arbor, MI 48106-0486
(734) 930-5890
http://www.patientsafety.gov

- Root Cause Analysis Tools
- Triage Cards™

Additional listings can be found in ECRI's Healthcare Standards Directory, *a comprehensive source of healthcare standards, guidelines, laws, and regulations. The* Directory *is available from ECRI.*

"Who" means identifying who should be accountable at various implementation stages. At least one senior leader should have had a role in the RCA process, and this individual may be the one who "owns" the improvement activity. Leaders and managers should take an active role in overseeing and setting priorities for action plans and should be responsible for processes within their area.

"Where" addresses where in the organization the improvement plan will be implemented. It might be organizationwide, or it might focus on a selected location, a selected patient population, or selected staff members. Often, organizations start with a pilot test, make modifications based on that test, and implement the new process or procedure on a larger scale.

"How" refers to the final step in action planning: developing appropriate measurements. The team must develop outcome measures to confirm that what was hoped to be changed did, in fact, change. In other words, has the action plan made improvements or not? Were there any unintended consequences?

Outcome measures should (1) measure effectiveness of the action, not completion of the action (e.g., measure that falls assessment occurs for X% of new patients admitted, not that X% of the staff have been trained in falls assessment); (2) be quantifiable with a defined numerator and denominator (if appropriate); (3) define the sampling strategy and the time frame for the measurement (e.g., random sampling of 15 charts per quarter); and (4) set a realistic performance threshold (e.g., do not set a 100% compliance goal unless it can be achieved).[37]

A time to complete outcome measures and communicate the results of those measures should be included in the action plan.

CHEM RECOMMENDATIONS

- Review your organization's sentinel event policy to ensure that it does the following:
  - — Meets the JCAHO requirements for the minimum scope of review for all reviewable sentinel events

  - — Adequately addresses confidentiality issues
  - — Describes how to create an RCA team
  - — Covers all aspects of the RCA process as set forth in this Analysis
- Review any recent RCAs that your organization has completed to ensure that they do not focus blame on individuals, but rather address system and process issues.
- Review any recent action plans to determine whether recommended risk reduction strategies did indeed work.
- Discuss your organization's RCA process with your patient safety and performance improvement/quality control departments to coordinate activities and performance measurements. Suggest to the performance improvement department that it conduct an RCA on a "near miss" as a way to comply with the JCAHO performance improvement standard requirement to analyze at least one high-risk process a year.

Notes

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