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# Root Cause Analysis in Health Care: Tools and Techniques

FIFTH EDITION

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Joint Commission  
Resources

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Joint Commission  
International



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# Introduction

Patient safety events can cause serious harm or death. They affect anyone. To address and prevent these threats, health care organizations must dig deep to unearth the root cause(s) and develop solutions that address the problems from a systems perspective.

Indeed, the very presence of patient safety events indicates a continuing paradox in contemporary health care. Despite remarkable advances in almost every field of health care, the occurrence of errors, or *failures*—the term used increasingly instead of *errors*—persists. When such failures harm patients, the results can be heartbreaking. Most failures and *sentinel events*—that 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 death, permanent harm, or severe temporary harm—are the result of system and process flaws. These flaws are often not immediately apparent and require investigation

The prevalence of patient safety events had been thrust into the limelight with the watershed report *To Err Is Human: Building a Safer Health System*, published in 2000 by the Institute of Medicine (IOM). The IOM report, however, was just the tip of the iceberg. More reports followed, illustrating the need to improve the quality of care being delivered in the United States. For example, researchers at Johns Hopkins Children’s Center and the US Agency for Healthcare Research and Quality reviewed 5.7 million records of patients younger than 19 years of age from 27 states who were hospitalized in 2000. Of the 52,000 children identified by the researchers as being harmed by unsafe medical care during their hospital stays, 4,483 suffered a fatal injury.<sup>1</sup>

Quality-of-care issues such as these are a problem for hospitals around the world. According to a 2007 report, hospital chart reviews in various countries indicate that

adverse events in acute care hospital admissions range from 2.9% in the United States to 5.0%–10.0% in the United Kingdom, 7.5% in Canada, 12.9% in New Zealand, and 16.6% in Australia.<sup>2</sup>

Although these reports and chart reviews illuminate the problem, it is virtually impossible to know how many patients suffer as a result of health care system failures; however, any single patient safety event is a cause for concern. These events can result in tragedy for individuals served and their families, add costs to an already overburdened health care system, adversely affect the public’s perception of an organization, and lead to litigation. They can also deeply affect health care professionals who are dedicated to the well-being of their patients.

Health care organizations, then, have no choice but to answer one key question: Why do these errors or failures continue to occur?

To answer this, a comprehensive systematic analysis must be done. The most commonly used form of comprehensive systematic analysis among Joint Commission–accredited organizations is *root cause analysis*—a process for identifying the basic or causal factor(s) underlying variation in performance, including the occurrence or possible occurrence of a sentinel event—and all of its related tools. Root cause analysis can be used to uncover the factors that lead to patient safety events and move organizations to deliver safer care.

Although health care organizations in the United States often use root cause analysis to help improve quality en route to accreditation, such analysis has many broader applications around the world. High-quality care is high-quality care, whether it is delivered in New York City or Dubai or Singapore. Organizations worldwide should

consider how root cause analysis can be used to help improve quality.

### The Current Health Care Environment

Health care continues to experience dramatic change. Health care organizations are evolving constantly because of changes in reimbursement, new technology, regulatory requirements, and staffing levels. These modifications cause policies and procedures to change often and, in most cases, quickly. As health care organizations become more complex, their systems and processes are increasingly interdependent. This interdependence increases the risk of failures and can make the recovery from failure more difficult. Clinical and support staff workloads are growing heavier, resulting in greater stress and fatigue for many health care professionals. Caregivers are working in new settings and performing new functions, sometimes with minimal training. Consequently, maintaining consistency in processes and systems is challenging, leading to variation. Often, this variation results in increased risk to patients.

Media reports about patient safety events are occurring with increasing regularity, including the following examples:

- In September 2013, researchers estimated that the number of premature deaths associated with preventable harm to patients in US hospitals was more than 400,000 per year. This makes patient safety events the third leading cause of death in the United States. Incidents resulting in serious patient harm were estimated to be 10- to 20-times more common than lethal harm.<sup>3</sup>
- In November 2014, the journal *Pediatrics* reported that an annual average of 63,358 medication errors occur in children younger than age 6 in the United States in nonhospital settings and that 25% of those errors are in infants, younger than 12 months old. This means that a medication error affecting a child in the United States occurs every eight minutes.<sup>4</sup>
- In February 2015, the state of Minnesota reported that 98 patients in that state were seriously injured, and another 13 patients died, as a result of patient safety events during 2014.<sup>5</sup>
- In May 2015, the Jordanian Ministry of Health began investigating an alleged medical error that resulted in a Saudi patient becoming comatose.<sup>6</sup>
- In May 2015, the State of California fined a hospital \$100,000 after the unintended retention of a foreign object in a patient's body following an invasive

procedure—in this case a plastic surgical clip that was left inside a patient's skull.<sup>7</sup>

- In May 2015, the United Kingdom's National Health Service paid £15,000 in damages to the mother of an infant who died in utero due to a medical error.<sup>8</sup>

The above examples are only a few of the serious patient safety events that have attracted media attention in recent years. These events cast a shadow on the public's trust of health care. Stakeholders, including patients, justifiably ask, "What's going on?" Failure detection, reduction, and prevention strategies are receiving new impetus as the health care community recognizes the value of a proactive approach to reducing risk.

Root cause analysis is one such approach. Historically used to investigate sentinel events, root cause analysis shows great promise as a proactive tool. Increasingly, health care organizations are using this methodology to investigate close calls (or near misses), no-harm patient safety events, and other signals of risk. Health care organizations no longer have to wait until after a sentinel event occurs to perform a root cause analysis.

When an adverse outcome, a sentinel event, or a cluster of less serious incidents or near misses occurs, organizations must develop an understanding of the contributing factors and the interrelationship of those factors. Next, the organization must implement an action plan to fortify its systems against vulnerabilities with the potential to impact patients. *Resilience* is the degree to which a system continuously prevents, detects, mitigates, or ameliorates hazards or incidents.<sup>9</sup>

### Purpose of This Book

*Root Cause Analysis in Health Care: Tools and Techniques*, Fifth Edition, is intended to help health care organizations prevent systems failures by using root cause analysis to do the following:

- Identify causes and contributing factors of a sentinel event or a cluster of incidents
- Identify system vulnerabilities that could lead to patient harm
- Implement risk reduction strategies that decrease the likelihood of a recurrence of the event or incidents
- Determine effective and efficient ways of measuring and improving performance



Root cause analysis is an effective technique most commonly used *after* an error has occurred to identify underlying causes. Failure mode and effects analysis (FMEA) is a proactive technique used to prevent process and product problems *before* they occur.<sup>10</sup> Health care organizations should learn both techniques to reduce the likelihood of adverse events.

*Root Cause Analysis in Health Care: Tools and Techniques*, Fifth Edition, provides health care organizations worldwide with up-to-date information on The Joint Commission's Sentinel Event Policy and safety-related requirements. It also describes the Sentinel Event Policy of Joint Commission International. The book includes examples that guide the reader through application of root cause analysis to the investigation of specific types of sentinel events, such as medication errors, suicide, treatment delay, and elopement. For ease of access and use by root cause analysis teams, practical checklists and worksheets are offered at the end of each chapter.

This publication provides and explains The Joint Commission's framework for conducting a root cause analysis. It also helps organizations do the following:

- Identify the processes that could benefit from root cause analysis
- Conduct a thorough and credible root cause analysis
- Interpret analysis results
- Develop and implement an action plan for improvement
- Assess the effectiveness of risk reduction efforts
- Integrate root cause analysis with other programs

Even without the occurrence of an adverse event, health care organizations should embrace the use of root cause analysis to minimize the possibility of patient safety events and thereby to improve the care, treatment, and services provided at their facilities.

## Overview of Contents

*Root Cause Analysis in Health Care: Tools and Techniques*, Fifth Edition, provides health care organizations with practical, how-to information on conducting a root cause analysis. Twenty-one steps are described (in Chapters 3 through 6). Teams conducting a root cause analysis might not follow these steps in a sequential order. Often, numerous steps will occur simultaneously, or the team will return to earlier steps before proceeding to the next step. It is crucial for teams to customize or adapt the process

to meet the unique needs of the team and organization. Appropriate tools for use in each stage of root cause analysis are identified in each chapter. A chapter-by-chapter description of the contents follows.

*Chapter 1, "Root Cause Analysis: An Overview,"* takes a holistic look at root cause analysis. It describes variation, how proximate and root causes differ, when root cause analysis can be conducted, and the benefits of root cause analysis. One of the benefits involves effectively meeting Joint Commission and Joint Commission International requirements that relate to the management of sentinel events. The chapter also provides guidelines on the characteristics of a thorough and credible root cause analysis and action plan.

*Chapter 2, "Addressing Sentinel Events in Policy and Strategy,"* describes the types of adverse events occurring in health care. The Joint Commission's Sentinel Event Policy and requirements are listed in full, including a description of reportable and reviewable events. Joint Commission International's Sentinel Event Policy also is discussed. The chapter provides practical guidelines on how an organization can develop its own sentinel event policy, including the role that an organization's culture and leadership play in risk reduction and prevention. It describes the need for root cause analysis and provides practical guidance on the early steps involved in responding to an adverse or sentinel event.

*Chapter 3, "Preparing for Root Cause Analysis,"* covers the early steps involved in performing a root cause analysis. The first of four hands-on workbook chapters, it describes how to organize a root cause analysis team, define the problem, and gather the information and measurement data to study the problem. Details are provided about team composition and ground rules. The chapter also covers how to use information gleaned from The Joint Commission's Sentinel Event Database and accreditation requirements to identify problem areas in need of root cause analysis. The chapter provides guidance on recording information obtained during a root cause analysis, conducting interviews, and gathering physical and documentary evidence.

*Chapter 4, "Determining Proximate Causes,"* provides practical guidance on the next stage of root cause analysis—determining what happened and the reasons it happened. Organized in a workbook format, the chapter describes how to further define the event, identify process problems,

determine which care processes are involved with the problem, and pinpoint the human, process, equipment, environmental, and other factors closest to the problem. The chapter also addresses how to collect and assess data on proximate and underlying causes. In addition, the chapter describes the process of designing and implementing interim changes.

*Chapter 5, “Identifying Root Causes,”* provides practical guidance, through workbook questions, on identifying or uncovering the root causes—the systems that underlie sentinel events—and the interrelationship of the root causes to one another and to other health care processes. Systems are explored and described, including human resources, information management, environment of care, leadership, communication, and uncontrollable factors. The chapter also addresses how to differentiate root causes and contributing factors.

*Chapter 6, “Designing and Implementing an Action Plan for Improvement,”* includes practical guidelines on how to design and implement an action plan—the improvement portion of a root cause analysis. During this stage, an organization identifies risk reduction strategies and designs and implements improvement strategies to address underlying systems problems. Characteristics of an acceptable action plan are provided, as is information on how to assess the effectiveness of improvement efforts. The chapter concludes with information on how to effectively communicate the results in improvement initiatives.

*Chapter 7, “Tools and Techniques,”* presents the tools and techniques used during root cause analysis. Each tool profile addresses the purpose of the tool, the appropriate stage(s) of root cause analysis for the tool’s use, simple steps for success, and tips for effective use. Twenty-three tools are profiled: affinity diagrams, brainstorming, capability charts, change analysis, change management, check sheets, control charts, failure mode and effects analysis, fishbone diagrams, flowcharts, Gantt charts, histograms, run charts, scatter diagrams, SIPOC process maps, stakeholder analysis, and other tools. Preceding the tool descriptions is a discussion of a performance improvement methodology, Lean Six Sigma, that incorporates many of these tools.

*Chapter 8, “Root Cause Analysis Case Studies from the Field,”* presents root cause analyses that resulted from real-life incidents at health care organizations. In these studies, the tools and techniques used to dig down to the root causes of the events are identified and explained.

Finally, the *Glossary* provides definitions of key terms used throughout the book.

## A Word About Terminology

The terms *patient*, *individual served*, and *care recipient* all describe the individual, client, consumer, or resident who actually receives health care, treatment, and/or services. The term *care* includes care, treatment, services, rehabilitation, habilitation, or other programs instituted by an organization for individuals served.

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# Root Cause Analysis: An Overview

## Learning Objectives

- Understand the need for comprehensive systematic analysis of sentinel events and other adverse outcomes
- Learn the basics of root cause analysis (RCA), the most common method of comprehensive systematic analysis
- Know how RCA and action plans relate to The Joint Commission's Sentinel Event Policy

## Investigating Patient Safety Events: The Need for Comprehensive Systematic Analysis

The Joint Commission's Sentinel Event Policy requires accredited health care organizations to conduct a *comprehensive systematic analysis* in the wake of a sentinel event. Comprehensive systematic analysis seeks to go beyond individual performance issues to determine how gaps in policies and safety systems may have contributed to an adverse event and to identify changes to policies and procedures that may prevent similar events from occurring in the future. The Joint Commission reviews methods of comprehensive systematic analysis on a case-by-case basis to determine their credibility, thoroughness, and acceptability. The Joint Commission also provides advice and resources to institutions to assist them in assessing analytical tools. However, RCA is by far the most common method and is the method preferred by The Joint Commission.

### What Is Root Cause Analysis?

*Root cause analysis* is a process for identifying the basic or causal factor(s) underlying variation in performance. Variation in performance can (and often does) produce unexpected and undesired adverse outcomes, including the occurrence or risk of a *sentinel event*. The Joint Commission defines sentinel event as 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 death, permanent harm, or severe temporary harm.\* Similarly, Joint Commission International (JCI) defines

*sentinel event* as an unanticipated occurrence involving death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition. A root cause analysis focuses primarily on systems and processes, not individual performance. To be successful, the objective of an RCA must not be to assign individual blame. Rather, through the RCA determine process, a team works to understand a process or processes, the causes or potential causes of variation that can lead to error, and identify process changes that would make variation less likely to recur.

A *root cause* is the most fundamental reason (or one of several fundamental reasons) a failure, or a situation in which performance does not meet expectations, has occurred. In common usage, the word *cause* suggests responsibility or a factor to blame for a problem. In the context of an RCA, however, the use of the word *cause* does not imply an assignment of blame. Instead, the cause refers to a relationship or potential relationship between certain factors that enable a sentinel event to occur. The focus in

\* *Severe temporary harm* is critical, potentially life-threatening harm lasting 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. Adapted from Healthcare Performance Improvement, LLC. *The HPI SEC & SSER Patient Safety Measurement System for Healthcare*, rev. 2. Throop C, Stockmeier C. May 2011. Accessed Oct 15, 2015. <http://hpireresults.com/publications/HPI%20White%20Paper%20-%20SEC%20&%20SSER%20Measurement%20System%20REV%20%20MAY%202011.pdf>.



an RCA is on a positive, preventive approach to system and process changes following a sentinel event, a near-miss sentinel event, or a cluster of less serious yet potentially harmful incidents.

As shown in Sidebar 1-1, right, root cause analysis can do more than discover that “*A* caused *B*.” The process also can help an organization determine that “if we change *A* because we had a problem with it, we can reduce the possibility of *B* recurring or in fact prevent *B* from occurring in the first place.”

RCA is a powerful and useful tool that can help health care organizations around the world reduce errors and move quality efforts forward. However, health care organization leaders must realize that RCA is not a panacea but one tool that should be used in conjunction with others to improve care.

### When Can a Root Cause Analysis Be Performed?

Historically, root cause analysis has most commonly been used *retrospectively*—to probe the reasons for a bad outcome or for failures that have already occurred. Root cause analysis can also be used to probe a near-miss event or pattern of events or as part of other performance improvement redesign initiatives, such as gaining an understanding of variations observed in systematically collected data. The best RCAs look at the entire process and all support systems involved in a specific event to minimize overall risk associated with that process, as well as the recurrence of the event that prompted the root cause analysis.<sup>1</sup> The goal of the root cause analysis is to produce an *action plan* that identifies the strategies the organization intends to implement to reduce the risk of similar events occurring in the future.

Root cause analysis is also used increasingly by organizations as one step of a proactive risk reduction effort using *failure mode and effects analysis* (FMEA). FMEA is a proactive, *prospective* approach used to prevent process and product problems before they occur. It provides a look not only at what problems could occur—the failure modes—but also at how severe the effects of those problems could be. The goal is to prevent poor results, which in health care means harm to patients. One step of FMEA involves identifying the root causes of the failure modes.<sup>2</sup> At this point in the process, the FMEA team can use the RCA approach.

### Sidebar 1-1. Root Cause Analysis Case Example

A 16-year-old patient came to the hospital to deliver her baby. During the process of her care, an infusion intended exclusively for the epidural route was connected to the patient’s peripheral intravenous line and infused by pump. The patient experienced cardiovascular collapse. A cesarean section resulted in the delivery of a healthy infant, but the medical team was unable to resuscitate the mother.

The media attention surrounding the error accelerated through the national provider and safety community when the nurse was charged with a criminal offense. These events set in motion intense internal and external scrutiny of the hospital’s medication and safety procedures.

To further understanding about latent systems gaps and process failure modes, a root cause analysis of the event was conducted. A team conducted a one-week evaluation of the medication use system and the organization’s current environment, systems and processes, staffing patterns, leadership, and culture to help shape the recommended improvements. For each of the four proximate causes of the event, performance-shaping factors were identified.

Although the hospital’s organizational learning was painful, this event offered an opportunity for increasing organizational competency and capacity for designing and implementing patient safety. Structures and processes, including safety nets and fail-safe mechanisms, were implemented to promote safer behavioral choices for providers.

The hospital took a number of clinical steps to improve the safety of medication administration, including removing the barriers to scanning medication bar codes, implementing consistent scanning-compliance tracking, and providing teamwork training for all nursing and physician staff practicing in the birth suites.

**Source:** Smetzer J, et al. Shaping systems for better behavioral choices: Lessons learned from a fatal medication error. *Jt Comm J Qual Patient Saf.* 2010 Apr;36(4):152–163.

Figure 1-1, page 3, shows a frequency/severity matrix one organization uses to help decide when to conduct a root cause analysis as part of an FMEA. In this matrix, if a process failure gets a high score both for severity (or potential severity) of outcome and for frequency, then a root cause analysis should be done.

**RCA in High Reliability Industries**

Industries that are regarded as highly reliable, such as nuclear power or the aerospace industry, also employ RCA methodology to investigate adverse events. In the nuclear power and aerospace industries, sentinel events are rare because they have been anticipated. These high reliability industries have adopted a *systems approach*, in which errors are viewed as an expected part of the workplace, the result of a chance misalignment of weaknesses in the underlying system.<sup>3</sup> (Imagine a stack of slices of Swiss cheese. Each slice has holes in different places, thus only if a hole in each slice aligned perfectly with a hole in all the other slices could an object pass through the entire stack. The Swiss cheese model shown in Figure 1-2, page 4, represents how an error could possibly penetrate multiple layers of barriers, defenses, and safeguards in a system.)

Consequently, systems, often with significant redundancies, have been built to protect against the occurrence of errors,

and workers are trained accordingly to anticipate, recognize, and either avoid or quickly recover from errors. In contrast, sentinel events in the health care environment occur with relative frequency and tend to be handled reactively.

**Domestic and International Requirements**

Both The Joint Commission, which accredits health care organizations in the United States, and Joint Commission International (JCI), which accredits health care organizations in countries other than the United States, have a Sentinel Event Policy and standards related to sentinel events. For example, JCI Quality Improvement and Patient Safety (QPS) standards require each accredited organization to establish which unanticipated events are significant and the process for their intense analysis.

While the determination of what constitutes a significant event must be consistent with the general definition of *sentinel event* as described in JCI’s policy, accredited

**Figure 1-1. Frequency/Severity Matrix for Prioritizing Safety-Related Problems**

	SEVERITY				
	Catastrophic	Major	Moderate	Minor	
Frequency	Frequent	3	3	2	1
	Occasional	3	2	1	1
	Uncommon	3	2	1	1
	Remote	3	2	1	1

*This matrix helps the organization apply its resources (such as time) to areas where the opportunity to improve safety is greatest. The larger the number, the more urgent the problem and the more useful a root cause analysis would be.*

**Source:** US Department of Veterans Affairs National Center for Patient Safety. *VHA National Patient Safety Improvement Handbook*. Mar 4, 2011, page B-2. Accessed Oct 15, 2015. [http://www.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=2389](http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2389).

organizations have some latitude in setting more-specific parameters to define *unanticipated* and *major permanent loss of function*. At a minimum, an organization must include those events that are subject to review under JCI standards, such as unanticipated death related to the natural course of the patient's illness or underlying condition; major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition; or wrong-site, wrong-procedure, wrong-patient surgery.

For organizations based in the United States, standards require the organization to have an organizationwide, integrated patient safety program within its performance improvement activities.

Particularly, thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events they are required to conduct. RCA is the most commonly used form of comprehensive systematic analysis used by Joint Commission–accredited organizations to comply with this requirement.

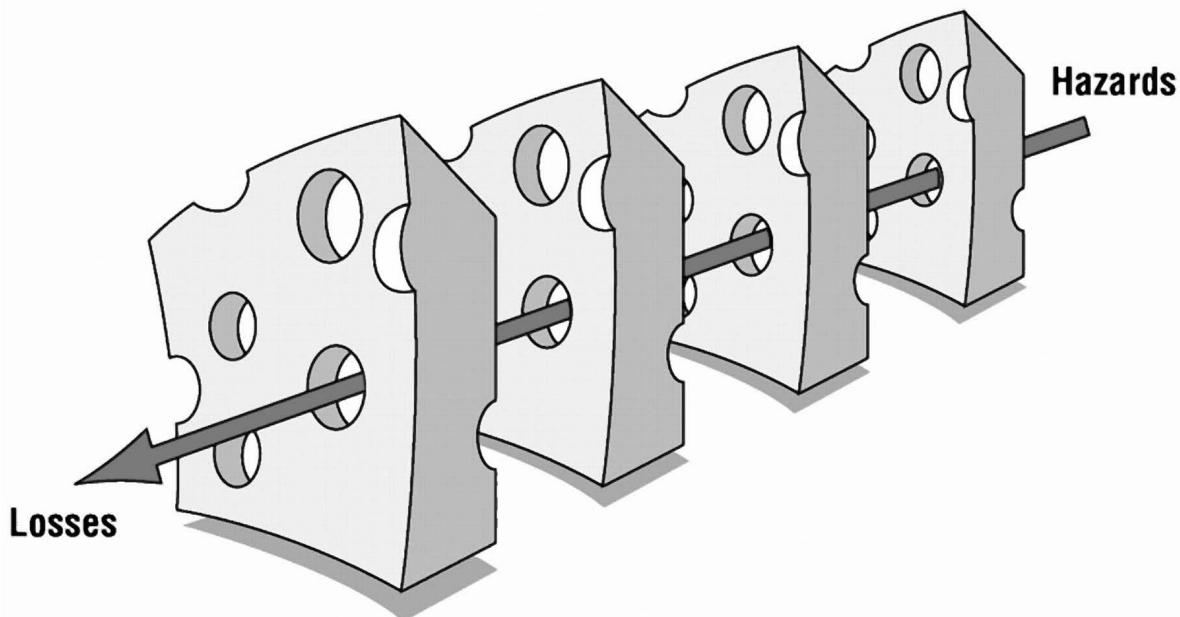
Both JCI– and Joint Commission–accredited organizations are expected to identify and respond appropriately to all sentinel events that occur in the organization or that are associated with services that the organization provides or provides for. Appropriate response includes conducting a timely, thorough, and credible comprehensive systematic analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements. (See Sidebar 1-2, page 5, for a discussion of multiple events.)

### Variation and the Difference Between Proximate and Root Causes

Whether addressing a sentinel event or a cluster of less serious low-harm or near-miss events, root cause analysis in all environments provides two challenges:

1. To understand why the event occurred
2. To prevent the same or a similar event from occurring in the future through prospective process design or redesign

Figure 1-2. Swiss Cheese Model



The Swiss cheese model shows how an error could penetrate multiple layers of defenses, barriers, and safeguards in a system.

Source: Reason J.: *The Human Contribution: Unsafe Acts, Accidents and Heroic Recoveries*. Farnham, England: Ashgate Publishing, 2008.  
 © *Managing the Risks of Organizational Accidents*, by James Reason, 1997, Ashgate. Reproduced by permission.

### Sidebar 1-2. Investigating Multiple Patient Safety Events

Although root cause analysis (RCA) is associated frequently with the investigation of a single sentinel event, the methodology also can be used to determine the cause of multiple occurrences of low-harm events. For example, 40 Danish community pharmacies worked together, using RCA, to gain insight into medication errors, a problem that can result in serious consequences for patients.

The root cause analysis included investigation of 401 errors, many of which had potential clinical significance, even though each error did not necessarily result in harm. Analyzed as a cluster, however, the RCA resulted in the identification of four common medication error causes<sup>1</sup>:

1. Illegible handwritten prescriptions
2. Similarities in packaging or names, or strength and dosage stated in misleading ways
3. Lack of effective control of prescription label and medicine
4. Lack of concentration caused by interruptions.

**Reference:**

1. Knudsen P, et al. Preventing medication errors in community pharmacy: Root-cause analysis of transcription errors. *Qual Saf Health Care*. 2007 Aug;16(4):285–290.

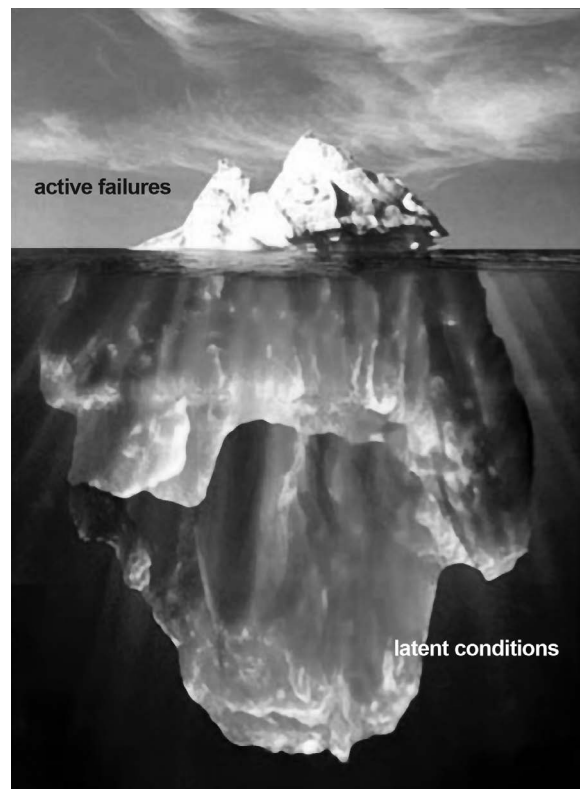
To meet these challenges, organizations must understand not only the *proximate causes*, or *active failures* (the apparent, seemingly obvious reasons an error occurred) but also the *underlying causes*, or *latent conditions* (the aspects of a process that can allow an error to occur), and the interrelationship of the two. As shown in Figure 1-3, right, active failures are only the “tip of the iceberg”—that which is visible or proximal to the patient—while latent conditions lurk unseen “underwater,” posing a hidden potential danger. Root cause analysis helps organizations delve beneath the proximate causes to find the underlying causes of a sentinel event.

Conducting an RCA has significant resource implications. A team approach, involving a full range of disciplines and departments in the process being studied, is mandatory, as will be described in Chapter 3. Organizations therefore will want to conduct root cause analysis principally to explore

those events or possible events with a significant negative or potentially negative impact on the patient. The criterion for a sentinel event is generally death, permanent harm, or severe temporary harm to the patient.

Adverse or sentinel events involve unexpected variation in a process. When this variation occurs, the probability of a serious adverse outcome increases. As mentioned previously, RCA is a process for identifying the basic or causal factor(s) underlying variation in performance. *Variation* is a change in the form, position, state, or qualities of a thing. Although a sentinel event is the result of an unexpected variation in a process, variation is inherent in every process. To reduce variation, it is necessary to determine its cause. What’s more, variation can be classified by what caused it.

**Figure 1-3. The Relationships Between a Sentinel Event and Its Causes**



Active failures, shown as the “tip of the iceberg,” reveal only the proximate causes of a sentinel event; latent conditions loom below the waterline, representing the underlying causes.

### ***Understand Common-Cause Variation***

*Common-cause variation*, although inherent in every process, is a consequence of the way a process is designed to work. For example, an organization is examining the length of time required by the emergency department to obtain a routine radiology report. The time may vary depending on how busy the radiology service is or by when the report is requested. On a particular day, the radiology department may have received many concurrent requests for reports, making it difficult for the department to fill one specific request. Or the report may have been requested between midnight and 6:00 A.M. when fewer radiology technologists are on duty. Variation in the process of providing radiology reports is inherent, resulting from common causes such as staffing levels and emergency department census.

A process that varies only because of common causes is said to be *stable*. The level of performance of a stable process or the range of the common-cause variation in the process can be changed only by redesigning the process. Common-cause variation is systemic and endogenous (that is, produced from within). The organization needs to determine whether the amount of common-cause variation will be tolerated.

### ***Special-Cause Variation***

*Special-cause variation* arises from unusual circumstances or events that may be difficult to anticipate and may result in marked variation and an unstable, intermittent, and unpredictable process. Special-cause variation is not inherently present in systems. It is exogenous (that is, produced from the outside), resulting from factors that are not part of the system as designed. Mechanical malfunctions, fatigued employees, and natural disasters such as floods, hurricanes, and earthquakes are examples of special causes that result in variation. Organizations should strive to identify, mitigate, and/or eliminate special causes wherever possible. However, removing a special cause eliminates only that current abnormal performance in the process. It does not prevent the same special cause from recurring. For example, firing an overly fatigued employee who was involved in a medication error does little to prevent the recurrence of the same error. Instead, organizations should investigate, understand, and address underlying common causes within their systems and processes such as staffing arrangements, employee education, complacency, information management, and communication.

Special causes in one process are usually the result of common causes in a larger system of which the process is a part. For example, mechanical breakdown of a piece of equipment used during surgery may indicate a problem with an organization's preventive maintenance activities.

### ***Understand the Relationships Between Common and Special Causes***

In health care, all the clinical and organizational processes and subprocesses associated with an event under review need to be delineated and evaluated to identify the degree of common-cause and/or special-cause variation. This process will help organizations identify whether variation is due to clinical processes or organizational processes or both.

Any variation in performance, including a sentinel event, may be the result of a common cause, a special cause, or both. In the case of a sentinel event, the direct or proximate special cause could be uncontrollable factors. For example, a patient death results from a hospital's total loss of electrical power during a storm. This adverse outcome is clearly the result of a special cause in the operating room that is uncontrollable by the operating room staff. Staff members may be able to do little to prevent a future power outage and more deaths. However, the power outage and resulting death can also be viewed as the result of a common cause in the organization's system for preparing for and responding to a utility failure and other emergencies. Perhaps the backup generator that failed was located in the basement, which flooded during the storm, and the organization had no contingency plan for such a situation.

When looking at the chain of causation, proximate or direct causes tend to be nearest to the origin of the event. For example, proximate causes of a medication error may include an outdated drug, product mislabeling or misidentification, or an improper administration technique. By contrast, root causes are systemic and appear far from the origin of the event, often at the foundation of the processes involved in the event. For example, root causes of a medication error might include manufacturer's production or labeling of two different types or strengths of drugs so that one looks too much like the other, storage setup that places different dosages of the same medication too close together, an inadequate medication procurement process, communication problems, or any number of system issues that set people up to make a mistake.



Most root causes alone are not sufficient to cause a failure; rather, the combination of root cause(s) and other *contributing factors* sets the stage. For example, flaws in the process for communicating changes in the condition of a patient, a poorly designed emergency call system, and an inadequate assessment process can be root causes of a patient's fall from bed. Organizations that are successful in effectively identifying all the root causes and their interactions can eliminate a plethora of risks when redesigning processes.<sup>4</sup> Elimination of one root cause reduces the likelihood of that one specific adverse outcome occurring again. However, if the organization misses two or three other root causes, it is possible that they could interact to cause a different but equally adverse outcome.

### TIP

Organizations must steer clear of the “myth of one root cause” and expect to find several possibilities.

## Benefits of Root Cause Analysis

All health care organizations experience problems of varying persistence and magnitude. Organizations can improve the efficiency and effectiveness of their operations and the quality and safety of care through addressing the roots of such problems. Individual accountability for faulty performance should not be the focus of a root cause analysis. (See Chapter 3 for additional discussion of individual accountability.) If a question arises regarding whether an individual acted appropriately, it should be addressed through the organization's employee or physician performance management system. For the purpose of an RCA, the focus should be on systems—how to improve systems to prevent the occurrence of sentinel events or problems. This approach involves digging into the organization's systems to find new ways to do things. Root cause analysis helps organizations identify risk or weak points in processes, underlying or systemic causes, and corrective actions. Moreover, information from RCAs shared between and among organizations can help prevent future sentinel events. Knowledge shared in the health care field can contribute to proactive improvement efforts and yield results across the health care delivery system.

## Maximizing the Value of Root Cause Analysis

Root cause analysis is designed to answer the following three questions:

1. What happened?
2. Why did it happen?
3. What can be done to prevent it from happening again?

The problem, however, is that health care organizations frequently use root cause analysis to answer these questions but never determine whether the risk of recurrence of an adverse event has actually been reduced. Therefore, some health care organizations may dedicate resources to root cause analysis without knowing whether the investment has any payoff. To make root cause analysis more useful, follow-up activities that measure the implementation of process changes and improvements in patient outcomes should become a standardized component of the process.<sup>5</sup>

To ensure that the RCA yields improvement, health care leaders must address fundamental challenges that can limit the value of the incident investigation. Consider the strategies listed in Sidebar 1-3, page 8.

The outcome of the root cause analysis is an action plan that the organization intends to implement in order to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of actions.

## The Root Cause Analysis and Action Plan: Doing It Right

How can an organization ensure that its RCA and action plan represent an appropriate response to a particular sentinel event? The Joint Commission and JCI provide guidance to organizations conducting RCAs in their respective sentinel event policies. These policies provide criteria that organizations can use to evaluate their RCA for acceptability, thoroughness, and credibility. Organizations can use the tool in Figure 1-4, pages 9–10, to review their RCAs based on these criteria.

### *Crafting an Acceptable Action Plan*

The Joint Commission and JCI also provide criteria for an acceptable action plan within their sentinel event policies.

### Sidebar 1-3. Strategies for an Effective RCA

To ensure the effectiveness of their root cause analyses (RCAs), organizations and their leaders should implement the following strategies:

- ▶ *Find and resolve latent conditions as well as root causes.* Finding the cause of a problem is a good start, but to be effective, identify the latent conditions that allowed the problem to materialize in the first place.
- ▶ *Treat the cause rather than try to change people.* Many RCA actions are aimed at changing the behavior of staff members. Such interventions are rarely effective. Although one person might change his or her behavior, another person might still do the same thing as before because the underlying problem with the system has not changed. Leaders must understand that processes need to be changed—and, therefore, more effective systems-based solutions should be developed.
- ▶ *Follow through to ensure change.* Often health care organization leaders initiate an improvement program based on the findings of a root cause analysis, but the initiative loses steam. It is important for leaders to make sure that improvement programs are fully implemented.

**Source:** The Joint Commission. Patient safety systems. In *2015 Comprehensive Accreditation Manual for Hospitals*. Oak Brook, IL: 2015.

According to these policies, an action plan will be considered acceptable if it does the following:

- Identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking such changes
- Identifies, in situations in which improvement actions are planned, including the following:
  - Who is responsible for implementation
  - When the action will be implemented (including any pilot testing)
  - How the effectiveness of the actions will be evaluated
  - The point at which alternative actions will be considered if improvement targets are not met

Review of the root cause analyses of sentinel events has allowed The Joint Commission to identify patterns for risk

reduction activities. This information may benefit organizations that are developing their own action plans. Data gathered by The Joint Commission between January 1995 and December 2014 from review of more than 8,876 sentinel events indicate that nearly 90% of these events fall into the following categories:

- Anesthesia-Related Event
- Criminal Event
- Delay in Treatment
- Dialysis-Related Event
- Elopement
- Fall
- Fire
- Infant Abduction
- Infant Discharge to Wrong Family
- Infection-Related Event
- Inpatient Drug Overdose
- Maternal Death
- Medical Equipment-Related
- Medication Error
- Op/Post-Op Complication
- Perinatal Death/Injury
- Radiation Overdose
- Restraint-Related Event
- Self-Inflicted Injury
- Severe Neonatal Hyperbilirubinemia
- Suicide
- Transfer-Related Event
- Transfusion Error
- Unassigned
- Unintended Retention of a Foreign Body
- Utility System Failure
- Ventilator Death
- Wrong-Patient, Wrong-Site, Wrong-Procedure

An organization experiencing a sentinel event in one of these categories is expected to conduct a thorough and credible root cause analysis, which, at a minimum, investigates each of the areas identified for that category of event. This inquiry should determine that there is, or is not, opportunity with the associated system(s), process(es), or function(s) to redesign or otherwise take action to reduce risk. A root cause analysis submitted in response to a sentinel event in one of the listed categories is considered unacceptable if it does not, at a minimum, address each of the areas specified for that type of event.

**Figure 1-4. Root Cause Analysis Evaluation Checklist**

<b>Root Cause Analysis Evaluation Checklist</b>			
Date of Evaluation:		Date of Event:	
Completed by:			
Brief Description of Incident:			
Root Cause Analysis Team Participants:			
<b>Evaluation Level 1: Acceptability</b>			
Criteria	Criteria Met? (Y/N)	Follow-Up Action Required?	Follow-Up Action Completed (Date)
Progresses from special causes in clinical processes to common causes in organizational processes.			
Repeatedly digs deeper by asking “Why?” and then, when answered, asks “Why?” again, until it no longer makes sense to ask again.			
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.			
<b>Evaluation Level 2: Thoroughness</b>			
Criteria	Criteria Met? (Y/N)	Follow-Up Action Required?	Follow-Up Action Completed (Date)
Determines the factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence, including <i>human factors</i>			
Analyzes the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk			
Inquires into all areas appropriate to the specific type of event			
Identifies the risk points and their potential contributions to this type of event			

(continued)

**Figure 1-4. Root Cause Analysis Evaluation Checklist** *(continued)*

<b>Evaluation Level 2: Thoroughness</b> <i>(continued)</i>			
Determines 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			
<b>Evaluation Level 3: Credibility</b>			
<b>Criteria</b>	<b>Criteria Met? (Y/N)</b>	<b>Follow-Up Action Required?</b>	<b>Follow-Up Action Completed (Date)</b>
Includes participation by the patient safety director and by individuals most closely involved in the processes and systems under review.			
Is internally consistent (that is, the analysis does not contradict itself or leave obvious questions unanswered).			
Provides an explanation for all findings of “not applicable” or “no problem.”			
Includes consideration of any relevant literature, guidelines, or evidence-based best practices.			

When conducting a root cause analysis, investigators must ask questions that meet the minimum scope of root cause analysis for specific types of sentinel events. The following are sample questions that might be used when investigating a medication error.

**Patient Identification Process**

- Are specific patient identification processes and protocols in place?
- Did the nurse verify the patient’s identity?
- Was the patient identified by a bar-coded wristband or any other means?

**Staffing Levels**

- What are the typical staffing levels on the unit?
- How many staff members were working on the unit where the error occurred?
- How many patients were assigned to the nurse who was involved in the error?

**Orientation and Training of Staff**

- Does the hospital offer medication safety training?
- Did the nurse involved in the error participate in medication safety training?

**Competency Assessment/Training**

- Are nurses at the hospital required to demonstrate competency in medication administration?
- Did the nurse who was involved in the error demonstrate medication administration competency?

**Supervision of Staff**

- Who was supervising the nurse who was involved in the error?
- How many other nurses was the supervisor responsible for?
- Does the supervisor specifically oversee the medication administration process?

**TIP**

Use a WWW (Who, What, When): A WWW is a simple tool that helps RCA teams clarify the actions that need to be taken, who is responsible for completing or facilitating those actions, the time frames for when those actions will be completed. The tool consists of a simple grid, such as in the example below. The first column lists the individual responsible for the action, the second lists the action itself, and the third indicates a due date.

WHO	WHAT	WHEN

**Communication Among Staff Members**

- Are there established processes and protocols in place for nurses to communicate with physicians and pharmacists about medication orders?
- Did all staff members involved properly follow the communication protocols?

**Availability of Information**

- Does the hospital routinely supply information about medications?
- Did the staff members involved review all information available to them?

**Adequacy of Technological Support**

- Are there any technologies in place to support the medication administration process?
- If “yes,” were these technologies properly used?
- If “no,” are there technologies available that would enhance the medication administration process?

**Equipment Maintenance/Management**

- Were all medication distribution systems (for example, medication cabinets) in working order?
- How often are these systems maintained?

**Sidebar 1-4. Get Support**

An organization can seek clarification of any questions about The Joint Commission’s Sentinel Event Policy and the requirements for a comprehensive systematic analysis by visiting <http://www.jointcommission.org>, which includes detailed information on the Sentinel Event Policy and root cause analysis (see Figure 1-5, pages 13–16). Note that The Joint Commission will not give a determination of reviewability at this point but can answer questions and provide support.

The Joint Commission established the Sentinel Event Hotline to respond to inquiries about the Sentinel Event Policy. For more information visit <http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/>.

**Physical Environment**

- Did any environmental factors make it difficult for the nurse to properly carry out medication administration duties?
- What environmental factors (for example, lighting, space considerations) would make it easier for staff members to properly carry out the medication administration process?

**Control of Medications: Storage/Access**

- Were the medications in question stored in the accepted manner?
- Were the medications accessed in the accepted manner?

**Labeling of Medications**

- Were the medications in question properly labeled?
- What processes or protocols are in place to verify that the label matched the medication?
- Are there any protocols in place to ensure that “look-alike” prescriptions are properly identified on the label?

Sidebar 1-5, page 12, outlines the high-level key tasks involved in performing a thorough and credible root cause analysis and action plan. Overall, a thorough and credible root cause analysis should do the following:

- Be clear (understandable information)
- Be accurate (validated information and data)
- Be precise (objective information and data)



### Sidebar 1-5. Conducting a Root Cause Analysis and Implementing an Action Plan

1. Assign an interdisciplinary team to assess the sentinel event.
2. Establish a way to communicate progress to senior leadership.
3. Create a high-level work plan with target dates, responsibilities, and measurement strategies.
4. Define all the issues clearly.
5. Brainstorm all possible or potential contributing causes and their interrelationships.
6. Sort and analyze the cause list.
7. For each cause, determine which process(es) and system(s) it is a part of and the interrelationship of causes.
8. Determine whether the causes are special causes, common causes, or both.
9. Begin designing and implementing changes while finishing the root cause analysis.
10. Assess the progress periodically.
11. Repeat activities as needed (for example, brainstorming).
12. Be thorough and credible.
13. Focus improvements on the larger system(s).
14. Redesign to eliminate the root cause(s) and the interrelationship of root causes that can create an adverse outcome.
15. Measure and assess the new design.

- Be relevant (focus on issues related or potentially related to the sentinel event)
- Be complete (cover all causes and potential causes)
- Be systematic (methodically conducted)
- Possess depth (ask and answer all of the relevant “Why” questions)
- Possess breadth of scope (cover all possible systemic factors wherever they occur)

The Joint Commission’s framework and JCI’s framework for a root cause analysis and action plan are similar and appear as Figure 1-5 at the end of this chapter. This framework, to be used extensively in Chapters 3 through 6, provides a solid foundation for root cause analyses and action plans. The tool selection matrix, found in Chapter 7 as Table 7-1 (page 135), can also be used as a guide to ensure that an organization considers and selects the most appropriate tools and techniques for root cause analysis.

### References

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Figure 1-5. A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event

## A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event

Page 1 of 4

Level of Analysis	Questions	Findings	Root Cause?	Ask "Why?"	Take Action
What happened?	Sentinel Event				
Why did it happen?	What are the details of the event? (Brief description)				
	When did the event occur? (Date, day of week, time)				
	What area/service was impacted?				
What were the most proximate factors? <small>(Typically "special cause" variation)</small>	The process or activity in which the event occurred				
	Human factors				
Equipment factors	How did the equipment performance affect the outcome?				
	Controllable environmental factors				
Uncontrollable external factors	What factors directly affected the outcome?				
	Are they truly beyond the organization's control?				
Other	Are there any other factors that have directly influenced this outcome?				
	What other areas or services are impacted?				

(continued)

**Figure 1-5.** A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event (continued)

## A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event (continued)

**Page 2 of 4**

**This template is provided as an aid in organizing the steps in a root cause analysis. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest for “root cause” and risk reduction.**

As an aid to avoiding “loose ends,” the three columns on the right are provided to be checked off for later reference:

- Root Cause? should be answered “yes” or “no” for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a “Why?” question. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan.
- Ask “Why?” should be checked off whenever it is reasonable to ask why the particular finding occurred (or didn’t occur when it should have) – in other words, to drill down further. Each item checked in this column should be addressed later in the analysis with a “Why?” question. It is expected that any significant findings that are not identified as root causes themselves have “roots.”
- Take action? should be checked for any finding that can reasonably be considered for a risk reduction strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated Action Item on page 4 of this tool in the Take Action? column for each of the findings that requires an action.

Level of Analysis	Questions	Findings	Root Cause?	Ask “Why?”	Take Action
<b>Why did that happen? What systems and processes underlie those proximate factors?</b> (Common-cause variation here may lead to special-cause variation in dependent processes)	Human Resources				
	To what degree are staff properly qualified and currently competent for their responsibilities?				
	How did actual staffing compare with ideal levels?				
	What are the plans for dealing with contingencies that would tend to reduce effective staffing levels?				
	To what degree is staff performance in the operant process(es) addressed?				

(continued)

Figure 1-5. A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event (continued)

### A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event (continued)

Page 3 of 4

<u>Level of Analysis</u>	<u>Questions</u>	<u>Findings</u>	<u>Root Cause?</u>	<u>Ask "Why?"</u>	<u>Take Action</u>
	How can orientation and in-service training be improved?				
Information management issues	To what degree is all necessary information available when needed? Accurate? Complete? Unambiguous?				
	To what degree is communication among participants adequate?				
Environmental management issues	To what degree was the physical environment appropriate for the processes being carried out? What systems are in place to identify environmental risks? What emergency and failure-mode responses have been planned and tested?				
Leadership issues: - Corporate culture	To what degree is the culture conducive to risk identification or reduction?				
- Encouragement of communication	What are the barriers to communication of potential risk factors?				
- Clear communication of priorities	To what degree is the prevention of adverse outcomes communicated as a high priority? How?				
Uncontrollable factors	What can be done to protect against the effects of these uncontrollable factors?				

(continued)

**Figure 1-5.** A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event (continued)

## A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event (continued)

**Page 4 of 4**

<u>Action Plan</u>	<u>Risk Reduction Strategies</u>	<u>Measures of Effectiveness</u>
<p>For each of the findings identified in the analysis as needing an action, indicate the planned action expected, implementation date, and associated measure of effectiveness. OR . . .</p>	<u>Action Item #1:</u>	
<p>If after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rationale for not taking action at this time.</p>	<u>Action Item #2:</u>	
<p>Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action.</p>	<u>Action Item #3:</u>	
<p>Consider whether pilot testing of a planned improvement should be conducted.</p>	<u>Action Item #4:</u>	
<p>Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvements will be implemented.</p>	<u>Action Item #5:</u>	
	<u>Action Item #6:</u>	
	<u>Action Item #7:</u>	
	<u>Action Item #8:</u>	
<p><b><u>Cite any books or journal articles that were considered in developing this analysis and action plan:</u></b></p>		

*This framework outlines several questions that may be used to probe for systems problems underlying problematic processes. In each area, consider whether and how the factors can be improved, as well as the pros and cons of expending resources to make improvements.*