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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.

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.

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.²
- 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.³
- 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 2014.⁵
- In May 2015, the Jordanian Ministry of Health began investigating an alleged medical error that resulted in a Saudi patient becoming comatose.⁶
- 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.⁷
- 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.⁸

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.⁹

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. 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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References

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 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

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.

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. At this point in the process, the FMEA team can use the RCA approach.

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**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.


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.³ (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

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

<table>
<thead>
<tr>
<th>SEVERITY</th>
<th>Catastrophic</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequent</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Occasional</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Uncommon</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Remote</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*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.*

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.

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 than 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.

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:

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:
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. 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.

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.

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.
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

### Root Cause Analysis Evaluation Checklist

<table>
<thead>
<tr>
<th>Date of Evaluation:</th>
<th>Date of Event:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed by:</td>
<td></td>
</tr>
<tr>
<td>Brief Description of Incident:</td>
<td></td>
</tr>
</tbody>
</table>

### Root Cause Analysis Team Participants:

#### Evaluation Level 1: Acceptability

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Criteria Met? (Y/N)</th>
<th>Follow-Up Action Required?</th>
<th>Follow-Up Action Completed (Date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progresses from special causes in clinical processes to common causes in organizational processes.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeatedly digs deeper by asking “Why?” and then, when answered, asks “Why?” again, until it no longer makes sense to ask again.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Evaluation Level 2: Thoroughness

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Criteria Met? (Y/N)</th>
<th>Follow-Up Action Required?</th>
<th>Follow-Up Action Completed (Date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determines the factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence, including human factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analyzes the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inquires into all areas appropriate to the specific type of event</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identifies the risk points and their potential contributions to this type of event</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(continued)
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.

<table>
<thead>
<tr>
<th>WHO</th>
<th>WHAT</th>
<th>WHEN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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/PoliciesandProcedures/.

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
**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**

<table>
<thead>
<tr>
<th>Level of Analysis</th>
<th>Questions</th>
<th>Findings</th>
<th>Root Cause?</th>
<th>Ask “Why?”</th>
<th>Take Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>What happened?</td>
<td>Sentinel Event</td>
<td>What are the details of the event? (Brief description)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>When did the event occur? (Date, day of week, time)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>What area/service was impacted?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Why did it happen?</td>
<td>The process or activity in which the event occurred</td>
<td>What are the steps in the process, as designed? (A flow diagram may be helpful here)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>What steps were involved in (contributed to) the event?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Human factors</td>
<td>What human factors were relevant to the outcome?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Equipment factors</td>
<td>How did the equipment performance affect the outcome?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Controllable environmental factors</td>
<td>What factors directly affected the outcome?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uncontrollable external factors</td>
<td>Are they truly beyond the organization’s control?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>Are there any other factors that have directly influenced this outcome?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>What other areas or services are impacted?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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.

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

This table provides a framework for a root cause analysis and action plan in response to a sentinel event. Each finding should be considered for a root cause, and if not, it should be addressed later with a “Why?” question. The “Ask “Why?”” column is intended to help drill down to the root cause of the finding. The “Take action?” column is used to determine if an action is needed to reduce risk.
**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)

<table>
<thead>
<tr>
<th>Level of Analysis</th>
<th>Questions</th>
<th>Findings</th>
<th>Root Cause?</th>
<th>Ask “Why?”</th>
<th>Take Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information management issues</td>
<td>How can orientation and in-service training be improved?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information management issues</td>
<td>To what degree is all necessary information available when needed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information management issues</td>
<td>Accurate? Complete? Unambiguous?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environmental management issues</td>
<td>To what degree was the physical environment appropriate for the processes being carried out?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environmental management issues</td>
<td>What systems are in place to identify environmental risks?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environmental management issues</td>
<td>What emergency and failure-mode responses have been planned and tested?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leadership issues:</td>
<td>To what degree is the culture conducive to risk identification or reduction?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leadership issues:</td>
<td>- Corporate culture</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leadership issues:</td>
<td>- Encouragement of communication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leadership issues:</td>
<td>- Clear communication of priorities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncontrollable factors</td>
<td>What can be done to protect against the effects of these uncontrollable factors?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

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

<table>
<thead>
<tr>
<th>Action Plan</th>
<th>Risk Reduction Strategies</th>
<th>Measures of Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 . . .</td>
<td><strong>Action Item #1:</strong></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td><strong>Action Item #2:</strong></td>
<td></td>
</tr>
<tr>
<td>Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action.</td>
<td><strong>Action Item #3:</strong></td>
<td></td>
</tr>
<tr>
<td>Consider whether pilot testing of a planned improvement should be conducted.</td>
<td><strong>Action Item #4:</strong></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td><strong>Action Item #5:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Action Item #6:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Action Item #7:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Action Item #8:</strong></td>
<td></td>
</tr>
</tbody>
</table>

Cite any books or journal articles that were considered in developing this analysis and action plan:
Addressing Sentinel Events in Policy and Strategy

Learning Objectives

- Become familiar with The Joint Commission’s Sentinel Events Policy and that of Joint Commission International
- Understand the differences among types of patient safety events
- Explore the components and value of a culture of safety in reducing variation in performance and the occurrence of patient safety events

Root cause analysis (RCA) plays a key role in the identification and prevention of sentinel events. A number of questions arise in considering sentinel events, such as the following:

- What is a sentinel event and how does it differ from other events, incidents, or occurrences that take place routinely in health care organizations?
- What role does an organization’s culture play in the identification and prevention of adverse events?
- What do The Joint Commission and Joint Commission International (JCI) require when a sentinel event occurs?
- What types of events require comprehensive systematic analysis, such as an RCA?
- What issues should be considered as an organization develops its own sentinel event policy?
- How should an organization respond after a sentinel event?
- Who must be notified after a sentinel event occurs?
- What are the legal and ethical considerations of disclosure to patients?

Although the answers to these questions tend to be organization-specific, some general guidelines can be useful. This chapter provides such guidelines, but organizations should consult additional sources of information as needed.

The Range of Adverse Events in Health Care

The Joint Commission’s Sentinel Event Policy is designed to improve patient safety in all health care organizations by working with and learning from organizations that experience serious adverse events in patient care. The policy encourages the self-reporting of sentinel events to The Joint Commission that enables it to learn about the relative frequencies and underlying cause(s) of sentinel events and to share “lessons learned” with other health care organizations, thereby reducing the risk of future sentinel events in other organizations. Accredited organizations and those outside the United States are guided by the similar Sentinel Event Policy of JCI. A comparison of the Joint Commission and JCI policies appears later in this chapter.

As of the 2015 revision of the Sentinel Event Policy, 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 any of the following:

- Death
- Permanent harm
- Severe temporary harm*

Such events are considered “sentinel” because they signal a need for immediate investigation and response. All sentinel events must be reviewed by the organization and are subject to review by The Joint Commission. Accredited organizations are expected to identify and respond appropriately to all sentinel events (as defined by The Joint Commission) occurring in the organization or associated with services that the organization provides. An appropriate response includes all of the following:

- A formalized team response that stabilizes the patient, discloses the event to the patient and family, and provides support for the family as well as staff involved in the event
- Notification of organization leadership
- Immediate investigation
- Completion of a comprehensive systematic analysis for identifying the causal and contributory factors
- Corrective actions
- Time line for implementation of corrective actions
- Systemic improvement

Sentinel events are one type of patient safety event, which is an event, incident, or condition that could have resulted or did result in harm to a patient. Patient safety events also include adverse events, no-harm events, close calls, and hazardous conditions. (See Sidebar 2-1, right, for definitions.) A patient safety event can be, but is not necessarily, the result of a defective system or process design, a system breakdown, equipment failure, or human error.

Sidebar 2-1.
Taxonomy of Patient Safety Events

- **Patient safety event**: an event, incident, or condition that could have resulted or did result in harm to a patient
- **Adverse event**: a patient safety event that resulted in harm to a patient
- **Sentinel event**: 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
- **No-harm event**: a patient safety event that reaches the patient but does not cause harm
- **Near miss (or close call)**: a patient safety event that did not reach the patient
- **Hazardous (or unsafe) condition**: a circumstance (other than a patient’s own disease process or condition) that increases the probability of an adverse event

The patient could have suffered harm if the discrepancy had not been caught and perhaps would even be expected to suffer harm with a similar error.

The Joint Commission does not require health care organizations to conduct a comprehensive systematic analysis for a near miss. However, doing so is a best practice. Using a root cause analysis or other investigation methodology to identify the contributing factors to a near miss can help organizations address any risk points that could lead to patient harm down the road. This is one example of how RCA can be used proactively to prevent system failures or process variations from reaching your patients.

The health care organization determines how it will respond to patient safety events that do not meet the definition of a sentinel event. For example, adverse events should result in prompt notification of organization leaders, investigation, and corrective actions, in accordance with the organization’s process for responding to patient safety events that do not meet the definition of a sentinel event. An adverse event may or may not result from an error. (See the box on page 19 for a discussion of error.)
Which Events Does the Joint Commission Review?
The Sentinel Event Policy was updated extensively effective January 1, 2015. As of that date, all sentinel events are considered reviewable. This means that organizations are required to conduct a comprehensive systematic analysis, such as an RCA. Reporting the sentinel event to The Joint Commission is voluntary, but strongly encouraged. Prior to 2015, The Joint Commission classified some sentinel events as “reviewable.” The 2015 revision eliminates that distinction.

Also included in the 2015 revision is a list of patient safety events that are considered sentinel events regardless of whether they result in death, permanent harm, or severe temporary harm. Organizations should respond to these events the same way they would to any other sentinel event. See Sidebar 2-2, page 20, to review several events from this list.

The Joint Commission’s Sentinel Event Policy
When developing and implementing a sentinel event policy of their own, organizations should understand the Joint Commission’s Sentinel Event Policy. Figure 2-1, page 21, provides a graphic representation of the sentinel event process flow.

The information provided here is current as of the time of this book’s publication. The Sentinel Event Policy is contained in the “Sentinel Events” chapter of the Comprehensive Accreditation Manual for each accreditation program (Hospital, Home Care, Laboratory, and so forth). The accreditation manuals are updated twice annually, which may include updates to the Sentinel Event Policy. Changes to policy are reported in The Joint Commission Perspectives® which is accessible via your organization’s Joint Commission Connect™ extranet site.

Goals of the Sentinel Event Policy
The policy has the following four goals:
1. To have a positive impact in improving patient care, treatment, and services and in preventing unintended harm
2. To focus the attention of an organization that has experienced a sentinel event on understanding the factors that contributed to the event (such as underlying causes, latent conditions and active failures in defense

Understanding Error
Though not all sentinel events result from errors, many do. These can include both errors of commission or errors of omission. An error of commission occurs as a result of an action taken—for example, when surgery is performed on the wrong limb, when a medication is administered by an incorrect route, when an infant is discharged to the wrong family, or when a transfusion error occurs involving blood crossmatched for another patient. An error of commission occurs as a result of an action not taken—for example, when a delayed diagnosis results in a patient’s death, when a medication dose ordered is not given, when a physical therapy treatment is missed, or when a patient suicide is associated with a lapse in carrying out frequent observation.

Errors of commission and omission may or may not lead to adverse outcomes. For example, suppose a patient in seclusion is not monitored during the first two hours. The staff corrects the situation by beginning regular observations as specified in organization policy. The possibility of failure is present, however, and the mere fact that the staff does not follow organization policy regarding seclusion, and thereby violates acceptable professional standards, signals the occurrence of a failure requiring study to ensure that it does not happen again. In this case, the error of omission was insufficient monitoring. If the patient suffers serious physical or psychological harm during seclusion, the sentinel event is the patient’s adverse outcome. By definition, sentinel events require further investigation each time they occur.
3. To increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention
4. To maintain the confidence of the public and clinicians, and that patient safety is a priority in accredited organizations

**Sidebar 2-2. Examples of Sentinel Events**

All instances of the following types of patient safety events are considered sentinel, even if event did not cause death or severe harm:

- Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital’s emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, and services
- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, or services while on site at the organization
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization
- Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
- Severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative dose > 1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or > 25% above the planned radiotherapy dose Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care*
- Any intrapartum (related to the birth process) maternal death
- Severe maternal morbidity when it (not primarily related to the natural course of the patient’s illness or underlying condition) reaches a patient and results in any of the following: Permanent harm or severe temporary harm†

* Fire is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion process that results in smoldering condition (no flame) is still classified as fire. **Source:** National Fire Protection Association (NFPA). NFPA 901: Standard Classifications for Incident Reporting and Fire Protection Data. Quincy, MA: NFPA, 2011.

† Severe maternal morbidity is defined, by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society for Maternal-Fetal Medicine, as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hrs), that requires the transfusion of four or more units of packed red blood cells and/or admission to the intensive care unit (ICU). Facilities are strongly encouraged to review all cases of severe maternal morbidity for learning and improvement. Admission to the ICU is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support.

How The Joint Commission Becomes Aware of a Sentinel Event

Each accredited US health care organization is encouraged, but not required, to report to The Joint Commission any patient safety event that meets The Joint Commission's definition of a sentinel event. Likewise, health care organizations outside of the United States are encouraged to report sentinel events to JCI. Alternatively, accreditor may become aware of a sentinel event by some other means, such as communication from a patient, family member, or employee of the organization or via media reports.
Figure 2-1. Sentinel Event Process Flow

**Process Flow:**

1) New sentinel event reported to The Joint Commission (via self-report, complaint, or referral from survey)

2) Create incident report

3) Sentinel event specialist contacts the organization to obtain additional details and make determination of reviewability
   a. Events not meeting reviewable criteria are forwarded to the CRU to request an organization response
   b. Events meeting reviewable criteria
      i. Alternative type is selected by the organization within 5 days and the due date is confirmed
         1. Electronic submission
         2. On-site educational session and review by a specially trained Joint Commission staff member
            a. On-site visit by the organization to the Joint Commission Central Office, with sharing of the documentation
            b. On-site visit to the organization by one Joint Commission staff member, with sharing of documentation
            c. On-site visit to the organization by one Joint Commission staff member, without sharing of documentation
      3. One-day survey by a surveyor

4) Organization provides the RCA action plan information, within 45 days of having become aware of the event, via the selected alternative type

5) RCA and action plan are reviewed for thoroughness and credibility
   a. Not acceptable
      i. The Joint Commission will work with the organization to facilitate development of a thorough and credible RCA and action plan
      ii. Clarifications requested and due within 15 days
   b. Acceptable
      i. Request 4 months of data
      ii. Sentinel Event Measures of Success (SE MOS) due in 45 days

6) SE MOS reviewed for sustainability of the improvement efforts
   a. Not acceptable
      i. The Joint Commission will work with the organization to facilitate improvement efforts
      ii. Request 4 additional months of data
   b. Acceptable
      i. File closed as complete
      ii. Letter posted to the CEO

7) Information de-identified and entered into the Sentinel Event Database

This outline displays the steps in the implementation of Sentinel Event Policy and its procedures. (CRU, Complaint Response Unit; RCA, root cause analysis)
Voluntary Reporting of Sentinel Events to The Joint Commission

If an organization wishes to report a sentinel event the organization is required to submit the information through the secure and encrypted extranet (http://www.jointcommissionconnect.org/accreditation/SentinelEvent/self_report.htm).

Sentinel event inquiries may be directed anonymously to the Sentinel Event Hotline at 630-792-3700. Sidebar 2-3, right, presents examples of reasons to call the hotline.

Each organization will be contacted by a Joint Commission patient safety specialist to determine whether the event meets the definition of a sentinel event. After the event is identified as a sentinel event, the specialist will confirm the method for sharing the comprehensive systematic analysis and action plan and will confirm the due date.

Reasons for Reporting a Sentinel Event to The Joint Commission

When an organization reports a sentinel event, The Joint Commission or JCI is able to help it through the response process. Self-reporting a sentinel event gives organizations the opportunity to work with someone who may have more exposure to and more experience in addressing similar issues. Joint Commission patient safety specialists work with a wide spectrum of health care organizations on a regular basis to address many types of sentinel events. We can lend valuable support to any and every organization that experiences a sentinel event.

Any organization that experiences a sentinel event can benefit from this review process. In particular, organizations for which such events are very rare may see the most benefit. In these organizations, the staff may be experiencing an event for the first time or for the first time in several years. The Joint Commission is a valuable collaborative resource due to our cumulative knowledge of sentinel events gleaned from working with many other organizations on similar incidents.

The rewards of reporting sentinel events extend beyond the organization itself. Reporting sends a message to the public that the organization is doing all it can to prevent recurrence of a sentinel event.

Sidebar 2-3. Reasons to Call The Joint Commission’s Sentinel Event Hotline

- To discuss any hypothetical scenario regarding an adverse event
- Interpretation of any aspect of the Sentinel Event Policy
- Education/guidance regarding the root cause analysis process
- Education/guidance regarding the development of risk reduction strategies and action plans

Further, reporting the event enables the addition of the “lessons learned” from the event to be added to The Joint Commission’s Sentinel Event Database, thereby contributing to the general knowledge about sentinel events and to the reduction of risk for such events in many other hospitals. (See Sidebar 2-4, page 23, for a discussion of government reporting requirements.)

How to Report a Sentinel Event

Reporting a sentinel event can be done online with a form accessible on an organization’s Joint Commission Connect™ extranet site. Once logged in, place the cursor over “Continuous Compliance Tools.” A dropdown list will appear. From this list, select “Self Report Sentinel Event.” (See a screenshot of this tool in Figure 2-2, page 24.)

Addressing Concerns About Reporting

Concerns about potential legal issues can give an organization pause before reporting. Often the chief concern is that a comprehensive systematic analysis will be obtained and used in a lawsuit against the organization. Organizations should be aware that it would be very difficult for any parties to obtain access to that information under any circumstances. In the event of a subpoena, The Joint Commission adheres to its Public Information Policy.

Legal Concerns over Confidentiality

The basic tenets of the Sentinel Event Policy are that an organization must perform a comprehensive systematic analysis in response to a sentinel event and that if The Joint Commission becomes aware of the event, the organization must share relevant information with The Joint Commission. Almost all organizations experiencing sentinel events appear to be moving quickly to address
Sidebar 2-4. State and Federal Reporting Requirements

In addition to reporting sentinel events to The Joint Commission, many hospitals are required to report patient safety events at the state level. Also many hospitals voluntarily report as Patient Safety Organizations that were established with the passage of the Patient Safety and Quality Improvement Act of 2005 (http://www.pso.ahrq.gov).

The National Academy for State Health Policy (NASHP) collected information about all state adverse event reporting systems. As of January 1, 2015, the shaded states were found to have reporting systems.

NASHP made the following findings:

► The number of adverse event reporting systems has changed for the first time since 2007, with Texas in January 2015 becoming the 28th state to adopt such a system. There continues to be wide variation in the types of individual events reported to states. In 2014, 15 states have adopted or adapted the National Quality Forum’s list—a slight increase from 2007.

► Reporting systems are now more technologically advanced. Twenty-two systems are now partially or fully electronic, compared to nine in 2007.

► Communication of findings to providers and the public continues to be common, with 22 systems publicly reporting data and 20 sharing system data with facilities. Eight states have increased the frequency of public reporting since 2007.

► Formal evaluations of reporting systems are rare (three states), however officials from most (23) systems have anecdotal, survey or other sources indicating an impact on communication among facilities, provider education, internal agency tracking or trending, and/or implementation of facility processes to address quality of care. Nine states report increased levels of provider and facility transparency and awareness of patient safety as a result of their reporting systems.

► System officials partner with provider, patient safety, and state agency representatives to carry out patient safety initiatives. Despite potential opportunities in delivery system and payment reform, there are few specific examples of states integrating adverse event reporting systems with statewide quality improvement or other initiatives that demonstrate the importance of patient safety as a crosscutting statewide priority.

If you are uncertain whether a patient safety event meets the definition of a sentinel event, err on the side of caution by reporting the event. Self-reporting does not automatically mean that an incident will be considered a sentinel event.

If there are questions as to whether the event meets the definition of a sentinel event, The Joint Commission’s patient safety specialists can help make that determination. The Joint Commission is there to help through the process, and patient safety specialists may work with the organization to identify potential solutions even if the incident does not meet the definition of a sentinel event.

A number of years ago, in response to these concerns, The Joint Commission, after being advised by an outside group of health care lawyers from various groups, including some state hospital association lawyers, offered several alternative ways for a health care organization to report, and The Joint Commission to review, information regarding the organization’s response to a sentinel event. These alternatives, outlined on page 27, are intended to offer methods for sharing information with The Joint Commission that

Accredited health care organizations can use this tool to self-report a sentinel event via their Joint Commission Connect™ extranet site.
some lawyers and organizations may find provide additional comfort about any potential exposure of sensitive sentinel event–related information.

Also, and again, with the advice of outside lawyers, The Joint Commission agreed to sign contractual agreements, the basic form of which is set out in Figure 2-3 on pages 28–29, that some lawyers and organizations may also find helpful. These agreements emphasize that The Joint Commission should not be viewed as an external third party in the limited context of an intensive assessment of a sentinel event, and therefore no waiver of confidentiality protections should occur by sharing sentinel event–related information with The Joint Commission.

Essentially, the agreements involve having the health care organization and The Joint Commission agree to the following:

- The Joint Commission is appointed to the organization’s peer review or quality improvement activities.
- The Joint Commission is appointed to the organization’s peer review or quality improvement committee.

Finally, The Joint Commission firmly believes that the sharing of information between The Joint Commission and accredited organizations should not waive confidentiality protection granted to any particular information by any particular state law. If requested, The Joint Commission would strongly make this point in any court or legislature. Although The Joint Commission cannot guarantee favorable decisions on this point, at the time of the publication of this book, The Joint Commission knows of no such waiver case in which confidential information was discovered or otherwise disclosed because it was shared with The Joint Commission.

Questions regarding legal protections of sentinel event information can be directed to the Office of the General Counsel. Contact information under “Legal Issues Relating to Accreditation” can be found online at http://www.jointcommission.org/AboutUs/ContactUs/contact_us_directory.htm.

**Sentinel Events That Are Not Reported by the Organization**
The Joint Commission sometimes becomes aware of a sentinel event through other means besides self-reporting, such as through media reports or calls from patients. Whether the organization voluntarily reports the event or The Joint Commission becomes aware of the event by some other means, there is no difference in the expected response, time frames, or review procedures.

If The Joint Commission becomes aware of a sentinel event that was not reported to The Joint Commission by an accredited organization, the chief executive officer of the organization, or his or her designee, is contacted, and a preliminary assessment of the sentinel event is made. If the occurrences meets the definition of a sentinel event, the organization is required to submit or make available an acceptable root cause analysis and action plan, or choose an approved protocol within 45 calendar days of the event or becoming aware of the event.

**Disclosable Information**
If, during the 45-day analysis period, The Joint Commission receives an inquiry about the accreditation status of an organization that has experienced a sentinel event, the organization’s accreditation status is reported in the usual manner without making reference to the sentinel event. If the inquirer specifically references the sentinel event, The Joint Commission acknowledges that it is aware of the event and is working with the organization through the sentinel event review process. All RCAs and action plans will be considered and treated as confidential by The Joint Commission in accordance with The Joint Commission’s Public Information Policy.

**Required Response to a Reviewable Sentinel Event**
If The Joint Commission becomes aware of a sentinel event in an accredited organization, and the occurrence meets the definition of a sentinel event, the organization is required to do the following:

- Prepare a thorough and credible comprehensive systematic analysis and action plan within 45 business days of the event or of becoming aware of the event. Root cause analysis is the most common type of comprehensive systematic analysis used by Joint Commission–accredited organizations.
- Select and provide information under an approved alternative protocol within 45 business days of the known occurrence of the event.
Requirements Related to Sentinel Events

Joint Commission standards include the following requirements related to sentinel events and associated elements of performance (EPs). The organization has an organizationwide, integrated patient safety program within its performance improvement activities.

► The leaders implement a organizationwide patient safety program.
► One or more qualified individuals or an interdisciplinary group manages the safety program.
► The scope of the safety program includes the full range of safety issues, from potential or no-harm errors (sometimes referred to as near misses, close calls, or good catches) to hazardous conditions and sentinel events.
► All departments, programs, and services within the organization participate in the safety program.
► As part of the safety program, the leaders create procedures for responding to system or process failures.
► The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment.
► The leaders define patient safety event and communicate this definition throughout the organization.
► At least every 18 months, the organization selects one high-risk process and conducts a proactive risk assessment.
► To improve safety and to reduce the risk of medical errors, the organization analyzes and uses information about system or process failures and the results of proactive risk assessments.
► The leaders disseminate lessons learned from comprehensive systematic analyses (for example, root cause analyses), system or process failures, and the results of proactive risk assessments to all staff who provide services for the specific situation.
► At least once a year, the leaders provide governance with written reports on the following:
  • All system or process failures
  • The number and type of sentinel events
  • Whether the patients and the families were informed of the event
  • All actions taken to improve safety, both proactively and in response to actual occurrences
  • **For organizations that use Joint Commission accreditation for deemed status purposes:**
    The determined number of distinct improvement projects to be conducted annually
  • All results of the analyses related to the adequacy of staffing
► The leaders encourage external reporting of significant adverse events, including voluntary reporting programs in addition to mandatory programs.
► The organized medical staff has a leadership role in organization performance improvement activities to improve quality of care, treatment, and services and patient safety.
► Information used as part of the performance improvement mechanisms, measurement, or assessment includes the following:
  • Sentinel event data.
  • Patient safety data.
► The organization respects the patient’s right to participate in decisions about his or her care, treatment, and services.
► The organization informs the patient or surrogate decision-maker about unanticipated outcomes of care, treatment, and services that relate to sentinel events as defined by The Joint Commission. (Refer to the Glossary for a definition of sentinel event.)
► The licensed independent practitioner responsible for managing the patient's care, treatment, and services, or his or her designee, informs the patient about unanticipated outcomes of care, treatment, and services related to sentinel events when the patient is not already aware of the occurrence or when further discussion is needed.
The Joint Commission will then determine whether the root cause analysis and action plan are acceptable. If the determination that an event is sentinel occurs more than 45 business days following the known occurrence of the event, the organization will be allowed 15 calendar days for its response. If the root cause analysis or action plan is not acceptable, The Joint Commission will work with the organization to facilitate development of a thorough and credible root cause analysis and action plan.

Submission of Root Cause Analysis and Action Plan

An organization that experiences a sentinel event is required to complete two documents: (1) the root cause analysis, which includes enough detail to demonstrate that the analysis is thorough and credible, and (2) the resulting action plan that describes the organization’s risk reduction strategies and plan for evaluating their effectiveness.

A framework for a root cause analysis and action plan (see Figure 1-5, pages 13–16) is available to organizations as an aid in organizing the steps in a root cause analysis and developing an action plan. It is also available on The Joint Commission's website at http://www.jointcommission.org. The root cause analysis and action plan are not to include the patient’s name or the names of caregivers involved in the sentinel event.

Reporting Options

The handling of sensitive documents regarding reviewable sentinel events is restricted to specially trained Joint Commission staff in accordance with procedures designed to protect the confidentiality of the documents. An organization that has experienced a reviewable sentinel event has several alternate methods for sharing information with The Joint Commission. These sharing options include electronic submission and on-site interaction, described as follows.

1. **On-site visit by the organization to the Joint Commission Central Office in Oakbrook Terrace, Illinois.** During this visit, the root cause analysis and action plan are reviewed by The Joint Commission in a collaborative way. This collaboration may result in an enhancement of the RCA and action plan with further risk reduction strategies as discussed during the visit. This can also be performed via Web-based video conferencing with a patient safety specialist who is located at The Joint Commission. When the Web-based videoconference is used, the hospital’s participants remain at the hospital.

2. **On-site visit to the organization by one Joint Commission staff member, with sharing of documentation.** As with option 1, during this visit, the RCA and action plan are reviewed by The Joint Commission in a collaborative way. This collaboration may result in an enhancement of the RCA and action plan with further risk reduction strategies as discussed during the visit. Please note that no survey activities are conducted during this visit.

3. **On-site visit to the organization by one Joint Commission staff member, without sharing of documentation.** During this visit, the organization discusses the sentinel event with The Joint Commission but does not show its root cause analysis and action plan. Please note that no survey activities are conducted during this visit.

4. **On-site visit by a specially trained surveyor arranged to conduct the following:**

   a. Interview and review of relevant documentation to evaluate the following:
      * The process the hospital uses in responding to sentinel events
      * The relevant policies and procedures preceding and following the organization’s review of the specific event, and the implementation thereof, sufficient to permit inferences about the adequacy of the organization’s response to the sentinel event
      * A standards-based survey that traces a patient’s care, treatment, and services and the organization’s management functions relevant to the sentinel event under review
Figure 2-3. Contractual Agreement Example

HOSPITAL

MEMORANDUM OF UNDERSTANDING AND AGREEMENT

1. This Memorandum of Understanding and Agreement is effective as of __________, 19__, by and between ______________, a [insert applicable state] hospital or other health care provider, on behalf of itself and its medical staff committee, meeting the definition in [insert applicable statutory reference] (hereinafter collectively referred to as "Hospital") and the Joint Commission on Accreditation of Healthcare Organizations (hereinafter referred to as "Joint Commission").

2. Joint Commission establishes standards for the operation of hospitals and other health care providers, conducts survey and accreditation programs that encourage and assist hospitals and other health care providers in the task of promoting high quality patient care, and recognizes compliance with its standards by issuance of certificates of accreditation. In connection with the foregoing, Joint Commission establishes policies and procedures with respect to quality improvement initiatives by hospitals and other health care providers. These policies and procedures include (among others) Joint Commission’s Sentinel Event Policy and Procedures as described below.

3. Pursuant to Joint Commission’s Sentinel Event Policy and Procedures, Hospital prepares a root cause analysis and improvement plan in response to a sentinel event as defined by Joint Commission (hereinafter collectively referred to as “sentinel event response information”).

4. Hospital seeks to establish and/or maintain accreditation by Joint Commission and in doing so desires its participation, assistance and consultation in Hospital’s quality monitoring and improvement efforts, including the preparation and analysis of any sentinel event response information, as provided herein.

5. Hospital and Joint Commission agree that the accreditation process involves working together to improve the quality of health care and that the quality of health care can be improved through root cause study of certain unexpected events and outcomes. Because Joint Commission has the expertise in root cause analysis, Joint Commission shall serve as a consultant to Hospital’s medical staff committee, formed pursuant to [insert applicable statutory reference] and Hospital’s medical staff bylaws, for the purpose of studying sentinel and other events in the hospital to assist individual physicians and surgeons practicing in the hospital and the administrators and nurses employed in the operation of the hospital in maintaining and providing a high standard of medical and hospital care. Hospital desires to retain Joint Commission to review root cause analyses to provide additional assistance, as requested by Hospital, with regard to preparation of sentinel event response information, and to report back to the committee on such matters as thoroughness and credibility. Joint Commission acknowledges that it will be reviewing confidential information and agrees to return all information without retaining copies to the committee without making any prior or subsequent disclosures, except as provided below.

6. It is intended that any and all guidance provided by Joint Commission to Hospital’s medical staff committee and any and all responses and materials provided by Hospital’s medical staff committee to Joint Commission, including sentinel event response information, are part of the proceedings, minutes, records, reports and communications of Hospital’s medical staff committee and shall be confidential and privileged as provided in [insert applicable statutory reference], and shall be classified as “confidential information” under the Joint Commission’s Public Information Policy.
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**Figure 2-3. Contractual Agreement Example (continued)**

7. Joint Commission agrees to hold in strict confidence the proceedings, minutes, records, reports and communications, whether written or oral, received by it from Hospital’s medical staff committee, including sentinel event response information, as well as all aspects of its review of said materials, as provided by [insert applicable state] law. Unless otherwise authorized or required by law or compelled to do so by court order, such information shall be disclosed only to those individuals retained or employed by Joint Commission to perform this work, including Joint Commission surveyors, staff, management, members of the Board of Commissioners, members of its Accreditation Committee and other committees, members of hearing review panels and legal counsel. This restriction shall not prevent Joint Commission from making disclosures of non-confidential information pursuant to its Public Information Policy.

8. Joint Commission also agrees that if release of any of the privileged information is sought by request or by legal process, Joint Commission will (i) immediately notify Hospital of the same, (ii) resist any such disclosure and (iii) refuse to make any disclosure unless Joint Commission is authorized or required by law or compelled to do so by court order.

9. It is intended that Joint Commission shall receive the same immunity under [insert applicable statutory reference] as any member of Hospital’s medical staff committee for any act or proceeding relating to peer review activities undertaken or performed within the scope of the functions of the medical staff committee.

10. This Memorandum of Understanding and Agreement may be terminated by either party upon 60 days notice to the other party. In the event of termination, the parties agree that the privileges and immunities provided by [insert applicable statutory reference] shall remain applicable to all information, documents, knowledge and communications which occurred between the parties prior to the termination of this agreement. The Joint Commission’s obligation to hold all such information as confidential as provided in this agreement shall survive the termination of this agreement.

11. This Memorandum of Understanding and Agreement shall become effective when signed by Joint Commission at its home office in the State of Illinois. It is recognized that Joint Commission’s activities as provided herein will be noncontinuous and an incidental part of Joint Commission’s accreditation activities in interstate commerce.

Dated: ____________________________  Dated: ____________________________

JOINT COMMISSION ON  HOSPITAL: ____________________________
ACCREDITATION OF
HEALTHCARE ORGANIZATIONS

By: ____________________________  By: ____________________________
Duly Authorized Agent  Duly Authorized Agent

This is the basic contractual agreement signed by The Joint Commission and an accredited hospital regarding information shared with The Joint Commission about the hospital’s response to a sentinel event.
The Joint Commission's Review of the Root Cause Analysis and Action Plan

Joint Commission staff members assess the acceptability of an organization's response to a reviewable sentinel event, including the thoroughness and credibility of any root cause analysis information reviewed and the organization's action plan.

Follow-Up Activity

Through the completion of the root cause analysis, the organization is able to identify important contributing factors to a sentinel event. An action plan is developed to mitigate the possible recurrence of such an event. The Joint Commission requires that organizations measure the effectiveness of those improvement activities. This measurement is most frequently done through a Sentinel Event Measure of Success (SE MOS). An SE MOS is a numerical or quantifiable measure usually related to an audit that determines if a planned action was effective and sustained. (In some instances, The Joint Commission will consider other forms of mutually agreed-upon follow-up activities to evaluate the effectiveness of an action plan.)

Upon submission of SE MOS data indicating sustainability of the improvement efforts, the file will be closed as complete. The information will be de-identified and entered into the Sentinel Event Database, as discussed in the following section.

The Sentinel Event Database

To achieve the third goal of the Sentinel Event Policy—to increase the general knowledge about sentinel events, their causes, and strategies for prevention—The Joint Commission collects and analyzes data from the review of sentinel events, root cause analyses, action plans, and follow-up activities. These data and information form the content of The Joint Commission's Sentinel Event Database.

In response to concerns about potential increased legal exposure for accredited organizations through the sharing of such information with The Joint Commission, The Joint Commission has committed to the development and maintenance of this Sentinel Event Database in a fashion that excludes organization, caregiver, and patient identifiers.

Aggregate data relating to root causes and risk reduction strategies for sentinel events that occur with significant frequency form the basis for future error-prevention advice to health care organizations through Sentinel Event Alerts, National Patient Safety Goals, and other methods of information sharing. In handling sentinel event–related documents, The Joint Commission destroys original root cause analysis documents and any copies, or, upon request, the original documents are returned to the organization. Handling of these sensitive documents is restricted to specially trained Joint Commission staff in accordance with procedures designed to protect the confidentiality of the documents.

The action plan resulting from the analysis of the sentinel event is initially retained to serve as the basis for the follow-up activity. After the action plan has been implemented to the satisfaction of The Joint Commission, as determined through follow-up activities, The Joint Commission destroys the action plan.

Joint Commission International's Sentinel Event Policy

The JCI Sentinel Event Policy, applicable to accredited organizations outside the United States, has a great deal of similarity to that of The Joint Commission.1 (For a comparison of the two sentinel event policies, see Table 2-1 on pages 32–33) The JCI Sentinel Event Policy has four similar goals:

1. To have a positive impact in improving patient care, treatment, and services and preventing sentinel events
2. To focus the attention of an organization that has experienced a sentinel event on understanding the causes that underlie that event and on changing the organization's systems and processes to reduce the probability of such an event in the future
3. To increase general knowledge about sentinel events, their causes, and strategies for prevention
4. To maintain the confidence of the public and internationally accredited organizations in the accreditation process

Reporting of sentinel events to JCI is voluntary but encouraged. As stated in the Sentinel Event Policy, JCI's definition of a reviewable sentinel event takes into account a wide array of occurrences applicable to a wide variety of health care organizations. The following sentinel events are subject
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To review by JCI and include any occurrence that meets the following criteria:

- The event has resulted in an unanticipated death or major permanent loss of function.
- The event resulted from wrong-site, wrong-patient, wrong-procedure surgery.

If, through voluntary reporting by the accredited organization or through other means (such as communications from a patient, a patient's family member, employees, or the media), JCI becomes aware of the occurrence of a reviewable sentinel event, then the event becomes subject to JCI's Sentinel Event Policy. In that case, the organization is expected to prepare a thorough and credible action plan within 45 calendar days of the event or of becoming aware of the event and then submit its root cause analysis and action plan to JCI, which evaluates them and determines whether they are acceptable. All root cause analyses and action plans are considered and treated as confidential by JCI.

A root cause analysis will be considered acceptable by JCI if it has the following characteristics:

- The analysis focuses primarily on systems and processes, not individual performance.
- The analysis progresses from specific causes in the clinical care process to common causes in the organizational process.
- The analysis repeatedly digs deeper.
- The analysis 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.

Although reporting a sentinel event to JCI is voluntary, an organization may be required to report sentinel events to a governmental or private agency within its country. Sidebar 2-5, below, describes some of these national reporting systems.

Sidebar 2-5.
National Mandatory Reporting Systems for Selected Countries

**Czech Republic:** Health care professionals are required by the government to report such events as adverse drug reactions, medical equipment failures, nosocomial (health care–associated) infections, and transfusion reactions. Information is aggregated at levels ranging from hospital and medical specialization through regional and national. Reports are not accessible to the public.

**Denmark:** Under the Act on Patient Safety in the Danish Health Care System that took effect January 1, 2004, health care professionals who become aware of an adverse event resulting from a patient’s treatment at or stay in the hospital are required to report the event to a national database. After analysis by the county in which the event occurred, the report is de-identified and forwarded to the National Board of Health, which issues periodic alerts and publishes an annual report.

**Ireland:** Under the Clinical Indemnity Scheme (CIS) law established in 2002, all covered enterprises are required to report adverse events and near misses related to clinical care. The report data are aggregated through a secure Web-based system to detect trends. The CIS maintains a website, disseminates a quarterly newsletter, and conducts seminars to share lessons learned.

**Japan:** The Ministry of Health, Labour and Welfare does not directly administer its own reporting system, but it requires that hospitals have internal reporting systems. Teaching hospitals submit mandatory reports of patient injuries, equipment failures, and near misses to the Japan Council for Quality Health Care implemented a private national reporting system in 2004. Reporting by other types of hospitals is voluntary. The council aggregates data and distributes summary reports to health care providers and the public.

Table 2-1. Comparison of The Joint Commission and Joint Commission International Sentinel Event Policies

<table>
<thead>
<tr>
<th>Definition of Sentinel Event</th>
<th>The Joint Commission Sentinel Event Policy</th>
<th>Joint Commission International (JCI) Sentinel Event Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>A patient safety event (not primarily related to the natural course of the patient’s illness or underlying condition) that reaches a patient and results in any of the following:</td>
<td>Death</td>
<td>An unanticipated occurrence involving death or serious physical or psychological injury.</td>
</tr>
<tr>
<td>• Death</td>
<td>Permanent harm</td>
<td></td>
</tr>
<tr>
<td>• Severe temporary harm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Other Information About Sentinel Events | | |
|----------------------------------------|-----------------------------------|
| Such events are called “sentinel” because they signal the need for immediate investigation and response. The terms sentinel event and medical error are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events. | Such events are called “sentinel” because they signal a need for immediate investigation and response. The terms sentinel event and medical error are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events. A sentinel event may occur due to wrong-site, wrong-procedure, wrong-patient surgery. |

| Goals of the Sentinel Event Policy | | |
|-----------------------------------|-------------------------------------|
| 1. To have a positive impact in improving patient care, treatment, and services and in preventing unintended harm | 1. To have a positive impact in improving patient care, treatment, and services and preventing sentinel events |
| 2. To focus the attention of a hospital that has experienced a sentinel event on understanding the factors that contributed to the event (such as underlying causes, latent conditions and active failures in defense systems, or hospital culture), and on changing the hospital’s culture, systems, and processes to reduce the probability of such an event in the future | 2. To focus the attention of an organization that has experienced a sentinel event on understanding the causes that underlie that event and on changing the organization’s systems and processes to reduce the probability of such an event in the future |
| 3. To increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention | 3. To increase general knowledge about sentinel events, their causes, and strategies for prevention |
| 4. To maintain the confidence of the public, clinicians, and hospitals that patient safety is a priority in accredited hospitals | 4. To maintain the confidence of the public and internationally accredited organizations in the accreditation process |

| Organization-specific Definition of Sentinel Event | Standards require each accredited organization to define patient safety event and communicate this definition throughout the organization. At a minimum, an organization’s definition must encompass sentinel events as defined by The Joint Commission. An accredited organization is encouraged to include in its definition events, incidents, and conditions in which no or only minor harm occurred to a patient. The hospital determines how it will respond to patient safety events that do not meet the Joint Commission definition of a sentinel event. | 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 this policy, accredited 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 and Sentinel Event Policy. |

(continued)
CHAPTER 2  | Addressing Sentinel Events in Policy and Strategy

**Table 2-1. Comparison of The Joint Commission and Joint Commission International Sentinel Event Policies (continued)**

<table>
<thead>
<tr>
<th></th>
<th>The Joint Commission Sentinel Event Policy</th>
<th>Joint Commission International (JCI) Sentinel Event Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-Reporting a Sentinel Event</td>
<td>Encouraged but not required</td>
<td>Encouraged but not required</td>
</tr>
<tr>
<td>Reviewable Sentinel Events</td>
<td>All sentinel events must be reviewed by the organization and are subject to review by The Joint Commission.</td>
<td>Any event that has resulted in an unanticipated death or major permanent loss of function or from wrong-site, wrong-patient, wrong-procedure surgery</td>
</tr>
<tr>
<td>Expectations for an Organization’s Response to a Sentinel Event</td>
<td>Prepare a thorough and credible root cause analysis and action plan within 45 business days of the event or of becoming aware of the event.</td>
<td>Identify and respond appropriately to all sentinel events. Appropriate response includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of the improvements. When JCI becomes aware of a reviewable sentinel event in an accredited organization, the organization is expected to prepare a thorough and credible action plan within 45 calendar days of the event or of becoming aware of the event and to submit to JCI its root cause analysis and action plan or otherwise provide for JCI evaluation of its response to the sentinel event.</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>All root cause analyses and action plans will be considered and treated as confidential by The Joint Commission in accordance with the Joint Commission’s Public Information Policy.</td>
<td>All root cause analyses and action plans will be considered and treated as confidential by JCI.</td>
</tr>
<tr>
<td>Follow-Up to Review</td>
<td>Organizations are required to measure the effectiveness of the improvement activities outlined in the action plan accepted by The Joint Commission. This measurement is done through a Sentinel Event Measure of Success (SE MOS) submission. If the SE MOS data indicate sustainability of improvement efforts, the file will be closed as complete.</td>
<td>Upon acceptance of the organization’s root cause analysis and action plan, JCI will assign an appropriate follow-up activity, typically a written progress report due in four months.</td>
</tr>
</tbody>
</table>

**Related Joint Commission International Standards**

Quality Improvement and Patient Safety (QPS) standards require that qualified individuals guide the implementation of the organization’s program for quality improvement and patient safety and manage the activities needed to carry out an effective program of continuous quality improvement and patient safety within the organization.

Additional requirements include the following:

- An individual(s) who is experienced in the methods and processes of improvement is selected to guide the implementation of the organization’s quality and patient safety program.
- The individual(s) with oversight for the quality program selects and supports qualified staff for the program and supports those staff with quality and patient safety responsibilities throughout the organization.
- The quality program provides support and coordination to department/service leaders for like measures across the organization and for the organization’s priorities for improvement.
  - The quality program implements a training program for all staff that is consistent with staff’s roles in the
quality improvement and patient safety program. The quality program is responsible for the regular communication of quality issues to all staff.
• The hospital uses a defined process for identifying and managing sentinel events.
• Hospital leadership has established a definition of a sentinel event that at least includes a) through f) found in the intent.
• The hospital completes a root cause analysis of all sentinel events in a time period specified by hospital leadership that does not exceed 45 days from the date of the event or when made aware of the event.
• Hospital leadership takes action on the results of the root cause analysis.
• Those responsible for governance approve the hospital’s program for quality and patient safety and regularly receive and act on reports of the quality and patient safety program.
• Those responsible for governance annually approve the hospital’s program for quality and patient safety.
• Those responsible for governance at least quarterly receive and act on reports of the quality and patient safety program, including reports of adverse and sentinel events.
• Minutes reflect actions taken and any follow-up on those actions.
• Hospital leadership communicates quality improvement and patient safety information to governance and hospital staff on a regular basis.
• Hospital leadership reports on the quality and patient safety program quarterly to governance.
• Hospital leadership reports include, at

Why a Defined Process?

A sentinel event is an unanticipated occurrence involving death or serious physical or psychological injury. Serious physical injury specifically includes loss of limb or function. Such events are called sentinel because they signal the need for immediate investigation and response. Each hospital establishes an operational definition of a sentinel event that includes at least

a) an unanticipated death, including, but not limited to,
   • death that is unrelated to the natural course of the patient’s illness or underlying condition (for example, death from a postoperative infection or a hospital-acquired pulmonary embolism);
   • death of a full-term infant; and
   • suicide;

b) major permanent loss of function unrelated to the patient’s natural course of illness or underlying condition;

c) wrong-site, wrong-procedure, wrong-patient surgery;

d) transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or transplanting contaminated organs or tissues;

e) infant abduction or an infant sent home with the wrong parents; and

f) rape, workplace violence such as assault (leading to death or permanent loss of function); or homicide (willful killing) of a patient, staff member, practitioner, medical student, trainee, visitor, or vendor while on hospital property.

The hospital’s definition of a sentinel event includes a) through f) above and may include other events as required by laws or regulations or viewed by the hospital as appropriate to add to its list of sentinel events. All events that meet the definition of sentinel event must be assessed by performing a credible root cause analysis. Accurate details of the event are essential to a credible root cause analysis, thus the root cause analysis needs to be performed as soon after the event as possible. The analysis and action plan is completed within 45 days of the event or becoming aware of the event. The goal of performing a root cause analysis is for the hospital to better understand the origins of the event. When the root cause analysis reveals that systems improvements or other actions can prevent or reduce the risk of such sentinel events recurring, the hospital redesigns the processes and takes whatever other actions are appropriate to do so.

It is important to note that the terms sentinel event and medical error are not synonymous. Not all errors result in a sentinel event, nor does a sentinel event occur only as a result of an error. Identifying an incident as a sentinel event is not an indicator of legal liability.
least once every six months, the number and type of sentinel events and root causes, whether the patients and families were informed of the sentinel event, actions taken to improve safety in response to sentinel events, and if the improvements were sustained.

- Information on the quality improvement and patient safety program is regularly communicated to staff, including progress on meeting the International Patient Safety Goals.

- The hospital integrates the human subjects research program into the quality and patient safety program of the hospital.

- The research program is a component of the hospital’s processes to report and act on sentinel events, adverse events of other types, and the processes to learn from near misses.

- The research program is included in the hospital’s programs for hazardous material management, medical technology management, and medication management.

- The evaluation of staff participating in the research program is incorporated into the ongoing monitoring processes of professional performance.

Developing Your Own Sentinel Event Policy

Both US–based and international health care organizations should consider developing their own sentinel event policy. The first step in developing an organization’s sentinel event policy is to determine which events warrant root cause analysis. The Joint Commission expects accredited organizations to identify and respond appropriately to all sentinel events, as defined by The Joint Commission, occurring in the organization or associated with services that the organization provides or provides for. Doing so helps ensure improvement of the organization’s processes. As outlined earlier, appropriate response includes a thorough and credible RCA, implementation of improvements to reduce risk, and monitoring of the effectiveness of those improvements.

An organization may wish to define a sentinel event as a serious event involving staff and visitors as well as patients. Or an organization may wish to include the following:

- All unusual events, even though they may result in only minor adverse outcomes
- All events that must be reported to an external agency
- Events with potential for an adverse public, economic, or regulatory impact

An organization’s definition should, at a minimum, include those events that meet the definition of a sentinel event under The Joint Commission’s or JCI’s Sentinel Event Policy. The definition should also apply organizationwide and should appear in writing in an organization plan or policy. Through a collaborative process, organization leaders as well as medical, nursing, and administrative staff should develop the definitions or categories of events that warrant root cause analysis.

In developing the organization’s sentinel event policy, leaders may also address the process for reporting a sentinel event to leadership, how organizations should handle near misses, and the process for the ongoing management of sentinel events and prevention efforts. Leaders may also wish to identify the following:

- The individual responsible for receiving initial notification of a sentinel event
- The individual responsible for assessing whether or not the event warrants an in-depth root cause analysis based on the organization’s definition of a sentinel event (this may be the same individual—for example, a physician, risk manager, quality assurance coordinator, or program manager)
- How this individual communicates the need for in-depth investigation and necessary information to a team of individuals responsible for performing the root cause analysis
- The individual responsible for facilitating and overseeing a team-based root cause analysis process

Addressing Discoverability and Disclosure

Leaders should also address confidentiality, discoverability, and disclosure. Information obtained during the investigation of sentinel events through RCA or other techniques is often highly sensitive. The organization’s sentinel event policy should address how confidentiality will be protected. The policy should also address the procedure for obtaining legal consultation to protect relevant documents such as meeting minutes, reports, and conversations from discovery in the event of a future lawsuit. The policy should be clear

* Please note that although The Joint Commission requires organizations to define the term sentinel event and communicate its definition throughout the organization, The Joint Commission does not require organizations to develop a sentinel event policy. The information provided here is intended to provide advice on how an organization might develop a sentinel event policy if it wishes to do so.
on whether the state in which the organization operates protects the details of a sentinel event investigation from discovery under the organization’s quality management, peer review, or risk management programs.

Following the development of the organization’s sentinel event policy, leaders should ensure that all staff and physicians are knowledgeable about the organization’s sentinel event policies and procedures. In-service programs and new staff and physician orientation should address the organization’s sentinel event policy on a regular and continuing basis, including regular updates concerning sentinel events that may be identified through the organization’s compliance with the National Patient Safety Goals. Sidebar 2-6, right, outlines the steps described in this section.

Leadership, Culture, and Sentinel Events
For the sentinel event policy to be effective, the culture of an organization and the role of its leaders need to support the prevention and identification of sentinel events.

Leaders must be deeply committed to patient safety and to ensuring that members of their organization truly embody their mission, vision, and values. They play a critical role in fostering an organization culture in which sentinel event reporting, root cause analyses, and proactive risk reduction are encouraged. Reporting helps an organization start the process of both identifying root causes and developing and implementing risk reduction strategies. Understanding that continuous improvement is essential to an organization’s success, leaders must have the authority and willingness to allocate resources for root cause analyses and improvement initiatives. They must ensure that the processes for identifying and managing sentinel events are defined and implemented. They must be willing and able to set an example for the organization and empower staff to identify and bring about necessary change. Effective leaders empower staff throughout the organization to acquire and apply the knowledge and skills needed to continuously improve processes and services.

An organization’s response to a sentinel event speaks volumes about the culture of that organization. Its response can also significantly influence the likelihood of similar events occurring in the future. Historically, the response to sentinel events has been to identify the individual(s) most closely associated with the event and take some form of punitive action. “Who did it?” has too often been the first question asked, rather than “Why did it happen?”

The organization that routinely asks “Why?” rather than “Who?” will, over time, learn more about the quality and safety of the care it is providing—as well as its sentinel events, near misses, and hazardous conditions—and will better understand the relationship between its staff members and the processes, systems, and environment in which they function.²

Through commitment to performance improvement, patient safety, and proactive risk reduction, leaders build an
organization culture that values change, creativity, teamwork, and communication. Teams provide much of the impetus for performance improvement. Communication and information flow throughout the organization to foster a barrier-free learning environment.

**Early Response Strategies**
An organization has just experienced a sentinel event leading to a serious adverse outcome. What must be done? Following the occurrence of a sentinel event, staff members must simultaneously take a number of actions. An organization’s sentinel event policy should outline early response strategies. These strategies include the following:

- Providing prompt and appropriate care for the affected patient(s)
- Containing the risk of an immediate recurrence of the event
- Preserving the evidence

**Appropriate Care**
The prompt and proper care of a patient who has been affected by a sentinel event should be the providers’ and staff members’ first concern following the event. Care could involve, as appropriate, stabilizing the patient, arranging for his or her transportation to a health care facility for surgery or testing, providing medications, taking actions to prevent further harm, and reversing the harm that has occurred, if possible. When appropriate, physicians should obtain medical consultation related to the adverse event and arrange to receive necessary follow-up information.

**Risk Containment**
Following a sentinel event, the organization must respond by immediately containing the risk of the event occurring again. For example, if a patient suffered a stroke after receiving an incorrect drug that looked very similar to the correct drug and was stored in the same area, are other patients at risk for the same type of incident? If so, the organization must take immediate action to safeguard patients from a repetition of the unwanted occurrence. In the example given, one of the two drugs would immediately be moved to a separate storage area farther away from the other. Risk management texts, articles appearing in the literature, and associations such as the American Society for Healthcare Risk Management (ASHRM) can provide detailed guidance. Contact ASHRM by phone at 312-422-3980 or go online at http://www.ashrm.org.

**Preservation of Evidence**
To learn from a failure and understand why it occurred, it is critical to know exactly what occurred. Preserving the evidence is essential to this process. Immediate steps should be taken to secure any biological specimens, medications, equipment, medical or other records, and any other material that might be relevant to investigating the failure. In medication-related events, syringes of recently used medications and bottles of medications should be preserved and sequestered. Because such evidence may be discarded as a part of routine operations, such as when empty vials are thrown into trash cans, it must be obtained and preserved promptly. Protocols established by the health care organization should specify the steps to be taken to preserve relevant evidence following a sentinel event.

**Event Investigation**
Documentation and appropriate communication and disclosure to relevant parties must also be considered immediately following the occurrence of a sentinel event.

**Documentation**
Proper medical record documentation of errors or sentinel events is critical for the continuity of care. Documentation tips appear in Sidebar 2-7, page 38. A thorough incident-reporting form can be very helpful during the early stages of event investigation and during Steps 2 through 4 of root cause analysis (discussed in Chapters 3 and 4). Health care organizations use a variety of occurrence or incident-reporting tools and generally have a policy and procedure covering their use. Forms or questionnaires may be general in nature, covering all types of adverse events, or be specific to event types.

**Communication and Disclosure**
With the occurrence of a sentinel event, personnel involved in the incident should promptly notify those responsible for error reporting and investigation within the organization. Supervisors, quality and risk management professionals, and administrators should be informed. These individuals can determine how best to notify other parties, including the press and external agencies such as federal, state, and local authorities. Legal counsel should be sought early in the process. Counsel can provide guidance on how to discuss the situation with the patient and family, how to prevent disclosure of potentially defamatory information, and how to handle media relations.
One recommendation states that organizations maintain two lists of key people to contact following a sentinel event: (1) key individuals within the organization and (2) individuals outside the organization. Both lists should be kept up-to-date with current telephone numbers and should be accessible to managers, supervisors, and members of a crisis management team. A sample sentinel event notification checklist appears as Figure 2-4, page 39.

Responding to media queries through organization protocols helps avert complications related to patient confidentiality, legal discovery, and heat-of-the-moment coverage. Notification requirements should be reflected in organization policies and procedures. They should include policies for communication with the patient and family.

A provider’s communication and disclosure with relevant parties following the occurrence of an event that led to or could have led to patient injury is critical. Relevant parties include the following:

- Patients and families affected by the event
- Colleagues who could provide clarification, support, and the opportunity to learn from the error
- The health care organization’s and individual provider’s liability insurers
- Appropriate organization staff, including risk managers or quality assurance representatives
- Others who could provide emotional support or problem-solving help

Conferring with other members of the care team following an adverse event enables the provider to clarify factual details and the proper sequence of what occurred. It can also help identify what needs to be done in response.

Good communication between providers and patients is instrumental in achieving positive care outcomes. Yet health care professionals often do not tell patients or families about their mistakes. Fear of malpractice litigation and the myth of perfect performance reinforce poor provider communication of errors to patients and their families. There is little doubt that the current malpractice crisis is a deterrent to the openness required for quality improvement. However, errors not communicated to patients, families, fellow staff members, and organizations are errors that do not contribute to systems improvement.

Disclosing mistakes to patients and their families is difficult at best. Yet legal and ethical experts generally advise practitioners to disclose mistakes to patients and their families in as open, honest, and forthright a manner as possible. One suggestion is that physicians have an ethical duty to disclose errors when the adverse event does one of the following:

- Has a perceptible effect on the patient that was not discussed in advance as a known risk
- Necessitates a change in the patient’s care
- Potentially poses an important risk to the patient’s future health
- Involves providing a treatment or procedure without the patient’s consent

This idea maintains that disclosure of a mistake may foster learning by compelling the physician to acknowledge it truthfully and that the physician-patient relationship can be enhanced by honesty. Disclosing a mistake might even reduce the risk of litigation if the patient appreciates the physician’s honesty and fallibility as a fellow human being. One study reports that the risk of litigation nearly doubles when patients are not informed by their physicians of moderately serious mistakes. Physician guidelines in disclosing medical mistakes to patients are offered by yet another report. Sidebar 2-8, page 40, outlines practical issues a physician may encounter in disclosing an error to a patient or his or her family. Please note that these are guidelines about issues to consider, not Joint Commission requirements. Organizations should be aware that the disclosure of an error or event requires individualized
**Figure 2-4. Sentinel Event Notification Checklist**

| Sentinel Event | Occurrence: ___________________________ | Date and Time: ___________________________
| Contact Person: ___________________________ |

**Chief Executive Officer**

| Name: ___________________________ | Office Phone Number: ___________________________ |
| After-hours Phone Number: ___________________________ | Name/Phone of Designated Backup: ___________________________ |
| Notified by: ___________________________ | Date and Time: ___________________________ |
| Results of Contact: ___________________________ |

**Chief Nursing Officer**

| Name: ___________________________ | Office Phone Number: ___________________________ |
| After-hours Phone Number: ___________________________ | Notified by: ___________________________ |
| Date and Time: ___________________________ | Results of Contact: ___________________________ |

**Medical Staff Director**

| Name: ___________________________ | Office Phone Number: ___________________________ |
| After-hours Phone Number: ___________________________ | Notified by: ___________________________ |
| Date and Time: ___________________________ | Results of Contact: ___________________________ |

**Risk Manager**

| Name: ___________________________ | Office Phone Number: ___________________________ |
| After-hours Phone Number: ___________________________ | Notified by: ___________________________ |
| Date and Time: ___________________________ | Results of Contact: ___________________________ |

**Legal Counsel**

| Name: ___________________________ | Office Phone Number: ___________________________ |
| After-hours Phone Number: ___________________________ | Notified by: ___________________________ |
| Date and Time: ___________________________ | Results of Contact: ___________________________ |

**Public Relations Director**

| Name: ___________________________ | Office Phone Number: ___________________________ |
| After-hours Phone Number: ___________________________ | Notified by: ___________________________ |
| Date and Time: ___________________________ | Results of Contact: ___________________________ |

**Chair, Board of Directors**

| Name: ___________________________ | Office Phone Number: ___________________________ |
| After-hours Phone Number: ___________________________ | Notified by: ___________________________ |
| Date and Time: ___________________________ | Results of Contact: ___________________________ |

This checklist can be used as a guide to properly notify the relevant officers following the occurrence of a sentinel event. Fill in the appropriate names and phone numbers and keep the information in a location readily accessible to managers and supervisors. The list should be periodically reviewed and updated.

**Source:** Adapted from Spath P. Avoid panic by planning for sentinel events. *Hosp Peer Rev.* 1998 Jun;23(6):112–117. Reproduced by permission.
Definition of a Medical Mistake
A **medical mistake** is a commission or an omission with potentially negative consequences for the patient that would have been judged incorrect by skilled and knowledgeable peers at the time it occurred.

Deciding Whether to Disclose a Mistake
In general, a physician has an obligation to disclose clear mistakes that cause significant harm that is remediable, mitigable, or compensable. In cases in which disclosing a mistake seems controversial, the decision should not be left to the individual physician’s judgment. Obtaining a second opinion is important to represent what a reasonable physician would do and be willing to defend in public. This second opinion is best obtained from an institution’s ethics committee or quality review board rather than from informal consultation with peers.

Timing of Disclosure
Disclosure should be made as soon as possible after the mistake but at a time when the patient is physically and emotionally stable.

Who Should Disclose the Mistake?
When a mistake is made by a physician in training, responsibility is shared with the attending physician. It may be most appropriate for the attending and house officer to disclose the mistake to the patient together.
When a mistake is made by a practicing physician, he or she should disclose the mistake to the patient. When the mistake results from the system of medical care delivery, it may be appropriate to involve an institutional representative in the disclosure, such as an administrator, risk manager, or quality assurance representative.

What to Say?
Disclosure is often difficult, for technical as well as emotional reasons. The facts of the case may be too complicated to be explained easily and may not be known precisely. The physician may be tempted to frame the disclosure in a way that obscures that a mistake was made. In telling the patient about an error, the physician should do the following:
► Treat it as an instance of breaking bad news to the patient.
► Begin by stating simply that he or she regrets that he or she has made a mistake or error.
► Describe the decisions that were made, including those in which the patient participated.
► Describe the course of events, using nontechnical language.
► State the nature of the mistake, consequences, and corrective action taken or to be undertaken.
► Express personal regret and apologize for the mistake.
► Elicit questions or concerns from the patient and address them.
► Ask if there is anyone else in the family to whom he or she should speak.

Consequences of Disclosure
Physicians are most often concerned about the potentially harmful consequences of disclosing a mistake—particularly the risk of a lawsuit. Serious mistakes may come to light even if the physician does not disclose them. Any perception that the physician tried to cover up a mistake might make patients angry and more litigious. The risks inherent in disclosing a mistake may be minimized if the following things happen:
► Patients appreciate the physician’s honesty.
► Patients appreciate that physicians are fallible.
► Disclosure is prompt and open.
► Disclosure is made in a manner that diffuses patient anger.
► Sincere apologies are made.
► Charges for associated care are forgone.
► A prompt and fair settlement is made out of court.

Disclosure of Mistakes Made by Other Physicians
A physician may encounter situations in which he or she recognizes that a colleague physician has made a mistake. That colleague may choose to disclose the mistake or not. The physician recognizing the mistake has the following options:
► Wait for the other physician to disclose the mistake.
► Advise the other physician to disclose the mistake.
► Simultaneously advise quality assurance or risk management.
► Arrange a joint meeting to discuss the mistake.
► Tell the patient directly of the error.

The physician may be reluctant to disclose a colleague’s error due to the following:

- **Lack of definitive information**
  ► Fear of hurting the colleague’s feelings
  ► Fear of straining a professional relationship
- **Fear of a libel suit**
  ► The sense that he or she could easily have made the same error
  ► Social norms against “tattling” on peers

handling. Risk management or legal counsel should be involved in helping to guide communication with the patient and his or her family.

**Survey Process**

In conducting an accreditation survey, Joint Commission surveyors seek to evaluate the organization's compliance with the applicable requirements discussed in Chapter 1 and to score those requirements based on performance throughout the organization over time (for example, the preceding 12 months for a full accreditation survey). Under the sentinel event requirements, accredited organizations are expected to identify and respond appropriately to all sentinel events occurring in the organization or associated with services that the organization provides or provides for.

Surveyors are instructed not to seek out specific sentinel events beyond those already known to The Joint Commission. The intent is to evaluate compliance with the relevant Leadership and Performance Improvement requirements—that is, how the organization responds to sentinel events when they occur. However, if a surveyor becomes aware of a sentinel event while on site, he or she will take the following steps:

1. Inform the CEO or the CEO's designee that the event has been identified.
2. Inform the CEO or the CEO's designee that the event will be reported to the Joint Commission Sentinel Event Unit for further review and follow-up under the provisions of the Sentinel Event Policy.

During the on-site survey, the surveyor(s) will assess the organization's compliance with sentinel event–related standards in the following ways:

- Review the organization’s process for responding to a sentinel event.
- Interview the organization’s leaders and staff about their expectations and responsibilities for identifying, reporting, and responding to sentinel events.
- Ask for and review an example of a root cause analysis that has been conducted in the past year to assess the adequacy of the organization’s process for responding to a sentinel event. Additional examples may be reviewed if needed to more fully assess the organization’s understanding of, and ability to conduct, root cause analyses. In selecting an example, the organization may choose a previously Joint Commission–reviewed root cause analysis or a near miss to demonstrate its process for responding to a sentinel event.

Surveyors also review the effectiveness and sustainability of organization improvements in systems and processes in response to sentinel events previously evaluated under the Joint Commission’s Sentinel Event Policy.

**Onward with Root Cause Analysis**

Having developed and implemented a sentinel event policy, the organization is now ready to start performing root cause analyses and developing an action plan. The next four chapters describe in a step-by-step, workbook format, how to perform a root cause analysis and develop, implement, and assess an improvement-driven action plan.

**References**

Learning Objectives

- Prepare for root cause analysis by recruiting and organizing a team and identifying roles and responsibilities for each member
- Identify and define the problem to be investigated, including identifying the systems involved
- Learn about the various types of evidence to be collected and how they may be used to illuminate the problem

Now suppose a sentinel event or a near miss has occurred in an organization. Leadership has been informed and, in the case of an actual sentinel event, the organization has completed preliminary response procedures, including ensuring patient safety, risk containment, and preservation of evidence (as described in Chapter 2). The appropriate staff members have documented the event and ensured communication with appropriate stakeholders. What happens next?

This chapter describes how to prepare for a root cause analysis. It covers strategies for organizing a team, defining the problem, and studying the problem. To help illustrate the steps of root cause analysis, sentinel events involving suicide, elopement, treatment delay, and medication error are described as examples throughout this and subsequent chapters. A description of each of these sentinel events appears in Sidebar 3-1, page 46. Checklists appear throughout the chapter. Worksheets are grouped together at the end of the chapter. Use this chapter and the following three chapters as a workbook—fill in the blanks. Where the icon appears, a corresponding full description of that tool appears in Chapter 7.

Root Cause Analysis: Step-by-Step

- **STEP 1:** Organize a Team
- **STEP 2:** Define the Problem
- **STEP 3:** Study the Problem
- **STEP 4:** Determine What Happened
- **STEP 5:** Identify Contributing Process Factors
- **STEP 6:** Identify Other Contributing Factors
- **STEP 7:** Measure—Collect and Assess Data on Proximate and Underlying Causes
- **STEP 8:** Design and Implement Immediate Changes
- **STEP 9:** Identify Which Systems Are Involved—The Root Causes
- **STEP 10:** Prune the List of Root Causes
- **STEP 11:** Confirm Root Causes and Consider Their Interrelationships
- **STEP 12:** Explore and Identify Risk Reduction Strategies
- **STEP 13:** Formulate Improvement Actions
- **STEP 14:** Evaluate Proposed Improvement Actions
- **STEP 15:** Design Improvements
- **STEP 16:** Ensure Acceptability of the Action Plan
- **STEP 17:** Implement the Improvement Plan
- **STEP 18:** Develop Measures of Effectiveness and Ensure Their Success
- **STEP 19:** Evaluate Implementation of Improvement Efforts
- **STEP 20:** Take Additional Action
- **STEP 21:** Communicate the Results

A series of steps comprise the root cause analysis process. These are listed in the box, above. The process begins with the selection of a multidisciplinary team.
STEP 1  Organize a Team
The first step involved in conducting a root cause analysis is to convene a team to assess the sentinel event or potential sentinel event. The team should be organized immediately after the event occurs to ensure that the root cause analysis process is not delayed. The team should collect information from all the involved parties while the incident is still fresh in their minds and then examine what they have collected to identify obvious follow-up questions.

When the team is assembled, work groups and a detailed work plan should be created. The work plan must include

Sidebar 3-1. Sentinel Event Examples

Suicide
A 20-year-old male patient is admitted for observation to the behavioral health care unit of a general hospital. He has a well-documented history of depression. On his second day in the unit, he attends a particularly clamorous group session. Following the session, between 10:00 A.M. and 11:00 A.M., he commits suicide in his bathroom by hanging himself with bedding sheets from the shower head. A registered nurse finds him at 11:05 A.M., calls a code, and starts unsuccessful resuscitation efforts.

Elopement
Nursing staff in a long term care facility note that an 80-year-old woman with a history of progressive dementia is unusually irritable and restless. She is pacing, talking in a loud voice, and complaining about a number of issues. The nurses on duty are unable to appease her or to determine the cause of her distress. Staff members frequently remind the woman to move away from the exit door. In the evening, staff members discover that the woman is no longer on the unit nor in the building. The woman left the facility without warm clothing on during a cold evening with subzero temperatures. She is found dead the following morning in a wooded area near the facility. Cause of death was exposure.

Treatment Delay
A 60-year-old female patient goes to an ambulatory health care organization to receive her annual physical from her longtime physician. The physician orders a mammogram, which she schedules for two weeks later. A week after the mammogram, a nurse in the physician’s office calls the woman and informs her that additional mammogram views are required but does not convey any sense of urgency and then files the x-ray reports in the woman’s medical record rather than in the proper file for tests requiring follow-up. When the woman calls the physician’s office to ascertain whether the repeat mammogram has been ordered, another office employee tells the woman not to worry about it if she did not get a call from the physician directly.

Several weeks later, the woman calls the physician’s office again, noting that she can feel a hard lump in her breast and mentioning that it hurts. The physician tells her to come into the office right away. Upon review of her record, the physician finds the results and orders another mammogram with needle localization right away. The test reveals a change in the size of a nodule from a previous mammogram. This result requires an immediate biopsy, which is positive. Subsequent surgery reveals that the cancer has metastasized.

Medication Error
A 60-year-old male patient receiving home care services complains about a headache to his home health nurse on each of the nurse’s three visits during a one-week period. The man indicates that he is tired of “bothering” his primary care physician about various symptoms. At the conclusion of the third visit, the nurse offers to discuss the man’s complaint with his primary care physician upon return to the agency.

When the nurse discusses the headache with the man’s physician, the physician instructs the nurse to call the local pharmacy with the following prescription: “Fioricet Tabs. #30 Sig: 1-2 tabs q 4-6 hours prn headache Refill x3.” In error, the nurse telephones the pharmacy and provides the following prescription: “Fiorinal Tabs. #30 Sig: 1-2 tabs q 4-6 hours pm headache Refill x3.” The man has a long history of peptic ulcer disease, which resulted in several hospitalizations for gastrointestinal bleeding.

The man takes the Fiorinal, which contains 325 milligrams of aspirin per tablet. In contrast, the intended medication—Fioricet—contains 325 milligrams of acetaminophen per tablet. The man completes the entire first prescription and 15 tablets of the first refill. At this point, he goes to the emergency department with acute abdominal pain, blood in the stool, and a hemoglobin count of 4.9. He is immediately admitted to the intensive care unit. Within hours, he needs life support. After several units of blood and a four-week hospital stay, the man recovers and is able to return to his home.
target dates for accomplishing specific objectives. Target dates help guide the analysis process and provide a structured game plan for the team moving forward.¹

Team leaders, however, sometimes experience difficulty when trying to keep team members focused. A study reported in the Australian Health Review found that team leaders can struggle to maintain focus primarily because teams lack an understanding of the root cause analysis process. Another significant challenge for team leaders in the study was organizing a team within seven days after the incident occurred.²

Leaders must lay the groundwork by creating an environment conducive to root cause analysis and improvement through team initiatives. Often, leaders need to assure staff that organization improvement through the identification and reduction of risks, rather than the assignment of blame, is the objective. Guilt, remorse, fear, and anxiety are common emotions felt by staff following the occurrence of a sentinel event. These emotions must be addressed and discussed at the earliest stages of team formation. Leaders must put staff members at ease so that staff members can contribute to risk reduction. Leaders further lay the groundwork by empowering the team to make changes or recommendations for changes, providing the resources (including time to do the work), and ensuring a defined structure and process for moving forward. See Checklist 3-1, below.

Checklist 3-1.

Essential Elements for a Team Go-Ahead

While developing a team and selecting team members, ensure that the following three elements are present in the organization’s leadership:

- Awareness of and support from top leadership
- Leadership commitment to provide necessary resources, including time
- An empowered team with authority and responsibility to recommend and implement process changes

What Is a Team?
The word team implies a group that is dynamic and working together toward a well-defined goal. In the health care environment, a team should be interdisciplinary. Unlike committees that hold recurring meetings for an ongoing purpose, a team generally meets for shorter periods to address a specific issue. After a particular project is completed, the team often disbands—with a sense of accomplishment.

Why Use a Team?
A team approach brings increased creativity, knowledge, and experience to solving a problem. Just as a patient’s care is provided by a team, the analysis of that care should be carried out by a team that includes representatives of all the professional disciplines involved in that care. Multidisciplinary teams distribute leadership and decision making to all levels of an organization. Teams in health care organizations provide a powerful way to integrate services across the continuum of care.³ They also provide a powerful and often successful way to effect systemwide improvement.

Who Should Work on the Team?
A team may be established on an ad hoc basis, or, if the relevant disciplines or services are represented, the core of an appropriate team may already exist in the form of a targeted performance improvement team or some other type of team. The selection of team members is critical. The team should include staff members at all levels closest to the issues involved—those with fundamental knowledge of the particular process involved. These individuals are likely to be those with the most to gain from improvement initiatives. If the organization has a quality improvement department, it is helpful to include a representative from that department who was not directly involved with the event to act as a facilitator.

The team may include the individual(s) directly involved in the sentinel event if the organization chooses to include the person(s). The decision about whether to include the individual(s) directly involved in the sentinel event can be made on a case-by-case basis. For instance, if an individual is emotionally traumatized by the event, it may make sense to instead invite another person of the same discipline with comparable process knowledge to join the team. Later, during the action planning stage when systems and processes are being redesigned, it may make sense to bring the individual(s) directly involved with the sentinel event onto the team to experience the feeling of making a positive contribution to the change process. The team also
should include an individual with some distance from the process but who possesses excellent analytic skills. In addition, the team should include at least one individual with decision-making authority as well as individuals critical to the implementation of anticipated changes. Team members should bring to the table a diverse mix of knowledge bases and should be well-versed in and committed to performance improvement. See Checklist 3-2, below.

**Checklist 3-2. Team Composition**

While drawing up a tentative list of team members, check to ensure that the team includes the following:

- Individuals closest to the event or issues involved
- Individuals critical to implementation of potential changes
- A leader with a broad knowledge base, who is respected and credible
- A person with decision-making authority
- Individuals with diverse knowledge bases

Physician participation on performance improvement teams varies. Improvement initiatives resulting from root cause analyses often address some aspect of clinical care. In such cases, medical staff involvement is essential. However, at times physician involvement is not essential (for example, in a situation in which a pharmacy stocked an incorrect drug in a medication drawer and a nurse administered the drug without noticing the discrepancy). Leaders should consider carefully whether a physician needs to be involved in the case at hand. Leaders also must understand the barriers to physician involvement and take steps to overcome those barriers, which include skepticism about the purpose of root cause analyses and improvement teams, concerns about relevance and effectiveness of teams, and lack of time and incentive to participate. In cases in which physician participation is vital, the physician must be convinced to take part.

Be creative when considering possible team members. Might a former patient, family member, or other community member be able to provide a unique perspective and valuable input? For example, perhaps the town’s retired pharmacist or a former patient who experienced a near-miss sentinel event could be invited to join the root cause analysis team. If one of the suspected root causes of a sentinel event relates to information management, perhaps a member of the local chapter of an information management association or organization could be invited.

Team composition may need to change as the team moves in and out of areas within the organization that affect or are affected by the issues being analyzed. An organization should allow for and expect this change to happen. However, the core team members should remain as stable as possible throughout the process, at least in terms of leadership and areas or functions represented. Realistically, the selection of all team members cannot take place until the broad aim of the improvement initiatives to be generated by the root cause analysis and improvement action plan is identified.

For example, to investigate the root cause of a medical gas utility disruption that led to the death of a patient when his oxygen supply was inadvertently cut off, the core team should include physicians, representatives from clinical staff (nursing and/or respiratory therapy), management, administration, and information management; someone who works primarily with medical gases and the utility management program; and if vendors are a primary part of the analysis, someone from the purchasing or contracting services department. Possible team members could include the following:

The core team investigating the suicide in a behavioral health care unit might include the following individuals:

- Any staff member, such as a psychiatrist, who was attending the patient at the time of the sentinel event and can discuss the specific circumstances of the event
- A nurse from the behavioral health care unit
- An occupational therapist, physical therapist, or recreation therapist (who has clinical skills and knowledge but would not necessarily spend much time on the behavioral health care unit)
- A social worker on the unit
- A medical staff leader who understands processes and has the authority to change medical staff policy
- The manager of the behavioral health care unit
- A representative from quality improvement or risk management (who will act as the facilitator)
- An administrative representative at the level of vice president (such as nursing, patient care, or an associate vice president) who can make changes
• A safety engineer
• A safety consultant (on an ad hoc basis)

The core team investigating the elopement of a resident from a nursing care center might include the following individuals:
• The director of nursing
• A unit nurse (regular care provider)
• A nursing assistant (who regularly cared for the resident)
• The medical director
• The safety director or person responsible for the safety program
• The individual responsible for performance improvement (facilitator of the group)
• A social service worker
• A unit activity staff member

The core team investigating the treatment delay in an ambulatory health care organization might include the following individuals:
• The director of the ambulatory health care organization
• A staff physician
• The medical director
• The appointments scheduler
• A staff nurse
• The office manager
• The manager of the laboratory from which the results were delayed
• The director or manager of quality or performance improvement

The core team investigating the medication error in a home care organization might include the following individuals:
• A home health nurse
• A nursing supervisor
• An agency director or administrator
• A member of the pharmacy supplier’s staff
• A local pharmacist (on an ad hoc basis)
• The medical director
• The quality or performance improvement coordinator
• An information technology or management staff member, as available

The team should have a leader who is knowledgeable, interested, and skilled at group consensus building and applying the tools of root cause analysis. This person guides the team through the root cause analysis process while encouraging open communication and broad participation. The leader may function as a facilitator, or a separate team member can be assigned to play the facilitator role. This individual should be skilled at being objective and moving the team along. It is best if the leader and facilitator are not stakeholders in the processes and systems being evaluated.

**TIP**
Core teams limited in size to no more than nine individuals tend to perform with greater efficiency.

Experts needed at various points can be added as ad hoc team members and attend only the relevant meetings.

Ad hoc members who can provide administrative support, additional insight, and resources should be identified as well. Use Worksheet 3-1 at the end of this chapter, page 60, to indicate proposed team members.

**Ground Rules**
At the first team meeting, the leader should establish ground rules that will help the team avoid distractions and detours on the route to improvement. The following ground rules provide a framework that will allow the team to function smoothly:

• **Team mission:** The leader should establish the group’s mission or focus as one of systems improvement rather than individual fault finding (see Sidebar 3-2, page 48, on creating a “no-blame” environment).

• **Sentinel event policy:** The leader should provide copies of the organization’s sentinel event policy and procedures, enabling all team members to become familiar with expectations.

• **Decision making:** The group must decide what kind of consensus or majority is needed for a decision, recognizing that decisions belong to the entire team.

• **Attendance:** Attendance is crucial. Constant late arrivals and absences can sabotage the team’s efforts. Set guidelines for attendance.

• **Meeting schedule:** For high attendance and steady progress, the team should agree on a regular time, day, and place for meetings. These matters should be revisited at various times during the team’s life.
• **Time line:** The leader should present a time line at the initial meeting to keep the group on track as it moves toward its quality improvement goals.

• **Opportunity to speak:** By agreeing at the outset to give all members an opportunity to contribute and to be heard with respect, the team will focus its attention on the important area of open communication.

• **Disagreements:** The team must agree to disagree. It must acknowledge and accept that members will openly debate differences in viewpoint. Discussions may overflow outside the meeting room, but members should feel free to say in a meeting what they say in the hallway.

• **Assignments:** The team should agree to complete assignments within the particular time limits so that delayed work from an individual does not delay the group.

• **General rules:** The team should discuss all other rules that members believe are important. These rules can include whether senior management staff can drop in; how electronic devices such as cell phones, pagers, and the like should be handled to minimize distraction; what the break frequency should be; and so forth.

See Sidebar 3-3, right, for techniques team leaders or facilitators can use to ensure high-quality group discussion.

### Sidebar 3-2.
Creating a “No-Blame” Environment

To create a “no-blame” environment at meetings, leaders should do the following:

► Act as a role model by demonstrating a “let’s learn from this” type of response when a mistake is made.

► To show that everyone makes errors, give an example of a mistake that the leader personally has made.

► Provide examples or positive responses to errors and some of the lessons learned from errors.

► Thank staff members for speaking up and offering suggestions.

► Reward staff members for suggestions that are shown to result in a measurable, positive impact.

► Communicate directly and frequently

### Sidebar 3-3.
Leadership Techniques for Promoting High-Quality Group Discussion

The following techniques for team leaders or facilitators can help ensure high-quality group discussion:

► Use small groups to report ideas.

► Offer quiet time for thinking.

► Ask each person to offer an idea before allowing comments or second turns at speaking.

► Keep the discussion focused on observations rather than opinions, evaluations, or judgments.

► Keep the discussion moving forward within the allotted time frame.

► Pull the group together if the discussion fragments into multiple conversations.

► Encourage input from quiet members.

► Seek consensus or group decisions.

When starting a root cause analysis, the biggest challenge for a group leader often is ensuring that the team is providing an honest, objective assessment of what actually happened. Team members from the department where the sentinel event occurred often will be defensive about the incident and might try, consciously or otherwise, to minimize or cover up the role of their department. Some team members also may try to blame others for the incident in an attempt to deflect possible criticism away from their coworkers.
A group leader must devise ways to get team members to talk honestly about the event and provide the details necessary for an effective root cause analysis. An initial step is to emphasize and maintain the confidentiality of the team's work. Some organizations require team members to sign a confidentiality agreement stipulating that information shared within the team is not transmitted or disclosed outside of the team's established communication mechanisms.

Group leaders also can set the stage for open, honest discussions by being aware of group dynamics and keeping team members focused on the task at hand. Group dynamic issues that can detract a team from its goals include fear, dominant personalities, lack of participation, the use of blaming language, and predetermination of the correct solutions or changes.

The group leader should set the ground rules for discussion and establish that certain behavior will not be tolerated. Do not tolerate the use of blaming language. Do not permit one person or group to dominate the discussion. Group leaders who ensure that confidentiality is established and who reinforce the rules of discussion will find that participation will increase over time when team members are reassured that the goal is to address systems issues and not to blame individuals.

One way the group leader can help team members relax and feel more comfortable about expressing themselves is to start each meeting with an “ice breaker”—that is, a brief, informal activity designed to help participants become more familiar with one another. The ice breaker may be a brief game or puzzle or simply having each person in turn answer a general, open-ended, perhaps even whimsical question unrelated to the business at hand, for example, “What was your favorite food when you were a child?” or “If you could take a free vacation anywhere in the world, where would you go?” A good ice breaker sets a positive, inclusive tone for the meeting.

**STEP 2  Define the Problem**

One of the first steps taken by the root cause analysis team is to define the problem—that is, to describe, as accurately as possible, what happened or what nearly happened. The purpose of defining the problem as clearly and specifically as possible is to help focus the team's analysis and improvement efforts. If the team defines and understands the problem clearly, much time and effort can be saved and much frustration avoided.

Often, when using root cause analysis, the problem is defined as a single or sentinel event that caused death or serious injury. However, root cause analysis also can be used to address a series of adverse events that do not in and of themselves carry the significance of a sentinel event but taken in aggregate do pose a serious problem to the health care organization.

**TIP**

A well-defined problem statement describes what is wrong and focuses on the outcome, not why the outcome occurred.

Whether the root cause analysis is addressing a single incident or a series of events, it is essential to clearly define the problem.

In response to a sentinel event, the team might ask, “What actually happened or what alerted the staff to a near miss?” Initially, the problem or event can be defined simply, such as the following:

- Surgery was performed on the incorrect site.
- Patient committed suicide by hanging.
- Patient could have died following overdose of drug.
- Abductor tried to leave the unit with a child that did not belong to him or her.

These simple statements focus on what happened or the outcome, not on why it happened. During later steps in the root cause analysis process, the team will focus on the sequence of events, on the *whys*, and on contributing factors.

For near misses or improvement opportunities, the preceding problem statements could be restated as follows:

- Surgery was almost performed on the incorrect site.
- Patient attempted to commit suicide by hanging.
- Patient almost received overdose of drug.
- Abductor was discovered by nurse before leaving the unit.
Use Worksheet 3-2 at the end of this chapter, page 61, to define the problem.

Particularly in the event of a near miss, multiple contributing factors may be present. Which factor should be selected first for analysis? Each team needs to develop ranking criteria to help meet this challenge. One option is to rank contributing factors by their cost impact, organization priority, consequence or severity, safety impact, or real or potential hazard. Contributing factors should be addressed one at a time. The highest-ranked factor should be tackled and solved before initiating work on lower-ranked factors. (This topic will be explored in greater depth in Chapter 6.)

Help with Problem Definition
The information disseminated from the Sentinel Event Database of The Joint Commission can be helpful in an organization’s identification of a problem or area for analysis. The purpose of this database is to increase general knowledge about sentinel events, their causes, and strategies for prevention. The Joint Commission collects and analyzes data from the review of actual sentinel events, root cause analyses, action plans, and follow-up activities in all types of health care organizations. The hope is that by sharing the lessons learned with other health care organizations, the risk of future sentinel events will be reduced.

Organizations can learn about sentinel events that occur with significant frequency, their root causes, and possible risk reduction strategies through The Joint Commission’s publication Sentinel Event Alert (see Sidebar 3-4, on page 51) and the official newsletter The Joint Commission Perspectives received by every accredited organization. Sentinel events reported in the national media, such as the medication error described in the Introduction, can also serve as a source of ideas for problem analysis. All organizations can use the areas or problems outlined here as a starting point in the identification of a problem area for analysis.

Identify Complex Systems
Identification of failure-prone systems yields problem areas requiring focus through root cause analysis. A number of factors increase the risk of system failures, including complexity—a high number of steps and handoffs in work processes. Complex systems may be dynamic, with constant change and tight time pressure and constraints. The tight coupling of process steps can increase the risk of failure. Tightly coupled systems or processes do not provide much slack or the opportunity for recovery. Sequences do not vary, and delays in one step throw off the entire process. Variable input and process steps that are nonstandardized can also increase the risk of process failure. So can processes carried out in a hierarchical rather than team structure.

For example, medication ordering is frequently cited as a risk-prone system due to organization hierarchies. Nurses and pharmacists may be reluctant to question physicians writing the orders. Some organization cultures may create a hierarchical rather than team structure for the entire medication use process. Similarly, verification of surgical sites by surgical team members can suffer from hierarchical pressures. Nurses may be reluctant to question physicians. The hierarchical mind-set can affect everyday scenarios as well, as in a situation in which a housekeeper hesitates to question a respiratory therapist observed touching patients without first performing hand hygiene. Language barriers coupled with a hierarchical culture can present a particularly dangerous scenario.

Identify High-Risk Processes
Most frequently, sentinel events result from multiple system failures. They also frequently occur at the point at which one system overlaps or hands off to another. An organization should be tracking high-risk, high-volume, and problem-prone processes as part of its performance improvement efforts. High-risk, high-volume, problem-prone areas vary by organization and are integrally related to the care, treatment, and services provided. For example, to reduce the risk of infant abductions, a large maternity unit should focus on its infant-parent identification process. To reduce the risk of patient suicide, a behavioral health care unit should focus on its process for suicide risk assessment. Starting places to find such processes include the list of frequently occurring sentinel events published by The Joint Commission; an organization’s risk management data, morbidity and mortality data, and performance data (including sentinel event indicators and aggregate data indicators); and information about problematic processes generated by field-specific or professional organizations.
Sidebar 3-4. Sentinel Event Alert

The following topics have been covered in the Joint Commission’s Sentinel Event Alert publication:

- Preventing falls and fall-related injuries in health care facilities (Sep. 2015)
- Safe use of health information technology (Mar. 2015)
- Managing risk during transition to new ISO tubing connector standards (Aug. 2014)
- Preventing infection from the misuse of vials (Jun. 2014)
- Preventing unintended retained foreign objects (Oct. 2013)
- Exposure to Creutzfeldt-Jakob Disease (Sep. 2013)
- Medical device alarm safety in hospitals (Apr. 2013)
- Safe use of opioids in hospitals (Aug. 2012)
- Health care worker fatigue and patient safety (Dec. 2011)
- Radiation risks of diagnostic imaging (Sep. 2011)
- A follow-up report on preventing suicide: Focus on medical/surgical units and the emergency department (Nov. 2010)
- Preventing violence in the health care setting (Jun. 2010)
- Preventing maternal death (Jan. 2010)
- Leadership committed to safety (Aug. 2009)
- Safely implementing health information and converging technologies (Dec. 2008)
- Preventing errors relating to commonly used anticoagulants (Sep. 2008)
- Behaviors that undermine a culture of safety (Jul. 2008)
- Preventing pediatric medication errors (Apr. 2008)
- Preventing accidents and injuries in the MRI suite (Feb. 2008)
- Preventing adverse events caused by emergency electrical power system failures (Sep. 2006)
- Tubing misconnections—a persistent and potentially deadly occurrence (Apr. 2006)
- Using medication reconciliation to prevent errors (Jan. 2006)
- Preventing vincristine administration errors (Jul. 2005)
- Patient controlled analgesia by proxy (Dec. 2004)

- Preventing, and managing the impact of, anesthesia awareness (Oct. 2004)
- Revised guidance to help prevent kernicterus (Aug. 2004)
- Preventing infant death and injury during delivery (Jul. 2004)
- Preventing surgical fires (Jun. 2003)
- Infection control–related sentinel events (Jan. 2003)
- Bed rail–related entrapment deaths (Sep. 2002)
- Delays in treatment (Jun. 2002)
- Preventing ventilator-related deaths and injuries (Feb. 2002)
- Medication errors related to potentially dangerous abbreviations (Sep. 2001)
- Preventing needlestick and sharps injuries (Aug. 2001)
- Medical gas mix-ups (Jul. 2001)
- Exposure to Creutzfeldt-Jakob disease (Jun. 2001)
- Look-alike, sound-alike drug names (May 2001)
- Kernicterus threatens healthy newborns (Apr. 2001)
- Fires in the home care setting (Mar. 2001)
- Mix-up leads to a medication error (Feb. 2001)
- Infusion pumps (Nov. 2000)
- Fatal falls (Jul. 2000)
- Making an impact on health care (Apr. 2000)
- Operative and postoperative complications (Feb. 2000)
- High-alert medications and patient safety (Nov. 1999)
- Blood transfusion errors (Aug. 1999)
- Infant abductions (Apr. 1999)
- Preventing restraint deaths (Nov. 1998)
- Inpatient suicides (Nov. 1998)
- Examples of voluntarily reportable sentinel events (May 1998)

Current and past issues of Sentinel Event Alert are posted on The Joint Commission’s website at http://www.jointcommission.org/sentinel_event.aspx.
Developing a Preliminary Work Plan and Reporting Mechanism

Brainstorming

After a team has defined the problem, it can develop a preliminary work plan for investigating the sentinel event through root cause analysis. The plan should outline the overall strategy, key steps, individuals responsible for each step, target dates, and reporting mechanisms. It is essential at this point to define the scope of the plan so that team members can provide a specific answer to the question, “How will we know if we are successful?”

The creation of a detailed work plan is critical to the process and to securing management support. A plan outlining target dates for accomplishing specific objectives provides a tool against which to guide and measure the team’s progress.

The full work plan should include target dates for major milestones and key activities in the root cause analysis process. These dates can mirror the steps of the root cause analysis and action plan itself, including the following:

- Defining the event and identifying the proximate and underlying causes
- Collecting and assessing data about proximate and underlying causes
- Designing and implementing immediate changes
- Identifying the root causes
- Planning improvement
- Testing, implementing, and measuring the success of improvements

For a sentinel event that is reviewable by The Joint Commission or Joint Commission International, the root cause analysis must be completed within 45 days of the occurrence of the sentinel event.

Checklist 3-3, page 53, indicates the key steps to include in a work plan for a root cause analysis. Each activity is described further in later chapters. Use Worksheet 3-3 at the end of this chapter, page 62, to outline key steps, individuals responsible, and target dates for a root cause analysis. Also outline the reporting mechanisms and use the checklist portions to double-check overall strategy and report quality.

Gantt chart, stakeholder analysis

A team’s outline of the reporting mechanism aims to ensure that the right people receive the right information at the right time. At the beginning of the process, the team leader or facilitator should establish a means of communicating team progress and findings to senior leadership. Keeping senior leaders informed on a regular basis is critical to management support of the root cause analysis initiative and implementation of its recommendations. Although it is difficult to provide guidelines on how a regular basis should be defined because the time frame varies widely depending on circumstances, communication with senior leaders should increase in frequency with the following:

- Serious adverse outcomes
- Repeated adverse events
- Events requiring solutions from multiple parts of the organization
- Possible solutions requiring the investment of significant amounts of money
- Media involvement in the case and its solutions

Frequency of communication also varies according to the actions required in the short term to prevent recurrence of the event. Communication frequency should be weighed against the speed with which information emerges from the investigation. If information is emerging rapidly, the team leader should give thought to the most productive timing for communication. A description of reporting considerations for each of the sample root cause analysis investigations follows.

The reporting mechanism for a suicide investigation should ensure that the psychiatrist on the team is providing his or her colleagues with regular updates on the team’s progress at clinical department meetings. Such updates prepare the medical staff for recommended policy changes. Similarly, at executive staff meetings, the vice president on the team should be providing the CEO, chief operating officer, and other leaders with regular updates on the team’s progress. Communication should be frequent to foster leadership acceptance of future recommendations, particularly those involving significant resources. Safety should be a standing agenda item at board meetings as well.
CHAPTER 3  |  Preparing for Root Cause Analysis

The reporting mechanism for the elopement investigation should ensure that the safety director is providing the facility management and operations staff with regular updates on the team’s progress. Such updates prepare the staff for any recommended building alterations to enhance the safety of the care environment.

The reporting mechanism for the treatment delay investigation in an ambulatory health care organization should ensure that the office manager is keeping the physician or medical director informed of the team’s progress on a regular basis. This regular communication prepares the medical director for any changes that might be warranted with respect to staffing levels and staff orientation, training, and ongoing competence assessment.

The reporting mechanism for the medication error investigation should ensure that the information technology staff member is keeping his or her colleagues informed of the team’s progress. This information flow facilitates the smooth integration of any new processes or technology that may be recommended to enhance safe medication ordering.

STEP 3  Study the Problem

The team is now ready to start studying the problem. Doing so involves collecting information surrounding the event or near miss. Time is of the essence because key facts can be forgotten in a matter of days. The individual(s) closest to the event or near miss may have already collected some information that the team can use as a starting point. Often a written statement provided by individuals involved in the event and prepared as near the time of the event as possible can be useful throughout the root cause analysis process. At times, the individual(s) closest to the event may withhold critical information due to fear of blame. The team should consider how to minimize such fear (see Sidebar 3-5, on page 56, which provides sample statements for enhancing comfort). It may be necessary in some instances to obtain an individual’s written statement and then proceed without his or her contribution in the early stages of the analysis.
Early on, the team should give thought to how information should be recorded. Some methods are more suitable than others. For example, audio recording or video recording an interview with someone intimately involved with the event is likely to increase that individual’s defensiveness. Note taking is an effective way to record interviews. Video recordings, drawings, and/or photographs are effective media to record physical evidence. For instance, if an organization experienced an accidental death when an individual served was strangled after slipping through guard rails on a bed, a video image or photo of the bed with guard rails in place provides evidence of the position of the device following the event. The team should not rely on anyone’s memory. Instead, complete notes, audio recordings, video recordings, photographs, and drawings ensure accuracy and thoroughness of information collection. Drawings can be particularly helpful for events such as patient falls, in which the team wants to get a sense of the layout of the room where a fall occurred. In addition, these various methods of recording information aid in reporting the team’s progress. See Sidebar 3-6, on page 57, for ways of recording information.

In all cases, the team should seek guidance from the organization’s legal counsel regarding protection of information from discovery through its inclusion in peer review and other means. The team also should seek guidance from the organization’s risk management department or legal counsel along with representatives of the health information management department concerning patient confidentiality and the information collected during the root cause analysis.

Sidebar 3-5.
Sample Strategies for Enhancing Comfort

When collecting information about a sentinel event or near miss, health care leaders can use statements such as those presented here to help the staff member(s) involved feel more comfortable about offering information by doing the following:

► Emphasizing that the goal is to learn from the event, not to blame or punish anyone: “Our objective is to learn how to deliver better, safer care at our hospital. We’re not here to punish anyone.”

► Providing examples of mistakes made in the past, how the organization learned from the mistakes, and how patients benefitted from the subsequent improvements: “Last year, when nurses shared details on their medication administration practices, we found three areas in which we could make process improvements. As a result, our drug error rates dropped significantly.”

► Encouraging staff members to speak freely without fear of retribution from management or peers: “Please go ahead and talk freely about the incident. We’re not interested in assigning blame, we’re only interested in helping patients. Isn’t that really why we’re all here in the first place?”

► Rewarding staff members for providing insight into the event: “We want to gather insight into what works and what doesn’t work with our current processes. Therefore, we are offering a $25 bookstore gift card to anyone who can point to a process that needs improvement.”

► Stating that the goal of the inquiry is to look at organizational processes, not at individual behaviors: “We really don’t want to know what you did or what your coworkers did during this event because your individual responses to the situation are not the thing that matters to us. It’s the overall process that we are looking at.”

► Asking for suggestions on how processes can be changed: “Everyone has an opinion, and we truly value yours. We realize that in our hectic day-to-day work lives, you don’t always get a chance to share opinions. Well, here is your chance: Tell us what needs to be changed.”

► Reinforcing the idea that frontline staff are the only true process experts—they have the best knowledge and vantage point to help come up with effective improvements: “You are the real expert. You’re on the front line, so you know what really goes on when you are delivering care. We’re trying to understand everything you go through, so we truly want you to share your expertise.”
The team must ensure focus of data collection. Collecting a huge amount of data, much of which might not be related in any way, is both unproductive and confusing. To focus collection efforts, examine the problem statement and collect data along potential lines of inquiry. The list of questions in Sidebar 3-7, on page 57, can provide guidance for potential lines of inquiry. For example, if a problem statement such as “Patient was given wrong medication” suggests an equipment maintenance or human resources problem, then collect data relevant to medication distribution systems, training, and so forth. A sampling of information that might be collected relevant to the suicide, elopement, treatment delay, and medication error examples described in Sidebar 3-1, page 46, follows:

Information to be collected in a suicide investigation might include an environment of care inventory of all fixtures in the behavioral health care units and data on which fixtures are breakaway compliant and which are not—that is, those that are or are not capable of breaking automatically in response to a predetermined external force (for example, the weight of an individual).

Information to be collected in an elopement investigation might include an environment of care inventory of unattended or unmonitored exits; availability and functionality of wander-prevention technology such as electric bracelets and wired exits; data related to the thoroughness and frequency of initial resident assessment and ongoing reassessment for elopement risk; and information regarding how data about individuals at risk for elopement are integrated into initial and ongoing care plans.

Information to be collected in a treatment delay investigation might include data about how test results are processed within the organization and how staff members are trained in these processes initially and on a continuing basis. Data related to competence assessment testing and staffing levels would also be valuable.

Information to be collected in a medication error investigation might include data on how medication orders are transmitted to local pharmacies and the percentage of queries and errors due to illegible physician handwriting, misinterpretation of physician handwriting, telephone or verbal orders, and order transcription. Data related to the frequency of nurse communication about a new medication and patient education efforts would also be valuable.

Although information or data collection occurs throughout the root cause analysis process, the team may also want to gather the following three types of information at this early stage:
1. Witness statements and observations from those closest to the event or near miss as well as those indirectly involved
2. Physical evidence related to the event or near miss
3. Documentary evidence

Each type of information is further addressed in the following sections.

**Witness Statements and Observations**

Interviews with staff members can provide a wealth of information during a number of stages of root cause analysis. Shortly after an event or near miss, interviews with staff members directly involved can probe for what happened or almost happened and why (proximate causes). Interviews with staff members indirectly involved can explore possible root causes. Later in the process, interviews can provide insight into possible improvement initiatives and implementation strategies. The team should try to strike a balance between individual interviews and group interviews. Individual interviews are important for obtaining as accurate an account of the situation as possible from each person, without the influence of others in the room. However, additional group interviews afterward can
encourage greater interplay of ideas and reinforcement of the process improvement message.

Conducting interviews is both an art and a science. Some people do it well; some do not. The team should carefully consider who is best suited to interview each subject and the best possible timing and sequence of interviews to be conducted. The goal of the interviews is to identify facts, possible systemic causes, and improvement opportunities—

not to place blame. The team should identify all likely interview candidates at each stage and be aware that people tend to forget information or remember it incorrectly, rationalize situations, and perceive situations differently.

Four discrete stages of what normally appears to be a continuous interview process are preparing for the interview, opening the interview, conducting the interview, and closing the interview. Consider the following descriptions:

Preparing for the interview. The interviewer plans the interview. Planning involves reviewing previously collected information, developing carefully worded interview questions that are open-ended (see Sidebar 3-7, page 57), scheduling the interview, determining how information will be recorded and documented, preparing to answer questions that the interviewee is likely to ask, identifying material that should be available as a reference during the interview, and establishing the physical setting. Carefully worded responses to such questions as “Why do you want to talk with me?” and “What will you do with the information I provide?” can go a long way toward reducing the interviewee’s defensiveness, and so can a neutral setting where privacy is ensured and interruptions avoided.

Opening the interview. The interviewer should greet the interviewee, exchange informal pleasantries, state the purpose of the interview, and answer the interviewee’s questions. The goal is to establish rapport, put the interviewee at ease, establish credibility, and get the interviewee involved in the interview process as quickly as possible. The interviewer should indicate at this stage the amount of time the interview is expected to take.

Conducting the interview. The interviewer poses the open-ended questions that were developed during the preparation stage. Open-ended questions elicit information by encouraging more than a “yes” or “no” response. Refer back to Sidebar 3-7 for examples of ways to pose such questions and for examples of question types that can help ensure that the questions sound natural.

A two-step probing technique, using an open-ended exploratory question and then a follow-up question asking “why,” can yield valuable information. For example, the interviewer might first ask, “What can you tell me about the administration of medication in the unit?” After the interviewee responds, the interviewer might follow up with, “Why do you think that is the case?” This technique should be used judiciously and reserved for important areas because its repetition could make the interviewee feel “drilled.”

TIP

Overcome interviewee defensiveness by doing the following:

- Restate the focus and purpose of the interview and reiterate that information obtained will be used to help prevent future occurrences of an adverse event rather than to assign blame.
- Send positive, supportive messages through statements such as “What you have said is so helpful” and “I understand, and you have obviously given this a lot of good thought.”
- Gently ask about a defensive reaction and probe why the interviewee feels threatened. (Take great care here to ensure that this inquiry will not do more harm than good.)

Throughout the interview, the interviewer should listen well, avoid interrupting the interviewee, avoid talking excessively, ask purposeful questions, and summarize throughout the interview to confirm a proper understanding of what the interviewee has related. The interviewer should also be aware of his or her own body language, as well as of the interviewee’s body language and other nonverbal cues.

Closing the interview. The interviewer should check to ensure that he or she has obtained all necessary information; ask the interviewee if he or she has any questions or concerns; summarize the complete interview to ensure that the information accurately reflects the interviewee’s words;
and thank the interviewee, expressing appreciation for his or her time, honesty, and assistance.

After the interviewee leaves the interview area, the interviewer should document any further observations and identify follow-up items. Conclusions and results should be communicated to the root cause analysis team as appropriate.

Remember the following points when gathering information from caregivers:
- People's memories and their willingness to help can be affected by the way questions are asked.
- Interviewees should be informed that follow-up interviews are a normal part of the root cause analysis process and do not reflect any suspicion of the information provided in initial interviews.
- Interviewees should be encouraged to contact the team leader with any concerns or additional information.

Group interviews can be more efficient than individual interviews, but disadvantages should be considered and weighed with care. Disadvantages include dominance by more vocal members of the group and the emergence of groupthink, which can stifle individual accounts of an event.

When in-person interviews are not possible, telephone interviews can provide an alternative. However, the telephone has some serious limitations. It is much more difficult to establish and maintain rapport when eye contact is not part of the interview, and, of course, nonverbal cues are much harder to detect.

Written responses from an observer to specific questions raised by the team are another alternative (see Worksheet 3-4 at the end of this chapter, pages 63–65). However, this method is less likely than either in-person or telephone interviews to elicit in-depth information. A matter as seemingly trivial as how much space is provided for answers on the form can have a significant impact on the quantity of information provided. In addition, when the observer must put something in writing, his or her concern about the privacy and confidentiality of the information may increase defensiveness, thereby preventing full disclosure and honesty.

**Physical Evidence**

Interviews with personnel closest to the event can help the team identify relevant physical evidence, including equipment, materials, and devices. Physical evidence related to the event or near miss should be gathered at an early stage. Preserving the evidence immediately following the event or near miss can be essential to understanding why an event occurred or almost occurred. In many instances, physical evidence inadvertently (or deliberately) may be taken, misplaced, destroyed, moved, or altered in some way.

Physical evidence for a sentinel event involving a medication error, for example, might include the drug vial, syringe, prescription, IV drip, filter straws, and medication storage area. Physical evidence for a suicide in a 24-hour care setting might include breakaway bars and fixtures in the
shower or elsewhere, a window, a ceiling, and other sites. Physical evidence for a wrong-site surgery might include the x-rays, the operative arena, surgical instruments, and so forth.

The evidence should be thoroughly inspected by a knowledgeable team member, ad hoc member, or consultant. Perhaps equipment was not fully assembled or parts were missing. Observations from the inspection should be documented. All physical evidence should be labeled with information on the source, location, date and time collected, basic content, and name of the individual collecting it and then secured in a separate area, if feasible. If not, such as with a large piece of equipment, the item should be tagged to indicate that it failed and that its use is prohibited, pending investigation results.

**Documentary Evidence**

Documentary evidence includes all material in paper or electronic format that is relevant to the event or near miss. It could include the following:

- Patient records, physician orders, medication profiles, laboratory test results, and all other documents used to record patient status and care
- Policies and procedures, correspondence, and meeting minutes
- Human resources–related documents such as performance evaluations, competence assessments, and physician profiles
- Indicator data used to measure performance
- Maintenance information such as work orders, equipment logs, instructions for use, vendor manuals, and testing and inspection records

All such evidence should be examined, secured, and labeled appropriately.

Documentary evidence varies considerably, based on the actual sentinel event or possible sentinel event. Examples of documentary evidence for various error types follow. This information is a starting place in considering the kind of documentary evidence needed for any organization’s root cause analysis.

For a suicide, documentary evidence could include the following:

- The patient’s history and physical on admission
- Staff observation notes
- Attendance logs for unit activities
- Policies and procedures for patient observation
- An inventory of items in the patient’s possession on admission
- The patient’s psychosocial assessment
- All physician and nursing notes prior to the incident

For a medication error involving the administration of the wrong medication and the subsequent death of a patient, documentary evidence could include the following:

- The patient’s medical record
- Trending data on medication errors
- Procedures for medication allergy interaction checking
- Pharmacy lot number logs
- Pharmacy recall procedure
- Maintenance logs for equipment repair
- Downtime logs for computer software
- Equipment procedure logs for mixing of solutions
- The error report to the US Pharmacopoeia and state licensing agency (for Joint Commission customers) or to the local, regional, or national agency (for Joint Commission International customers)
- Lab test results of drug samples
- Interdepartmental and interorganizational memos or reports regarding the event

For a mechanical error involving the shutoff of oxygen and the subsequent death of a patient, documentary evidence could include the following:

- Procedures for informing patient care areas about downtime of mechanical or life-support systems
- Construction and technical documents and drawings of the medical gas distribution system
- Inspection, performance measurement, and testing policies and procedures
- Policies and procedures for shutoff of utility systems
- Utility system performance measurement data
- Documents related to the utility systems planning process
- Management competence assessment programs
- Technical staff training, retraining, and competence assessment programs in utilities systems processes
- Incident and emergency reporting procedures
- Maintenance procedures and logs
**Literature Review**

At this point and throughout the root cause analysis, a thorough review of the professional literature is an important component of the process. Literature searches can yield helpful information about the event at hand and other organizations’ experiences with a similar event. The literature can help identify possible root causes and improvement strategies. Appropriate professional or industry associations and societies can provide a good starting point in the review process. Obtain a variety of information on the subject. A review of other organizations’ practices and experiences can help avoid mistakes and inspire creative thinking. Information that might be obtained to investigate causes and improvement strategies for the sample sentinel events shown in Sidebar 3-1, page 44, includes the following possibilities.

For a suicide event, the team might obtain policies, procedures, and forms for suicide risk assessment from other organizations. A team member might conduct an online literature search to obtain protocols for suicide risk assessment from relevant professional journals.

For an elopement event, the team might obtain resident assessment policies, procedures, and forms from other long term care organizations and specifically information related to how they assess at-risk-for-elopement status. The facility or safety manager might obtain information from other organizations related to systems used to ensure appropriate security in the environment of care, such as wander-prevention technology. Assessment protocols from relevant professional journals might be helpful as well.

For a treatment delay event, the team might obtain policies, procedures, and protocols for communicating abnormal test findings from the professional literature and peer ambulatory health care organizations. Training and competence assessment literature could also provide insight for improvement strategies. Professional organizations might be a source of information on criteria for calling in additional specialists.

For a medication error event, the team might contact other home care organizations to obtain information about the policies and protocols used to ensure a safe medication use process. An online literature review could provide improvement strategies recommended by other health care organizations following a sentinel event or near miss.

**Tools to Use**

The team should begin to consider performance measurement tools that might be helpful in the next step of the root cause analysis—determining what happened and why. The tool list that follows includes the tools that will be used in the Chapter 4 search for proximate causes.

*Flowchart, control chart, brainstorming, fishbone diagram, change analysis, Gantt chart*

**References**

Worksheet 3-1. Composing the Team

Fill in the team leader, facilitator, and team members, including ad hoc members who serve on an as-needed basis. Ensure interdisciplinary representation by including information such as job titles, degrees, and responsibilities.

Core Team Members
1. Leader ________________________________
2. Facilitator ________________________________
3. ________________________________
4. ________________________________
5. ________________________________
6. ________________________________
7. ________________________________
8. ________________________________
9. ________________________________
10. ________________________________

Ad Hoc Members
______________________________
______________________________
______________________________
______________________________
______________________________
______________________________
______________________________
______________________________
______________________________
______________________________
Worksheet 3-2. Defining the Problem

Use this space to formulate a simple, one-sentence definition of the event or near miss.

A sentinel event occurred: What happened?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

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________________________________________________________________________

A sentinel event occurred: What happened?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Worksheet 3-3. Preliminary Planning

Use this form to guide initial planning.

**Overall strategy**

- □ Does it include the team’s aim?
- □ Is it objective?
- □ Is it measurable?

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**Reporting mechanisms**

Who receives copies of the reports?

- ________________________________
- ________________________________
- ________________________________
- ________________________________
- ________________________________
- ________________________________
- ________________________________
- ________________________________
**Worksheet 3-4. Gathering Information**

Use this worksheet as a place to start gathering written information from individuals who cannot be interviewed in person or by telephone. Be aware that the amount of space you provide for each question often determines the amount of information provided by the respondent. If a detailed answer to a certain question is desired, be sure to leave plenty of space and provide a prompt such as “Please provide as much information as possible.”

What conditions existed prior to the event?

________________________________________________________________________
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________________________________________________________________________
________________________________________________________________________
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What procedures or processes were being conducted prior to and during the event?

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________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Who was present and involved in the event?

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________________________________________________________________________

(continued)
Worksheet 3-4. Gathering Information (continued)

What indicated that a problem was occurring?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

How did you respond?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

How did others in the area respond?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

What procedures or processes might have been associated with the event?

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(continued)
**Worksheet 3-4. Gathering Information (continued)**

What might have caused the event?

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________________________________________________________________________

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________________________________________________________________________

How might the event be prevented in the future?

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________________________________________________________________________

Any other comments or thoughts?

________________________________________________________________________

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________________________________________________________________________
Prior to this point in the process, the team has created a very simple, one-sentence definition of what happened or could have happened. The next step involves creating a more detailed description or definition of the event.

**STEP 4 Determine What Happened**

This description provides the *when*, *where*, and *how* details of the event. It should include the following:

- Briefly describe of what happened
- Where and when did the event occurred (place, date, day of week, and time)
- What areas or services were affected by the event

(See Worksheet 4-1 at the end of the chapter, page 77, for questions to ask in developing a detailed definition of an event.)

For example, with a sentinel event involving a medication error, a more detailed definition of the event might state, "A 60-year-old man receiving home care services complains about a headache to his home health nurse on each of the nurse's three visits during a one-week period. The man indicates that he is tired of bothering his primary care physician about various symptoms. At the conclusion of the third visit, the nurse offers to discuss the man's complaint with his primary care physician upon return to the agency. The discussion results in the physician prescribing a medication. A transcription error results in the patient receiving Fiorinal, instead of Fioricet, which results in gastrointestinal bleeding, a trip to the emergency department, and a four-week hospital stay. The prescription was delivered on Friday, January 1, and the patient was admitted to the hospital on Monday, January 4."

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**Learning Objectives**

- Learn to identify contributing process factors
- Identify what needs to be measured and learn to apply a variety effective measurements
- Explore the tools with which a team can search for proximate or direct causes.

**Root Cause Analysis: Step-by-Step**

- **STEP 1:** Organize a Team
- **STEP 2:** Define the Problem
- **STEP 3:** Study the Problem
- ✔️ **STEP 4:** Determine What Happened
- ✔️ **STEP 5:** Identify Contributing Process Factors
- ✔️ **STEP 6:** Identify Other Contributing Factors
- ✔️ **STEP 7:** Measure—Collect and Assess Data on Proximate and Underlying Causes
- ✔️ **STEP 8:** Design and Implement Immediate Changes
- **STEP 9:** Identify Which Systems Are Involved—The Root Causes
- **STEP 10:** Prune the List of Root Causes
- **STEP 11:** Confirm Root Causes and Consider Their Interrelationships
- **STEP 12:** Explore and Identify Risk Reduction Strategies
- **STEP 13:** Formulate Improvement Actions
- **STEP 14:** Evaluate Proposed Improvement Actions
- **STEP 15:** Design Improvements
- **STEP 16:** Ensure Acceptability of the Action Plan
- **STEP 17:** Implement the Improvement Plan
- **STEP 18:** Develop Measures of Effectiveness and Ensure Their Success
- **STEP 19:** Evaluate Implementation of Improvement Efforts
- **STEP 20:** Take Additional Action
- **STEP 21:** Communicate the Results
The relevant areas for this sentinel event might be nursing, medicine, home care, and pharmacy.

Developing a flowchart is often helpful to determine the sequence of events. These tools can help the team retain focus on seeking the facts of the event. Ensure that the source of each piece of information is noted on the tool so the source can be consulted if more information is needed.

In creating this more detailed definition of an event, team members should stick to the known facts and not speculate, prior to completing the root cause analysis, on what is not yet known or why things happened. For example, perhaps the team’s problem statement at this point reads, “80-year-old female found in room beside her bed, lying on floor, dead. Event occurred sometime between 0200 and 0330, Thursday, March 4.” Did the patient die because of a fall? Or did the patient fall after or while dying? A root cause analysis will help the team identify the cause of death. In this example, relevant areas or services affected by the event might include nursing (to investigate monitoring systems and medication administration), biomedical (to investigate the type of bed, alarm, and call light system), staffing office (to investigate whether the type of staff—regular or float—affected the event), education (to investigate orientation and training provided to staff and patient), pharmacy (to investigate patient medications), medical staff protocols (to investigate medications ordered for the patient), and policies and procedures (related to fall risk assessment, interventions, patient education, and so on).

Flowchart

**STEP 5 Identify Contributing Process Factors**

Root cause analysis involves repeatedly asking “Why?” to identify the underlying root causes of an event or possible event. At this point, the team asks the first of a series of “why” questions. The goal of the first “why” question is to identify the proximate causes of the event. **Proximate causes, or direct causes,** are the most apparent or immediate reasons for an event. They involve factors closest to the origin of an event, and they can generally be gleaned by asking, “Why did the event happen?”

In most cases, identifying the proximate causes is simple; in other cases, it might take some digging. For example, in the case of the patient found dead by her bed, proximate causes could include “failure to monitor patient,” “bed alarm not working,” “call light not working,” “patient not properly oriented to use of call light,” “incorrect sedation dispensed,” or “incorrect administration of sedation.”

**Underlying causes** in the health care environment may relate to the provision of care or to other processes. Hence, identification of the patient care processes or activities involved in the sentinel event or potential sentinel event will help the team identify contributing causes. At this point, asking and answering the following three questions will assist the team:

1. Which processes were involved in the event or almost led to an event?
2. What are the steps and linkages between the steps in the process (a) as designed, (b) as routinely performed, and (c) as occurred with the sentinel event?
3. Which steps and linkages were involved in, or contributed to, the event?

A variety of tools can help ensure a thorough response to these questions. A flowchart is a useful way to visualize the response to the questions “What are the steps in the process?” and “What actually happens?” Brainstorming can be used to identify processes and supplement the list of process steps to ensure that all relevant steps are included. Fishbone diagrams and change analysis are useful techniques in analyzing a response to the question “Which steps and linkages were involved in or contributed to the event?”

Flowchart, brainstorming, fishbone diagram, change analysis

The team can then probe further by asking three more questions:

1. What is currently done to prevent failure at this step or its link with the next step?
2. What is currently done to protect against a bad outcome if there is failure at this step or linkage?
3. What other areas or services are affected?

Comparing the flowchart of the process as designed and specified in written policies and procedures to the flowcharts of the process as routinely performed and as occurred
with the sentinel event can alert the team to staff actions that circumvent policies and procedures either knowingly or unknowingly. Staff members who perform the processes in question should routinely compare their actual actions to the prescribed policies and procedures to detect any discrepancies. (Use Worksheet 4-2 at the end of the chapter, page 78, as a summary of questions to raise and tools to consider using.)

**STEP 6  Identify Other Contributing Factors**

In health care environments, proximate causes tend to fall into a number of distinct categories beyond and in addition to process factors. They include the following:

- Human factors
- Equipment factors
- Information-related factors
- Controllable or uncontrollable environmental factors

To identify additional proximate causes of an event involving human factors, the team might ask:

- What human factors were relevant to the outcome?
- How did the equipment performance affect the outcome?
- What information-related factors were relevant to the outcome?
- What factors directly affected the outcome? Were such factors within or truly beyond the organization’s control?

Finally, the team might ask, “Are there any other factors that have directly influenced this outcome?” Figures 4-1 through 4-3, pages 70–71, identify common factors associated with failures related to procedure, and equipment. (Use Worksheet 4-3 at the end of the chapter, pages 79–80, to identify factors closest to the event.)

Communication-related errors often set in motion the cascade of events that result in procedure-related failures. By far, the majority of these errors involve two types of communication: (1) communication of relevant patient information among staff members and (2) communication between physicians and other physicians or staff members. Other communication-related errors include communication between staff and the patient or family; oral communication problems, such as incomplete change-of-shift reports; problems with administration, such as delayed reporting of hazardous conditions; and electronic communication problems.

Two other common factors in procedure-related failures are flawed processes and failure to follow a defined process. It is important to distinguish between the two when analyzing root causes and developing improvement actions.

A flawed process is a process that can become a root cause of errors, even when people are following the process correctly. When a flawed process is identified as the cause of an error, then the process must be analyzed and changed to eliminate the possibility of more errors.

Failure to follow a defined process occurs when staff members fail to follow an established process and then that mistake in turn causes an error. When failure to follow a defined process is identified as a factor, there must be an inquiry as to why the process wasn’t followed: Is it a bad policy or is it that staff members were not informed about the policy? Are shortcuts tolerated in the organization?

Continuing the example of a patient suicide as described in Sidebar 3-1, in identifying the proximate causes, a team might conclude that proximate causes include the following:

- Human factors such as failure to follow policies on precaution orders or failure to conduct appropriate staff education or training
- Assessment process factors such as a faulty initial assessment process that did not include identification of a history of suicide attempts or an immediate psychiatric consultation
- Process or human factors such as a faulty history and physical assessment that did not identify patient suicide risk factors
- Equipment factors such as a nonfunctional paging system that delayed communication with the patient’s physician

Brainstorming to identify all possible or potential contributing causes may be a useful technique for teams at this stage of the root cause analysis. Following traditional brainstorming ground rules—such as not labeling anything a bad idea and ensuring that team members do not express reactions or provide commentary as ideas are expressed—is critical to success. The focus must be on improving patient outcomes rather than
Figure 4-1. Common Factors Associated with Procedure-Related Failures

PROCEDURES

- Not Used
  - no procedure
  - difficult to use
  - not available
  - use not enforced

- Inadequate
  - facts or methods wrong
  - poor organization
  - wrong revision used
  - situation not covered

- Followed Incorrectly
  - format confusing
  - excessive references
  - too technical


Figure 4-2. Common Factors Associated with Training-Related Failures

TRAINING

- Not Training
  - task not analyzed
  - decided not to train
  - no learning objective
  - training not enforced

- Inadequate
  - no learning objectives
  - no lesson plan
  - poor instruction
  - no practical application

- Not Learned
  - retention lacking
  - too technical
  - did not attend course
  - mastery not verified

individual performance. Affinity diagrams can be used to help sort or organize the causes or potential causes into natural, related groupings. Fishbone diagrams can help highlight the numerous factors involved in an event.

**Brainstorming, affinity diagram, fishbone diagram**

While asking questions to uncover causes, the team leader should keep team members focused on processes, not people. One individual’s actions generally will not be a root cause. The team must focus on the systems within which people are operating. That is the level at which most root causes are found. By repeatedly asking “Why?” the team can continue working until it feels it has exhausted all possible questions and causes. The importance of this stage cannot be overstated. It provides the initial substance for the root cause analysis without which a team cannot proceed.

After sorting and analyzing the cause list, the team may start to determine which process or system each cause is a part of and whether the cause is a special or common cause in that process or system. This process, described fully in the next chapter, helps unearth systems-based root causes.

**STEP 7 Measure—Collect and Assess Data on Proximate and Underlying Causes**

To advance further toward discovering root causes, the team must explore in depth proximate and underlying causes. This exploration involves measurement—collecting and assessing relevant data. Although this exploration is presented here as Step 7, data collection and analysis initiatives may occur throughout root cause analysis and need not be sequential or follow Step 6 and precede Step 8.

Measurement is the process of collecting and aggregating data. The process helps assess the level of performance, determine whether improvement actions are necessary, and ascertain whether improvement has occurred.

Data gathering must begin as soon as possible after the event occurs to prevent loss or alteration of the data. Data from people are the most easily altered or destroyed and need to be made a priority. Other forms of data are more stable; however, physical data need to be identified quickly to prevent their inadvertent loss or destruction.

**Figure 4-3. Common Factors Associated with Equipment-Related Failures**

![Figure 4-3. Common Factors Associated with Equipment-Related Failures](image-url)

**Purposes of Measurement**

Organizations collect data to monitor the stability of existing processes, identify opportunities for improvement, identify changes that lead to improvement, and maintain changes.

The first purpose of measurement is to provide a baseline when little objective evidence exists about a process. For example, a health care organization may want to learn more about the current level of staff competence. A dementia long-term care or psychiatric special care unit may want to know more about the effectiveness of the bed alarm systems to prevent patient falls and elopement. Specific indicators for a particular outcome or a particular step in a process may be used for ongoing data collection. When assessed, these data can help management and staff determine whether a process is ineffective and needs more intensive analysis. Data about costs, including costs of faulty or ineffective processes, may also be of significant interest to leaders and can be part of ongoing performance measurement.

The second purpose of measurement is to gain more information about a process chosen for assessment and improvement. For example, a performance rate varies significantly from the previous year, from shift to shift, or from the statistical average. Records may indicate that the staff members on duty during weekend hours do not complete suicide risk assessments at intake. Or perhaps the data indicate that patient observations are incomplete or infrequent when specific personnel are present. Perhaps patient assessment methods or other care planning factors are suspected as root causes of a sentinel event. Such findings may cause a health care organization to focus on a given process to determine opportunities for improvement.

The target for further study should be time limited and can test a specific population, a specific diagnosis, a specific service provided, or an organization management issue. Detailed measurement is then necessary to gather data about exactly how the process performs and about factors affecting that performance.

A third purpose of measurement is to determine the effectiveness of improvement actions. For example, a nursing unit that begins to use a new piece of equipment needs to establish a baseline performance rate and continue to measure use. Measurement can also demonstrate that key processes (for example, the preparation and administration of medications) are in control. When a process has been stabilized at an acceptable level of performance, it may be measured periodically to verify that the improvement has been sustained. Measurement to monitor improvement actions is described fully in Chapter 6.

**Choosing What to Measure**

Choosing what to measure is extremely important. An organization may wish to start by defining the broad processes or systems most likely to underlie proximate causes. For example, if a team is investigating a medication error involving the process used to communicate an order to the pharmacy and the process used by pharmacy staff to check the dosage ordered, the team may decide to measure the following for a defined period of time:

- Time elapsed between when an order is written by medical staff and when the pharmacy receives the order by fax, pickup, or phone
- Number of calls to prescribers for clarification of an order
- Time elapsed between when the dosage is checked by pharmacy staff and when medication is dispensed
- Time elapsed between when medication is dispensed and when medication is administered

**Process and Outcome Measures**

A *process measure* is an intermediate indicator of the success of an intervention. An *outcome measure* is a specific,
measurable indicator of the end result of an action. For example, monitoring the number of speeding tickets a person receives is a process measure of that person’s safety as a driver. The number of car accidents that person has is an outcome measure of how safe a driver that person actually is.

Outcome measures are often misleading in health care. For example, a root cause analysis could be used to change a process that theoretically led to a sentinel event. The organization can measure outcomes, and the sentinel event might not occur again for many years. However, because sentinel events occur only rarely, it is difficult to make a direct correlation between the outcome measure and the change. This is a limitation of the use of outcome measures to assess the effectiveness of process changes intended to reduce the incidence of rare events. For example, if a wrong-site surgery typically occurs in each hospital only once every four to five years, can a hospital that has gone without a wrong-site surgery for several years claim that the root cause analysis has led to improved outcomes?

Examples of an outcome indicator are “catheter-associated sepsis for patients with a central venous access device” or “percentage of patients at risk for falls who actually experience falls while in the health care organization.” An example of a process indicator is “patients older than 65 having medication monitoring for drugs that can decrease renal function.”

In addition to categorizing indicators as measures of process or outcome, they can be classified as single-event indicators and aggregate data indicators. A special type of single-event, outcome indicator is a sentinel event. A sentinel event indicator identifies an individual event or phenomenon that is significant enough to trigger further investigation each time it occurs. Such indicators are well known to risk managers, who help ensure that each event is promptly evaluated to prevent future occurrences.

Although sentinel event indicators are useful to ensure patient safety, they are less useful than aggregate data indicators in measuring the overall level of performance in an organization. An aggregate data indicator quantifies a process or outcome related to many cases. Unlike a sentinel event, the events typically measured by an aggregate data indicator may occur frequently. Aggregate data indicators are divided into two groups: rate-based indicators and continuous variable indicators.

Rate-Based Indicators
Rate-based indicators express the proportion of the number of occurrences to the entire group within which the occurrence could take place, as in the following examples:

Patients receiving cesarean sections
All patients who deliver

Total number of elopements
Patients at risk for elopement (wandering and confused)

Patients with central line catheter infections
All patients with central line access devices

Patient falls associated with adverse drug reactions
All patient falls

The rate can also express a ratio comparing the occurrences identified with a different but related phenomenon, as in the following example:

Patients with central line infections
Central line days

Continuous Variable Indicators
This type of aggregate data indicator measures performance along a continuous scale. For example, a continuous variable indicator might show the precise weight in kilograms of a patient receiving total parenteral nutrition (TPN). Or it might record the number of written pharmacist recommendations accepted by the attending physicians. While
a rate-based indicator might relate the number of patients approaching goal weights to the total number of patients on TPN, a continuous variable indicator measures the patient’s average weight change (that is, the patient’s weight one month minus the patient’s weight the previous month).

See Checklist 4-1, above, for criteria that will help the team ensure that the data collected are appropriate for monitoring performance. See Sidebar 4-3, right, for key questions the team should ask about measurement throughout the root cause analysis process.

Additional information on measurement, including how to measure the effectiveness of improvement initiatives and ensure the success of measurement, appears in Chapter 6.
unsecured window may need to be repaired and secured right away; an intoxicated employee should be immediately removed from the environment; and broken or malfunctioning equipment should be promptly taken out of the area of care, treatment, or service, and secured.

Second, immediate changes may also uncover additional causes that were previously masked but are critical to the search for the root cause(s). Finally, immediate changes can be part of a performance improvement cycle such as Plan-Do-Study-Act (PDSA) to test process redesign before implementing it organizationwide. For instance, an organization may wish to test the use of new bathroom hardware in one room before changing hardware throughout the facility.

In addition, the organization could evaluate the assessment tool for suicide risk and the process used to check for contraband, and it could then initiate meetings with the medical staff to discuss revisions to requirements for histories and physicals.

Or the organization could start conducting mandatory in-service training for all staff on suicide risk assessment. Or it could place all patients with psychiatric or substance abuse diagnoses on suicide precautions. A Gantt chart used by one organization to outline the key steps and time frames for a plan to eliminate proximate causes that led to a patient suicide appears as Figure 4-4, page 78.

In the case of an organization that experienced a wrong-site surgery, the organization could require a second staff member to observe operating room team procedures to assess compliance with the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™.
### Figure 4-4. Gantt Chart

<table>
<thead>
<tr>
<th>TASK</th>
<th>Person(s) Responsible</th>
<th>3rd Qtr 2009</th>
<th>4th Qtr 2009</th>
<th>1st Qtr 2010</th>
<th>2nd Qtr 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish review team</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expand security round to include helipad</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revise suicide precaution policy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff training: Suicide precaution policy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff training: Assessment and interventions for patients with mental health needs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff training: Patients leaving until unattended</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Team meetings to assess Plan-Do-Study-Act (PDSA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical record review of all suicide precaution charts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concurrent assessment of patients or suicide precautions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This Gantt chart details the target date and person(s) responsible for each task in the process of identifying and eliminating proximate causes of a patient suicide.
Worksheet 4-1. Further Defining What Happened

In developing a more detailed definition of what happened, the team should consider the following three questions:

1. What are the details of the event? (Write a brief, two- or three-sentence description.)

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

2. When and where did the event occur (place, date, day of week, and time)?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

3. What area(s) or service(s) was affected?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
## Worksheet 4-2. Further Defining What Happened

To determine proximate causes of a sentinel event or possible sentinel event involving patient care or organization processes, the team can ask the following questions and consider using the following tools to aid in answering each question.

1. Which processes were involved or could have been involved in the event or near miss?
   
   Suggested Tools: [ ] Brainstorming  [ ] Fishbone diagram

2. What are the steps in the process, as designed?
   
   Suggested Tools: [ ] Flowchart  [ ] Brainstorming

3. What are the steps in the process, as it occurred?
   
   Suggested Tools: [ ] Flowchart

4. Which steps were (or could have been) involved in, or contributed to, the event or near miss?
   
   Suggested Tools: [ ] Fishbone diagram  [ ] Change analysis  [ ] Failure mode and effects analysis (FMEA)

5. What is currently done to prevent failure at this step?
   
   Suggested Tools: [ ] Flowchart

6. What other areas or services are affected?
   
   Suggested Tools: [ ] FMEA  [ ] Brainstorming
Worksheet 4-3. Identifying Factors Close to the Event

Use this worksheet to identify factors closest to the event or possible event.

Human factors included or could include

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Equipment factors included or could include

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Controllable environmental factors included or could include

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

(continued)
Worksheet 4-3. Identifying Factors Close to the Event (continued)

Uncontrollable environmental factors included or could include

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Other factors included or could include

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
The probing continues. At this point, the team has a detailed description of the event or near miss, a description of the patient care processes involved, and a list of proximate causes and other factors that might have caused or contributed to the problem or could do so in the future. The team has also started to collect data on proximate causes.

STEP 9  Identify Which Systems Are Involved—The Root Causes

Now the team again asks, “Why did that proximate cause happen? Which systems and processes underlie proximate factors?” The goal of asking questions at this stage is to identify the underlying causes for the proximate causes. For example, in the case of the elderly patient found dead on the floor by her bed, questions might include the following:

- Why was the patient not monitored for an hour to an hour and a half?
- Why was a new graduate nurse assigned to this patient’s care? Did the nurse have the assistance of ancillary staff?
- How much orientation had the nurse completed?
- Why was the patient given a sedative?
- Why was the call light not by the patient’s hand?
- Was the patient assessed to be at risk for falling?
- Were interventions established? If so, why were they not done?

Learning Objectives

- Identify which systems underlie the proximate cause(s) of the event
- Find the root causes within those systems that contributed to the event
- Consider how the root causes in different systems relate to and affect each other

Root Cause Analysis: Step-by-Step

- **STEP 1:** Organize a Team
- **STEP 2:** Define the Problem
- **STEP 3:** Study the Problem
- **STEP 4:** Determine What Happened
- **STEP 5:** Identify Contributing Process Factors
- **STEP 6:** Identify Other Contributing Factors
- **STEP 7:** Measure—Collect and Assess Data on Proximate and Underlying Causes
- **STEP 8:** Design and Implement Immediate Changes
- **STEP 9:** Identify Which Systems Are Involved—The Root Causes
- **STEP 10:** Prune the List of Root Causes
- **STEP 11:** Confirm Root Causes and Consider Their Interrelationships
- **STEP 12:** Explore and Identify Risk Reduction Strategies
- **STEP 13:** Formulate Improvement Actions
- **STEP 14:** Evaluate Proposed Improvement Actions
- **STEP 15:** Design Improvements
- **STEP 16:** Ensure Acceptability of the Action Plan
- **STEP 17:** Implement the Improvement Plan
- **STEP 18:** Develop Measures of Effectiveness and Ensure Their Success
- **STEP 19:** Evaluate Implementation of Improvement Efforts
- **STEP 20:** Take Additional Action
- **STEP 21:** Communicate the Results

As in all stages of the process, it is critical to keep the team focused on probing for system or common-cause problems rather than focusing on human errors. Teams often
have trouble at this stage of the root cause analysis. The tendency is to stop short after identifying proximate causes and not to probe deeper. The probing must continue until a reason underlying a cause can no longer be identified. The resulting cause, then, is a root cause.

Underlying causes may involve special-cause variation, common-cause variation, or both. Being “special” or “common” is not an inherent characteristic of the cause itself. Rather, it describes the relationship of the cause to a specific process or system. It is possible for the same cause to be a special cause in one process and a common cause in another. A flowchart of the process(es) at this stage may be very helpful.

Flowchart

For a special cause in a process, teams should search for the common cause in the system of which the process is a part. Keep asking, “Why did the special-cause variation occur?” to identify one or more common-cause variations in the supporting systems that may represent root causes. There should be a review of the processes and subprocesses that compose the system. This examination should include a review of existing policies and procedures by the process owners in comparison with the actual practice. Any variations should be evaluated for the extent of common-cause variation and the presence of special-cause variation.

For example, a special cause is created when one group of surgeons and their assistants do not follow hospital procedures for hand hygiene, resulting in a sentinel event. This special cause might be part of a common-cause variation in a larger system: the hospital’s inconsistent education in sterile techniques and hand washing. Use Worksheet 5-1 at the end of this chapter, page 89, to organize the team’s probe for underlying causes.

A logical starting point in the team’s effort to determine the systems involved with the event or near miss is listing and categorizing the possible causal factors. Common or root causes of a sentinel event in a health care organization can be categorized according to the important organization functions or processes performed by the organization.

They include processes for the following:
- Human resources
- Information management
- Environmental management
- Leadership—embracing organization culture, encouragement of communication, and clear communication of priorities

In addition, factors beyond an organization’s control should be considered a separate category. Organizations must exercise caution in assigning factors to this category, however. Although a causative factor may be beyond an organization’s control, the protection of patients from the effects of the uncontrollable factor is within the organization’s control in most cases and should be addressed as a risk reduction strategy.

Concrete questions about each function listed above can help team members reach the essence of the problem—the systems that lie behind or beneath problematic processes. At this stage, questions can be worded in the following form: “To what degree does . . . ?” Follow-up questions for each could be “Can this be improved, and if so, how?” See Sidebar 5-1, page 83, for a fuller itemization of possible questions.

Other questions may emerge in the course of an analysis. The team should fully consider all questions. One team investigating a patient suicide found that systems involving human resources, information management,
and environmental management issues were root causes of the sentinel event:

- In the human resources area, age-specific staff competence had not been assessed adequately, and staff needed additional training in management of suicidal patients.
- In the information management area, information about the patient’s past admission was not available. Communication delays resulted in failure to implement appropriate preventive actions.
- In the environmental management area, the team found that access to the appropriate unit for the patient was denied.

Patient safety events can be very complex and involve multiple causes. Understanding causes is essential if the organization is to create lasting improvements. Certain tools can be particularly helpful in systematically looking at an event to determine its causes. The tools are designed to help root cause analysis team members understand processes and factors that contribute to both good and problematic performance. Groups can also use the tools to study a process, without requiring a statistical background. They may be used singly or in combination to show the relationship between processes and factors, reach conclusions, and systematically analyze causes.

Sidebar 5-1. Root Cause Analysis Questions

The following questions may be used to probe for systems problems that underlie problematic processes.

Questions concerning human resources issues may include the following:

► To what degree were staff members involved in this event properly qualified and currently competent for their responsibilities? Can these qualifications be improved, and if so, how?

► How did actual staffing at the time of the event compare with ideal levels? Can the staffing level be improved, and if so, how?

► What are the plans for dealing with contingencies that tend to reduce effective staffing levels? Can these plans be improved, and if so, how?

► To what degree is staff performance in the operant processes addressed? Can such staff performance be improved, and if so, how?

► How can orientation and in-service training be improved?

Questions concerning information management issues may include the following:

► To what degree was all necessary information available when needed in the case of this event? What are the barriers to information availability and access? To what degree is the information accurate, complete, and unambiguous? Can these factors be improved, and if so, how?

► How adequate is the communication of information among participants? Can such communication be improved, and if so, how?

Questions concerning environmental management issues may include the following:

► How appropriate is the physical environment for the processes being carried out? Can it be improved, and if so, how?

► To what degree are systems in place to identify environmental risks? Can these systems be improved, and if so, how?

► What emergency and failure-mode responses have been planned and tested? Can these responses be improved, and if so, how?

Questions concerning leadership issues may include the following:

► How conducive is the culture to risk identification and reduction? Can this culture be improved, and if so, how?

► What are the barriers to communication of potential risk factors? Can these barriers be reduced or eliminated, and if so, how?

► To what degree is the prevention of adverse outcomes communicated as a high priority? How is such prevention communicated? Can this communication be improved, and if so, how?

Questions concerning uncontrollable factors may include the following:

► What can be done to protect against the effects of uncontrollable factors?
Fishbone diagrams are particularly helpful in categorizing and visualizing multiple system or process problems that have contributed to a sentinel event or near miss. The standard categories coming off the main “spine” of the diagram include people, procedures, equipment or materials, environment, and policies. Such categories as communication, education, leadership, and culture may also be appropriate. Subcauses branch off each major category. Checklist 5-1 on page 85 provides a handy way to help ensure that the team has considered selected systems-based issues.

Another proposed classification system for causal factors is geared more toward a manufacturing environment. However, it may be helpful to review this and other classification systems to ensure that the team has identified all possible causal factors. This causal factor category list follows.1

**Human Factors**
- **Verbal communication:** The spoken presentation or exchange of information
- **Written procedures and documents:** The written presentation or exchange of information
- **Human-machine interface:** The design of equipment used to communicate information from the plan to a person
- **Environmental conditions:** The physical conditions of a work area
- **Work schedule:** Factors that contribute to the ability of a worker to perform his or her assigned task in an effective manner
- **Work practices:** Methods workers use to ensure safe and timely completion of tasks
- **Work organization and planning:** The work-related tasks including planning, identifying the scope of, assigning responsible individuals to, and scheduling the task to be performed
- **Supervisory methods:** Techniques used to directly control work-related tasks; in particular, a method used to direct workers in the accomplishment of tasks
- **Training and qualification:** How a training program is developed and the process of presenting information on how a task is to be performed prior to accomplishing the task
- **Change management:** The process whereby the hardware or software associated with a particular operation, technique, or system is modified
- **Resource management:** The process whereby personnel and material are allocated for a particular task or objective
- **Managerial methods:** An administrative technique used to control or direct work-related plan activities, which includes the process whereby staff and material are allocated for a particular task objective

**Equipment Factors**
- **Design configuration and analysis:** The design layout of a system or subsystem needed to support plan operation and maintenance
- **Equipment condition:** The failure mechanism of the equipment that is the physical cause of the failure
- **Environmental conditions:** The physical conditions of the equipment area
- **Equipment specification, manufacture, and construction:** The process that includes the manufacture and installation of equipment in a plant
- **Maintenance and testing:** The process of maintaining components and systems in optimal condition
- **Plant and system operation:** The actual performance of the equipment or component when performing its intended function

**External Factor**
- **External:** Human or nonhuman influence outside the usual control of the company

**STEP 10** Prune the List of Root Causes
The team’s list of causal factors may be lengthy. Regardless of the list’s length or the technique used, the team should analyze each cause or factor using reasoning skills based on logic. Asking two questions helps clarify whether each cause or problem listed is actually a true root cause:
1. If we fix this problem, will the problem recur in the future?
2. If this problem is a root cause, how does it explain what happened or what could have happened?
Checklist 5-1. Problematic Systems or Processes

Use this checklist to identify and rank problematic systems or processes. Use a 1 to indicate a problem that is a primary factor and a 2 to indicate a problem that is a contributing factor.

**Human Resources Issues**

- **Qualifications of staff**
  - Defined
  - Verified
  - Reviewed and updated on a regular basis

- **Qualifications of physicians**
  - Defined
  - Verified
  - Reviewed and updated on a regular basis

- **Qualifications of agency staff**
  - Defined
  - Verified
  - Reviewed and updated on a regular basis

- **Training of staff**
  - Adequacy of training program content
  - Receipt of necessary training
  - Competence/proficiency testing following training

- **Training of physicians**
  - Adequacy of training program content
  - Receipt of necessary training
  - Competence/proficiency testing following training

- **Training of agency staff**
  - Adequacy of training program content
  - Receipt of necessary training
  - Competence/proficiency testing following training

- **Competence of staff**
  - Initially verified
  - Reviewed and verified on a regular basis

- **Competence of physicians**
  - Initially verified
  - Reviewed and verified on a regular basis

- **Competence of agency staff**
  - Initially verified
  - Reviewed and verified on a regular basis

- **Supervision of staff**
  - Adequate for new employees
  - Adequate for high-risk activities

- **Current staffing levels**
  - Based on a reasonable patient acuity measure
  - Based on reasonable workloads

- **Current scheduling practices**
  - Overtime expectations
  - Time for work activities
  - Time between shifts for shift changes

**Information Management Issues**

- **Availability of information**
- **Accuracy of information**
- **Thoroughness of information**
- **Clarity of information**
- **Communication of information between relevant individuals/participants**

**Environmental Management Issues**

- **Physical environment**
  - Appropriateness to processes being carried out
  - Lighting
  - Temperature control
  - Noise control
  - Size/design of space
  - Exposure to infection risks
  - Cleanliness

- **Systems to identify environmental risks**
  - Quality control activities
  - Adequacy of procedures and techniques
  - Inspections
  - Planned, tested, and implemented emergency and failure-mode responses

**Leadership and Communication Issues**

- **Data use**
  - Use in decision making
  - Use to identify changes in the internal and external environments

- **Planning**
  - For achievement of short-term and long-term goals
  - To meet challenge of external changes

- **Design of services and work processes**
  - Creation of communication channels
  - Performance improvement
  - Introduction of innovation

- **Communication**
  - Present, as appropriate
  - Appropriate method
  - Understood
  - Timely
  - Adequate

- **Management of change**

- **Staffing**
  - Sufficient number and mix of staff members
  - Competent to perform job responsibilities
Using three criteria to determine whether each cause is a root cause or a contributing (or proximate) cause, the following three questions may then be asked:

1. Is it likely that the problem would have occurred if the cause had not been present?
2. Is the problem likely to recur due to the same causal factor if the cause is corrected or eliminated?
3. Is it likely that similar conditions will recur if the cause is corrected or eliminated?

If the answer to each question is “no,” then the problem is a root cause. If the answer to any of the questions is “yes,” then the problem is a contributing/proximate cause. It may be helpful to develop a checklist with these questions built in. A sample checklist with the questions appears as Checklist 5-2, left.

**STEP 11 Confirm Root Causes and Consider Their Interrelationships**

The team will very likely identify more than one root cause for a sentinel event or near miss. Even in those very rare instances when a sentinel event results from the intentional act of an individual, more than one root cause is likely (for example, personnel screening, communication, and so forth). Sentinel events in industry tend to have two to four root causes, and these root causes tend to be interrelated. To date, The Joint Commission’s Sentinel Event Database indicates four to six root causes identified by participating organizations for each sentinel event.

For example, organizations that experienced suicides in a 24-hour care setting reviewed by The Joint Commission identified the following root causes:

- **The environment of care**, such as the presence of nonbreakaway bars, rods, or safety rails; lack of testing of breakaway hardware; and inadequate security
- **Patient assessment methods**, such as incomplete suicide risk assessment at intake, absent or incomplete reassessment, and incomplete examination of patients (for example, failure to identify contraband)
- **Staff-related factors**, such as insufficient orientation or training, incomplete competency review or credentialing, and inadequate staffing levels
- **Communication issues and information-related factors**, such as incomplete communication among caregivers and information being unavailable when needed
Organizations that experienced **infant abductions** reviewed by The Joint Commission identified the following root causes:

- **Physical environment factors**, such as no line of sight to entry points as well as unmonitored elevator or stairwell access to postpartum and nursery areas
- **Security equipment factors**, such as security equipment not being available, operational, or used as intended
- **Staff-related factors**, such as insufficient orientation or training, competency and credentialing issues, and insufficient staffing levels
- **Communication issues**

Organizations that experienced **medication errors** reviewed by The Joint Commission identified the following root causes:

- **Communication issues**
- **Storage and access issues**
- **Staff-related factors**, such as insufficient orientation and training, competency and credentialing issues, and insufficient staffing levels
- **Lack of procedural compliance**

Organizations that experienced **wrong-site surgery** reviewed by The Joint Commission identified the following root causes:

- **Miscommunication by operating room teams**
- **Insufficient orientation and training of staff**
- **Lack of procedural compliance**
- **Lack of available information**
- **Distraction**
- **Leadership issues**

Although this information may provide insight into areas to explore, organizations should not rely exclusively on these lists but should also uncover their own unique root causes.

The identification of all root causes is essential to preventing a failure or near miss. Why? Because the interaction of the root causes is likely to be at the root of the problem. If an organization eliminates only one root cause, it has reduced the likelihood of that one very specific adverse outcome occurring again. But if the organization misses two other root causes, it is possible that those root causes could interact in another way to cause a different but equally adverse outcome.

The root causes collectively represent latent conditions—conditions that exist as a consequence of management and organizational processes and which can be identified and corrected before they contribute to mishaps. The combination of root causes sets the stage for sentinel events. Effective identification of all root causes and an understanding of their interaction can aid organizations in changing processes to eliminate a whole family of risks, not just a single risk.

If a team identifies more than four root causes, a number of the causes may be defined too specifically. In this case, the team may wish to determine whether one or more of the root causes could logically be combined with another to...
reflect more basic, system-oriented causes. The team then should verify each of the remaining root causes. Doing so involves cross-checking for accuracy and consistency all facts, tools, and techniques used to analyze information. Any inconsistencies and discrepancies should be resolved.

How does an organization know whether and when it has identified all true root causes of a sentinel event?

Most root cause analysis teams ultimately reach a point where they ask themselves, “When can we stop asking ‘Why?’” This question is best answered by considering whether an identified cause is actionable in a way that will likely prevent recurrences or otherwise protect patients from recurrences. If the answer is “yes,” then it might be acceptable to stop there, but it is by no means necessary to stop there. Even root causes can have deeper root causes—they usually do.

Organizations often struggle to identify root causes because they are reluctant to confront sensitive, politically charged issues such as organizational culture, resources, pressure to produce or to move patients quickly through surgery, and lack of leadership or support. Employees typically are reluctant to address the problems they perceive because they fear that their candor could cause repercussions within the organization. As a result, for root cause analysis to be successful, it must be seen as confidential and nonpunitive. There must also be timely, relevant feedback to personnel reporting the adverse events to help them see that their input is meaningful.

Health care employees often struggle with the root cause analysis process because it requires them to scrutinize not only one another but also one another’s errors. A recent study of root cause analysis meetings found that even when the analysis focused on near-miss situations that did not result in death, staff members were extremely wary about how they positioned themselves in relation to the issues and staff involved. The “talk” of root cause analysis work is difficult in all situations.

A team should report its root cause findings to the leaders of its organization. Leaders must be informed, as should the individuals likely to be affected by changes emerging from the findings, during the next stage of the root cause analysis. Chapter 6 provides information on communicating the results of the team’s efforts.

References

Worksheet 5-1. Probing for Underlying Causes

The team might find it helpful to use a worksheet when probing for the underlying causes of proximate causes.

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Learning Objectives

- Identify risk reduction strategies
- Set priorities and objectives for improvement in areas identified as at the root of the problem
- Develop, test, implement, and measure the effectiveness of improvement efforts

The team asks, “So what are we going to do with the problematic systems now that we have identified them?” When the team has a solid hypothesis about one or more root causes, the next step is to explore and identify risk reduction strategies to help ensure that system flaws are corrected.

STEP 12 Explore and Identify Risk Reduction Strategies

Organizations that have root cause analysis experience should consider conducting data analysis of multiple root cause analyses. Sentinel and adverse events are not isolated occurrences—the underlying root causes often have been identified in past root cause analyses as contributing or root causes of other, similar occurrences. Even dissimilar events often will be found, through root cause analysis, to have certain root causes in common. This kind of convergence to common root causes by separate root cause analyses of dissimilar events is a good demonstration that root cause analyses are delving deeply enough. The questions root cause analysis teams need to ask are the following:

- What have we done before?
- What worked?
- What didn’t work? Why not?
- Why are we continuing to have this type of event?

After a team is ready to move forward with a risk reduction strategy, it might start by exploring relevant literature on risk reduction and error-prevention strategies. Much has been written about the engineering approach to failure prevention and how it differs from the medical approach. Some of the literature’s key points are described here.
The pervasive view of errors in the engineering field is that humans err frequently and that the cause of an error is often beyond the individual’s control. In designing systems and processes, engineers begin with the premise that anything can go wrong—and will. (Recall the Swiss cheese model discussed in Chapter 1.) Their role is a proactive one: to design accordingly. Because engineering-based industries do not expect individuals to perform flawlessly, they incorporate forcing functions into their designs—that is, they try to design systems that make it extremely difficult for individuals to make mistakes. As shown in Figure 6-1, below, forcing functions represent the strongest, most effective intervention in systems design. By compensating for less-than-perfect human performance, engineering systems achieve a high degree of reliability through process standardization, backup systems, and designed redundancy. A failure rate as low as even 1% is not tolerated. The emphasis is on systems rather than individuals.

**Taking Safety to the Next Level: High Reliability**

A high-reliability organization is an organization that has succeeded in avoiding catastrophes in an environment where normal accidents can be expected due to risk factors and complexity. A preoccupation with failure is one of the key characteristics of high reliability organizations (see Sidebar 6-1, on page 93). Organizations in the aviation and nuclear energy industries as well as the military have put programs and processes in place to become high reliability organizations.

In contrast, the still-pervasive view among many is that errors are the result of individual human failure and that humans generally perform flawlessly. Hence, the design of processes in health care organizations tends to be based on the premise that nothing will ever go wrong. Education and training, more extensive in health care than in most other fields, focus on teaching professionals to do the right thing. The assumption is that properly educated and

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**Figure 6-1. Strength of Intervention**

**More Effective**

1. Forcing functions
2. Automation, computerization
3. Protocols and preprinted orders
4. Checklists
5. Rules and double-checking
6. Education
7. Information

**Less Effective**

*This illustration shows the relationship between strength of intervention and effectiveness in systems design. The stronger the intervention, the more effective it is.*
trained health care professionals will never make mistakes. Those who do are “retrained,” punished, or sanctioned—in essence, blamed. The immediate causes of errors are identified and corrected but not planned or designed for. Root causes are rarely identified.

Lucian L. Leape, MD, is a pioneer in comparing risk reduction approaches in various other industries to those in the health care industry. He suggests four safety design characteristics from the aviation industry that could, with some modification, prove useful in improving safety in the health care industry:

- **Built-in multiple buffers, automation, and redundancy.** Instrumentation in airplane cockpits includes multiple and purposely redundant monitoring instruments. The design systems assume that errors and failures are inevitable and should be absorbed.
- **Standardized procedures.** Protocols that must be followed exist for operating and maintaining airplanes.
- **A highly developed and rigidly enforced training, examination, and certification process.** Pilots take proficiency exams every six months.
- **Institutionalized safety.** The airline industry reports directly to two agencies that regulate all aspects of flying, prescribe safety procedures, and investigate all accidents.

A confidential safety reporting system established by the Aviation Safety Reporting System operated by the National Aeronautics and Space Administration enables pilots, controllers, or others to report dangerous situations, including errors they have made, to a third party without penalty. This program greatly increases error reporting in aviation, resulting in enhanced communication and prompt problem solving.

Organizations planning risk reduction strategies should consider three levels of design to reduce the risk of harm to patients:

1. Design the process to minimize the risk of a failure.
2. Design the process to minimize the risk that a failure will reach the patient.
3. Design the process to mitigate the effects of a failure that reaches the patient.

These levels are similar to the epidemiological concepts of degrees of disease prevention, which can be defined as follows:

- **Primordial prevention:** minimizes hazards to health
- **1° prevention:** reduces the risk of disease
- **2° prevention:** reduces the prevalence of disease
- **3° prevention:** reduces the impact of complications

An example of a consideration for the first level of design is ensuring a positive interlock between tubes in a ventilator airflow circuit that might prevent a failure such as an inadvertent disconnection of the tubes. On the second level of design, an example of a consideration is ensuring that there is an airway pressure alarm that can detect a pressure drop due to a tubing disconnection and alert staff before a patient is harmed. An example of a consideration for the third level of design is the ready availability of resuscitation equipment that can mitigate the effect of oxygen deprivation due to a prolonged tubing disconnection.

It is also critical that error-prevention strategies used in the health care industry include standardizing tasks and processes to minimize reliance on weak aspects of cognition, testing of professional performance, and institutionalizing safety through near miss and nonpunitive reporting. For example, clinical practice guidelines and organization policies and protocols designed to reduce inappropriate variation in the care provided by practitioners can help reduce the likelihood of failures. In a general sense, the tendency for a process to fail is diminished in relation to the consistency with which it is carried out; that is, the degree to which it is standardized. Yet efforts in recent years to standardize health care processes through the introduction of practice parameters, protocols, clinical pathways, and so forth have been met with limited enthusiasm among practitioners and are only slowly affecting the actual delivery of care. Achieving process consistency while retaining the ability to recognize and accommodate variation in the input to the process (for example, the patient’s severity of illness, comorbidities, other treatments,
and preferences) is one of the major challenges to standardization in health care. Process variation to meet individual patient needs is an essential principle of modern medicine; variation to meet individual health care organization or practitioner preferences need not be. Standardization is advantageous—that is, it will get better overall results more safely—even if each practitioner might individually get better results than the others by using a personally favored but different process than that used by others. Practitioners do not work alone within health care organizations; they are members of teams, and those teams interact with other teams. Thus, assuming each personally favored practice is a good practice, it matters less which process is selected as the basis for standardization than that the process is performed consistently for safety.

**A Systems Approach to Risk Reduction**

Risk reduction strategies must emphasize a systems rather than an individual human approach. A system can be thought of as any collection of components and the relationships between them, whether the components are human or not, when the components have been brought together for a well-defined goal or purpose. As Leape writes, "Creating a safe process, whether it be flying an airplane, running a hospital, or performing cardiac surgery, requires attention to methods of error reduction at each stage of system development: design, construction, maintenance, allocation of resources, training, and development of operational procedures." If errors are made, if deficiencies are discovered, individuals at each stage must revisit previous decisions and redesign or reorganize the process.

Designing for safety means making it difficult for humans to err. However, those designing systems must recognize that failures do occur and that recovery or correction should be built into the system. If that is not possible, failures must be detected promptly so that individuals have time to take corrective actions. For example, as required by The Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™, a preprocedure verification process must be used. For example, a checklist could be used to confirm that appropriate documents (such as medical records and imaging studies) are available. The Universal Protocol also states that the procedure site must be marked. Ideally, the marking takes place with the patient involved, awake and aware, if possible.

Finally, a time-out is performed immediately prior to starting the procedure so that the medical team can confirm the correct patient, site, positioning, and procedure and, as applicable, verify that all relevant documents, related information, and necessary equipment are available.

Risk points—specific points in a process that are susceptible to failure or system breakdown—must be eliminated through design or redesign efforts. They generally result from a flaw in the initial design of the process or system, a high degree of dependence on communication, nonstandardized processes or systems, and/or failure or absence of backup.

For example, risk points during the medication use process include interpretation of an illegible order by a pharmacist and the time during which a registered nurse mixes the medication dose to administer to a patient. In surgical procedures requiring the use of lasers, a risk point occurs during the use of anesthetic gases: The high concentration of oxygen, if not properly synchronized with use of the laser, can allow tubes, drapes, and other potentially flammable materials to ignite. During preoperative procedures, verification of the body side and site constitutes a risk point.

Built-in buffers and redundancy, task and process simplification and standardization, and training are all appropriate design mechanisms to reduce the likelihood of failure at risk points and elsewhere. For example, prior to the administration of medications, multiple and redundant checks such as asking the patient his or her name and checking the patient's armband can help confirm that a medication is given to the right patient.

See Sidebar 6-2, on page 97, for risk points for medication errors and risk reduction strategies to prevent such failures.

Systems engineering literature includes numerous other design concepts that could be useful tools to prevent failures and sentinel events in health care organizations. Redundancy is one such concept familiar to the aerospace and nuclear power industries, where systems have backups and even the backups normally have backups. System reliability can be increased by introducing redundancy into system design. However, the cost of designing in redundancy is an issue in most health care environments. The engineering literature also describes the benefits of simplification, standardization,
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and loose coupling to reduce the possibility of systems-related problems.

Fail-safe design is also a concept familiar to high reliability industries, including aerospace and nuclear engineering. The design may be fail-passive, fail-operational, or fail-active. For example, a circuit breaker is a fail-passive device that opens when a dangerous situation occurs, thereby making an electrical system safe. A destruct system on a satellite or an air-to-air missile is an example of a fail-active device. If the satellite or missile misses its target within a set time, the destruct system blows the satellite or missile apart to halt its flight and limit any damage it might cause by falling to the ground. Checklist 6-1, on page 98, provides the key risk reduction strategies suggested in the medical and engineering literature.

Sidebar 6-2. Medication Errors: Risk Points and Risk Reduction Strategies

Risk points or common causes:
- Training/education
- Competence (lapses in performance, failure to comply with policies and procedures)
- Supervision
- Staffing (excessive workload, incorrect mix)
- Communication
- Distraction due to environmental issues
- Information availability
- Medication storage and access
- Labeling
- Nomenclature
- Dosage calculation
- Equipment
- Abbreviations
- Handwriting

Risk reduction strategies:

To reduce the likelihood of failures associated with prescribing errors:
- Implement a system of computerized order entry by physicians (to decrease the likelihood of dosage error, prompt for allergies, and provide information on drug–drug and drug–food interactions).
- Redefine the role of pharmacists to enable them to perform daily rounds with physicians, work with registered nurses, and serve as on-site resources.

To reduce the likelihood of failures associated with dispensing:
- Do not rely on color coding.
- Remove or separate look-alike/sound-alike medications.
- Use bar coding if possible.
- Avoid lethal medications in bolus form.
- Use premixed solutions whenever possible.
- Minimize supplier and product changes.
- Use auxiliary labels (such as “for IM [intramuscular] only”).
- Support questioning of unclear orders.
- Eliminate guessing.

To reduce the likelihood of failures associated with access to medications:
- Remove high-risk medications from care units.
- Label high-risk medications as such.
- Establish and implement policies and procedures for use of off-hours pharmacy.

To reduce the likelihood of failures associated with medication delivery:
- Be sure that equipment defaults to the least-harmful mode.
- Use automated pharmacy units as a tool for improving the process, not an inherent solution.
- Recognize that polypharmacy equals higher risk.

To reduce the likelihood of failures associated with human resources and competence factors:
- Address education and training issues (orientation, competence assessment, and training with new medications and devices).
- Support professional ethics and judgment.
- Implement systems involving double checks.
- Make safe staffing choices.
- Avoid reliance on illegible handwriting by providing alternatives such as requiring orders to be printed or using electronic order entry.
- Discourage use of acronyms and abbreviations in general and prohibit the use of specific, high-risk acronyms and abbreviations.
- Control availability of high-risk drugs.
- Address environmental issues such as distraction.
- Standardize medication times.
- Use patients as safety partners.
Risk points and risk reduction strategies for wrong-site surgery, suicide, and infant abductions or release to wrong families follow. Not all these strategies are specific Joint Commission requirements, but they are presented for consideration by all health care organizations.

Risk points for **wrong-site surgery** include the following:
- Communication before reaching operating suite
- Communication in operating suite
- Hierarchical issues of communication
- Communication with patient and patient’s family
- Information availability
- Multiple surgery sites on patient’s body
- Conflicting chart information
- Confused patient
- X-ray quality, labeling, and accuracy of interpretation

Risk reduction strategies to reduce the likelihood of failures associated with **preoperative procedures** include the following:
- Mark the operative site.
- Require the surgeon to obtain informed consent.
- Require preoperative verification by the surgeon, anesthesiologist/anesthetist, and patient or family.
- Personally review x-rays.
- Revise equipment setup procedures.

To reduce the likelihood of failures in the **operating suite**, do the following:
- Verify patient identity, intended procedure, and operative site before prep and drape.
- Make sure site marking is visible after draping.
- Obtain verbal verification with a time-out.
- Confirm the level of spinal surgery with intraoperative fluoroscopy.

Risk points for **suicide** include the following:
- Suicide risk assessment
- Communication of risk to direct care staff
- Levels of monitoring required for those at risk
- Policies for risk assessment and monitoring outside of behavioral health care units (for example, in the emergency department)
- Interventions for high-risk patients
- Psychotropic medications
- Contraband
- Physical environment, including such potential hazards as door frames, doorknobs, shower heads, and bedsheets

**Checklist 6-1. Identifying Risk Reduction Strategies**

To reduce the likelihood of failures, the medical and engineering literature offers the following tips:
- Use an engineering (proactive, systems-based) approach to failure prevention.
- Start with the premise that anything can and will go wrong.
- Design systems that make the safest thing to do the easiest thing to do.
- Design systems that make it difficult for individuals to err.
- Build in as much redundancy as possible.
- Use fail-safe design whenever possible.
- Simplify and standardize procedures.
- Automate procedures.
- Ensure rigidly enforced training and competence assessment processes.
- Ensure nonpunitive reporting of near misses.
- Eliminate risk points.

Strategies to reduce the risk of **suicide** in a staffed around-the-clock care setting include the following:
- Revise assessment and reassessment procedures and assure adherence.
- Update the staffing model.
- Educate staff on suicide risk factors.
- Update policies on patient observation.
- Monitor consistency of implementation.
- Revise information transfer procedures.
- Revisit contraband policies.
- Identify and remove nonbreakaway hardware.
- Weight test all breakaway hardware.
- Redesign or retrofit security measures.
- Educate family and friends on suicide risk factors.
- Consider patients in all areas.
- Ensure that staff members ask about suicidal thoughts every shift.
- Be cautious at times of shift change (admission, discharge, passes).
- Avoid reliance on pacts.
- Be suspicious if symptoms lighten suddenly.
- Involve all staff in solutions.
Risk points for infant abduction include the following:
- Mother and infant identification
- Staff identification
- Visitor identification
- Physical layout of the obstetrics unit
- Entry and exit security
- Mother’s education level or ability to comprehend security instructions
- Policy for issuing alarms when an infant is missing
- Public access to birth information

Strategies to reduce the risk of infant abductions include the following:
- Develop and implement a proactive infant abduction prevention plan.
- Include information on visitor and provider identification as well as identification of potential abductors or abduction situations during staff orientation and in-service curriculum programs.
- Enhance parent education concerning abduction risks and parent responsibility for reducing risk, and then assess the parents’ level of understanding.
- Attach secure identically numbered bands to the baby (wrist and ankle bands), mother, and father or significant other immediately after birth.
- Footprint the baby, take a color photograph of the baby, and record the baby’s physical examination within two hours of birth.
- Require staff to wear up-to-date, conspicuous, color photograph identification badges.
- Discontinue publication of birth notices in local newspapers.
- Consider options for controlling access to the nursery or postpartum unit, such as swipe-card locks, keypad locks, entry point alarms, or video surveillance. (Any locking systems must comply with fire codes.)
- Consider implementing an infant security tag or abduction alarm system.

**Failure mode and effects analysis (FMEA)**

**Root Cause Analysis in Proactive Risk Assessment**
Expanding the use of risk assessment has emerged as a strong trend in health care. Facilities can implement a strategy of assessing risk proactively by using failure mode and effects analysis (FMEA) to identify risk reduction opportunities. Also known in the literature as failure mode, effects, and criticality analysis (FMECA), FMEA offers a systematic way of examining a design prospectively for possible ways in which failure can occur. Potential failures are identified in terms of failure modes or symptoms. For each failure mode, the effect on the total system or process is studied, and factors that might cause or enable those failures are identified.

Actions (planned or already taken) can be reviewed for their potential to minimize the probability of failure or to reduce the effects of failure. FMEA’s goal is to prevent poor results, which in health care means harm to patients. Its greatest strength lies in its capability to focus users on the process of redesigning potentially problematic processes to prevent the occurrence of failures.

Although the technique has been used effectively in the engineering world since the 1960s, its use in the health care world began as late as the 1990s. FMEA is now gaining broader acceptance in health care as a tool for prospective analysis due to the efforts of The Joint Commission, the Department of Veterans Affairs National Center for Patient Safety, and the Institute for Safe Medication Practices, among others. FMEA is discussed further in Chapter 7.

FMEA is described here because root cause analysis teams may also wish to use FMEA to proactively identify risk reduction opportunities during their root cause analysis of a sentinel event or near miss or to carry out a proactive risk assessment on a process that is being redesigned in response to the findings of a root cause analysis. The interrelationship between FMEA and root cause analysis is further discussed in Sidebar 6-3, on page 98.

A performance improvement team at a community hospital in Michigan used FMEA for one of the first times in health care to proactively analyze and reduce medication errors associated with potassium chloride. The focus was on developing strategies to reduce the risk of future fatal errors. The team followed the steps outlined in Sidebar 6-4, on page 98.

The process flow diagram developed by the team for the medication use process from point of initiation through
Sidebar 6-3: The Interrelationship Between FMEA and RCA

Failure mode and effects analysis (FMEA) and root cause analysis (RCA) differ in critical ways but also share similarities.

The fundamental difference is timing: RCA is a retrospective approach, while FMEA is designed to keep sentinel events from occurring in the first place. RCA asks “Why?” after an event occurred to identify the root causes of an event. FMEA asks “What if?” to explore what could happen if a failure occurred at a particular step in a process or link.

FMEA and RCA have the following characteristics in common:

► Nonstatistical method of analysis
► Goal of reducing the possibility of future patient harm
► Involves identifying conditions that lead to harm
► Team activity

In addition, the two methodologies can be—and often are—interconnected. FMEA can be used during an RCA to help evaluate various improvement strategies that resulted from the RCA. FMEA can look at where the various strategies might fail and identify any new failure modes that have been introduced as a result of new design processes. RCA can be used to identify the root causes of failure modes.


Sidebar 6-4: Steps in FMEA

1. Select a high-risk process and assemble a team.
2. Diagram the process.
3. Brainstorm potential failure modes and determine the effects of the failure modes.
4. Prioritize failure modes.
5. Identify root causes of failure modes.
6. Redesign the process.
7. Analyze and test the new process.
8. Implement and monitor the redesigned process.


STEP 13 Formulate Improvement Actions

With the list of root causes in hand, the team is now ready to start devising potential solutions to systems-related problems. Known as corrective actions or improvement actions, these solutions are required to prevent a problem from occurring or recurring due to the same root cause(s) or interaction of root causes. The team may include the same members as during the early stages of the root cause analysis, or new members might be brought on board as required by the recommended improvements.

Improvement actions fall into three basic categories:
1. Actions to prevent errors
2. Actions to shield the patient from the effects of an error
3. Actions to mitigate the effects of an error that reaches the patient

“Mistake Proofing”

The ultimate goal of a root cause analysis is the development of actions to reduce the potential for recurrence of a similar event. The initial focus of improvement actions should be on eliminating the circumstances that allowed the outcome. If no action can be applied to eliminate the cause, the team should seek appropriate measures to reduce the possibility of recurrence.

As discussed in Step 12, the most effective actions are developed by using a systematic approach to mistake-proofing processes to avoid inevitable human error in care delivery. An early example of incorporating mistake proofing in a design was the 3.5-inch diskette. The diskette could be inserted only if it was oriented correctly. It could not be inserted sideways because it was not square; the sides were too long to fit. It could not be inserted backward or inverted.

The drive was designed to stop the diskette unless the right front corner was chamfered (angled). When the disk was
Figure 6-2. The Medication Use Process at a Community Hospital

This figure illustrates the simplified process flowchart one community hospital created as step 1 in a failure mode and effects analysis. In Step 2 the organization went through the flowchart, action by action, to brainstorm what might go wrong. Sidebar 6.5, page 100, lists the possible risk points the hospital staff brainstormed. CMAR, computerized medication administration record.

inserted correctly, the mistake-proofing device was not noticeable. When it was inserted incorrectly, however, the device completely stopped the process. The only cost was that of initial design implementation. No user training was required.

The members of the design team that created the disk drive believed that getting the orientation right was important enough to design a process that allowed users only one way to use the device. Their decision also indicated a preference for using design as an error-prevention strategy instead of alternatives such as training, instructions, or warning labels.

A more recent attempt to incorporate mistake proofing in design is the “smart pump” system for medication infusion. This system prevents errors by “remembering” the organization’s defined dosing limits and other clinical advisories entered into the medication library and applying those “rules” during pump programming, thereby helping ensure that the right dosage of the medication is infused. The

Sidebar 6-5. Possible Risk Points in the Medication Use Process

For each risk point in the process, a list of possible failures follows.

Order Received
- Phone order not clarified.
- Verbal order not clarified.
- Written order illegible.
- Dose may be incorrect.
- Incorrect route.
- Order written on wrong chart.
- Order written on right chart, but stamped with wrong name.
- Wrong drug.
- Drug not indicated.
- Language barrier present with verbal phone order.

Unit Secretary Processes Order
- Does not take order out of chart.
- Sends order to department other than pharmacy.
- Misplaces order and does not send it at all.
- Misinterprets and thus processes incorrectly.
- Delays in processing occur.
- Stamps wrong name on order sheet.

Registered Nurse Signs Off Order
- Delays order.
- Does not read order carefully but processes it anyway.
- Does not take time to read order but processes it anyway.
- Cosigns order without giving it to secretary; does not go through correct process.
- Cannot read or misreads order.
- Orders added by physician after initial order processed; registered nurse (RN) does not see additional orders.
- Unfamiliar with drug: allergy, dose, and/or cross sensitivity.

Order Transcribed onto CMAR
- RN’s handwriting unclear.
- Order transcribed onto wrong computerized medical administration record (CMAR).
- Order transcribed incorrectly.
- Order not transcribed in a timely manner.
- Lack of nursing communication to RN or licensed practical nurse (LPN) giving medication.
- Forgetting or failure to transcribe.
- RN Mixes Medication
- Miscalculated dose.
- Miscalculated measurement of volume.
- Selects wrong drug.
- Prepares wrong drug brought by supervisor (after hours).
- Does not match the order to the chart.
- Labeling errors: drug is not actually added to IV or IV contains drug but no label.
- Lacks knowledge of administration policies and procedures.
- Lacks knowledge regarding IV versus oral dosing guidelines.
- Interrupted during preparation.
- Lacks routine or organization when doing the task.

RN or LPN Administers Medication to Patient
- Wrong patient.
- Incorrect labeling.
- Intravenous accurate control (IVAC) not used.
- No IVAC available.
- Wrong rate of flow set on IVAC.

system also warns clinicians about potential unsafe drug therapy before the medication is administered.\(^8\)

When formulating action plans, teams also should analyze the strength of their proposed solutions. The US Department of Veterans Affairs National Center for Patient Safety has devised a hierarchy of corrective actions that can be used to gauge the effectiveness of improvement actions based on how likely they are to reduce vulnerability to an adverse event.\(^9\)

Stronger actions typically involve modifications to the physical environment. For example, after a patient attempted to commit suicide by hanging from an exposed pipe, the pipe was removed and the hazard thus eliminated. Weaker actions include changes in policies, procedures, and training. Although they are necessary components of an improvement action, they are considered weaker because they do not change the underlying conditions that lead to errors, they tend to rely on human cooperation and vigilance to succeed, and they often show less immediate results. In a study of root cause analysis action plans reported by the NCPS, stronger actions were easier to implement and more effective than weaker actions.\(^9\)

Improvement actions should be formulated by thinking in terms of the everyday work of the organization. Work can be defined in terms of functions or processes. A function is a group of processes with a common goal, and a process is a series of linked, goal-directed activities. Improvement actions should be directed primarily at processes. As stated earlier in this book, process improvement holds the greatest opportunity for significant change, whereas changes related to an individual’s performance tend to have limited effect. Competent people often find themselves carrying out flawed processes.

Practice guidelines or parameters and other standardized patient care procedures are useful reference points for comparison. Whether developed by professional societies or in-house practitioners, these procedures represent an expert consensus about the expected practices for a given diagnosis or treatment. Assessing variation from such established procedures can help the team identify how to improve a process.

Returning to the sentinel events described in Chapter 3, consider the following examples of how root cause analysis teams could approach the identification of improvement actions.

In the suicide example, the team has completed a fishbone diagram indicating multiple system problems, including assessment of suicide risk, environment of care, and emergency procedures. The team might break into smaller subgroups. One group (including the psychiatrist, medical staff leader, and nurse) would address the failed patient assessment process. They might start by reviewing the current standard for assessment of suicide risk and how this standard is communicated in the behavioral health care unit. Another group (including the administrator and plant safety representative) might start working on environment of care issues such as nonbreakaway shower heads. Another group (including emergency department physicians and the nursing staff) might work on emergency procedures.

In the elopement example, the root cause analysis team has identified multiple system problems, including an unsafe environment of care; inadequate assessment and reassessment; and inadequate staff orientation, training, and ongoing competence assessment. One subgroup (including the safety director, a nurse from the unit, and a social worker) might address possible actions to improve the long term care organization’s security and safety measures. Another small group (including the medical director, director of nursing, activity staff member, and unit staff nurse) might address opportunities to improve the process used to assess and reassess patients at risk for elopement. Another group (including the medical director, the director of nursing, and the performance improvement coordinator) might address strategies to ensure that staff know elopement risk factors and who is at risk for elopement and are assessed regularly for competence in identifying and caring for at-risk patients.

In the treatment delay example, the team has identified system problems that led to the missed diagnosis of metastasized breast cancer. They include communication problems between caregivers, insufficient staff orientation and training, and inadequate information management. Subgroups of the ambulatory health care organization’s team probe each of these areas for improvement opportunities, looking at such issues as care documentation and the availability of clinical records, the timeliness and thoroughness of initial and regular reassessments, and shift-to-shift communication of information related to patient needs.
In the medication error example, the root cause analysis team has identified communication of medication orders and the failure to ensure safe medication storage and access as two key problems, among others. A subgroup (including the information technology staff member, pharmacist, medical director, and home health nurse) might investigate possible strategies to improve the accuracy of orders communicated to local pharmacies. Another subgroup, including the nursing supervisor, pharmacy supplier, home health nurse, and medical director, might investigate strategies to guard against medication theft and ensure proper implementation of the home health agency’s medication administration policies and procedures.

For each root cause, the team should work interactively either as a whole or in smaller groups to develop a list of possible improvement actions. Brainstorming can be used to generate additional ideas. The emphasis at this point is on generating as many improvement actions as possible, not on evaluating the ideas or their feasibility. The number of suggested improvement actions may vary based on the nature of the root cause and how it relates to other root causes. To ensure as thorough a list as possible, the team may wish to review the analyses of information used to identify root causes. Remember to encourage any and all ideas without critiquing them. In the hands of a skilled facilitator, even the seemingly wildest idea can lead to an effective improvement action during later stages of analysis. Tools used such as flowcharts or fishbone diagrams can prompt additional solutions. Ask questions of the group, such as the following:
- What might fix this problem?
- What other solutions can we generate?
- What other ideas haven’t we thought of?

Brainstorming, flowchart, fishbone diagram

Wilson and colleagues suggest using the scientific method to develop a list of potential solutions. They restate the scientific method in terms of steps used in developing solutions:
1. Become familiar with all the aspects of the problem and its causes.
2. Derive a number of tentative solutions.
3. Assemble as much detail as is needed to clearly define what is required to implement these solutions.
4. Evaluate the suggested solutions.
5. Objectively test and revise the solutions.
6. Develop a final list of potential solutions.

These steps may assist the team through the process of both developing and evaluating improvement actions.

**STEP 14 Evaluate Proposed Improvement Actions**

When the list of possible improvement actions is as complete as possible, the team is ready to evaluate the alternatives and select those actions to be recommended to leadership.

To begin the evaluation process, the team should rank the ideas based on criteria defined by the team. Gathering appropriate data is critical to this process. A simple 6-point scale ranging from a low rank of 0 for the worst alternative to a high rank of 5 for the best alternative can be used at this point. Spath suggests asking the team to rank the solutions in order of workability, reliability, risk, chance for success, management/staff/physician receptivity, cost, capability to fix the problem, and other factors. To rank the proposed solutions, Ammerman suggests using criteria such as compatibility with other organization commitments and the possible creation of other adverse effects.

Initially, to prevent groupthink, it is a good idea to ask each team member to rank the ideas on his or her own. The rankings can then be consolidated into a team ranking. Worksheet 6-1 at the end of the chapter, page 119, can be used to keep track of suggested improvement actions. Record the rankings assigned by individual team members and the team as a whole. FMEA may be a helpful tool at this point in the process. FMEA involves evaluating potential problems (or improvement actions) and prioritizing or ranking them on a proactive basis according to criteria defined by a team.

Failure mode and effects analysis (FMEA)

At the very least, every improvement action proposed by the team should be objective and measurable. If it is objective, implementation is easier and those affected by the change are more likely to be receptive. If it is measurable, the team can ensure that improvement actually occurs. See Sidebar 6-6, right, for evaluative criteria for improvement actions. Before ranking the actions, ensure that the team
reaches a consensus on which criteria are most relevant to the organization. Ranking the proposed ideas according to multiple criteria adds critical dimension to the evaluation.

In evaluating potential improvement actions, the team should consider the impact of the suggested improvement on organization processes, resources, and schedules. Sentinel events or near misses frequently shake up the organization’s notions of the resources that should be expended in particular areas. Organizations contemplating a design or redesign effort will certainly weigh the availability of resources against the potential benefits for patients, customers, and the organization.

Asking some key questions helps the team identify the potential barriers to implementation of each improvement action. Relevant questions include the following.

**Organization Processes**
How does the proposed action relate to other projects currently under way in the organization? Are there redundancies?
- How does the action affect other areas and processes?
- What process-related changes might be required?
- Can affected areas absorb the changes or additional responsibilities?

**Resources**
- What financial resources will be required to implement the action? (Include both direct and indirect costs—that is, costs associated with the necessary changes to other procedures and processes.) How will these resources be obtained?
- What other resources (staff, time, management) are required for successful implementation? How will these resources be obtained?
- What resources (capital, staff, time, management) are required for continued effectiveness? How will these resources be obtained?
- What other activities will have fewer resources as a result of shifting resource allocation for this change?

**Schedule**
- In what time frame can implementation be completed?
- Who will be responsible for making sure it happens?
- How will implementation of this action affect other schedules? How can this be handled?

**Sidebar 6-6. Evaluating Improvement Actions**

Use the following criteria to evaluate improvement actions:
- Likelihood of success (preventing recurrence or occurrence) within the organization’s capabilities
- Compatibility with organization’s objectives
- Risk
- Reliability
- Likelihood to engender other adverse effects
- Receptivity by management/staff/physicians
- Barriers to implementation
- Implementation time
- Long-term (versus short-term) solution
- Cost
- Measurability

- What initial and ongoing training will be required? How will this impact the schedule, and how will its impact be handled?

**Potential Negative Consequences**
- Could this action cause problems in other areas or have a negative impact on other processes?
- Is there a process in place to analyze and take action if there are unintended, negative consequences from implementing this action?
- Will the amount of resources required for this action detract from other quality improvement or patient safety initiatives?

With answers to these questions in hand, the team can better gauge whether the pluses outweigh the minuses. After completing this questioning process, the team may wish to revisit the ranking exercises described previously. Doing so can help clarify which corrective improvement actions should be selected. To summarize the potential of each proposed action, the team can ask, “What will result from implementing this action?” and “What would result from not implementing this action?” (as shown in Worksheet 6-2 at the end of this chapter, page 120).
At this point, the team should be ready to select a finite number of improvement actions. Each action must do the following:

- Address a root cause
- Offer a long-term solution to the problem
- Have a greater positive than negative impact on other processes, resources, and schedules
- Be objective and measurable
- Have a clearly defined implementation time line
- Be assignable to staff for implementation
- Be acceptable to staff most directly affected by the change

The next section describes how the team designs improvements and develops an action plan covering each of these aspects.

**STEP 15 Design Improvements**

The product of the root cause analysis is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The team is now ready to start drafting such a plan. The plan should address the five issues of what, how, when, who, and where involved in implementing and evaluating the effectiveness of proposed improvement actions.

**Issue One: What**

Designing what involves determining the scope of the actions and specific activities that will be recommended. A clear definition of the goals is critical. To understand the potential effects of the improvement activity, the organization must determine which dimension of performance—safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity—will be affected. At times, the relationship between two or more dimensions must be considered. Redesign in response to a sentinel event most often focuses on safety, but it may affect any or all of the other dimensions. What specific activities will be needed to achieve the necessary improvement? Use Worksheet 6-3 at the end of the chapter, page 121, to articulate responses to questions concerning goals, dimensions of performance, and required specific activities.

**Issue Two: How**

How does the organization expect, want, and need the improved process to perform? The team carrying out the effort should set specific expectations for performance resulting from the design or improvement. Without these expectations, the organization cannot determine the degree of success of the efforts. These expectations can be derived from staff expertise, consumer expectations, experiences of other organizations, recognized standards, and other sources. What sequence of activities and resources will be required to meet these expectations? How and what will the team measure to determine whether the process is actually performing at the level expected?

The organization or group needs specific tools to measure the performance of the newly designed or improved process to determine whether expectations are met. These measures can be taken directly, adapted from other sources, or newly created, as appropriate. It is important for the measures to be as quantitative as possible, meaning that the measurement can be represented by a scale or range of values. For example, if improving staff competence in calculating medication doses is cited as a corrective solution, the measure should evaluate competence before and after each training or educational session. If pretraining competence is tested at 80% to 85% proficiency, posttraining competence might be set at 90% to 95% proficiency. Or, in the patient suicide example described in Sidebar 3-1, page 46, measures might include the percentage of accurately and appropriately completed suicide risk assessments as determined through peer review and the percentage of rooms with breakaway shower fixtures.

At times, it may be difficult to establish quantitative measures—the improvement simply seems to lend itself more to qualitative measures. Quantification of improvement is critical, however, and even when solutions can be measured only in terms of risk reduction potential, it is important to try to quantify such potential as much as possible through concrete measures. Use Worksheet 6-4 at the end of the chapter, page 122, to articulate responses to questions concerning expectations, the sequence of activities, measures, and resources required.

**Issue Three: When**

Next, the team must define when the organization must meet its improvement goals. What time frame will be established for implementing the improvement action? What time line will be established for each activity comprising the steps along the way? What are the major milestones and their respective dates? A Gantt chart of one organization’s
improvement plan appears as Figure 6-3, pages 106–107. Use Worksheet 6-5 at the end of the chapter, page 123, to articulate responses to questions concerning time frames and milestones.

**Gantt chart**

**Issue Four: Who**
Who is closest to this process and therefore should “own” the improvement activity? Who should be accountable at various stages? To a great extent, the success of an improvement effort hinges on involving the right people from all disciplines, services, and offices involved in the process being addressed. The process for taking action consists of several stages, each of which may have different players.

The group that creates the process should include the people responsible for the process, the people who carry out the process, and the people affected by the process. As appropriate, the group members could include staff from different units, branch offices, or teams, services, disciplines, and job categories. When the group needs a perspective not offered by its representatives, it should conduct interviews or surveys outside the group or invite new members into the group. It is important to consider customers and suppliers such as purchasers, payers, physicians, referral sources, accreditors, regulators, and the community as a whole. See Worksheet 6-6 at the end of the chapter, pages 124–125, for more information on key players at each stage.

Leaders and managers must take an active role in overseeing and setting priorities for design and redesign. Generally, managers are responsible for processes within their areas. Design or redesign of processes with a wider scope may be overseen by upper management or by a team of managers. Leaders must ensure that the people involved have the necessary resources and expertise. Furthermore, their authority to make changes should be commensurate with their responsibility for process improvements. Although regular feedback and contact with management are important, rigid control can stifle creativity.

**Issue Five: Where**
Where will the improvement action be implemented? Will its implementation be organizationwide, in a selected location, with a selected patient population, or with selected staff members? Are the location, target population, and target staff of the improvement action likely to expand with success? Use Worksheet 6-7 at the end of the chapter, page 126, to indicate where the improvement action will be implemented. Worksheet 6-8, page 127, can be used to provide a summary look at the what, how, when, who, and where involved in implementing proposed improvement actions.

**Considering the Impact of Change**
When designing improvements, the team should also consider the impact of change on the organization. No matter how minor, improvements require change, and it is normal for individuals and organizations to resist change. Resistance to change can come from inertia, the challenge of managing the change process, the challenge of obtaining necessary knowledge to ensure that the change can be implemented effectively, and resource limitations.

Change comes in two basic forms: Physical and behavioral. A physical change as a result of a root cause analysis might be the use of new equipment, such as medication administration carts. Behavioral change occurs when staff members are asked to abandon established processes and procedures.

Understanding the underlying rationale and process whereby people modify their thinking and practice can help team leaders gain better insight into why people behave the way they do, which in turn can help leaders identify motivators for helping personnel adopt and maintain desired behaviors. It can also help direct project resources to areas where they are likely to have the greatest impact.

**Stages of change** theory is based on the idea that when individuals attempt to change a behavior, they progress along a continuum comprising five phases: Precontemplation, contemplation, preparation, action, and maintenance.14 By gauging where stakeholders are on the continuum, root cause analysis teams are can identify the motivators that encourage behavioral change.

For example, an organization planning to introduce standardized order sets learns through surveys, interviews, and in-person discussions that cardiologists have not thought about standardizing their order sets. Each cardiologist uses his or her own set and is content with it that way. These physicians do not see a need for change; they are in the precontemplation stage.
### Figure 6-3. Improvement Plan and Implementation Status

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<tr>
<td>26</td>
<td>Approval by standards committee and board of directors</td>
<td>10/24/95 8:00am</td>
<td>10/24/95 5:00pm</td>
<td>Completed</td>
<td>Jul</td>
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<tr>
<td>27</td>
<td>Phase II: Hospitalwide</td>
<td>10/15/95 8:00am</td>
<td>3/25/96 5:00pm</td>
<td>Partial</td>
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<td>28</td>
<td>Assess standards</td>
<td>10/15/95 8:00am</td>
<td>10/16/95 5:00pm</td>
<td>Completed</td>
<td>Nov</td>
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**KEY:**
- Critical
- Progress
- Summary
- Noncritical
- Milestone
- Rolled Up

(continued)
This Gantt chart shows a detailed plan created by an organization following a sentinel event involving a mechanical failure. The chart shows the plan's steps in implementing strategies, priorities, and expected time frames. The status of each phase is recorded so that everyone involved has a clear idea of the progress being made.
The transition from precontemplation to contemplation is a difficult one. People who do not recognize a need to change are less likely to be willing to change behavior than people who are already considering it. In this situation, the team would have more success implementing standardized order sets with a group of physicians who already recognize the potential benefits.

These physicians would be in the contemplation stage, and when provided with the necessary information, resources (for example, template order sets, best practices, the latest evidence and quality measures), and tools (such as content and process management systems), they will likely be ready and willing to adopt the new behavior.

The team can identify areas where resistance to change might arise and plan countermeasures using Worksheet 6-9 at the end of the chapter, page 128.

**STEP 16 Ensure Acceptability of the Action Plan**

The team has defined the what, how, when, who, and where in an improvement action plan. How does the team know whether it is acceptable to The Joint Commission or Joint Commission International (JCI) as part of a root cause analysis in response to a sentinel event?

As mentioned in Chapter 1, an action plan is considered acceptable by The Joint Commission or JCI if it does the following:

- Identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking such changes
- Where improvement actions are planned, identifies who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated

The action plan also should include resource considerations, leadership approval, and buy-in by affected staff. Teams should consider conducting an FMEA of the proposed action plan and then proceeding with some pilot testing.

**Checklist 6-2. Criteria for an Acceptable Action Plan**

Check to ensure that the action plan has the following attributes:

- Identifies changes to reduce risk or provides rationale for not undertaking changes
- Identifies who is responsible for implementation
- Identifies when action(s) will be implemented
- Identifies how the effectiveness of action(s) will be evaluated

Checklist 6-2, above, lists the criteria for an acceptable action plan.

**STEP 17 Implement the Improvement Plan**

When the goals for improvement have been established, the organization can start planning and carrying out the improvements. A pilot test implementing improvement on a small scale, monitoring its results, and refining the improvement actions is highly recommended. The pilot test enables the team to ensure that the improvement is successful before committing significant organization resources. Pilot testing also aids in building support for the improvement plan, thereby facilitating buy-in by opinion leaders. To pilot-test an improvement, the team should follow a systematic method that includes performing the subsequently described Steps 18 through 21 on a limited scale.

A systematic method for design or improvement of processes can help organizations pursue identified opportunities. A standard yet flexible process for carrying out these changes should help leaders and others ensure that actions address root causes, involve appropriate personnel, and result in desired and sustained changes. Depending on an organization’s mission and improvement goals, any of the methods described here may be used to implement a process improvement. Three improvement methods are described:

- The scientific method
- The Plan-Do-Study-Act (PDSA) cycle
- The Define, Measure, Analyze, Improve, Control (DMAIC) process
The Scientific Method
The fundamental components of any improvement process are the following:
• Planning the change
• Testing the change
• Studying its effects
• Implementing changes determined to be worthwhile

Many readers will readily associate the activities listed—plan, test, study, implement—with the scientific method. Indeed, the scientific method is a fundamental, inclusive paradigm for change and includes the following six steps:
1. Determine what is known now (about a process, problem, topic of interest).
2. Decide what needs to be learned, changed, or improved.
3. Develop a hypothesis about the effect of the change.
4. Test the hypothesis.
5. Assess the results of the test. (Compare results of before versus after the change.)
6. Implement successful improvements, or rehypothesize and conduct another experiment.

This orderly, logical, inclusive process for improvement serves organizations well as they attempt to assess and improve performance.

The Plan-Do-Study-Act (PDSA) Cycle
A well-established process for improvement that is based on the scientific method is the Plan-Do-Study-Act (PDSA) cycle. This method is also called the Plan-Do Check-Act (PDCA) cycle. A brief explanation of this process follows (see Figure 6-4, below). This process is attributed to Walter Shewhart, a quality improvement pioneer with Bell Laboratories in the 1920s and 1930s, and is also widely

Figure 6-4. The PDSA Approach to Performance Improvement

The Plan-Do-Study-Act (PDSA) approach to performance improvement includes identifying design or redesign opportunities, setting priorities for improvement, and implementing the improvement project.
associated with W. Edwards Deming, a student and later a colleague of Shewhart. Deming made the PDCA cycle central to his influential teachings about quality. The cycle is compelling in its logic and simplicity.

During the Plan step, an operational plan for testing the chosen improvement action is created. Small-scale testing can help determine whether the improvement actions are viable, whether they will have the desired result, and whether any refinements are necessary before putting them into full operation. The list of proposed improvement actions should be narrowed to a number that can be reasonably tested—perhaps two, three, or four, but not often more.

During the planning stage, a number of issues should be resolved:
- Who will be involved in the test?
- What must these people know to participate in the test?
- What are the testing timetables?
- How will the test be implemented?
- Why is the idea being tested?
- What are the success factors?
- How will the process and outcomes of the test be measured and assessed?

The Do step involves implementing the pilot test and collecting actual performance data.

During the Study (or Check) step, data collected during the pilot test are analyzed to determine whether the improvement action was successful in achieving the desired outcomes. To determine the degree of success, actual test performance is compared to desired performance targets and baseline results achieved using the established process.

The last step is the Act step—to take action. But if the pilot test is not successful, the Plan-Do-Study cycle repeats. When actions have been shown to be successful, they are made part of standard operating procedure. The process does not stop here. The effectiveness of the action should continue to be measured and assessed to ensure that improvement is maintained.

The components of the four-step PDSA cycle as they relate to designing and improving processes appear as Checklist 6-3, above right. A single initiative can involve a number of different testing phases or different change strategies and can therefore require the use of consecutive PDSA cycles.

To help teams and individuals involved in design or improvement initiatives apply the method effectively, the organization, depending on the nature of the improvement project, may want to consider the questions outlined in Sidebar 6-7, page 111, at each step of the method.

**DMAIC**

A newer process improvement model that has evolved from PDSA goes by the acronym DMAIC (pronounced duh-MAY-ick). The letters stand for Define, Measure, Analyze, Improve, and Control, the five phases of the process. Used in root cause analysis, DMAIC acts like...
Designing and Implementing an Action Plan for Improvement

CHAPTER 6

a funnel, filtering through the proximate causes to the most likely root cause(s), as shown in Figure 6-5, page 112.

Each phase carries with it a key question that must be clearly answered before proceeding to the next phase. The questions and the corresponding actions are the following:

**Define:** What is the problem? A team is formed and a project charter developed.

**Measure:** What is the extent of the problem? Baseline data are collected and key measures determined.

**Analyze:** Under what circumstances did the problem occur? Statistical analysis tools are used to analyze the data and the process to determine the root cause(s).

**Plan:**
- How was a design or improvement strategy selected for testing?
- Is there knowledge-based information (for example, from the literature, other organizations, or other external sources) supporting the new or improved process?
- What issues in the external environment (such as economy, politics, customer needs, competitors, regulations) will affect the performance of the new or improved process?
- What issues in the internal environment will affect the performance of the new or improved process?
- Who is (are) the customer(s) of the process?
- What is the current process?
- What is the desired process?
- Who are the suppliers of the process?
- What changes will have the most impact?
- Is there a plan for testing the design or improvement?
- Is there a time line for testing?
- What data will be collected to determine whether the test was successful (that is, whether the objective was met)?
- How is it determined that the measures actually address the desired issue?
- Can the measures used actually track performance?
- How will data be collected?
- Who will collect data?
- Are systems in place to support planned measurement?
- Is benchmarking feasible for this initiative?
- Are the right people involved?
- What resources are needed to design or redesign the process? What resources are available?

**Do:**
- Was the testing plan followed?
- Were needed modifications discussed with the appropriate people?

**Study:**
- Was data collection timely?
- Was data collection reliable?

**Act:**
- Should changes be recommended to others (for example, for purchasing equipment or implementing specific processes)?
- How will these changes be communicated to the appropriate people?
- Is any education or training needed?
- How will gain be maintained and backsliding be prevented?
- What measures should be used to assess the performance of the new or improved product or process?
- Should any of the measures identified previously be included in ongoing measurement activities?
**Improve:** *How can the problem be solved?* Solutions to the identified problems are developed, evaluated, refined, and implemented.

**Control:** *How can the solution be sustained?* Improvements and design controls are documented and monitored.

**Additional Improvement Tools**
The following tools are useful for taking action to improve processes:

- Brainstorming can be used to create ideas for improvement actions.
- Multivoting can help a team decide between possible improvement actions.
- Flowcharts can help a team understand the current process and how the new or redesigned process should work.
- Fishbone diagrams can indicate which changes might cause the desired effect, that is, the desired result or goal.

The DMAIC model for performance improvement includes five phases—Define, Measure, Analyze, Improve, and Control. Cause investigation occurs during the analyze phase, as the process filters through the proximate causes to reach the most likely root cause. Then improvements can be made and sustained.
• *Pareto charts* can help determine which changes are likely to have the greatest effect in reaching the goal.
• *Control charts* and *scatter diagrams* can measure the effect of a process change or variation in processes and outcomes.
• *Histograms* can show how much effect each change has had.

**Brainstorming, multivoting, flowchart, fishbone diagram, Pareto chart, control chart, scatter diagram, histogram**

These and the other tools shown in Chapter 7 may be used individually or in some combination as part of a performance improvement strategy such as Lean Six Sigma.

**Creating and Managing the Change**

Some suggested actions the team might take to help manage and lead the change or improvement process follow.15 These actions are based on eight sequential stages in the process of leading change in organizations.16 The steps in creating and managing the change process are as follows:

1. Establish a sense of urgency by doing the following:
   • Identifying the best anywhere and the gap between one process and another
   • Identifying the consequence of being less than the best
   • Exploring sources of complacency

2. Create a guiding coalition to do the following:
   • Find the right people
   • Create trust
   • Share a common goal

3. Develop a vision and strategy that is the following:
   • Easily pictured
   • Attractive
   • Feasible and clear
   • Flexible
   • Communicable

4. Communicate the changed vision in a way that has the following characteristics:
   • Is simple
   • Uses metaphor

5. Empower broad-based action by doing the following:
   • Communicating sensible vision to employees
   • Making organization structures compatible with action
   • Providing needed training
   • Aligning information and human resource systems
   • Confronting supervisors who undercut change

6. Generate short-term wins in the following ways:
   • Fixing the date of certain change
   • Doing the easy stuff first
   • Using measurement to confirm change

7. Consolidate gains and produce more change by doing the following:
   • Identifying true interdependencies and smooth interconnections
   • Eliminating unnecessary dependencies
   • Identifying linked subsequent cycles of change

8. Anchor new approaches in the culture with the following:
   • Results
   • Conversation
   • Turnover
   • Succession

**STEP 18 Develop Measures of Effectiveness and Ensure Their Success**

When a function or process is under way, the team should collect data about its performance. As described in Chapter 4, measurement is the process of collecting and aggregating these data, a process that helps assess the level of performance and determine whether further improvement actions are necessary. Specifically, measurement can be used as an integral technique throughout the PDSA cycle to do the following:

• Assist in process design or redesign (*the Plan step*)
• Test whether process design or redesign is implemented properly (*the Do step*)
• Assess the results of the test (*the Study step*)
• Provide assistance in implementing the improvement (the Act step)
• Maintain the improvement and determine whether the improvement should be part of the organization's ongoing monitoring process (repeat of the PDSA cycle)

The first step in measuring the success of improvement efforts is to develop high-quality measures of effectiveness. The choice of what to measure is critical. Measurement must relate to the improvement and validate the accomplishment of the goal (or failure to reach the goal). See Checklist 6-4, right, for key questions the team should ask concerning what to measure. Answer the questions in Worksheet 6-10 at the end of this chapter, pages 129–130, as the team identifies, measures, and designs the measurement plan.

Some measures or performance indicators may require specific targets, which should be set by the team prior to data collection. For example, in the patient suicide case described in Sidebar 3-1, the team should set 100% as the target for bringing rooms in the behavioral health care unit into compliance with breakaway shower fixtures. For the treatment delay example in the same sidebar, the team should set a score of 95% as the target for all posttraining test scores.

Data collection efforts should be planned and coordinated. Use a separate worksheet to plan and monitor the indicators selected to measure each improvement goal (see Worksheet 6-11 at the end of the chapter, page 131).

Who should be responsible for measurement? The team, empowered to study the process and recommend changes, is usually responsible for designing and carrying out the measurement activities necessary to determine how the process performs. After making changes to improve the process, the team should continue to apply some or all of its measures to determine whether the change has had the desired effect. Organizations may have various experts who can help design measurement activities, including experts in information management, quality improvement, and the function to be measured. The team can request such contribution on an ad hoc basis. For example, if the team is investigating a medication error and has a large amount of data to codify and process regarding the administration of a frequently ordered medication, the team may want to seek the help of information management staff with access to statistical software capable of analyzing a large volume of data.

Information management professionals and those responsible for carrying out the process being measured are key players in data collection and analysis. The people involved vary widely depending on the specific organization, the function being measured, and the measurement process.

**STEP 19 Evaluate Implementation of Improvement Efforts**

After data are collected as part of measurement, they must be translated into information that the team can use to make judgments and draw conclusions about

<table>
<thead>
<tr>
<th>Checklist 6-4. Ensuring the Success of Measurement</th>
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<tbody>
<tr>
<td>An affirmative answer to the following questions gives the team a good indication that it is on the right track with its efforts to measure the effectiveness of improvement initiatives.</td>
</tr>
<tr>
<td><strong>Yes</strong></td>
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<td>✓ ✓</td>
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<td>✓ ✓</td>
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<td>✓ ✓</td>
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<td>✓ ✓</td>
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<td>✓ ✓</td>
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the performance of improvement efforts. This assessment forms the basis for further actions taken with improvement initiatives.

Numerous techniques can be used to assess the data collected. Most types of assessment require comparing data to a point of reference. These reference points may include the following:

• Internal comparisons, such as unit-to-unit or time-to-time
• Aggregate external reference databases
• Desired performance targets, specifications, or thresholds

Internal Comparisons
The team can compare its current performance with its past performance using statistical quality control tools. Two such tools are particularly helpful in comparing performance with historical patterns and assessing variation and stability: control charts and histograms. These tools respectively show variation in performance and the stability of performance.

Aggregate External Reference Databases
In addition to assessing the organization’s own historical patterns of performance, the team can compare the organization’s performance with that of other organizations. Expanding the scope of comparison helps an organization draw conclusions about its own performance and learn about various methods to design and carry out processes. Aggregate external databases come in a variety of forms. Aggregate, risk-adjusted data about specific indicators help each organization set priorities for improvement by showing whether its current performance falls within the expected range.

One method of comparing performance is benchmarking. Although a benchmark can be any point of comparison, most often it is a standard of excellence. Benchmarking is the process by which one organization studies the exemplary performance of a similar process in another organization and, to the greatest extent possible, adapts that information for its own use. Or the team may wish to simply compare its results with those of other organizations or with current research or literature.

Assessment is not confined to information gathered within a single organization. To better understand its level of performance, an organization should compare its performance against reference databases, professional standards, and trade association guidelines.

Desired Performance Targets
The team may also establish targets, specifications, or thresholds for evaluation against which to compare current performance. Such levels can be derived from professional literature or expert opinion within the organization.

STEP 20 Take Additional Action
The team’s assessment of the data collected indicates whether established targets or goals are being achieved. If the goals are being achieved, the team’s efforts now should focus on communicating, standardizing, and introducing the successful improvement initiatives. The team can do the following:

• Communicate the results, as described in subsequent Step 21.
• Revise processes and procedures so that the improvement is realized in everyday work.
• Complete necessary training so that all staff members are aware of the new process or procedure.
• Establish a plan to monitor the improvement’s ongoing effectiveness.
• Identify other areas where the improvement could be implemented.

Organizations frequently falter when continued measurement indicates that improvement goals are not being sustained. More often than not, efforts tend to provide short-term rather than long-term improvement. If the team is not achieving the improvement goals, then it needs to revisit the improvement actions by circling back to confirm root causes, identify a risk reduction strategy, design an improvement, implement an action plan, and measure the effectiveness of that plan over time.

There are a number of reasons a team’s improvements may falter and fail. If the team is having trouble effecting improvement, consider the reasons and remedies shown in Sidebar 6-8, page 116.
STEP 21 Communicate the Results

Throughout the root cause analysis process, the team should be communicating to the organization’s leadership the team conclusions and recommendations as outlined by the team early in the process. Hence, the communication process occurs throughout the team’s effort and is critical to the success of improvement initiatives.

After determining what happened or could have happened and identifying root causes of the event or possible event, the team should provide leadership with the recommendations for improvement actions to prevent a recurrence of the event. Generally, a short written report provides leaders with the summary they need. An outline of the contents of such a report appears as Sidebar 6-9, page 119.

The team should consider with care how and to whom the report is to be presented. Participants during a formal oral presentation should include those whose approval and help is needed as well as those who could gain from the team’s recommendations. Consider the following questions in communicating an improvement initiative:

- How will implementation of this initiative be communicated throughout the organization?
- Who needs to know?
- What communication vehicles will the team use for various audiences (individuals both directly and indirectly affected by the improvement)?

The team also needs to ensure that communication about the results will be an ongoing activity that reinforces the reasons for the improvement initiative. Storytelling is an effective strategy when reporting the results to a wide audience at various staff meetings. Storytelling humanizes the event that caused the root cause analysis, which helps catch people's interest and get them emotionally invested.
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Sidebar 6-9.
Possible Content of Report to Leaders

Event Description
This section includes a brief description of the sentinel event or possible event. It includes what, when, where, who, and how information as articulated in the problem definition (see Step 2 in Chapter 3, pages 49-53). The emphasis is on facts related to the event and the areas involved.

Scope of Analysis
This section describes the team’s membership and purpose as well as the analytical methods used to investigate the event or possible event.

Proximate Causes and Immediate Responses
This section describes the circumstances leading to the event, proximate causes identified by the team, and any response strategies and corrective actions implemented by individuals immediately following the event.

Contributing Factors
This section describes the circumstances, actions, or influences thought to have played a part in the origin, development, or increased risk of an incident.

Root Causes
This section describes the analyses conducted to determine root causes and lists the root causes identified by the team.

Improvement Actions and Follow-Up Plan
This section describes the improvement actions recommended by the team for each root cause. It also describes the measures and time frame recommended to evaluate the effectiveness of improvement actions.

The improvement actions being implemented. Storytelling also helps safeguard an organization against communication leaks. Written reports have a greater tendency than oral accounts do to leak outside a facility to media outlets, which in some cases leads to organizations being publicly portrayed in the worst possible light when incident reports and improvement plans are taken out of context.

Following implementation of such actions and measuring and ensuring their success, the team should report to leadership on the results of the improvement actions. The report should include information regarding applicability to other processes, areas, and locations and the lessons learned.
References

Worksheet 6-1. Prioritizing Improvement Actions

Use the following worksheet to catalog improvement actions suggested by the team. Separate sheets for each root cause and its suggested improvement actions may be used. The team should also rate or rank improvement actions based on agreed-upon criteria. Use this worksheet to record the rankings of individual team members and the team as a whole.

<table>
<thead>
<tr>
<th>Root Causes</th>
<th>Suggested Improvement Actions</th>
<th>Ranking</th>
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<tr>
<td>Root Cause 1:</td>
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<td>Root Cause 3:</td>
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</table>
Worksheet 6-2. Summarizing the Potential of Improvement Actions

Two questions help the team summarize the potential of each proposed improvement action. Use the space following each question to provide a concise answer.

What will result from implementing this action?

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

What would result from not implementing this action?

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
**Worksheet 6-3. Defining Improvement Goals, Scope, and Activities**

This worksheet helps the team define what it is trying to improve. Use the space following each question to provide as concise an answer as possible.

**What goals does the organization have in implementing necessary improvements related to a sentinel event or possible event?**

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**What measures will be most affected by the change?**

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**What specific activities must be carried out to reach the goals and affect the dimensions of performance? (Provide a clear statement of the essential features of each proposed solution.) What are the sequential steps necessary to accomplish the proposed improvement?**

1. ____________________________________________________
2. ____________________________________________________
3. ____________________________________________________
4. ____________________________________________________
5. ____________________________________________________
6. ____________________________________________________
**Worksheet 6-4. Defining Improvement Expectations, Sequence, Resources, and Measures**

This worksheet helps the team define how the organization will meet its improvement goals. Use the space following each question to provide as concise an answer as possible.

**How must the improved process perform?**


**What sequence of activities will be required to meet these expectations?**


**What resources will be required to meet these expectations?**


**How and what will be measured to determine whether the process is actually performing at the level expected?**

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<tr>
<th>Improvement Action</th>
<th>Quantitative Measure</th>
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Worksheet 6-5. Defining Time Frames and Milestones

This worksheet helps the team define when the organization will meet its improvement goals. Use the space following each question to provide as concise an answer as possible.

What time frame will be established for implementing the overall improvement action?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

What time line will be established for each activity comprising the steps along the way?

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<th>Activity</th>
<th>Time Frame</th>
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What are the major milestones and their respective completion dates?

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<th>Milestone</th>
<th>Completion Date</th>
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Worksheet 6-6. Involving the Right People

Involving the right people at each stage of the improvement process is critical to the success of the improvement initiative. Consider which individuals should be involved at each stage and write their names in the appropriate spaces.

**Designing the action.** In general, the group that participated in the root cause analysis should have the necessary expertise to recommend improvements and may be in the best position to design or redesign the improvements. This group should include those who carry out or are affected by the process. They are

________________________________________________________________________

________________________________________________________________________

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**Approving recommended actions.** When substantial resources are involved and the potential effects are significant, the organization’s leaders usually have to approve the action. This is most certainly the case with improvements recommended following a sentinel event. If a group has obtained the necessary input and buy-in while devising an improvement, the approval should come readily. The appropriate leaders are

________________________________________________________________________

________________________________________________________________________

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(continued)
Worksheet 6-6. Involving the Right People (continued)

Testing the action. Testing should occur under real-world conditions, involving staff who will actually be carrying out the process. Effects can be measured with the same methods used to establish a performance baseline. Appropriate staff members include

Implementing the action. Although full-scale implementation of a process change should have positive results, any change can create anxiety. Therefore, care should be taken to prepare people for change and to explain the reason for the change in an educational, nonthreatening way. Cooperation is essential for changes to succeed, but it cannot exist if people believe a change is being forced on them without good reason. An effective team should have already acquired much of the necessary buy-in during earlier phases of the improvement process or during the early stages in the root cause analysis. Appropriate staff members include
Worksheet 6-7. Determining the Location of Improvement Actions

This worksheet helps the team define where the organization will implement improvement goals.

Where will the improvement action be implemented?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Will its implementation be organizationwide or in a selected location with a selected patient population or selected staff members?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Are the location, target population, and target staff of the improvement action likely to expand with success?

☐ No (If no, why not?)  ☐ Yes (If yes, how?)

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Worksheet 6-8. Integrating the Improvement Plan

Define the time lines and responsibilities associated with each of the project steps using the following table. (Customize column headers as desired.) Questions to consider include the following:
- What are the time lines for each step of the project and for the project as a whole?
- What will be the checkpoints, control points, or milestones for project assessment?
- Who is responsible for each step or milestone?
- Who is responsible for corrective course action?
- What staff members will be involved in the improvement project?
- What will be the nature and extent of their responsibilities?

<table>
<thead>
<tr>
<th>Steps to Be Taken</th>
<th>Date of Implementation</th>
<th>Areas for Implementation</th>
<th>Individuals Responsible</th>
<th>Other Considerations</th>
</tr>
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</tbody>
</table>
Worksheet 6-9. Identifying Change Barriers and Solutions

Use this worksheet to identify possible barriers to change and solutions to overcome such barriers.

Areas where resistance to change might emerge include

________________________________________________________________________
________________________________________________________________________
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Countermeasures to overcome such barriers include

________________________________________________________________________
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**Worksheet 6-10. Designing the Measurement Plan**

What is the scope of measurement for the improvement project?

Have any portions of the process under study been measured in the past, or are they currently being measured? If so, are assessments available?

What measurement tools will be used for this initiative?

Will the tools provide reliable data? Have they been tested?

What costs are associated with collecting the necessary data? Do benefits outweigh costs?

Can the data generated by the selected measurement tool be transformed into meaningful and useful information?

How can the team ensure that the data are complete, accurate, and unbiased?

(continued)
Worksheet 6-10. Designing the Measurement Plan (continued)

How will the staff collecting data be educated?
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

What format(s) will be used to report the data?
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

Where and how will any additional required data be obtained?
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

How will the success of the improvement be measured?
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
**Worksheet 6-11. Evaluating Target Goals**

Use a worksheet like this one to plan and monitor progress in measuring the effectiveness of each improvement goal.

<table>
<thead>
<tr>
<th>Goal</th>
<th>Measure</th>
<th>Person Responsible</th>
<th>Review Completed</th>
</tr>
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</tbody>
</table>
Tools and Techniques

Learning Objectives

• Become familiar with a variety of analytical tools and processes, when each is best used, and how best to apply them
• Implement these tools as part of a comprehensive systematic analysis

Root cause analysis is a key element in an organization’s efforts toward performance improvement. The Joint Commission has created its own organizationwide plan of Robust Process Improvement™ based on Lean Six Sigma methodology and geared toward the specific issues of patient safety and quality in health care.

Within this framework or other, similar methodologies, numerous tools exist to facilitate the process of root cause analysis.

What Is Lean Six Sigma?

Lean Six Sigma is a term describing an improvement methodology based on the scientific method, statistical methods, customer values, flow and pull principles, PDSA (Plan-Do-Study-Act), and change management, among other methods. In his book The Machine That Changed the World, James Womack coined the term Lean to describe the methods of the Toyota Production System, in which all employees work together to eliminate waste (of resources and time) and to keep the process focused on the value of the product to the customer. The term Six Sigma comes from Motorola’s attempt to describe its methods for improving quality in a systematic way. It refers to a statistical concept in which a process or output remains within six standard deviations of the mean value in a normal distribution. Both Toyota and Motorola have been widely recognized for high quality. For those who have worked with both companies and have applied their methods, Lean Six Sigma is an appropriate label because the Lean and Six Sigma methods are found in both companies and are considered inseparable.

DMAIC

Lean Six Sigma often is applied in a five-step problem-solving approach commonly known by the acronym DMAIC:
• D, for Define, is a critical first step to have a clear understanding of the issue or problem to be solved.
• M stands for Measure, wherein the team assesses the baseline performance of the process. This step also is essential because without knowing the current state, one cannot gauge whether the process improved.
• A is for Analyze, which is what one must do for all the critical contributing factors—that is, the root causes. Lean Six Sigma values the statistical validation of these root causes to better ensure that improvements are achieved.
• I stands for Improve, and the team will statistically validate that the interventions achieve the results.
• C is for Control to ensure sustained gains.

(DMAIC is described in greater detail in Chapter 6, pages 112–114.) Earlier problem-solving methodologies often have shown limited success in creating interventions that last. The methodologies forwarded by Toyota and Motorola thus include key tools to better control the process for long-term success.
Any employee can learn Lean Six Sigma. One's level of expertise is often signified by a “belt” designation: Green Belt, Black Belt, Master Black Belt, or Sensei, awarded following training at that level.

Green Belts are taught statistical methods such as performance improvement pioneer Kaoru Ishikawa's seven tools (see Sidebar 7-1, right) as well as the flow and pull concepts from the Toyota Production System. Flow (continuous forward movement) in a process is desired as a sign that the process quality and productivity are higher than a process that repeatedly stops and starts. Pull refers to how the inputs of the process are replenished based on the customer's demand rather than the organization's timetable.

This chapter provides information on tools and techniques that can be used during root cause analysis. The tools and techniques are presented in a uniform format, called a Tool Profile, to assist readers with their selection and use. Each Tool Profile identifies the stage of root cause analysis during which the tool or technique may be used, its purpose, basic usage steps, and tips for effective use. An example of the tool or technique follows each profile.

When embarking on a root cause analysis, team members may wish to start by consulting the tool matrix shown in Table 7-1 on page 135. This matrix lists many of the tools and techniques available during root cause analysis and indicates the stages during which they may be particularly helpful.

**Sidebar 7-1. Ishikawa’s Seven Tools**

According to performance improvement pioneer Kaoru Ishikawa, if used skillfully, the following seven basic quality control tools—all of which are visual, in the form of charts, graphs, or diagrams—will enable 95% of workplace problems to be solved.

1. Check sheet
2. Control chart
3. Fishbone diagram (also called cause-and-effect diagram or Ishikawa diagram)
4. Flowchart (also called stratification)
5. Histogram (also called frequency distribution)
6. Pareto chart
7. Scatter diagram

Each of these tools is described in a Tool Profile in this chapter.

<table>
<thead>
<tr>
<th>Tool Name (Alternate Name)</th>
<th>Identifying Proximate Causes</th>
<th>Identifying Root Causes</th>
<th>Identifying Improvement Opportunities</th>
<th>Implementing and Monitoring Improvements</th>
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</thead>
<tbody>
<tr>
<td>Affinity diagram</td>
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<tr>
<td>Brainstorming</td>
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<tr>
<td>Change management</td>
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<td>X</td>
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</tr>
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<td>Check sheet</td>
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<tr>
<td>Control chart</td>
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<td>Failure mode and effects analysis (FMEA)</td>
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<td>Fishbone diagram</td>
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<tr>
<td>Fishbone diagram (Cause-and-effect diagram, Ishikawa diagram)</td>
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<tr>
<td>Flowchart (Stratification)</td>
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<td>X</td>
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<tr>
<td>Gantt chart</td>
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<tr>
<td>Histogram</td>
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<td>Kaizen</td>
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<td>Multivoting</td>
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<td>Operational definition</td>
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<tr>
<td>Pareto chart</td>
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<td>Relations diagram</td>
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<td>Run chart</td>
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<td>Scatter diagram</td>
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<tr>
<td>Scatter diagram (Scattergram)</td>
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<td>SIPOC process map</td>
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<td>Stakeholder analysis</td>
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<td>Standard work</td>
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<tr>
<td>Value stream mapping</td>
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</table>

This matrix lists many of the tools and techniques available during root cause analysis and indicates the stages during which they may be particularly helpful. Each tool is described in greater detail in this chapter.
**Affinity Diagram**
*(See Figure 7-1)*

**Stages to Use:** Identifying proximate causes, identifying improvement opportunities

**Purpose:** To creatively generate a large volume of ideas or issues and then organize them into meaningful groups.

**Simple Steps to Success:**
1. Choose a team.
2. Define the issue in the broadest and most neutral manner.
3. Brainstorm (for example, for contributing factors or for suggested improvements) and record the ideas.
4. Randomly display sticky notes with the ideas so that everyone can see them.
5. Sort the ideas into groups of related topics.
6. Create header or title cards for each grouping.
7. Draw the diagram, connecting all header cards with their groupings.

---

**TIPS FOR EFFECTIVE USE**

Overcome interviewee defensiveness by doing the following:
- Keep the team small (four to six people) and ensure varied perspectives.
- Generate as many ideas as possible using brainstorming guidelines.
- Record ideas from brainstorming on sticky notes.
- Sort the ideas in silence, being guided in sorting only by gut instinct.
- If an idea keeps getting moved back and forth from one group to another, agree to create a duplicate note.
- Reach a consensus on how notes are sorted.
- Allow some ideas to stand alone.
- Make sure that each idea has at least a noun and a verb when appropriate; avoid using single words.
- Break large groupings into subgroups with subtitles, but be careful not to slow progress with too much definition.
Laboratory reports not on chart at 8 A.M.

Lab routine
- Labs designated as daily not drawn until 10 AM
- Intensive care unit and telemetry drawn first
- Time to draw certain labs
- No way to tell if patient is preoperative

Lab results
- Lab reports not printed until 10:30 AM
- Results available in lab system before until system
- Lab results not printed by secretary
- Labs not placed on front of chart
- Main secretary ill

Lab ordering
- Intensive care unit and stat orders take precedence
- Too many stat orders when physicians discover no labs
- Increased cost of stat labs
- Labs ordered incorrectly
- Too many types or times to choose from

This affinity diagram shows how a wide range of ideas can be arranged in manageable order. Using this type of diagram presents ideas on why laboratory results are not available as needed in three categories: routine, results, and ordering.
Brainstorming

(See Figure 7-2)

Stages to Use: Identifying improvement opportunities

Purpose: To generate multiple ideas in a minimum amount of time through a creative group process

Simple Steps to Success:
1. Define the subject. Doing so ensures that the session has direction.
2. Think briefly about the issue. Allow enough time for team members to gather their thoughts, but not enough time for detailed analysis.
3. Set a time limit. Allow enough time for every member to make a contribution, but keep it short to prevent premature analysis of ideas.
4. Generate ideas. Use a structured format in which the group members express ideas by taking turns in a predetermined order, one idea per turn. The process continues in rotation until either time runs out or ideas are exhausted.
5. Clarify ideas. The goal is to make sure that all ideas are recorded accurately and are understood by the group.

Tips for Effective Use:
- Create a nontoxic, safe environment for expressing ideas.
- Tell the group up front that any idea is welcome, no matter how narrow or broad in scope or how serious or light in nature. All ideas are valuable, as long as they address the subject at hand.
- Remember that the best ideas are sometimes the most unusual.
- Allow group members to occasionally say “pass” if they can’t think of an idea when it’s their turn to speak.
- Never criticize ideas. It is crucial that neither the leader nor the other group members comment on any given idea.
- In thinking briefly about the issue (Step 2), do not give group members time to second-guess their ideas. Be aware that self-censorship stifles creative thought.
- Write down all ideas on a chalkboard or easel so that the group can view them.
- Keep it short; enforce a time limit of 10 to 20 minutes.
- In organizations where staff may not regularly be in a centralized location, brainstorming can be done by asking staff to submit as many ideas as possible about the topic in writing, by voice mail, or by e-mail.
- Make a note of deeper root causes that emerge during brainstorming and place them in a “parking lot” list for consideration later.
Possible factors contributing to a surgical error include the following:

- No timely case review
- No mechanism to ensure patient identity
- Informal case referral process
- Untimely operative dictation
- Inadequate presurgical evaluation
- No review of patient care information prior to surgery
- Inadequate informed consent
- Patient care information unavailable for preoperative review
- Failure to perform surgery in a safe manner
- Laterality not clearly identified
- Delay in reporting of incident
- No multidisciplinary review
- Ignored pathology reports
- History of inadequate documentation in medical record
- Procedures performed without adequate expertise
- Failure to take responsibility for actions
- No surgical plan/preoperative findings

This figure shows an excerpt from a list one organization created using brainstorming to identify possible contributing factors in a surgical error that occurred. This list was used to create the fishbone diagram that appears as Figure 7-8, page 148. As the example shows, the ideas are widely varied, and some seem more viable than others. Remember that brainstorming is for generating ideas, not sorting or judging them.
**Capability Chart**

*(See Figure 7-3)*

**Stages to Use:** Identifying root causes; implementing and monitoring improvements.

**Purpose:** To analyze processes in order to determine whether they are capable of satisfying the given requirements.

**Simple Steps to Success:**
1. Determine the upper and lower parameters for acceptable performance within the process.
2. Collect or project data concerning actual or projected performance.
3. Plot data on a graph showing the upper and lower performance parameters.
4. Analyze graph to determine whether any part of the performance curve falls outside of the parameters.
5. Decide whether performance values that fall outside the parameters can be addressed by modifying the process, or the whole process needs to be redesigned.

**TIPS FOR EFFECTIVE USE**
- Divide the process into steps the performance of which can be quantified.
- Determine upper and lower parameters for the performance of each component of the process.
- For new processes, begin with a pilot program, which will provide initial data on performance.

---

**Figure 7-3. Capability Chart**

**Specification Limits (= Customer Requirements)**

Change Analysis

Stages to Use: Identifying proximate causes; identifying root causes

Purpose: To determine the proximate and root cause(s) of an event by examining the effects of change. This involves identifying all changes, either perceived or observed, and all possible factors related to the changes.

Simple Steps to Success:
1. Identify the problem, situation, or sentinel event.
2. Describe an event-free or no-problem situation. Try to describe the situation without problems in as much detail as possible. Include the who, what, where, when, and how information listed in Step 1.
3. Compare the two. Take a close look at the event and nonevent descriptions, and try to detect how these situations differ.
4. List all the differences.
5. Analyze the differences. Carefully assess the differences and identify possible underlying causes. Describe how these affected the event. Did each difference or change explain the result?
6. Integrate information and specify root cause(s). Identify the cause that, if eliminated, would have led to a nonevent situation.

TIPS FOR EFFECTIVE USE
- Describe the problem as accurately and in as much detail as possible. Include in the description who was involved, what might have been a factor in causing the event, where the event took place, and when it took place.
- After a change analysis is performed, additional questions must be asked to determine how the changes were allowed to happen.
- Continue the questioning process into the organization’s systems.
- Remember that not all changes create problems; rather, change can be viewed as a force that can either positively or negatively affect the way a system, process, or individual functions.

Figure 7-4. Change Analysis Worksheet

This generic worksheet shows a simple way of listing and comparing information for change analysis. The worksheet is arranged in columns to show logically what happened, what did not happen, the difference between them, and an analysis.
Change Management
(See Figure 7-5)

Stages to Use: Identifying improvements; implementing and monitoring improvements

Purpose: To encourage organizational acceptance of a change in process within a system

Simple Steps to Success:
1. Determine the need for the change.
2. Secure leadership buy-in.
3. Anticipate resistance to change from staff who will be affected by the change.
4. Communicate a vision of the improvement that will result from the change.
5. Seek input from staff members in designing the change.
6. Implement the change.
7. Gauge the effectiveness of the change.
8. Modify the change, if necessary, to reach the desired result.
9. Maintain support for the change.

TIPS FOR EFFECTIVE USE
- Calculate the costs of the change, both actual costs and opportunity costs, and be sure that the need for the change outweighs these costs before moving forward.
- Understand that resistance to change is a natural human reaction, and assure key stakeholders in the process that their voices will be heard.
- Consider the change’s effect on overall organizational culture, not just one process.

Figure 7-5. Change Management

Current State

Change Management converting “Energy” to move people to a better state

Desired State
Check Sheet
(See Figure 7-6)

**Stages to Use:** Identifying proximate causes

**Purpose:** To sort and group data, using check marks or similar symbols, onto a form that can be used with other tools

**Simple Steps to Success:**
1. Determine what data are to be collected.
2. Design a form on a blank sheet of paper with labeled rows and columns representing the appropriate values.
3. Have team members record the data by placing a check mark, hatch mark, X, or other symbol next to the value to which each measurement corresponds.

**TIPS FOR EFFECTIVE USE**
- Know which data matter for your purpose.
- Use the data recorded on the check sheet to create a Pareto diagram or flowchart.
### Figure 7-6. Example: Check Sheet

<table>
<thead>
<tr>
<th>Observation Number</th>
<th>Unit name (3 West, PICU, etc)</th>
<th>Check box if observed during rounds</th>
<th>Please circle role of health care professional observed</th>
<th>Today’s Date:</th>
<th>Hand Hygiene</th>
<th>Possible Contributing Factors to Washing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AM PM RN MD RT PT Diet Lab Other</td>
<td>Yes No Yes No Yes No Yes No Yes No Yes No Yes No Yes No Yes No Yes No Yes No Yes No Yes No</td>
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<tr>
<td>2</td>
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</tbody>
</table>

Guidelines and operational definitions on the back of this page.
Control Chart
(See Figure 7-7)

Stages to Use: Implementing and monitoring improvements

Purpose: To identify the type of variation in a process and whether the process is statistically in control

Simple Steps to Success:
1. Choose a process to evaluate, and obtain a data set.
2. Calculate the average.
3. Calculate the standard deviation. The standard deviation is a measure of the data set’s variability.
4. Set upper and lower control limits. Control limits should be three times higher or lower than the standard deviation relative to the mean.
5. Create the control chart. In creating the control chart, plot the mean (that is, center line) and the upper and lower control limits.
6. Plot the data points for each point in time, and connect them with a line.
7. Analyze the chart and investigate findings.

TIPS FOR EFFECTIVE USE

- Obtain data before making any adjustments to the process.
- In plotting data points, keep the data in the same sequence in which they were collected.
- Be aware that special causes of variation must be eliminated before the process can be fundamentally improved and before the control chart can be used as a monitoring tool.
- The terms in control and out of control do not signify whether a process meets the desired level of performance. A process may be in control but consistently poor in terms of quality, and the reverse may be true.
- Charting something accomplishes nothing; it must be followed by investigation and appropriate action.
- Processes as a rule are not static. Any change can alter the process distribution and should trigger recalculation of control limits when the process change is permanently maintained and sustained (that is, greater than 8 to 12 points on one side of the process mean, or center line).
- Some special causes of variation are planned changes to improve the process. If the special cause is moving in the right direction toward improvement, retain the plan. It is working.
- The following four rules are used to identify out-of-control processes:
  1. One point on the chart is beyond three standard deviations of the mean.
  2. Two of three consecutive data points are on the same side of the mean and are beyond two standard deviations of the mean.
  3. Four of five consecutive data points are on the same side of the mean and are beyond one standard deviation of the mean.
  4. Eight data points are on one side of the mean.
These two control charts illustrate different patterns of performance an organization is likely to encounter. When performance is said to be in control (top chart), it does not mean desirable; rather, it means a process is stable, not affected by special causes of variation (such as equipment failure). A process should be in control before it can be systematically improved. When one point jumps outside a control limit, it is said to be an outlier (bottom chart). Staff should determine whether this single occurrence is likely to recur.
**Failure Mode and Effects Analysis (FMEA)**
(Synonym: failure mode, effects, and criticality analysis, or FMECA)
(See Figure 7-8)

**Stage to Use:** Identifying opportunities for improvement

**Purpose:** To examine a prospective design for possible ways in which failure can occur so that actions can be taken to eliminate the possibility of failure, stop a failure before it reaches people, or minimize the consequences of a failure

**Simple Steps to Success:**
1. Select a high-risk process and assemble a team.
2. Diagram the process.
3. Brainstorm potential failure modes and determine their effects.
4. Prioritize failure modes (often accomplished through calculating a risk priority number).
5. Find root causes of failure modes.
6. Redesign the process.
7. Analyze and test the new process.
8. Implement and monitor the redesigned process.

**TIPS FOR EFFECTIVE USE**
- Risk priority numbers may be calculated as the product of ratings on frequency of occurrence, severity, and likelihood of detection.
- Remember that this type of analysis is generally proactive (used before an adverse event occurs), although use during root cause analyses to formulate and evaluate improvement actions is also recommended and described in this book in Chapter 6 on pages 99–100.
In conducting a health care FMEA (HFMEA*) the basic steps are:

- Identify the process to be examined.
- Assign FMEA team members, team leader and team facilitator.
- Explain the methodology to the team.
- Develop either a flowchart or detailed process flow (outline format) of the process under analysis. All steps in the process should be included.
- Designate which of the steps in the process constitute “Functions.”
- Determine which Functions represent potential “Failure Modes” or points of potential failure. Determine the worst potential adverse consequence or “Effect” of each of the Failure Modes.
- Determine the “Contributory Factors” for each Failure Mode. One or more Root Cause Analyses may be necessary to complete this step. Note that we advocate the use of the term “Contributory Factor” rather than “Cause.”
- Identify any “Controls” in the process. Controls are components of the process which (a) reduce the likelihood of a Contributory Factor or a Failure Mode, (b) reduce the severity of an Effect, or (c) detect the occurrence of a Failure Mode or Contributory Factor before it leads to the adverse outcome (Effect).
- Rate the Severity of each Effect (usually on a scale of 1–10, with 10 being the most severe). The impact of Controls that ameliorate the severity of an Effect are reflected in this rating as well.
- Rate the Occurrence (likelihood) of each Contributory Factor (usually on a scale of 1–10, with 10 being the most frequent, or “certain to occur”). The impact of Controls that reduce the likelihood of occurrence of a Failure Mode or Contributory Factor are reflected in this rating as well.
- Rate the effectiveness of each “Detection Control” (usually on a scale of 1–10, with 10 being the lack of a Detection Control, or the presence of a wholly ineffective one, and 1 being a 100% flawless detection system).
- Multiply the three ratings by one another for each Contributory Factor and the corresponding Effect and Detection Controls. The range of these products will be from 1 to 1,000. The resultant number is the Risk Priority number (RPN) for that Contributory Factor.
- Rank-order the Contributory Factors according to the Risk Priority Numbers.
- Use a Pareto Chart with the traditional 80% rule to determine which contributory Factors should be addressed first.
- Add to the above listing ALL Contributory Factors which result in an Effect with Severity of 10, irrelevant of RPN.
- Develop a plan addressing how the selected Contributory Factors will be addressed, by whom, when, how the improvement will be assessed, etc.
- Continue the improvement process.

Fishbone Diagram
(Synonyms: cause-and-effect diagram, Ishikawa diagram)
(See Figure 7-9)

Stages to Use: Identifying proximate causes; identifying root causes

Purpose: To present a clear picture of the many causal relationships between outcomes and the contributing factors in those outcomes

Simple Steps to Success:
1. Identify the outcome or problem statement.
2. Determine general categories for the causes.
3. List proximate causes under each general category.
4. List underlying causes related to each proximate cause.
5. Evaluate the diagram.

TIPS FOR EFFECTIVE USE
- Make sure everyone agrees on the problem statement or outcome.
- Be succinct and stay within the team’s realm of control.
- Place the outcome on the right side of the page, halfway down, and then, from the left, draw an arrow horizontally across the page, pointing to the outcome.
- Represent common categories, including work methods, personnel, materials, and equipment, on the diagram by connecting them with diagonal lines branching off from the main horizontal line.
- Brainstorm to come up with the important proximate causes. Place each proximate cause on a horizontal line connected to the appropriate diagonal line.
- Gather data to determine the relative frequencies of the causes.
- Look for causes that appear continually in the evaluation process.
- Keep asking “Why?” to reach the root cause.
- Focus on system causes, not on causes associated with individual performance.
This figure illustrates how the generic diagram can be adapted to specific needs. This detailed diagram breaks down the contributing factors that led to a sentinel event—the suicide of a patient in a mental health unit. By analyzing the proximate and underlying causes listed, staff members can identify and prioritize areas for improvement.
### TIPS FOR EFFECTIVE USE

- Ensure that the flowchart is constructed by the individuals actually performing the work being charted.
- Be sure to examine a process within a system, rather than the system itself.
- If the process seems daunting and confusing, create a simple high-level flowchart containing only the most basic components. Do not include too much detail; be wary of obscuring the basic process with too many minor components.
- Use adhesive notes placed on a wall to experiment with sequence until the appropriate one is determined.
- Make the chart the basis for designing an improved process, using spots where the process works well as models for improvement.
- Create a separate flowchart that represents the ideal path of the process, and then compare the two charts for discrepancies.
- Keep in mind that difficulties probably reflect confusion in the process being charted, and work through them.

---

**Flowchart**  
*(See Figure 7-10)*

**Stages to Use:** Identifying proximate causes; identifying root causes; identifying opportunities for improvement; implementing and monitoring improvements

**Purpose:** To help teams understand all steps in a process through the use of common, easily recognizable symbols; this illustrates the actual path a process takes or the ideal path it should follow.

**Simple Steps to Success:**

1. Define the process to be charted, and establish starting and ending points of the process.
2. Brainstorm activities and decision points in the process. Look for specific activities and decisions necessary to keep the process moving to its conclusion.
3. Determine the sequence of activities and decision points.
4. Use the information to create the flowchart. Place each activity in a box, and place each decision point in a diamond. Connect these with lines and arrows to indicate the flow of the process.
5. Analyze the flowchart. Look for unnecessary steps, redundancies, black holes, barriers, and any other difficulties.
Figure 7-10. Example: Medication Administration Flowchart

This flowchart shows the basic steps in a traditional medication-use system. The process components are arranged sequentially, and each stage can be expanded as necessary to show all possible steps.
**Gantt Chart**
(See Figure 7-11)

**Stages to Use:** Identifying proximate causes; identifying root causes; identifying opportunities for improvement; implementing and monitoring improvements

**Purpose:** To graphically depict the time line for long-term and complex projects, enabling a team to gauge its progress

**Simple Steps to Success:**
1. **Agree on start and stop dates** for the project, and outline its major steps.
2. **Draw a time line.**
3. **Write the first step** of the project under the appropriate time period. Enclose it in a rectangle long enough to stretch across the length of time estimated for completion.
4. **Do the same for each of the succeeding steps.**

---

**Figure 7-11. Example: Gantt Chart**

<table>
<thead>
<tr>
<th>Task: Design Phase</th>
<th>Person(s) Responsible</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify and appoint credentialing committee</td>
<td>SH</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identify performance measures</td>
<td>SH and SR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Define policies and procedures that outline appointment, reappointment, and privileging process</td>
<td>SH and SR</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Develop credentialing application</td>
<td>SH and SR</td>
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</table>

*This Gantt chart of a competency and privileging process helped one team determine what tasks to undertake in what order. The chart details the target date and person(s) responsible for each task in the development process.*
**Histogram**

*See Figure 7-12*

**Stages to Use:** Identifying proximate causes; identifying root causes; identifying opportunities for improvement; implementing and monitoring improvements

**Purpose:** To provide a snapshot of the way data are distributed within a range of values and the amount of variation within a given process, suggesting where to focus improvement efforts

**Simple Steps to Success:**
1. Obtain the data sets, and count the number of data points.
2. Determine the range for the entire data set.
3. Set the number of classes into which the data will be divided.
4. Determine the class width (by dividing the range by the number of classes).
5. Establish class boundaries.
6. Construct the histogram.
7. Count the data points in each class, and create the bars.
8. Analyze the findings.

**TIPS FOR EFFECTIVE USE**
- Data should be variable (that is, measured on a continuous scale such as temperature, time, weight, speed, and so forth).
- Make sure data are representative of typical and current conditions.
- Use more than 50 data points to ensure the emergence of meaningful patterns.
- Be sure that the classes are mutually exclusive so that each data point fits into only one class.
- Using $K = 10$ class intervals makes for easier mental calculations.
- Be aware that the number of intervals can influence the pattern of the sample.
- To construct the histogram, place the values for the classes on the horizontal axis and the frequency on the vertical axis.
- Be suspicious of the accuracy of the data if the histogram suddenly stops at one point without some previous decline in the data.
- Remember that some processes are naturally skewed; do not expect a normal pattern every time.
- Large variability or skewed distribution may signal that the process requires further attention.
- Take time to think of alternative explanations for the patterns seen in the histogram.

**Figure 7-12. Example: Histogram**

This sample histogram was developed by an infusion therapy service to analyze turnaround time for authenticating verbal orders from physicians. The irregular distribution suggests opportunities for improvement.
TIPS FOR EFFECTIVE USE

- Allow two to four weeks for the planning phase.
- Make sure that the team includes members who will contribute value to the process.
- If possible, give team members some training in use of tools before the workshop.
- Keep communication lines with the project champion open as the workshop progresses.
- Include a celebration for the team at the end of the project.
- Allow at least three to four weeks for the follow-up phase.

Kaizen

(See Figure 7-13)

**Stages to Use:** Implementing and monitoring improvements

**Purpose:** To improve a small, focused area in a week or less

**Simple Steps to Success:**

1. Using a value stream map (see Value Stream Mapping Tool Profile pages 172–173) as a road map, create a charter that clearly defines the issue or problem to be addressed through the kaizen effort.
2. Secure from the organization’s leadership a designated project champion who will be willing to act upon the result of the kaizen.
3. Assemble a multidisciplinary team of no more than 10 members, to be led by an experienced, impartial facilitator, such as a Six Sigma Master Black Belt.
4. Conduct the kaizen workshop, which may last two to five days, during which the team uses a variety of tools to determine an action plan.
5. The team presents its plan at a report-out to the project champion.
6. Implement and monitor.
Figure 7-13. Example: Kaizen Blitz Day-by-Day Plan

Kaizen Blitz Step-By-Step

- **Day 1 – Team and Kaizen Leader Introductions and Value Stream Map the Current State**
  - Purpose - Agenda - Ground Rules - Expectations - Roles and Responsibilities (PAGER)
  - Robust Process Improvement Lean Six Sigma Overview, as needed
  - Charter the Kaizen Effort with issue clearly defined, metrics, goals, team members and signoffs by leadership
  - Lean Six Sigma Demand Analysis Statistical Process Control chart
  - Customers defined
  - Stakeholder Analysis
  - Takt Time estimated
  - Value Stream Map the Current State
  - Focus areas verified
  - Who-What-When action plan for Kaizen developed and shared
  - Coach/train Just-In-Time as needed
  - Day 1 Wrap-up and PAGER for Day 2

- **Day 2 – Standard Work, Quality Stability and Capability Baseline and Flow Diagramming**
  - Standard work
  - Spaghetti Diagramming
  - Statistical Process Control and/or Capability measurement
  - Value Stream Mapping – Future State
  - WWW Action plans to achieve Future State
  - Day 2 Wrap-up and PAGER for Day 3

- **Day 3 – Future State Implementation**
  - Use Robust Process Improvement Lean Six Sigma tools to achieve Future State
  - WWW Action plans to achieve Future State
  - Day 3 Wrap-up and PAGER for Day 4

- **Day 4 – Implement Future State and continuously improve**
  - Continue with improvements
  - Ensure standard work, capacity manning and playbooks are complete
  - Complete remaining improvements – ensure goals are met
  - Ensure training is complete and documented for process owners, managers and employees
  - WWW Action plans to achieve Future State
  - Failure Modes and Effects Analysis and Control Plan to sustain the gains
  - Prepare Day 5 final presentation and metrics (before and after)
  - Day 4 Wrap-up and PAGER for Day 5

- **Day 5 – Noon**
  - Report Out by team members with process owners and leadership
  - Sign-off by Process Owner
  - Celebrate
Multivoting

(See Figure 7-14)

**Stages to Use:** Identifying proximate causes; identifying root causes; identifying opportunities for improvement

**Purpose:** To narrow down a broad list of ideas (that is, more than 10) to those that are most important and worthy of immediate attention

**Simple Steps to Success:**
1. Using a brainstorming list or other list, combine any items on the list that are the same or similar.
2. Assign letters to items on the new list.
3. Determine the number of points each group member can assign to the list. Each member uses a predetermined number of points (typically between 5 and 10) to vote on the items on the list.
4. Allow time for group members to assign points independently.
5. Indicate each member’s point allocation on the list.
6. Tally the votes.
7. Note items with the greatest number of points.
8. Choose the final group, or multivote again.

**TIPS FOR EFFECTIVE USE**
- Ensure that when combining ideas on the lists, the team members who suggested the ideas agree with the new wording.
- Use letters rather than numbers to identify each statement so that team members do not become confused by the voting process.
- Clearly define each idea so that it is easily understood by everyone voting.

**Figure 7-14. Example: Multivoting**

<table>
<thead>
<tr>
<th>Improvement Opportunities</th>
<th>Number of Votes</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Facility safety management</td>
<td>3</td>
</tr>
<tr>
<td>B. Patient education</td>
<td>7</td>
</tr>
<tr>
<td>C. Staff orientation</td>
<td>5</td>
</tr>
<tr>
<td>D. Referral (authorization)</td>
<td>3</td>
</tr>
<tr>
<td>E. Care coordination and communication</td>
<td>1</td>
</tr>
<tr>
<td>F. Laundry</td>
<td>7</td>
</tr>
<tr>
<td>G. Medication profile</td>
<td>5</td>
</tr>
</tbody>
</table>

This figure shows the results of multivoting on priorities for improvement at an Indian health center. The team was able to reach consensus on the need for prioritizing the laundering process.
**Operational Definition**  
*(See Figure 7-15)*

**Stages to Use:** Identifying improvement opportunities

**Purpose:** To remove ambiguity so that everyone has the same understanding of the issue being defined

**Simple Steps to Success:**
1. *Consider what is to be defined.* It may be a project charter, a customer requirement, or an aspect of data collection.
2. *Determine the particular means of measurement* that would be appropriate in supporting the definition.
3. *Write the definition,* including the specific, concrete measurement criteria to be used in determining whether the terms of the definition have been met.

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**Figure 7-15. Example: Operational Definition**

**Medication errors:** Number of patient deaths, paralysis, coma, or other major permanent loss of function associated with a medical error

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**TIPS FOR EFFECTIVE USE**
- Be as concise as possible.
- If the definition has no numbers in it, it may not be specific enough and could possibly be further revised.
**Pareto Chart**

*(See Figure 7-16)*

**Stages to Use:** Identifying opportunities for improvement

**Purpose:** To show which events or causes are most frequent and therefore have the greatest effect. Doing so enables a team to determine what problems to solve in what order.

**Simple Steps to Success:**

1. **Decide on a topic of study.** The topic can be any outcome for which several potential causes have been identified.
2. **Select causes or conditions to be compared.** Identify the factors that contribute to the outcome—the more specific, the better.
3. **Set the standard for comparison.** In many cases, the standard is frequency, although factors may be compared based on their cost or quantity.
4. **Collect data.** Determine how often each factor occurs (or the cost or quantity of each, as appropriate). Use a checklist to help with this task.
5. **Make the comparison.** Based on the data collected in the previous step, compare the factors and rank them from most to least.
6. **Draw the chart’s vertical axis.** On the left side of the chart, draw a vertical line and mark the standard of measurement in increments.
7. **List factors along the horizontal axis.** Factors should be arranged in descending order, with the highest ranking factor at the far left.

**TIPS FOR EFFECTIVE USE**

- If the team is working from a fishbone diagram, the topic is the effect that has been targeted for improvement. *(See Fishbone Diagram Tool Profile, pages 149–150.)*
- When selecting factors for comparison, beware of grouping several distinct problems together, which can skew the rank order. Refer to the fishbone diagram, and use the most specific causes and factors possible.
- Be sure to mark the chart clearly to show the standard of measurement.
- When analyzing the chart, keep in mind that numbers do not always tell the whole story. Sometimes two severe complaints deserve more attention than 100 minor complaints.

8. **Draw a bar for each factor.** The bars represent how often each factor occurs, the cost of each factor, or its quantity, as applicable.
9. **Include additional features, if desired.** By making a few simple additions to the chart, a team can show the cumulative frequency, cost, or quantity of the categories in percentages.
10. **Add up the percentages.** All the percentages for the causes need to add up to 100%.
One organization used a Pareto chart to rank the frequency of responses of selected root causes provided by team members investigating a sentinel event involving a wrong-site surgery.
Relations Diagram

(See Figure 7-17)

**Stages to Use:** Identifying proximate causes; identifying root causes; identifying opportunities for improvement

**Purpose:** To generate understanding of how various aspects of a problem are connected, including cause-and-effect relationships

**Simple Steps to Success:**

1. *Write a definition of the issue* (for example, a problem to be solved or a solution to be achieved) on a sticky note and put it at the top of a large sheet of paper such as a flipchart page on an easel.
2. *Give each member of the group a pad of sticky notes and then brainstorm for ideas* about the issue, writing down one idea per note.
3. *One at a time, put each idea on the paper.* As an idea is added, discuss whether it seems related to any other ideas already on the paper; if so, place it nearby (but not touching; there should be space between the notes).
4. *Determine what the relationships are between related ideas and draw arrows to represent them.* For example, if idea $A$ has an impact on idea $B$, draw a line with an arrow pointing from $A$ to $B$. Origination notes will indicate possible causes, destination notes possible effects. Ultimately each note will have one or more arrows leading toward and/or away from it.
5. *For each note, count the number of arrows to and from it, and write the totals beside each note.* For example, three arrows to and one arrow from could be written as “3/1.”
6. *Examine the totals.* Notes with the highest totals will be the most important ideas to address in resolving the issue. Those with the highest number of arrows out represent proximate or possibly even root causes; those with the highest number of arrows in represent the main effects. Circle these ideas for further analysis.

**TIPS FOR EFFECTIVE USE**

- Have team members take turns placing ideas on the paper so that everyone participates.
- Remembering the rules for brainstorming, do not criticize any ideas.
- Use bold markers for drawing the arrows.
Figure 7-17. Example: Relations Diagram—Hospital

6 in 1 out

Scheduled appointments

2 in 2 out

Emergency appointments

3 in 1 out

Administrative workload

Support functions availability

1 in 3 out

Equipment quality and reliability

0 in 1 out

Nurse availability

1 in 5 out

0 in 3 out

Changes in scheduled appointments

4 in 1 out

1 in 3 out

Doctors’ pay level

Run Chart
(See Figure 7-18)

Stages to Use: Identifying proximate causes; identifying opportunities for improvement; implementing and monitoring improvements

Purpose: To provide an overview of the variation in the performance of a process

Simple Steps to Success:
1. Select appropriate units by which to measure variation.
2. Select appropriate units of time over which to measure the variation.
3. Plot variation on the vertical axis along the horizontal time line.

TIPS FOR EFFECTIVE USE
- Be sure that the units and scale used in the chart present an accurate picture of the variation in order to avoid creating a distorted picture of the problem.
- Create a hypothesis as to the cause of any excessive variation.
- Interview the responsible staff members to determine the actual cause of excessive variation.
- Repeat the process and compare performance and levels of variation on an ongoing basis.

Figure 7-18. Run Chart

ED Wait Time: Average per Patient

Scatter Diagram
(Synonym: scattergram)
(See Figure 7-19)

**Stages to Use:** Implementing and monitoring improvements

**Purpose:** To display the correlation—not necessarily the cause-and-effect relationship—between two variables

**Simple Steps to Success:**
1. Decide which two variables are to be tested.
2. Collect and record relevant data. Gather 50 to 100 paired samples of data involving each of the variables, and record them on a data sheet.
3. Draw the horizontal and vertical axes.
4. Plot the variables on the graph. If a value is repeated, circle that point as many times as necessary.
5. Interpret the completed diagram.

**TIPS FOR EFFECTIVE USE**
- Select two variables with a suspected relationship (for example, delays in processing tests and total volume of tests to be processed).
- Use the horizontal (x) axis for the variable you suspect is the cause and the vertical (y) axis for the effect.
- Construct the graph so that values increase while moving up and to the right of each axis.
- The more the clusters form a straight line (which could be diagonal), the stronger the relationship between the two variables.
- If points cluster in an area running from lower left to upper right, the variables have a positive correlation. This means that as x increases, y may depend on an increase in x; if you can control x, you have a good chance of controlling y.
- If points cluster from upper left to lower right, the variables have a negative correlation. This means that as x increases, y may decrease.
- If points are scattered all over the diagram, these variables may not have any correlation. (The effect, y, may be dependent on a variable other than x.)
- Remember, if the diagram indicates a relationship, it is not necessarily a cause-and-effect relationship.
- Be aware that even if the data do not appear to have a relationship, they may be related.
- Although scatter diagrams cannot prove a causal relationship between two variables, they can offer persuasive evidence.
This scatter diagram compares two variables associated with self-administration errors—the number of medications prescribed and the ages of the patients involved. As might be expected, the clustering of points shows that the older the patient, the higher the number of medications involved in care.
Stages to Use: Identifying improvement opportunities

Purpose: To identify the basic elements or variables in a process

Simple Steps to Success:
1. SIPOC stands for suppliers, inputs, process, outputs, and customers. The SIPOC process map will have five columns corresponding to each of these categories. Begin with a process map, perhaps generated from a brainstorming session (see Brainstorming Tool Profile, pages 138–139), that shows a process of about four or five steps. List these steps in the center process column of the SIPOC process map.
2. Identify and list the outputs—that is, the products or services being offered to the customers—that result from this process.
3. Identify and list the customers—that is, the people who are to receive and use the outputs. Customers may be internal (another department in the organization) or external (patients).
4. Identify and list the inputs—that is, the information, materials, or personnel—needed for the process to produce the outputs.
5. Identify and list the suppliers of the inputs—that is, the individuals or organizational groups that provide the inputs.
6. If needed, make further refinements; for example, by rewording, combining, or moving the items listed within each column.

TIPS FOR EFFECTIVE USE
- Use a cross-functional team to create the SIPOC process map.
- Follow one of the key rules of brainstorming while going through the steps to create the SIPOC process map: Allow ideas to be expressed without judgment or critique.
**Figure 7-20. Example: SIPOC for a General Physician Visit**

**Suppliers**
- Universities/Institutions
- Pharmaceutical Companies
- Medical Equipment Companies
- Drug Stores
- Pharmacists
- FDA
- Hospitals
- Medical Centers
- Laboratories
- Insurance Companies

**Inputs**
- Doctors
- Nurses
- Experts
- Support Staff
- Medical Equipment
- Patient
- Supplies
- Laws
- Facilities
- Insurance Plan
- Drugs

**Process**
- Patient visits medical center
  - Register the patient
  - Patient receives service(s)
  - Patient pays and leaves medical center

**Outputs**
- Treatment
- Medical Report
- Medical Record/Data
- Guidance
- Experience

**Customers**
- Patients
- Patients’ Families
- Management
- Doctors
- Nurses
- Support Staff

Stakeholder Analysis
(See Figure 7-21)

**Stages to Use:** Implementing and monitoring improvements

**Purpose:** To gauge the level of support from key people involved in a process change

**Simple Steps to Success:**
1. Obtain a project charter.
2. Based on the project charter, identify potential stakeholders—that is, individuals who play a role in the project. Create a grid with column headings on the left side for the names and roles of these stakeholders. (Also allow space in the grid for at least three columns on the right side, to be filled in during subsequent steps.) Row by row, enter the name and role of each stakeholder.
3. Through focus groups or interviews, determine the level of support (also known as buy-in) that each stakeholder shows for the project. Assign numerical values to reflect each person’s level of support. For example, as shown in Figure 7-21, on a scale of 1 to 10, a value of 1 represents low support, and 10 represents high support. Another possible type of scale uses zero (0) as a midpoint, representing neutral feelings about the project. A positive 1 or 2 (+1, +2) indicates mild or strong support, respectively, while a negative 1 or 2 (-1, -2) represents mild or strong resistance. In the first of the right-side columns, fill in the level of support shown.
4. Determine the level of support needed from each stakeholder for the project to succeed. Assign numerical values, using the same scale as in the previous step, and place them in the second of the right-side columns.
5. Subtract the number in the column from Step 3 from the number in the column from Step 4. The difference between the two numbers represents the “gap,” which is placed in the third of the right-side columns. Using the 1-to-10 scale, if the gap number is 0, then the interests of the given stakeholder are perfectly aligned with the objectives of the process—congratulations! But more likely, the number will be greater than 0. The higher the number, the greater the discrepancy between support needed and support shown.
6. Based on the stakeholder analysis, an action plan may need to be developed to increase the level of support. An optional column (shown at the far right in Figure 7-21) may be added to the grid to indicate the strategy called for.

**TIPS FOR EFFECTIVE USE**
- Consider stakeholders at all levels, including both salaried and hourly employees.
- If employees involved in the project are unionized, meet with the union representative to explain the purpose of the project.
- Remember that while full support is ideal, not all stakeholders need to be at the same level of support for the project as a whole to succeed.
### Figure 7-21. Example: Stakeholder Analysis

<table>
<thead>
<tr>
<th>Location/area</th>
<th>Role in organization</th>
<th>Name</th>
<th>Target of change</th>
<th>Process owner</th>
<th>Leader of the change process</th>
<th>Decision maker</th>
<th>Interested</th>
<th>Supplier to the process</th>
<th>Current level of buy-in to change</th>
<th>Rate 1 - 10 with 1 being low need.</th>
<th>Needed level of buy-in</th>
<th>Rate 1 - 10 with 1 being low need.</th>
<th>Gap</th>
<th>Strategy to close the gap</th>
</tr>
</thead>
<tbody>
<tr>
<td>7W</td>
<td>Nurse Manager</td>
<td>H. A. Caring</td>
<td>Y</td>
<td>Y</td>
<td>9</td>
<td>10</td>
<td>1</td>
<td>Invite as Core team member</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7W</td>
<td>PT</td>
<td>Ree Hab</td>
<td>Y</td>
<td></td>
<td>2</td>
<td>8</td>
<td>6</td>
<td>Engage weekly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admin</td>
<td>CEO</td>
<td>Joy World</td>
<td>Y</td>
<td></td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>Update monthly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7W</td>
<td>Green Belt</td>
<td>Sharon Ways</td>
<td>Y</td>
<td></td>
<td>10</td>
<td>10</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Standard Work**

*(See Figure 7-22)*

**Stages to Use:** Implementing and monitoring improvements

**Purpose:** To create a logical workflow with a minimum of waste

**Simple Steps to Success:**
1. *Document the existing process steps* for each individual involved.
2. *Identify which steps are waste*—that is, they are of no value to the patient.
3. *Measure takt time* (the rate of patient demand) and cycle time (the time it takes to complete one cycle of an operation).
4. *Determine the optimum sequence of work steps* for each individual involved in the process.
5. *Implement changes in the process* to reflect the optimum sequence.
7. *If the changes are deemed successful, standardize the new process.*

---

**TIPS FOR EFFECTIVE USE**

- Strive for balance in the work required by each individual.
- Encourage everyone involved to think of standard work as “the right way—every time.”
Add picture(s) that assist with build - pictures used can show entire operation layout or finished Service at this station.

Circle required safety items
Root Cause Analysis in Health Care: Tools and Techniques, Fifth Edition

Stages to Use: Identifying opportunities for improvement; implementing and monitoring improvements

Purpose: To help health care organizations operate successfully by eliminating, or at least minimizing activities that do not add value—that is, any steps in a process that do not contribute to a patient’s experience of value

Simple Steps to Success:

1. Specify. Break down and analyze the entire value chain to calculate the value delivered by each process area, as perceived by the patient. This task involves having a cross-functional team literally walk through each step of the process, talking with workers in the value stream and taking measurements of the time it takes to do the work and the time spent waiting for the next step.

2. Map. After the value chain is broken down, the various steps are assigned value from the point of view of the patient and mapped in their respective places according to value delivered. Those areas that do not contribute value are considered waste and either minimized or eliminated. The remaining elements form the foundation for developing a true patient-centric value chain.

3. Flow. The purpose of this step is to create a smooth and efficient process flow between the value-added steps identified in order to transform the chain into a value stream for the organization. The increase in flow will ultimately improve lead times and eliminate “bullwhip” effects, creating maximum efficiency and productivity.

4. Pull. After the true value stream is established, services can be delivered in alignment with actual patient demand (that is, “pulled” along by the patient according to the patient’s timetable of need) and not by assumptions or arbitrary forecasts (that is, “pushed” onto the patient by the organization on a timetable set by the organization).

5. Perfect. The final, crucial step is bringing the principle of continuous improvement to the initiative. It is essential that an organization not allow the initial taste of success to get in the way of its continual pursuit of perfection. Ongoing process improvement is absolutely key to sustaining a competitive edge.

Value Stream Mapping

(See Figure 7-23)

TIPS FOR EFFECTIVE USE

- Keep the focus on the patient in any attempt to discern the value of a step in the process.
- Choose and use the correct tools.
- Provide advanced education to leaders.
- Explain the purpose of the walk-through to unit, section, or department staff.
- Communicate progress and results throughout the organization.
Figure 7-23. Example: Value Stream Mapping
CHAPTER 8

Root Cause Analysis Case Studies from the Field

CASE STUDY ONE

Root Cause Analysis of Serious Adverse Events Among Older Patients in the Veterans Health Administration

Alexandra Lee, MS; Peter D. Mills, MS, PhD; Julia Neily, MS, RN, MPH; Robin R. Hemphill, MD, MPH

In the United States, adults 65 years of age and older account for 13.0% of the population, and it is estimated that this demographic will grow to comprise 19.3% of the population by 2030.1 Hospitalized, older patients often have more complex medical needs than younger patients2–4 and are at higher risk for adverse events.5,6 Studies have shown that older adults, compared to other age groups, are more likely to experience significant morbidity and mortality as a result of falls in the hospital, polypharmacy, and surgical errors.7–9

In 1996, The Joint Commission required hospitals in the United States to conduct a root cause analysis (RCA) for adverse events causing sustained injury or death.10 The Veterans Health Administration (VHA) National Center for Patient Safety (NCPS) stores data about serious adverse events when a root cause analysis (RCA) has been performed. A primary objective of this study was to describe the types of adverse events occurring among older patients (age ≥ 65 years) in US Department of Veterans Affairs (VA) hospitals. Secondary objectives were to determine the underlying reasons for the occurrence of these events and report on effective action plans that have been implemented in VA hospitals.

Methods: In a retrospective, cross-sectional review, RCA reports were reviewed and outcomes reported using descriptive statistics for all VA hospitals that conducted an RCA for a serious geriatric adverse event from January 2010 to January 2011 that resulted in sustained injury or death.

Results: The search produced 325 RCA reports on VA patients (age ≥ 65 years). Falls (34.8%), delays in diagnosis and/or treatment (11.7%), unexpected death (9.9%), and medication errors (9.0%) were the most commonly reported adverse events among older VA patients. Communication was the most common underlying reason for these events, representing 43.9% of reported root causes. Approximately 40% of implemented action plans were judged by local staff to be effective.

Conclusion: The RCA process identified falls and communication as important themes in serious adverse events. Concrete actions, such as process standardization and changes to communication, were reported by teams to yield some improvement. However, fewer than half of the action plans were reported to be effective. Further research is needed to guide development and implementation of effective action plans.

Article-at-a-Glance

Background: Preventable adverse events are more likely to occur among older patients because of the clinical complexity of their care. The Veterans Health Administration (VHA) National Center for Patient Safety (NCPS) stores data about serious adverse events when a root cause analysis (RCA) has been performed. A primary objective of this study was to describe the types of adverse events occurring among older patients (age ≥ 65 years) in US Department of Veterans Affairs (VA) hospitals. Secondary objectives were to determine the underlying reasons for the occurrence of these events and report on effective action plans that have been implemented in VA hospitals.

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adverse events. By the end of 2000, the RCA process had been implemented across the VHA's 152 medical centers, which serve more than six million veterans.\textsuperscript{11,12}

There is limited research on systems-level action plans to improve care for hospitalized older adults. To date there are no studies describing reports of iatrogenic events in the older adult population within the VA health care system. The primary objective of this study was to describe the types and frequency of reported adverse events occurring among older patients (age ≥ 65 years) in VA hospitals nationally for one year. Secondary objectives were to determine the underlying reasons (root causes) for the occurrence of these events, report on action plans that have been implemented in VA hospitals, and to determine the extent of their effectiveness.

**Methods**

**Overview of the Veterans Health Administration National Center for Patient Safety Root Cause Analysis Program**

RCA is a systematic nonpunitive process to retrospectively analyze adverse events and develop action plans to prevent them from occurring in the future. The RCA process, as summarized in Figure 1 (above), is intended to answer three major questions: (1) What happened? (2) Why did it happen? (3) What can be done to prevent it from happening again?\textsuperscript{13}

When a serious adverse event occurs in the hospital, the VA facility's patient safety manager determines whether an RCA should be initiated. He or she codes the event according to a standardized Safety Assessment Code (SAC) Matrix.\textsuperscript{11,14} This matrix has two dimensions, one dimension based on the severity of the event (catastrophic, major, moderate, and minor injuries) and the other, on the probability of recurrence (Figure 2, page 177). The adverse event may result in a score of 3 (high risk), 2 (intermediate risk), or 1 (lowest risk). The patient safety manager is required to conduct an RCA review if the adverse event has scored a 3, which includes all events resulting in a catastrophic patient outcome and events resulting in major injury that are likely to reoccur several times in one year. Patient safety managers may also decide to conduct an RCA on events that have scored a 2, which includes all other events resulting in major injury or events resulting in moderate injury and likely to reoccur several times in one year. It is unlikely that the patient safety manager will conduct an RCA on a case that has scored a 1.
Within the VHA, tools to standardize the RCA process have been developed, such as a computer-aided tool and a flipbook containing triage questions to help teams determine a systems-based root cause for the event. Team members, who are chosen by the hospital’s patient safety manager, include any staff member who works in the hospital, including physicians, nurses, social workers, and facilities management personnel. The team members may be subject matter experts or nonexperts who were not directly involved in the event being investigated. An expert of the subject matter will be able to offer insight on how the process is carried out. A nonexpert may be helpful in identifying vulnerabilities in the current system.

Having individuals involved in the adverse event on the RCA team may introduce bias on the basis of his or her own perspective of the event. Instead, such individuals are typically interviewed by team members to obtain further details on the event. Finalized RCA reports include a brief summary of the adverse event, root causes, action items, how actions will be measured, and effectiveness (reported as “worse,” “same,” “better,” “much better,” “not measured,” “not reported,” or “not implemented”).

Action items are informed by human factors concepts. This means that proposed actions are developed to improve the process or environment to minimize the likelihood that a mistake would happen in the future, rather than placing blame on an individual. For example, if a patient fell because he or she did not have proper monitoring, the RCA team may consider whether fall prevention policies were comprehensively written and easily understood by staff members, if overall staffing was sufficient, or if providers had clear means of communication to know that there was a patient at high risk for falls under their care. These cases are stored in a secure computerized reporting system, where they are available for review by NCPS staff.

---

**Figure 2. Safety Assessment Code (SAC) Matrix**

<table>
<thead>
<tr>
<th>Severity</th>
<th>Catastrophic</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Severity</strong></td>
<td>Patient death, or permanent loss of function, not related to the patient’s illness or underlying condition</td>
<td>Permanent lessening of bodily functions, not related to the patient’s natural course of illness</td>
<td>Event leading to increased length of hospital stay, or increased level of patient care</td>
<td>No injury, no increased length of stay, or change in level of patient care</td>
</tr>
<tr>
<td><strong>Probability</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequent</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Frequent</td>
<td>Event is likely to reoccur several times in 1 year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occasional</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Occasional</td>
<td>Event may occur several times in 1 to 2 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Uncommon</td>
<td>May happen once in 2 to 5 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Remote</td>
<td>May happen once in 5 to 30 years</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The Safety Assessment Code (SAC) Matrix is used to score cases on the basis of the severity of the event and the probability of recurrence.

Selection of Included Geriatric Adverse Events RCA Reports
To identify all RCA reports of geriatric adverse events occurring within a one-year period, we searched the NCPS database from January 2010 to January 2011. All RCA reports that listed the patient as 65 years old or older were included in the analysis. Reports in which the patients’ age was unknown were manually reviewed and assessed on a case-by-case basis to determine eligibility ($n = 6$). We read each case summary and included RCA reports that mentioned characteristics that were likely to indicate that the patient was 65 years old or older, such as the fact that the patient was receiving care from a nursing home, community living center, or hospice or had a diagnosis typical for older patients.

Cases were coded on the basis of the type of adverse event, root causes, action items, outcome measures, and effectiveness of each outcome. The root causes were classified by using a predefined rubric developed by the NCPS that organizes root causes into five categories—communication, environment/equipment, training, rules/policies/procedures, and staff fatigue/scheduling problems, to which we added “patient characteristics.”

The type of outcome measure was classified into three categories using Donabedian’s framework for assessing quality of care: outcome, process, and structural indicators.\(^{17}\) An outcome indicator describes the effect of care on the health status of a patient or patients.\(^{18}\) In the context of measuring the effectiveness of fall prevention strategies, an example of an outcome indicator includes a reduced rate of patient falls resulting in injury. A process indicator assesses changes in the provision of care\(^ {18} \) (for example, the proportion of fall risk assessments conducted that include assessment of orthostatic hypertension), and a structural indicator measures changes made to the care setting\(^ {18} \) (for example, hiring of additional nursing staff.) A major limitation is that the progression from structure to process to outcome is poorly established.\(^ {17}\)

Two researchers [A.L., P.D.M.] coded the RCA reports. The first 10 cases were independently coded, with discrepancies discussed until consensus was reached. The subsequent 10 cases were coded achieving acceptable interrater reliability (kappa = 0.825). The remaining 305 cases were independently coded.

Defining an Effective Action Plan
Each case was reviewed to determine if implemented action plans had any reported effect on patient outcomes or changes in provider practices. An effective action plan was determined based on two criteria, as follows:

- The action must have resulted in a “better” or “much better” outcome (on the basis of the report from the VA facility where staff assessed the impact of the change).
- The type of the outcome measure must have been a process or outcome indicator as defined above.

We excluded structural indicators, as they do not clearly translate into improvements in patient care.\(^ {17}\)

Results
Number of Included Root Cause Analysis Reports
From January 2010 to January 2011, we identified 504 potentially eligible RCA reports. We focused on events that resulted in mortality or major to severe injury (permanent lessening of bodily functioning, events requiring surgical intervention or increased length of stay),\(^ {11}\) resulting in 325 RCA reports that were included in our final analysis. These reports revealed 333 adverse events, 699 root causes, and 1,183 proposed action plans.

Geriatric Adverse Events
Falls were the most commonly reported event leading to significant injury or death among patients (34.8%, $n = 116$). Other events included delays in diagnosis and/or treatment (11.7%, $n = 39$), unexpected death (that is, the clinical prognosis did not reflect the imminent death of the patient) (9.9%, $n = 33$), adverse drug events (9.0%, $n = 30$), and surgical errors (8.7%, $n = 29$). Figure 3 (page 179) provides an overview of these adverse events.

Root Causes
Figure 4 (page 180) summarizes root causes as identified using the NCPS framework.\(^ {14}\) Communication, including both verbal exchanges and written documentation, was the most common root cause of adverse events among older VA patients (43.9%, $n = 307$). Within the communication category, communication among providers (13.4% of all root causes, $n = 94$), missed assessments (7.9%, $n = 55$), lack of documentation (5.0%, $n = 35$), and communication with patients and/or their caregivers (3.6%, $n = 25$) accounted for most of the communication issues.
Problems related to equipment and the hospital environment accounted for 21.6% \((n = 151)\) of the root causes, with issues mostly arising from lack of medical equipment (4.3%, \(n = 30\)), practical issues that arise from work with various technology systems (2.1%, \(n = 15\)), and equipment malfunction (1.9%, \(n = 13\)).

Rules, policies, and procedures accounted for 16.9% \((n = 118)\) of the identified root causes, with the predominant reasons including procedures having a lack of a standardized protocol (10.4%, \(n = 73\)) and lack of staff adherence to a protocol (3.0%, \(n = 21\)).

Insufficient or lack of staff training accounted for 7.7% \((n = 54)\) of root causes. Adverse events related to insufficient/lack of training for one staff member (personal) accounted for 0.7% \((n = 5)\) of the root causes. Insufficient/lack of training for two or more staff members (institutional) accounted for 7.0% \((n = 49)\) of the root causes.

Staff fatigue and scheduling problems accounted for 7.3% \((n = 51)\) of root causes, with work overload (3.6%, \(n = 25\)) and lack of available services/access delays (0.9%, \(n = 6\)) as the main contributing factors.

The NCPS root cause analysis process advises RCA teams to focus on systems issues when developing root causes; therefore, few reports cite patient characteristics as a root cause for an adverse event.

However, in some cases, when the team cannot determine a systems-level root cause, the patient’s medical condition or compliance with the treatment plan may be reported as the underlying cause for an adverse event. In our analysis, patient characteristics accounted for 2.6% \((n = 18)\) of the root causes, specifically medical condition (2.1%, \(n = 15\)) and compliance (0.4%, \(n = 3\)).
Action Plans

Of the 1,183 proposed actions, 96.7% \((n = 1,144)\) were implemented, of which 60.8% \((n = 696)\) had outcomes assessed and were documented in the RCA report. Of the action plans for which outcomes were assessed, 39.5% \((n = 275)\) were considered effective on the basis of the two criteria defined in the Methods.

Figure 5 (page 181) summarizes all actions that were proposed by the RCA teams, as well as effective action plans. The most common action plans included process standardization (19.1%, \(n = 226\)), staff training (15.5%, \(n = 183\)), changes made to written documentation (11.3%, \(n = 134\)), changes made to information display (8.9%, \(n = 105\)), and revisions/updates made to a current policy (6.4%, \(n = 76\)). The most effective actions plans were related to process standardization, communication, equipment, and environmental changes.

Eighty-nine of the 226 (39.4%) action plans involving process standardization yielded an effective outcome. Examples of process standardization included a neurological examination in fall risk assessments, development of order sets for high-risk procedures, and implementation of a standard protocol for the transfer of patients. Both changes made to verbal communication (52%, 13 of 25 action plans) and written documentation (29.9%, 40 of 134 action plans) resulted in effective outcomes. Examples of action plans to enhance communication included conducting multidisciplinary meetings to ensure that patients at high risk of falling were receiving appropriate interventions, standardizing documentation to keep advance care directives up to date, and streamlining communication between providers and caregivers on the patient’s plan of care.

Equipment-related (50%, 9 of 18 action plans) and environmental changes (25.8%, 8 of 31 action plans) also led to improved outcomes. Examples of these changes included purchasing and implementing the use of nonskid socks for
CHAPTER 8 | Root Cause Analysis Case Studies from the Field

Figure 5. Root Cause Analysis (RCA) Reports of Action Plans for Geriatric Adverse Events Resulting in Serious Injury or Death in 2010, $N = 1,183$

This figure summarizes all actions that were proposed by the RCA teams, as well as effective action plans.

Discussion

Our findings indicate that communication problems were the most common underlying reason for reported adverse events among older VA patients. Such problems included inconsistent communication between providers and lack of clear documentation regarding the patient’s fall-risk status. For example, handoff communication between nurses at change of shift did not always include patients’ fall-risk status and needed precautions. In addition, physicians may not have been contacted when a patient was found to have orthostatic hypotension, and pharmacists may not have been consulted when a medication review was needed. Other significant contributors included problems with equipment and the hospital environment.

The NCPS root cause analysis process focuses on identifying root causes from a systems-level perspective and implementing subsequent action plans that provide a structure to minimize human error rather than placing blame on individual providers. Approximately 40% of the completed action plans resulted in an effective outcome. Concrete actions, such as process standardization, changes to communication, and changes to equipment or the environment, were most likely to yield improvement. The report from bedside clinicians regarding the effectiveness of action plans is a unique feature of this report.
There have been many studies conducted assessing falls, medication errors, and surgical errors among older patients. Falls, in particular, are a common and serious event in the hospital. Generally, fall rates among all ages have been reported from 2.9 to 13 falls per 1,000 bed-days of care.7 Falls may result in injury (both psychological and physical), leading to longer hospital stays and increased risk of discharge to a long term care facility.19,20 Reducing falls in the hospital is a complex problem that involves creating a safer environment and implementing individualized interventions to modify patient risk factors for falls and fall-related injuries.21

Although most medication errors do not result in injury,22,23 polypharmacy is common among older patients, which suggests that they may be at greater risk of experiencing an adverse drug event.8 For example, among 1,523 adverse drug events identified by Gurwitz and colleagues in older patients in an ambulatory setting, 27.6% were judged preventable. These events occurred in the prescribing (58.4%) and monitoring (60.8%) stages of pharmaceutical care. Patient adherence was implicated in 21.1% of the cases.8 In our analysis of the RCA database, issues that arose from the inpatient bar-coding medication administration system, patient monitoring, lack of medication reconciliation, and patient compliance were contributory factors toward adverse drug events in older VA patients.

Older patients have the highest mortality rate in the adult surgical population.9 Preoperative assessment can help guide the treatment course and determine if high-risk surgery is necessary for the older patient, or if a less invasive procedure is more appropriate.24 Furthermore, postoperative monitoring may prevent the occurrence of an adverse event. Again, we found problems with monitoring patients
and missed or incorrect assessment to contribute toward adverse events.

Among reported action plans, staff training (15.5%, \( n = 183 \)) and improving a policy (6.4%, \( n = 76 \)) were frequently implemented; however, they did not necessarily translate into improved processes and patient outcomes. Such actions are considered weak compared with actions that might change the environment in a way that will make a fall less likely to happen (for example, removing a rug that a patient might slip on). Moreover, our findings suggest that reporting a patient’s medical condition or compliance with the treatment plan as an underlying cause does not promote the development of effective action plans for hospital patient safety and quality improvement efforts.

After the RCA team has developed action plans, the next step is implementation. The NCPS root cause analysis framework does not specifically comment on how to implement actions; such strategies will differ for each institution, depending on numerous factors, such as the type of action and how they will meet the needs of patients and providers within a particular setting. However, the RCA team assigns an individual or team the responsibility of implementation within a predefined time period. Following implementation and outcome assessment, effectiveness of the action plan is reported back to the patient safety manager. We found that 59.3% of the proposed action plans were implemented and measured for effectiveness—a relatively low rate that highlights difficulty of implementing changes.

The NCPS root cause analysis process provides a standardized framework for identifying root causes of an adverse event and developing an action plan. The NCPS uses a variety of strategies to share aggregated RCA findings, such as sharing lessons learned, publishing manuscripts, issuing patient safety alerts, and sharing information among patient safety managers.

**Recommendations for Hospital Quality Improvement Teams**

We recommend implementation of the following action plans to provide effective care to patients and minimize geriatric adverse events. We were able to determine that these action plans or similar action plans were implemented at multiple VA facilities and yielded effective outcomes in the reviewed cases and that they seemed feasible to implement at other hospital facilities.

- Ensure that the patient’s advance care directives are documented and clearly communicated to hospital providers.
- Standardize handoff communication among providers, using tools such as pocket guides or electronic templates.
- Enhance education provided to hospital staff through interactive drills, such as a mock code or simulation training.
- Provide patients at high risk of fall with proper equipment (for example, nonslip footwear, bed alarms, or chair alarms) and mitigate environmental hazards (for example, unnecessary furniture and clutter). If these interventions cannot be put in place, one-on-one staff supervision may be necessary.
- Standardize the stocking of crash carts through the use of a checklist. In addition, human factors principles can be implemented in organizing the crash cart (for example, arranging supplies according to order or frequency of use in a way that is common to all units).
- Implement a time-out procedure before all surgical procedures, include discussion of potential complications of the case involving an older patient, and standardize the count of supplies prior to closing the patient. Support from hospital leadership, appropriate human factors education, and regular multidisciplinary team communication may help promote staff compliance with this process.
- Review of patient’s medications and medication reconciliation may avert many iatrogenic events, such as falls, unexpected death, and medication errors.

**Limitations and Conclusions**

Results obtained are based on the written reports of patient safety managers at local VA facilities, but the staff who originally submitted the reports of adverse events and conducted the RCAs did not have this study in mind. At the same time, the main purpose of submitting RCAs to a central database is to enable the aggregation and subsequent dissemination of the lessons with the field. This study does not include adverse events caused by individual practitioner-specific practice issues or errors in judgment, which are complex and difficult to determine and manage in a system other than RCA. We did not independently verify the process used to identify root causes or develop action
plans. Adverse events in the VA system are based on voluntary reports submitted to the facility patient safety manager. There is likely variation among facilities regarding the percentage of actual adverse events that are reported. We do not know how the actual rate of adverse events compares to the reported rate. We do know that events that are reported provide us with rich opportunities to improve the safety of care for older patients. Despite the variation that may occur in reporting among national VA hospital facilities, the NCPS does take steps to standardize the process. Parts of the program include a three-day training session for all new patient safety managers, resources via the NCPS intranet and Internet sites, and monthly conference calls.11

In addition, patient safety managers at VA facilities report on the effectiveness of their action plans. There is a potential for bias, as facilities may want to positively report on their efforts. However, all patient safety managers are trained in a standardized manner, and there are no penalties for reporting on an action plan that was found not to be effective.

In some cases, multiple actions were implemented simultaneously, and therefore it was difficult to determine the specific actions responsible for improved patient care. However, in the RCA reports, when multiple components of an action plan are implemented, patient safety managers are prompted on a computerized system to report outcomes on each individual action. Therefore, we were able to draw limited conclusions on the effectiveness of these components. Finally, patients included in the analysis are from VA hospitals and may not accurately reflect the general population. Despite these differences in patient characteristics, we believe that our findings fill a gap in knowledge toward describing adverse events among older patients in a national health care system and that the implemented action plans may provide insight for other institutions’ patient safety efforts.

References


CASE STUDY TWO

Using Root Cause Analysis and Form Redesign to Reduce Incorrect Ordering of HIV Tests

Reed A.C. Siemieniuk; Kevin Fonseca, PhD; M. John Gill, MB, FRCPC

The unrealistic expectation for physicians to practice flawless medicine persists to a great extent, both within the medical community and within the population at large, more than a decade of focused efforts to unearth and “humanize” the entrenched nature of medical errors notwithstanding.1,2 Although there have been sporadic advances in the identification and prevention of errors, particularly with regard to medication administration3,4 and surgical procedures,5,6 errors in arriving at the correct diagnosis remain elusive.

Errors in arriving at the correct diagnosis may make up a large proportion of all medical errors and cause considerable morbidity and mortality.7,8 The human factors components, including formulating a diagnosis (which involves appropriate clinical suspicion and acumen, requesting the originally intended tests, and accurate interpretation of these tests), are at high risk of error in the increasingly complex nature of medical practice. Reports of such errors to date, however, have been scarce8 and have relied on convenience samples such as retrospective self-reports by physicians9 or reviews of malpractice claims.10

Given the rapid changes in microbial nomenclature, it may be particularly difficult for practicing physicians to remain current and ensure appropriate ordering of tests for infectious diseases. With the increasing use of novel molecular techniques, more precision has become available for the classification and consequently for naming and even renaming of microorganisms and viruses. Taxonomy experts have identified the classification and naming of viruses as a “logistical challenge,” with thousands of new viruses and sequences needing classification.11 In the similar situation of naming of both new and generic drugs, confusing look-alike, sound-alike names have been shown to cause serious errors in drug administration, resulting in adverse patient outcomes. To protect practicing physicians from this systemic risk for medical errors, the World Health Organization and the US Food and Drug Administration

Article-at-a-Glance

Background: Advances in molecular biology and changes in microbial nomenclature may subject diagnostic microbiology to errors. A patient diagnosed with Pneumocystis jiroveci pneumonia and then with AIDS had received a negative “AIDS test”—“negative for antibodies to HTLV 1 and 2.” The test requisition showed that the physician had requested HTLV-I/II testing but not an HIV-1/2 test. A root cause analysis was performed to determine if the erroneous testing represented a systemic problem. A study was conducted to identify and address such testing errors.

Methods: For the 1,952 HTLV-I/II test requests in a 17-month period in the Southern Alberta region, a random representative sample of 555 requests for HTLV-I/II testing were evaluated for appropriateness. Physicians ordering “inappropriate” tests were surveyed to determine root causes, and the HTLV-I/II check box was subsequently removed from the requisition.

Results: Some 318 (94%) of the 340 clinically directed HTLV tests were likely or definitely inappropriate—that is, only an HIV-1/2 test was required. At least 81% (127/156) of the 8% (156/1,948) of the HTLV-I/II tests ordered without an HIV-1/2 test concurrently were ordered inappropriately. In the telephone survey, all 69 physicians suspected to have incorrectly ordered HTLV-I/II tests reported erroneously requesting HTLV for HIV. A root cause analysis identified confusing viral nomenclature, diagnostic testing menu, and form design as contributing factors. A requisition recall and redesign has reduced erroneous laboratory testing.

Conclusions: A high proportion of HTLV-I/II tests were ordered erroneously and confused with HIV-1/2. Careful attention to routine test menus and form design, including the exclusion of rare and confusing pathogens, reduces risk of error for practicing physicians.
have actively initiated major programs to preclude the use of confusing drug names.3

Human immunodeficiency virus (HIV) and human T-cell lymphotropic virus (HTLV) share some history. The virus responsible for causing AIDS was first described in 1983.12 In North America the name most commonly used was HTLV-III. This name was initially chosen because the virus was closely related to other members of the family Retroviridae_HTLV-I and -II.12,13 In 1986 a special subcommittee of the International Committee on Viral Nomenclature standardized the “AIDS virus” nomenclature, officially naming it HIV.14 HTLV-IV was discovered in 198615,16 and also had several names before its current name of HIV-2 was established in 1987.17

HTLV-I is a human pathogen associated with two rare conditions: Tropical spastic paraparesis and adult T-cell leukemia.18 These conditions are seldom seen in North America but are reported more widely in southwestern Japan, parts of Africa, parts of South America, and the Caribbean.19 Recent evidence suggests that HTLV-I may also be associated with bronchiectasis in some indigenous populations20 and a rare form of infective dermatitis.21 To date, the only evidence of HTLV-II–associated disease comes from occasional case reports; as such, its pathogeneity is uncertain.22 Because both viruses may be transmitted parenterally, testing for HTLV-I and HTLV-II has been undertaken routinely for more than a decade for tissue/blood screening purposes and on a case-by-case basis for clinical diagnosis of HTLV-I disease. Reports have described two potentially clinically significant retroviruses that have been named HTLV-3 and HTLV-4.23,24

In 2009 a 21-year-old man presented to the hospital with cough, fever, shortness of breath, and weight loss. He was diagnosed with Pneumocystis jiroveci pneumonia and subsequently with AIDS. This diagnosis surprised him because he had recently received a negative “AIDS test” after disclosing a high-risk lifestyle to his physician. He produced a copy of the report of this earlier test, which showed that he was “negative for antibodies to HTLV 1 and 2.” A review of the test requisition showed that the physician noted significant HIV risks and requested chlamydia, hepatitis, and HTLV-I/II testing but not an HIV-1/2 test. Subsequent testing of the original sample confirmed that this index patient was positive for HIV-1/2 at that time. A root cause analysis (RCA) was performed to determine if the erroneous testing for HTLV-I/II rather than HIV-1/2 (when AIDS was a concern) represented a systemic problem. We report on the identification and intervention of testing errors to reduce such risks for the future.

Methods
Design Overview and Setting
All laboratory requisition forms requesting HTLV-I/II testing submitted to the Southern Alberta Laboratory of Public Health (SALPH; Calgary, Alberta, Canada) between March 1, 2008, and July 31, 2009, were reviewed for appropriateness on the basis of clinical information provided by the physician (Figure 1, page 188).

The SALPH is the sole provider of HIV-1/2 and HTLV-I/II testing services (apart from blood transfusion service) for a diverse region composed of approximately 1.6 million people, most of whom live within the city of Calgary. There are 39 hospitals, with more than 3,500 practicing physicians, within the laboratory’s catchment area. A single standardized requisition form that requests clinical information is employed in the region.

All known HIV-1/2–positive patients, including the index patient, were excluded from the study, as were all tests performed within recognized and well-established fertility and tissue donation programs. This study was approved by the Conjoint Medical Bioethics Committee at the University of Calgary.

Requisition Review
The “study,” which we conducted from August 2009 through March 2011, consisted of two parts, known as Study 1 and Study 2. In Study 1, drawing on a computer-generated random number list, we selected a representative sample of 555 HTLV-I/II requisitions and reviewed each requisition for appropriateness. In Study 2, we evaluated all HTLV-I/II tests requisitions that did not concurrently order HIV-1/2 testing. Reviews of all requisitions was performed by one of the authors [R.A.C.S.] and reviewed by a second [M.J.G.].

The requisition’s mandatory fields, which were used to judge appropriateness of testing, included patient identifiers, ordering physician information, and check boxes for testing requested. Additional clinical information
requested included check boxes for HIV risk factors, such as homosexual/bisexual orientation, HIV–positive partner, multiple sexual partners, risks associated with an endemic country, sexual assault, HIV exposure, intravenous drug use, hemophilia, HIV–positive mother, tuberculosis, and anxiety because of undefined high-risk behavior. Check boxes for symptoms included fever, rash, respiratory symptoms, adenopathy, neurological symptoms, immune status, and systemic symptoms, as well as free-text space for details. The detailed risk information requested for public health purposes during the study period has now been eliminated as we move to the recommended widespread population-based testing with limited need for risk-based assessments. Additional check box testing included serologic testing for hepatitis (B and C) and syphilis, as well as specimen testing for chlamydia and other sexually transmitted pathogens.

In both Study 1 and Study 2, each HTLV-I/II test was assigned into one of the following four categories for appropriateness on the basis of the information available:

1. **Fertility/tissue donor screening:** Fertility screening prior to tissue or sperm donation ordered by individual physicians without formal laboratory preapproval
2. **Appropriate:** HTLV-I/II testing supported by disease-compatible history (for example, paresis or leukemia) or ordered by a neurologist, oncologist, or infectious disease specialist
3. **Likely inappropriate:** Unfocused HTLV-I/II testing ordered by a physician other than a neurologist,
oncologist, or infectious disease specialist with a lack of information for HTLV-I/II testing and testing for multiple unrelated viral and bacterial conditions

4. Inappropriate: HTLV-I/II testing with symptoms, risk factors, or concurrent sexually transmitted pathogen screening strongly suggestive of HIV-1/2 without any clinical information suggestive of HTLV-I/II

Blinded Seroprevalence Study
Provided there was an adequate residual sample, samples originating from inappropriate or likely inappropriate testing (categories 3 and 4) for HTLV-I/II alone were blinded and tested for antibodies to HIV-1/2 with enzyme-linked immunosorbent assay (Abbott, North Chicago, Illinois). The primary outcome was prevalence of HIV-1/2 infection among tests where the original intention was likely HIV-1/2 testing.

Physician Contact
All physicians ordering HTLV-I/II without concurrent HIV-1/2 testing and evidence of an intention for HIV-1/2 testing were sent registered mail in October 2009 to recommend contacting the patient for HIV-1/2 testing. A letter from the University of Calgary’s Chair of Ethics and a new laboratory requisition with completed patient identifiers were included. These physicians were also contacted by telephone by one of the investigators [K.F.] to determine the original testing intention and to solicit ways to improve the requisition process.

Root Cause Analysis
The incident case described in the introduction was brought to the attention of the medical director of the regional HIV program [M.J.G.], who, with the HIV testing laboratory, initiated an investigation into the root cause of the error. A voluntary group of three persons, representing the laboratory [K.F.] end-users [R.A.C.S., M.J.G.], and infectious diseases [M.J.G.], was established to determine the extent of the problem, all contributing factors, and any correctable systemic issues. Additional and extensive voluntary input from interested parties with expertise, including the laboratory academic staff, the Public Health Office, and the University Bioethics Committee, was formally sought out and provided.

The following three sources of concern were identified:
1. Test menu and form design. The provision of a check box on the test menu for a rare pathogen, the adjacency of HIV-1/2 and HTLV-I/II check boxes, and a small font (Arial, size 7)
2. Office practices. In some cases, nonprofessional office staff filled out requisition forms, and/or the exact source of the error remained unidentified but often suggestive of busy clinics with hasty form completion.
3. Confusing viral nomenclature. Some physicians were under the impression that HTLV and HIV were synonymous. This was particularly noted for HIV-1 versus HTLV-I/II.

Intervention
Following the RCA, HTLV-I/II testing and other uncommon tests were removed as check box options, on the requisition, and the form was officially recalled. The results of the interventions were reviewed by the testing laboratory, and process adjustments implemented as below.

Requisition Review, Recall, and Redesign
Because the RCA implicated, in part, test menu and poor form design in the inappropriate testing, a recall of the forms was initiated, with a replacement that excluded HTLV-I/II testing from the open menu but allowed a write-in option. The impact of this intervention on HTLV-I/II testing was assessed by evaluating the rate of HTLV-I/II tests likely mistaken for HIV-1/2 tests. On the basis of the results from the original review, the identification of any HIV-1/2 risk factor was again used as a marker of inappropriate HTLV-I/II testing. The primary outcome was a decrease in inappropriate tests per month before the form redesign (January 2008–April 2010) versus after the redesign (May 2010–November 2010). $P$ values were calculated with a two-tailed $t$-test.

Results
Requisition Reviews
Between March 2008 and July 2009, 1,952 HTLV-I/II tests were ordered, for which the requisitions were available for 1,948. In the random representative sample of 555 requisitions, 241 (43%) were requested from within Calgary, 96 (17%) from rural communities, and 218 (39%) did not list a location. Some 214 (39%) of the requisitions originated from fertility or tissue donation programs, and 1 requisition was not found; these screening programs were excluded from further analysis. Some 340 (61%) tests were ordered for clinical purposes, of which 318 (94%) were
inappropriate or likely inappropriate HTLV-I/II testing using criteria listed (Table 1, right). The most frequent risk factors listed were patient anxiety (49%) and multiple sexual partners (19%), while the most frequent ancillary tests requested were hepatitis B and/or C (61%) and syphilis (44%) (Table 2, right).

One hundred fifty-six (8%) of the 1,952 HTLV-I/II tests ordered in the 17-month period were not ordered with an HIV-1/2 test. In 29 (19%) of the 156 cases, the testing was likely appropriate, whereas HIV-1/2 testing was likely the intent in the other 127 (81%) cases (Table 3, on page 193). The ordering physician was identifiable in 123 of the 127 tests—69 physicians were identified. Thirteen of the physicians ordered more than one inappropriate HTLV-I/II test, and 3 physicians inappropriately tested more than 10 patients exclusively for HTLV-I/II.

### Blinded Seroprevalence Study

Some 97 (76%) of the 127 tests that were ordered inappropriately or likely inappropriately without concurrent HIV-1/2 testing had an adequate residual serum for further testing. These samples were blinded and tested for antibodies to HIV-1/2 by enzyme-linked immunosorbent assay—two (2%) of the samples were reactive. Confirmatory testing was positive in one case, while there was insufficient residual sample in the other for confirmation.

### Physician Contact

Before proceeding with the planned mail-out in March of 2010, a review of more recent HIV-1/2 testing revealed that 25 (20%) of the 127 patients had subsequently been tested for HIV-1/2 (all negative), supporting the notion that HIV-1/2 testing was the original intention. One patient included in the blinded seroprevalence study was later identified as having previously received an HIV-1/2 diagnosis outside the region. The reason for the HTLV-I/II test was unclear but may have represented the patient’s physician’s attempt to confirm the HIV diagnosis. The 69 physicians who inappropriately or likely inappropriately ordered HTLV-I/II testing without concurrent HIV-1/2 testing were contacted by telephone in March 2010 to determine the original intention of the HTLV-I/II test. They all confirmed that they did not intend to order HTLV testing but rather intended HIV testing. The physicians suggested that confusing viral nomenclature, poor form design, improper office practices, and inadequate knowledge contributed to the inappropriate tests.

### Testing Requests Postintervention

No complaints or inquiries regarding the redesigned form have been received in the two years since it was implemented. No requests for inappropriate HTLV-I/II tests have been received on the form.

### Table 1. Study 1: Analysis of a Random Sample of 555 HTLV-I/II Test Requisitions

<table>
<thead>
<tr>
<th>Indication</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Fertility/tissue donor screening</td>
<td>214 (39)</td>
</tr>
<tr>
<td>Clinically directed HTLV-I/II tests</td>
<td>340 (61)</td>
</tr>
<tr>
<td>2. Appropriate or likely appropriate</td>
<td>22 (6.5)</td>
</tr>
<tr>
<td>3. Likely inappropriate</td>
<td>80 (24)</td>
</tr>
<tr>
<td>4. Strong evidence of inappropriate testing</td>
<td>238 (70)</td>
</tr>
</tbody>
</table>

### Table 2. Clinical Indications for HTLV-I/II Testing*

<table>
<thead>
<tr>
<th>Clinical Information, n (%)</th>
<th>Study 1</th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Risks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gay/bisexual</td>
<td>10 (2.9)</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>HIV–positive partner</td>
<td>14 (4.1)</td>
<td>6 (3.8)</td>
</tr>
<tr>
<td>Multiple sexual partners</td>
<td>65 (19.1)</td>
<td>15 (9.6)</td>
</tr>
<tr>
<td>HIV–endemic area</td>
<td>10 (2.9)</td>
<td>7 (4.5)</td>
</tr>
<tr>
<td>HIV–positive mother</td>
<td>2 (0.6)</td>
<td>0</td>
</tr>
<tr>
<td>Bodily fluid exposure</td>
<td>34 (10.0)</td>
<td>9 (5.8)</td>
</tr>
<tr>
<td>Intravenous drug use</td>
<td>8 (2.4)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>1 (0.3)</td>
<td>0</td>
</tr>
<tr>
<td>Anxiety following nondefined risk</td>
<td>165 (48.5)</td>
<td>63 (40.4)</td>
</tr>
<tr>
<td>Symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td>5 (1.5)</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>Rash</td>
<td>5 (1.5)</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>Adenopathy</td>
<td>3 (0.9)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>4 (1.2)</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>Neurological</td>
<td>7 (2.1)</td>
<td>8 (5.1)</td>
</tr>
<tr>
<td>Immune status</td>
<td>3 (0.9)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>General/other</td>
<td>9 (2.6)</td>
<td>7 (4.5)</td>
</tr>
<tr>
<td>Representative Ancillary Testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B or C</td>
<td>207 (60.8)</td>
<td>58 (37.2)</td>
</tr>
<tr>
<td>Syphilis</td>
<td>148 (43.5)</td>
<td>40 (25.6)</td>
</tr>
<tr>
<td>Rubella</td>
<td>15 (4.4)</td>
<td>4 (2.6)</td>
</tr>
<tr>
<td>Varicella zoster virus</td>
<td>15 (4.4)</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>HIV-1/2</td>
<td>300 (88.2)</td>
<td>—</td>
</tr>
</tbody>
</table>

* Study 1: Random sample of all HTLV-I/II testing requests (fertility/tissue donation screening excluded). Study 2: All HTLV-I/II test requisitions ordered during a 17-month period without concurrent HIV-1/2 testing.
Requests for HTLV-I/II testing on clinical grounds with noted HIV risk factors continue to be received on the original forms but decreased from 24.8 to 17.3 tests per month seven months after the intervention ($p = .008$). The 29 ordering physicians were contacted promptly, all confirming that they did not intend to order HTLV-I/II testing.

Discussion

Confusing viral nomenclature, exacerbated by an extensive test menu and suboptimal form design, led to a high number of erroneous HTLV-I/II diagnostic tests, each incurring unnecessary costs and having the potential for patient harm. The potential for serious medical harm was evidenced not only by the index case but also by a higher-than-expected seroprevalence of HIV-1/2 (> 3%) among inappropriately ordered HTLV-I/II tests, compared with a population prevalence of about 0.1%. In our series, excessive and inappropriate testing for HTLV-I/II on clinical grounds was widespread—well over 90% of the HTLV-I/II tests were ordered erroneously.

Although we could not elucidate the precise contribution and relationship between the factors leading to the high error rates, the causation was likely multifactorial. We believe that this study reveals problems, as reflected in, for example, test menu, form design, and practitioner education—which can be addressed on a local-systems level—as well as the wider problem associated with viral nomenclature, which can be addressed only at the international level.

Health system issues such as optimizing teamwork in surgery\textsuperscript{5,6} and reducing medical errors from long work hours\textsuperscript{25} have received considerable attention following the Institute of Medicine’s landmark 2000 report \textit{To Err Is Human}.\textsuperscript{1,2} In contrast, form design has received little attention; it is essentially unregulated, with no international or national directives on how to limit potential for errors. Erroneous laboratory test ordering and interpretation, which are not easily systematically monitored or assessed, have likely been underrecognized and underreported.\textsuperscript{2,4,26} In our study, modification of the requisition form and monitoring for testing requested on original forms has immediately reduced risks. A broader, forward-looking oversight of the issue is required, particularly given the transition to electronic ordering.

Although this study was conducted with paper-based ordering, there are significant implications for computerized provider order entry (CPOE) systems. As the number of available laboratory tests in clinical medicine continues to proliferate and the tests become increasingly specialized, CPOE systems offer the opportunity to both educate physicians for optimal test ordering and to redirect any erroneous orders. An integrated clinical decision support system may be as simple as an automatic alert that HTLV is often confused for HIV. We recommend this approach, as opposed to one that prevents nonspecialists from ordering rare virology tests, which could lead to hazardous delays, as learned from experience with medication ordering systems.\textsuperscript{27} CPOE systems have a capacity to bring efficiency to our current system, in which physicians are contacted directly by a laboratory specialist when HTLV is likely to have been ordered in error. Although similar clinical decision support systems have been successful in increasing meaningful use of radiology testing\textsuperscript{28} and in reducing medication errors,\textsuperscript{29,30} these clinical decision support systems have not been widely adopted for reducing erroneous laboratory testing.

As the number of recognized pathogens, new names, and available diagnostic tests expands, this increasing complexity will inevitably lead to pressure on ordering physicians. Our study suggests that a broader approach to minimize the potential risks of look-alike, sound-alike names in viral nomenclature is needed. Sequential numbering of new viruses based on scientific grounds opens up the opportunity for clinical errors. This is a particularly pressing issue within the family Retroviridae, given that HIV-1 and -2 were originally named HTLV-III\textsuperscript{12–14} and -IV\textsuperscript{15,16} and that recently described human retroviruses are

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Table 3. Study 2: HTLV-I/II Testing During a 17-Month Period

<table>
<thead>
<tr>
<th>Tests</th>
<th>$n$ (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTLV-I/II requisitions</td>
<td>1,948</td>
</tr>
<tr>
<td>HIV-1/2 ordered concurrently</td>
<td>1,791 (92)</td>
</tr>
<tr>
<td>HIV-1/2 not ordered concurrently</td>
<td>156 (8.0)</td>
</tr>
<tr>
<td>1. Fertility/tissue donor screening</td>
<td>0</td>
</tr>
<tr>
<td>2. Likely appropriate testing</td>
<td>29 (19)</td>
</tr>
<tr>
<td>3. Likely inappropriate testing</td>
<td>27 (17)</td>
</tr>
<tr>
<td>4. Strong evidence of inappropriate testing</td>
<td>100 (64)</td>
</tr>
</tbody>
</table>

* For the 1,952 HTLV-I/III tests ordered, 4 requisitions could not be found for Study 2 and therefore could not be evaluated for appropriateness.
Currently, the International Committee on Taxonomy of Viruses, a subdivision of the International Union of Microbiological Societies, is tasked with recognizing and naming viral taxa. Although they attempt to “avoid or reject the use of names which might cause error or confusion,” their scope does not extend below the rank of species. The absence of formal oversight below the level of species can lead to confusion (for example, HTLV viruses are viruses of the species Primate T-lymphotropic virus, and therefore the committee has no influence on the common naming of HTLV viruses). The continuing exponential growth in the number of viruses recognized increases the possibility for further confusion between viruses.

Limitations
Our study was restricted to one geographic area and therefore may not be fully representative of other areas. However, it is a large and diverse area with urban and rural representation and included both outpatient and inpatient samples from all types of health care settings, thus mitigating the risk of sample bias. We determined appropriateness of HTLV-I/II testing on the basis of a limited number of risk factors, symptoms, and ancillary tests, which may have led to under- or overestimates of inappropriate testing. However, corroborating evidence from our telephone survey showing 100% specificity for inappropriate testing suggests that, if anything, we present a conservative estimate of the number of inappropriate HTLV-I/II tests. Moreover, although the requisitions were paper based, we believe that the risk factors identified are directly transferable to electronic health records, where the risk of patient harm may be further amplified or diminished or mitigated by testing of menu designs.

Conclusions
Physicians should be aware that test-ordering errors may not be infrequent and can lead to adverse patient outcomes. Two concerning areas leading to medical error were identified by our study at a regional reference laboratory. First, the issue of renaming pathogens for precise genetic phylogeny and the even more concerning practice of recycling older names (for example, HTLV-III and the recent HTLV-3) can be addressed only at the international level. Second, test-menu and requisition-form design can either amplify or mitigate the risk of testing errors. Laboratories should take explicit action to make test requisitions as clear as possible to mitigate this risk. A broad assessment of physician-ordering errors in the entire field of laboratory diagnostics is a logical but difficult next step in the quest of enhancing patient safety.

References


Counting Matters: Lessons from the Root Cause Analysis of a Retained Surgical Item

Abha Agrawal, MD, FACP

A retained surgical item (RSI)—a sponge, instrument, needle, or other item inadvertently left after a surgery or invasive procedure—is an uncommon but potentially serious event associated with significant morbidity and mortality for the patient and malpractice risk for the provider and the institution. In addition, a “foreign object retained after surgery” is one of 10 health care–acquired conditions for which the Centers for Medicare & Medicaid Services (CMS) does not provide hospitals with additional payment. RSI is subject to voluntary reporting as a sentinel event to The Joint Commission and mandatory reporting to the New York State’s incident reporting system (New York Patient Occurrence and Tracking System [NYPORTS]).

RSIs are uncommon but represent a persistent surgical complication. According to a 2003 report by Gawande et al., RSIs are estimated to occur in 1 of every 1,000 to 1,500 abdominal operations.

In the report, of the 61 RSIs (detected in 54 cases), 69% involved sponges, and 31% involved instruments; 54% of the RSIs were left in the abdomen or pelvis; 22% in the vagina; 7.4% in the thorax; and 17% elsewhere, including the spinal canal, face, brain, and extremities. Retained sponges are more common than instruments because of their small size, frequent use, and the ability to mimic intraabdominal contents when saturated in blood. The Minnesota Adverse Health Events Reporting System revealed that a quarter of all 161 RSIs between 2003 and 2008 occurred during obstetrical procedures, with nearly all of those cases involving vaginal deliveries.

RSIs can cause serious clinical complications, such as small-bowel fistulae, obstruction, visceral perforation, sepsis, or even death. They often lead to reoperation for removal of the object and management of complications. In addition to clinical complications, RSIs frequently lead to malpractice lawsuits. In one report, 87% cases of RSI resulted in malpractice litigation, with an average claim of $52,581.

Background: Retained surgical items (RSIs), such as a sponge, instrument, or needle, after a surgery or invasive procedure is an uncommon but potentially serious event associated with significant morbidity and mortality. A 27-year-old woman was discovered to have a retained vaginal sponge a week after she underwent the repair of a vaginal tear following normal vaginal delivery. The retained sponge was removed with no further complications.

Root Cause Analysis: The fundamental error involved the obstetric team’s failure to perform the standard protocol of counting sponges before, as well as after, the procedure. This was attributed to a lack of reminders to perform the count, relatively recent implementation of the sponge-count policy, and a breakdown in teamwork and communication between physicians and nurses.

Corrective Actions: The corrective actions focused on systems improvement, as opposed to the human error of the memory lapse. The sponge-counting process was reinforced by incorporating a sign-out at the end of obstetric procedures to ensure that the counts have been done and any discrepancies addressed. A specialized delivery note with mandatory field to document sponge count was implemented in the electronic health record as an additional reminder. All staff participated in a teamwork and communication training program.

Tracking Compliance: Since the incident’s occurrence in 2010, the staff has demonstrated 100% compliance with the corrective actions, and a retained surgical item complication has not recurred.

Conclusion: Individual accountability must be balanced with systems improvement, given that most medical errors are a result of fallible humans working in chaotic unpredictable, and complex clinical environment.
Another review of 40 cases of RSIs found that the average defense costs were $572,079 and the total indemnity payments were more than $2 million. RSI malpractice claims often fall under the doctrine of *Res ipsa loquitur* ("the thing speaks for itself"), implying that the presence of RSI itself is proof of negligence on the part of the defendant (the surgeon). In addition, RSIs drive up the cost of care and often attract critical media coverage implying proven negligence or recklessness on the part of the surgeon.

Regardless of the clinical outcome, this is a psychologically devastating complication both for patients, because it erodes their trust in our commitment to care for them, and for caregivers, in that it evokes a sense of personal failure, guilt, and embarrassment.

This article describes the root cause analysis (RCA) and lessons learned from the case of an unintentionally retained vaginal sponge in a patient following normal vaginal delivery. RCA is a structured method to analyze serious adverse events. Initially developed to analyze industrial accidents, RCA is now widely deployed as an error analysis tool in health care. A central tenet of RCA is to identify underlying systems problems that increase the likelihood of errors (called “latent errors”) while avoiding the trap of focusing on mistakes by individuals (called “sharp-end errors”).

This article provides a clinical summary of the case; the purpose and methodology of the RCA process; root cause findings; and corrective actions, including follow-up.

**Case Summary**

A 27-year-old woman presented to the hospital at 40 weeks of gestation with the complaint of lower abdominal pain. She had normal vital signs and category 1 fetal heart tracing. Labor was induced using vaginal misoprostol, and she delivered a healthy boy by normal vaginal delivery. She sustained a readily identifiable right vaginal sulcus tear during the delivery, which was repaired. The patient was monitored in the hospital for two days and discharged home in good condition.

She returned to the hospital a week later with lower abdominal pain and foul discharge from the vagina. On triage, the blood pressure was 145/88 mm Hg, the heart rate 94 beats per minute, and the temperature 98.7 degrees F (37.06°C). She was noted to have dark brown, malodorous vaginal discharge, as well as pelvic tenderness. The abdominal examination was normal except for mild lower abdominal tenderness. She had a white blood cell count of 11,830 per mm$^3$ with 76% neutrophils, hemoglobin of 13.5 gm per dL, and hematocrit of 40.6%. On sterile speculum examination, she was found to have a retained vaginal sponge, which was removed with ring forceps. There was no active bleeding and no clots. She was discharged home on oral antibiotics for one week, and recovered fully without complications. The attending obstetrician made a full disclosure of the error to the patient, who appeared comfortable with and accepting of the disclosure. To date, no further action has been taken by the patient, and she continues to follow up in the outpatient clinic.

**Methods**

**Setting**

The RCA for this case was conducted at a large academic, urban, tertiary care public hospital that performs about 2,600 deliveries annually, in addition to approximately 27,000 admissions, 130,000 emergency room visits, and 750,000 outpatient visits annually. The labor and delivery (L&D) area in the hospital has nine rooms, and the staff includes 19 obstetricians, 8 certified nurse midwives, 24 house officers, and 40 nurses.

**Root Cause Analysis**

**Process.** The RCA process at this institution is managed by the risk management department (RM). Following report of an adverse event, which is usually made by the clinical department where the incidence occurred, the RM director determines whether the event is reportable to NYPORTS and whether an RCA needs to be performed. NYPORTS has a mandatory requirement to conduct RCAs on some events, such as unexpected death or RSI.

For each RCA, RM convenes a work group, called an RCA Committee, which includes members from the key clinical areas involved in the case. In this case, the committee included the chief of obstetrics and gynecology, another senior obstetric attending, the director of nursing for labor and delivery, and a staff nurse, as well as leadership from perioperative services. The committee also included the RM director; representatives from patient safety and quality management; and senior members of hospital administration, such as the chief medical officer (CMO [A.A.]). The hospital policy does not permit the inclusion of clinicians involved in the adverse event in the RCA meetings. A senior
A physician is asked to chair the committee; for this case, the chief of orthopedic surgery served as chair. The director of RM facilitates the meetings, and a staff member from RM documents the discussion and minutes.

RM prepares a detailed clinical summary of the case, which is distributed to RCA participants in advance for review. In addition, the electronic health record (EHR), as well as the supplemental paper chart, is available for access to clinical information to facilitate the discussion.

The RCA process is designed to answer three basic questions: What happened, why did it happen, and what can be done to prevent it from happening again? Figure 1 (below) provides a schematic diagram of the three questions and how they were applied to this case. The RCA starts with clinical narrative followed by a discussion of the root cause(s). Participants are provided a copy of the locally developed “rules of conduct” that specifically prohibit the “name, blame, and shame” approach. The “Just Culture” algorithm is frequently used during the discussion. The discussion of “Why did it happen?” involves digging deeper by repeatedly asking “Why?” until no further causes can be identified. This allows the group to focus on root causes instead of proximal causes and permits discovery of potential systems vulnerability for improvement.

**Figure 1. Schematic Diagram of the Root Cause Analysis (RCA) Process**

- **What happened?**
  - A sponge was left behind inadvertently after repair of a vaginal tear postdelivery.

- **Why did it happen?**
  - Physician and nurse “forgot” to do the count: Human fallibility.
  - They failed to follow the mandatory sponge-count policy.
    - No reminders to do sponge count
    - Breakdown in teamwork and communication between nurse and physician
    - Relatively recent implementation of the policy about one year ago

- **What can be done to prevent it from happening again?**
  - Reminders
    - Time-out checklist and procedure at the end of the procedure
    - Mandatory reminder in postdelivery note
    - TeamSTEPPS™ training for L&D staff
    - Continuing education sessions for staff to reinforce policy

The RCA process is designed to answer three basic questions: What happened, why did it happen, and what can be done to prevent it from happening again? L&D, labor and delivery.
At the end of the RCA, the findings are summarized, and a standard of care determination is made with the following options in accordance with the NYPORTS requirements: (a) standard of care was met, (b) standard of care was met with room for improvement, (c) standard of care was not met attributable to systems, (d) standard of care was not met attributable to an individual practitioner. Options “c” and “d” can be combined. The standard of care determination is made by carefully following the just culture approach of balancing no blame with accountability.

**Findings.** The RCA elucidated the fundamental error in this case to be the failure of the obstetric team, including the physician and the nurse, to perform the standard protocol of counting sponges before, as well as after, the repair of the vaginal tear. This type of error, called *slips*, is described by Wachter as “... inadvertent, unconscious lapses in the performance of some automatic task,” which, he states, “probably represent the greater overall threat to patient safety.” In this case, there were no obvious extraneous factors to facilitate the memory lapse such as unexpected emergencies, other sick patients, understaffing, or excessive work hours. The team included a skilled nurse with years of experience in deliveries; a chief resident with excellent track record who was about to graduate as an independent physician; and an attending physician, also with an impeccable record of safety, who was closely supervising the team.

On further analysis, this error of omission was attributed to four root causes, as illustrated in Figure 2 (below) and as listed as follows:

1. Although the standard practice of performing sponge counts before and after a procedure has been widely adopted in the operating room (OR) for many years, it was only implemented in L&D about one year before the incident. Staff was provided in-services on the new policy, but no formal monitoring was in place to ensure compliance with the sponge-counting protocol after normal vaginal deliveries. In a busy clinical area with multiple rotating house officers, it was likely that the recently implemented sponge counting had not yet become an automated part of L&D staff’s work flow, leading to this RSI case.

2. The L&D is usually a busy area with multiple distractions; the presence of a newborn postdelivery unit was a particular source of distraction for the nurse involved.

3. There was no step downstream in the work flow to remind the team to do the sponge count if team members forgot to do it at the end of the procedure. In the absence of a reminder or a forcing function, this step remained dependent on imperfect human memory and therefore susceptible to failure. In the OR, unlike in L&D, sponge count is a part of the comprehensive World Health Organization (WHO) Surgical Safety Checklist, which includes a sign-out

![Figure 2. Root Causes in the Case of a Postdelivery Retained Vaginal Sponge](image-url)

*In the root cause analysis, the error of omission was attributed to a number of root causes.*
at the end of each procedure. The sign-out is held jointly by the surgeon and the nurse, and works as a final check to ensure that everything has been counted and discrepancies addressed.
4. Finally, because of a breakdown in the teamwork and communication between the physician and the nurse, they did not check on each other to prevent this error. A culture of hierarchy and resistance to escalation among clinical team members further exacerbated the lack of communication.

Following an extensive discussion of the root causes, the RCA Committee concluded that the standard of care was not met and was attributable to various systems vulnerabilities, as described above.

Corrective Actions
Because the fundamental error leading to RSI was an inadvertent omission of the already existent sponge-count protocol by the L&D staff, the corrective actions, including visual and electronic reminders, focused around strategies to reduce the probability of such omission in the future. The corrective actions were as follows:
1. The sponge count sheet used in L&D was modified to include the documentation of a sign-out process to verify that a sponge count has been performed correctly and any discrepancies have been reconciled (Figure 3, page 199). This sign-out is jointly performed at the end of the procedure by the surgeon and the nurse. The documentation of sign-out on the sponge-count sheet serves as a reminder and should help minimize omission of the sponge-counting protocol. Of note, the sign-out is already a part of the WHO Surgical Safety Checklist protocol in the ORs; incorporating it in the L&D workflow should also improve standardization of the work across clinical areas. It is noteworthy that we have not had a case of RSI in ORs since the case in 2010.
2. The postdelivery note in the EHR was modified to include a mandatory field to document the process and accuracy of the sponge/instrument count. A screenshot of the delivery note in the EHR is provided in Figure 4 (page 200). Although the EHR reminder will not prevent the retained sponge complication, it will alert the team of a potential omission sooner—that is, before the patient is discharged. There is strong evidence that computerized reminders and forcing functions are effective in ensuring that specific care tasks are completed. Our institution has implemented an enterprise-wide EHR, which is widely adopted across all areas of the hospital. Our own experience has demonstrated the positive role of computer-based reminders in improving adherence with specific clinical tasks, such as prescribing appropriate medications for congestive heart failure and performance of medication reconciliation on admitted patients.
3. The literature on RSIs suggests that a failure of communication among team members is the most frequent contributor to the event. Therefore, to improve teamwork and communication, all L&D staff members, including physicians, nurses, nurse midwives, and clerks, were required to participate in a structured team-building program. Because the institution had already been implementing one such program, TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety) across all departments, we decided to use TeamSTEPPS as the training tool to improve teamwork and communication in L&D as well.

TeamSTEPPS, a health care version of the aviation industry’s crew resource management program, was developed by the US Department of Defense and the Agency for Healthcare Research and Quality. The TeamSTEPPS framework is based on teaching four core skills—leadership, communication, situation monitoring, and mutual support, which are all intended to lead to desired outcomes in knowledge, attitudes, and performance (Figure 5, on page 200).

Tracking Compliance with Corrective Actions. The RM department compiles a list of corrective actions for all RCAs done at the hospital and distributes it to various departments for action. The clinical leadership of the department—the chief of service and the associate director of nursing—is responsible for implementing the corrective actions and reporting the status quarterly at the hospital’s quality council meeting, chaired by the CMO. RM presents a compiled report to the executive quality council, chaired by the CEO, and is responsible for ensuring compliance with corrective actions.

Results
For this case, the outcome measure to evaluate the effectiveness of corrective actions was the occurrence of an RSI in L&D—and we have not had any occurrence of an RSI in the department of obstetrics since the implementation
The sponge-count sheet used in labor and delivery (L&D) was modified to include the documentation of a sign-out process to verify that a sponge count has been performed correctly and any discrepancies have been reconciled. M.R., medical record; D.O.B., date of birth.

### Figure 3. Sponge Count Sheet

![Sponge Count Sheet](image)

The table and form are detailed as follows:

**BIRTHING ROOM-LABOR & DELIVERY VAGINAL DELIVERY COUNT RECORD**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>BEFORE PROCEDURE</th>
<th>FINAL COUNT (AFTER PROCEDURE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DETECTOS (4 X 4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADDED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAMpons</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADDED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAP RINGS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADDED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEEDLES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADDED</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pre-procedure Count**

Date/Time: _______  Signature/Title  Signature/Title

**Relief Count**

Time: _______  Signature/Title  Signature/Title

**Final Count**

Time: _______  Signature/Title  Signature/Title

**Correct:**

- [ ] YES  
- [ ] NO  → If NO complete additional information

**Notified:**

signature/title  Time: _______

**X-Ray Performed:**

- [ ] YES  
- [ ] NO  Time: _______

**Outcome:**

________________________________________________________

**Vaginal Packing:**

- [ ] YES  
- [ ] NO  

Type of Packing: ______________________________

Date to be removed: _______  By: __________________

Date packing removed: _______  Signature/Title

**Physician Signature:**

Date/Time: __________________

**RN Signature:**

Date/Time: __________________
of the corrective actions. Because an RSI is a rare event, the following two process indicators are tracked as proxies for the effectiveness of the interventions:

Random sampling of 45 charts per month from the L&D area to determine compliance with the sign-out and sponge-counting process. A sample monthly tracking form is provided in Figure 6 (page 201). The percentage of compliance with the process is tracked and reported on a monthly basis and has been sustained at 100% since January 2011.

Participation of 100% of L&D staff in the TeamSTEPPS training program. This goal was achieved in May 2011 within six months of the RCA—and has been maintained since.

**Discussion**

Lessons learned from adverse events are disseminated widely throughout the hospital at departmental meetings. In addition, selected cases are discussed at the monthly case-based patient safety grand rounds. The format of the grand rounds includes a clinical presentation of the case
followed by a discussion of the key lessons learned from the adverse outcome. The event is open to all staff and is widely attended by nurses, physicians, social workers, respiratory therapists, and administrators. As suggested in the literature, case-based learning is a valuable educational tool; sharing an actual clinical situation stimulates much greater clinician interest than discussing a generic patient safety topic.21,22

Strategies that were implemented in January 2011 on the basis of the findings of the RCA described in this article have helped us achieve sustained and perfect compliance with the corrective actions and no recurrence of an RSI. Three factors have been found to be significantly associated with an increased risk of RSI: emergency procedure, unplanned change in the procedure, and a high body-mass index (BMI).1 In a meta-analysis, Cima et al. concluded that the following surgical procedure characteristics and clinical variables were associated with a significantly increased risk for RSI and hence should require greater vigilance: complex surgical procedures, damage control (open abdominal procedures and staged and abbreviated procedures), emergency surgery, increased BMI, involvement of more than one surgical team, procedures that involve more than one body cavity (such as thoracoabdominal procedures and trauma), prolonged surgery, unexpected change in the course of a surgical procedure, and use of unusually large number of instruments.23 It is noteworthy that the RSI occurrence in this case was not associated with any of these risk factors; indeed, the literature suggests that not all reports of RSIs have been associated with these risk factors.24

**Limitations of Manual Sponge-Counting Process and Emerging Technology-Based Solutions**

Although ORs throughout the United States have widely adopted the protocol, sponge counting is frequently omitted after obstetrical procedures.1,2,25 In addition, as a manual practice, counting of sponges and other surgical items is not only labor intensive but fraught with vulnerabilities.26,27 Cima et al. concluded that the manual counting of surgical items is an inherently error-prone process and that a new technology was needed to break beyond this “performance boundary.”28(p. 131) Two technological adjuncts to the counting process have emerged that may hold the promise to make it more reliable in preventing RSI—bar coding (or data-matrix coding) of sponges and sponges embedded with radiofrequency identification (RFID).

In a randomized controlled trial in 300 general surgery operations, Greenberg et al. demonstrated that a bar-coded sponge system detected significantly more counting discrepancies than the traditional protocol. However, the system introduced new technical difficulties and increased the time spent counting sponges.29 An 18-month use of a data-matrix–coded sponge system eliminated RSIs from a high-volume surgical practice, as opposed to the finding of a retained sponge occurring an average of every 64 days when the former manual sponge-counting system

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**Figure 6. Sample Monthly Tracking Form to Audit Compliance with Corrective Actions**

<table>
<thead>
<tr>
<th>Indicators</th>
<th>No. of Charts Reviewed</th>
<th>Compliance Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponge/instrument counted prior to delivery</td>
<td>45</td>
<td>45/45 (100%)</td>
</tr>
<tr>
<td>Sponge/instrument counted after delivery</td>
<td>45</td>
<td>45/45 (100%)</td>
</tr>
<tr>
<td>Count correct</td>
<td>45</td>
<td>45/45 (100%)</td>
</tr>
<tr>
<td>If incorrect appropriate actions taken</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Patient left unit with vaginal packing</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Count documented in postdelivery note</td>
<td>45</td>
<td>45/45 (100%)</td>
</tr>
</tbody>
</table>
was used. Early experiments with RFID yielded encouraging results. It is important to note that cost can be an important consideration in the adoption of these new technological systems.

**Teamwork and Communication**

Better communication and teamwork among the OR team, including surgeons, assistants, and nurses, is an important component of reducing surgical errors. The literature suggests that is critical to not only provide training but also ensure that the training is continuously reinforced until the teamwork is fully integrated in the work flow and culture of the organization.

**Human Error and Accountability**

The path of least resistance in our RCA would have been to attribute the complication to an error by the nurse or the physician and pursue punitive actions. However, with the progress in patient safety during the last decade and a greater understanding of the concept of a just culture—or, a “safety culture”—we recognize that expecting humans to be perfect and therefore have no memory lapses will not solve the problem of medical errors. Instead, we must fight the instinct to blame individuals and replace it with a focus on identifying and improving systems flaws that allow the inevitable human error to occur and cause harm.

As Reason observed, “Human fallibility, like gravity, weather and terrain, is just another foreseeable hazard.” Now, a safety culture does not mean a lack of accountability; on the contrary, “balancing systems and individual accountability is . . . central to the operation of a safety culture.” It provides a framework to distinguish between “human error” (inevitable, and managed through systems change), “at-risk behavior” (such as work-arounds—managed by understanding and fixing the systems factors that promote such behavior), and “reckless behavior (“the conscious disregard of a substantial and unjustifiable risk”). A surgeon refusing to sign the operative site or to participate in time-out process will be considered reckless behavior and is worthy of punitive action. Fortunately, such instances are rare, and most errors fall into the category of human error or at-risk behavior.

In the case described in this article, it was concluded that in the absence of a behavioral pattern, the problem of the memory lapse was a typical human error. Our best defense against the almost inevitable memory lapses is to improve our system by creating memory aids such as checklists and read-backs, standardizing and simplifying routine tasks, improving teamwork among various care providers so that they can correct each other when they observe memory lapses, and most importantly, by learning from our errors when they do occur.

**Conclusion**

The case of an unintentionally retained vaginal sponge provides a vehicle for discussion of a balanced approach to analysis of surgical complication and formulation of strategies to prevent a recurrence of the event. This case also underscores the limitations of system improvement. No matter how rigorous the corrective actions, such as additional reminders after the already “mandatory” sponge-count process, there is no guarantee that someday somehow another team won’t forget to perform these new steps. Even with the application of technology, many vital tasks in clinical medicine will remain dependent on humans and their inherent fallibility.

**References**


action plan  The product of the root cause analysis that identifies the strategies that an organization intends to implement 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 the actions.

adverse drug event  An injury resulting from medical intervention related to a medication, including harm from an adverse drug reaction or a medication error.

adverse drug reaction  A response to a medicinal product that is noxious and unintended, and that occurs at doses normally used in humans for the prophylaxis, diagnosis, or treatment of disease or for the restoration, correction, or modification of physiological function.

adverse event  A patient safety event that resulted in harm to a patient.

affinity diagram  An illustrative tool used to organize a large volume of ideas or data into meaningful groups with logical connections.

aggregate  To combine standardized data and information.

aggregate data (measurement data)  Measurement data collected and reported by organizations as a sum or total over a given time period (for example, monthly, quarterly) or for certain groupings (for example, health care organization level).

benchmarking  Continuous measurement of a process, product, or service compared to those of the toughest competitor, to those considered industry leaders, or to similar activities in the organization to find and implement ways to improve it. This is one of the foundations of both total quality management and continuous quality improvement. Internal benchmarking occurs when similar processes within the same organization are compared. Competitive benchmarking occurs when an organization's processes are compared with best practices within the industry. Functional benchmarking refers to benchmarking a similar function or process, such as scheduling, in another industry.

brainstorming  The process of capturing people's ideas, without censoring or editing them, and organizing those thoughts around common themes.

capability chart  An analytical tool that uses upper and lower parameters for acceptable performance of tasks or processes in order to determine whether a given change in the process is capable of reducing variation in performance.

care  The provision of accommodations, comfort, and treatment to an individual, implying responsibility for safety, including care, treatment, service, habilitation, rehabilitation, or other programs instituted by the organization for the individual served.

change analysis  A study of the differences between the expected and actual performance of a process. Change analysis involves determining the root causes of an event by examining the effects of change and identifying causes.

change management  A tool used to encourage organizational acceptance of a change in process within a system.

check sheet  A form used to sort and group data, using check marks or similar symbols.
clinical error  A commission or an omission with potentially negative consequences for the patient that would have been judged incorrect by skilled and knowledgeable peers at the time it occurred. Synonym: medical mistake.

common-cause variation  See variation.

complexity  A high number of steps and handoffs in work processes.

complication  A detrimental patient condition that arises during the process of providing health care, regardless of the setting in which the care is provided. For instance, perforation, hemorrhage, bacteremia, and adverse reactions to medication (particularly in the elderly) are four complications of colonoscopy and its associated anesthesia and sedation. A complication may prolong an inpatient's length of stay or lead to other undesirable outcomes.

comprehensive systematic analysis  A process for identifying basic or causal factors underlying variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis is one type of systematic comprehensive analysis.

contributing factor  A circumstance, action, or influence that is thought to have played a part in the origin, development, or increased risk of an incident.

corrective action  See improvement action.

coupled system  A system that links two or more activities so that one process is dependent on another for completion. A system can be loosely or tightly coupled.

direct cause  See proximate cause.

discovery  In the legal sense, the required disclosure of pertinent facts or documents by parties in a legal action or proceeding.

DMAIC  The acronym for the five phases of Six Sigma implementation: Defining, Measuring, Analyzing, Improving, Controlling.

elopement  The unauthorized departure of a patient from a controlled care setting.

emergency  An unexpected or sudden event that significantly disrupts the organization's ability to provide care, treatment, or services, or the environment of care itself, or that results in a sudden, significantly changed or increased demand for the organization's services. Emergencies can be either human-made or natural (such as an electrical system failure or a tornado), or a combination of both, and they exist on a continuum of severity.

error of commission  A mistake that occurs as a result of an action taken. Examples include a drug being administered at the wrong time, in the wrong dose, or using the wrong route; surgeries performed on the wrong side of the body; and transfusion errors involving blood crossmatched for another patient.

error of omission  A mistake that occurs as a result of an action not taken. Examples include a delay in performing an indicated caesarean section, resulting in a fetal death; a nurse omitting a dose of a medication that should be administered; and a patient suicide that is associated with a lapse in carrying out frequent patient checks in a psychiatric unit. Errors of omission may or may not lead to adverse outcomes.

failure  Lack of success, nonperformance, nonoccurrence, breaking down, or ceasing to function. In most instances, and certainly within the context of this book, failure is what is to be avoided. It takes place when a system or part of a system performs in a way that is not intended or desirable.

failure mode and effects analysis (FMEA)  A systematic way of examining a design prospectively for possible ways in which failure can occur. It assumes that no matter how knowledgeable or careful people are, errors will occur in some situations and may even be likely to occur. Synonym: failure mode, effects, and criticality analysis (FMECA).

fishbone diagram (also called cause-and-effect diagram or Ishikawa diagram)  The visual representation to clearly display the various factors affecting a process. This can be a structured approach to root cause analysis. The diagram identifies the inputs or potential causes of a single output or effect. In a hospital, for example, work can be divided
into categories: responding to instructions (orders), using supplies and medications (materials), using equipment (machinery), providing the needed care or service in accordance with established procedures (methods), and the environment itself (environment). Those categories can be listed on a fishbone diagram as the different branches from which mistakes can arise. To complete the branches, brainstorm primary causes, ask together why they are occurring, analyze the causes, and prioritize and identify the likely root causes.

**five whys** A tool used to probe beyond the contributing factors or proximate causes to find the root cause(s) of an adverse event by repeatedly asking the question Why?

**flowchart** A pictorial summary that shows with symbols and words the steps, sequence, and relationship of the various operations involved in the performance of a function or a process.

**Focused Standards Assessment (FSA)** A requirement of the accreditation process whereby an organization reviews its compliance with a selected subset of applicable Joint Commission accreditation requirements (including the applicable National Patient Safety Goals, a subset of direct and indirect impact standards, a selection of standards that address accreditation program-specific high-risk areas, and the organization’s Requirements for Improvement [RFIs] from its last triennial survey); completes and submits to The Joint Commission a Plan of Action (POA) for any accreditation requirement with which it is not in full compliance, including identifying any required Measure of Success (MOS); and chooses whether to engage in a telephone discussion with a member of the Standards Interpretation Group staff to determine the acceptability of the POA or discuss any other area of concern. Alternatives for a Full FSA submission include FSA Option 1 (attestation that an FSA was completed, but not submitted to The Joint Commission), Option 2 (on-site survey with documented findings), and Option 3 (on-site survey without documented findings). The FSA encourages organizations to be in continuous compliance with the Joint Commission accreditation requirements and helps them to identify and manage risk. At the time of the next full survey, surveyors will validate that the MOS (if applicable or if submitted as part of the FSA process) was implemented and effective. The organization retains the option to complete self-assessment with all applicable accreditation standards in the FSA tool, available on the organization’s Joint Commission Connect™ extranet site. See also Intracycle Monitoring (ICM).

**function** A group of processes with a common goal.

**Gantt chart** A graphical depiction of the time frame for a long-term, complex project, including the numerous phases of the project, person(s) responsible, and targeted completion dates, used to help the project team gauge its progress.

**hazardous condition** A circumstance (other than a patient’s own disease process or condition) that increases the probability of an adverse event.

**histogram** A visual representation displaying the distribution of the data within a range of values.

**human factors** The study of the interaction of human performance (capabilities and limitations) in relation to elements of the system (the design of machines, jobs, and other aspects of the physical environment). Synonym: ergonomics.

**immediate cause** See proximate cause.

**improvement action** A solution required to prevent a problem from occurring or recurring due to the same root cause or interaction(s) of root causes. Synonym: corrective action.

**incident report (occurrence report)** A written report, usually completed by a nurse and forwarded to risk management personnel, that describes and provides documentation for any unusual problem, incident, or other situation that is likely to lead to undesirable effects or that varies from established policies and procedures.

**indicator** 1. A measure used to determine, over time, performance of functions, processes, and outcomes. 2. A statistical value that provides an indication of the condition or direction over time of performance of a defined process or achievement of a defined outcome.
individual served  The terms individual served, patient, and care recipient all describe the individual, client, consumer, or resident who actually receives health care, treatment, and/or services.

Intracycle Monitoring (ICM)  A process to help accredited organizations at various touch points in the triennial accreditation cycle with their continuous compliance efforts. The process involves access to an ICM Profile available on the organization’s Joint Commission Connect™ extranet site. The ICM Profile identifies high-risk areas and related standards areas and displays them within a Focused Standards Assessment (FSA) tool, which allows organizations to conduct a self-assessment of standards to identify and manage risk in the organization. See also Focused Standards Assessment (FSA).

The Joint Commission  An independent, not-for-profit organization, The Joint Commission is dedicated to improving the safety and quality of health care through standards development, public policy initiatives, accreditation, and certification. The Joint Commission accredits and certifies more than 15,000 health care organizations and programs in the United States.

Joint Commission International (JCI)  JCI extends The Joint Commission’s mission worldwide. Through both international consultation and accreditation, JCI helps to improve the quality and safety of patient care in many nations. JCI has extensive international experience working with public and private health care organizations and local governments in more than 40 countries.

Joint Commission Resources (JCR)  Not-for-profit affiliate of The Joint Commission designated by The Joint Commission to publish publications and multimedia products. JCR reproduces and distributes these materials under license from The Joint Commission. Go to www.jcrinc.org.

kaizen  An intensive process used to improve a small, focused issue in a week or less.

latent condition  A condition that exists as a consequence of management and organizational processes and poses the greatest danger to complex systems. Latent conditions can be identified and corrected before they contribute to mishaps.

Lean Six Sigma  A patient-focused health care management philosophy that promotes various proven methods of stabilizing, standardizing, and simplifying work processes to reduce waste and improve quality of care. Lean Six Sigma practices contribute to reducing adverse events, increasing patient perception of high-quality care, raising levels of staff retention and satisfaction, and saving the organization money.

licensed practical nurse (LPN)  A nurse who has completed a practical nursing program and is licensed by a state to provide routine patient care under the direction of a registered nurse or a physician. Referred to as licensed vocational nurse (LVN) in some states.

malpractice  Improper or unethical conduct or unreasonable lack of skill by a holder of a professional or official position; often applied to physicians, dentists, lawyers, and public officers to denote negligent or unskillful performance of duties when professional skills are obligatory.

measurement  The process of collecting and aggregating data.

medication  Any prescription medications, sample medications, herbal remedies, vitamins, nutriceuticals, vaccines, or over-the-counter drugs; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, and intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the US Food and Drug Administration (FDA) as a drug. This definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases.

medication error  A preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.
multivoting A tool used to narrow down a broad list of ideas (such as those generated through brainstorming) to those that the team members collectively find most worthy of immediate attention.

near miss A patient safety event that did not reach the patient; also called a close call or a good catch.

negligence Failure to use such care as a reasonably prudent and careful person would use under similar circumstances.

no-harm event A patient safety event that did not result in harm to the patient.

occurrence report See incident report.

operational definition A description of a concept demonstrated by the process that includes a means of measurement. An operational definition may be used during the creation of a project charter, when defining a customer's requirements, when collecting data, or when analyzing capability.

operative or other high-risk procedures Operative and other invasive and noninvasive procedures (performed in order to remedy an injury, ailment, defect, or dysfunction) that place the patient at risk. The focus is on procedures and is not meant to include medications that place the patient at risk.

outcome The result of the performance (or nonperformance) of a function(s) or process(es).

outcome measure A tool used to assess data that indicates the results of performance or nonperformance of a function or procedure.

Pareto chart A vertical bar graph that displays the data being studied in order from largest to smallest. The Pareto chart is useful in analyzing the frequency of problems or causes in a process, when wanting to focus on the most significant problems or concerns, when analyzing broad cases by looking at their specific components, and when communicating about data.

patient safety event An event, incident, or condition that could have resulted or did result in harm to a patient. See also adverse event, near miss, sentinel event.

Plan-Do-Study-Act (PDSA) cycle A four-part method for discovering and correcting assignable causes to improve the quality of processes. Synonyms: Deming cycle, Shewhart cycle, Plan-Do-Check-Act (PDCA) cycle.

policy A principle or method that is developed for the purpose of guiding decisions and activities related to governance, management, care, treatment, and services. A policy is developed by organization leadership, approved by the governing body of the organization, and maintained in writing.

practice guidelines Tools that describe a specific procedure or processes found, through clinical trials or by consensus opinion of experts, to be the most effective in evaluating and/or treating a patient, resident, or individual served who has a specific symptom, condition, or diagnosis. Synonyms include clinical practice guideline, practice parameter, protocol, preferred practice pattern, and guideline.

practitioner Any individual who is licensed and qualified to practice a health care profession (for example, physician, nurse, social worker, clinical psychologist, or respiratory therapist) and is engaged in the provision of care, treatment, or services.

prescribing or ordering The process of a licensed independent practitioner or prescriber transmitting a legal order or prescription to the organization directing the preparing, dispensing, and administering of a specific medication to a specific individual. It does not include requisitions for medication supplies.

prevention/early detection (domain) The degree to which appropriate services are provided for promotion, preservation, and restoration of health and early detection of disease.

privileging The process whereby the specific scope and content of patient care services (that is, clinical privileges) are authorized for a health care practitioner by a health care organization, based on evaluation of the individual’s credentials and performance.
procedure 1. A series of steps taken to accomplish a desired end, as in a therapeutic, cosmetic, or surgical procedure. 2. A unit of health care, as in services and procedures. A procedure is not necessarily developed by organization leadership, approved by the governing body of the organization, and maintained in writing.

process A goal-directed, interrelated series of actions, events, mechanisms, or steps that transform inputs into outputs.

process measure An intermediate indicator of the success of an intervention.

proficiency testing The assessment of technical knowledge and skills relating to certain occupations.

proximate cause A system failure that naturally and directly produces a consequence. It is the superficial or obvious cause for an occurrence. Treating only the symptoms, or the proximate special cause, may lead to some short-term improvements but does not prevent the variation from recurring.

pull system A system driven by the needs of the downstream lines. By specifying value, identifying the value stream, and creating flow, Lean thinking allows pull to take place. In a Lean Six Sigma health care system, patients pull the product along rather than having the marketplace push it onto them on the organization's timetable. Pull offers more flexibility and accommodates changes in customer demand.

push system Work that is driven by the output of the preceding lines. This is work that is pushed along regardless of need or request. It involves providing a service or product in anticipation of a need and is often associated with high inventory and the risk of errors or higher error rates. In a Lean Six Sigma health care system, push must be eliminated and replaced with a pull system to facilitate flow.

quality control A set of activities or techniques whose purpose is to ensure that all quality requirements are being met. In order to achieve this purpose, processes are monitored and performance problems are solved.

quality improvement An approach to the continuous study and improvement of the processes of providing health care services to meet the needs of individuals and others. Synonyms include continuous quality improvement, continuous improvement, organizationwide performance improvement, and total quality management.

quality of care The degree to which care, treatment, and services for individuals and populations increases the likelihood of desired health outcomes. Considerations include the appropriateness, efficacy, efficiency, timeliness, accessibility, and continuity of care; the safety of the care environment; and the individual's personal values, practices, and beliefs.

referral The sending of an individual (1) from one clinician to another clinician or specialist, (2) from one setting or service to another, or (3) by one physician (the referring physician) to another physician(s) or other resource, either for consultation or care.

registered nurse (RN) An individual who is licensed to practice professional nursing.

relations diagram A tool used to generate understanding of how various aspects of a problem are connected, including cause-and-effect relationships.

relevance The applicability and/or pertinence of the indicator to its users and customers. For Joint Commission purposes, face validity is subsumed in this category.

reliability The capability of an indicator to accurately and consistently identify the events it is designed to identify across multiple health care settings.

resilience The degree to which a system continuously prevents, detects, mitigates, or ameliorates hazards or incidents.

respect and caring The degree to which those providing services do so with sensitivity for an individual's needs, expectations, and individual differences, and the degree to which the individual or a designee is involved in his or her own care decisions.
**risk adjustment** A statistical process for reducing, removing, or clarifying the influences of confounding factors that differ among comparison groups (for example, logistic regression, stratification).

**risk containment** Immediate actions taken to safeguard individuals from a repetition of an unwanted occurrence. Actions may involve removing and sequestering drug stocks from pharmacy shelves, checking or replacing oxygen supplies or specific medical devices, or cordoning off an icy section of a walkway.

**risk management activities** Clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.

**risk points** Specific points in a process that are susceptible to failure or system breakdown. They generally result from a flaw in the initial process design, a high degree of dependence on communication, nonstandardized processes, and/or failure or absence of backup.

**root cause** A fundamental reason for the failure or inefficiency of a process.

**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.

**run chart** A tool for measuring variation in the performance of a given task or process.

**safety** The degree to which the risk of an intervention (for example, use of a drug or a procedure) and risk in the care environment are reduced for a patient and other persons, including health care practitioners. Safety risks may arise from the performance of tasks, from the structure of the physical environment, or from situations beyond the organization’s control (such as weather).

**safety management** Activities selected and implemented by the organization to assess and control the impact of environmental risk, and to improve general environmental safety.

**scatter diagram** A illustration graphically plotting pairs of numerical data to display the possible relationship—not necessarily a cause-and-effect relationship—between one variable and another. If the variables are correlated, the data points will fall along a line or curve; the better the correlation, the more closely the points will adhere to the line.

**scientific method** The systematic process of determining what is known about a problem, deciding what needs to be changed, forming a hypothesis for implementing change, testing the hypothesis, and evaluating the result. A successful result would lead to implementation of the change; an unsuccessful result would lead to restarting the process.

**seclusion** The involuntary confinement of an individual in a room alone, for any period of time, from which the individual is physically prevented from leaving. Seclusion does not include involuntary confinement for legally mandated but nonclinical purposes, such as the confinement of a person who is facing serious criminal charges or who is serving a criminal sentence.

**sentinel event** 1. As defined by The Joint Commission: 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. Sentinel events are a subcategory of adverse events. 2. As defined by Joint Commission International: An unanticipated occurrence involving death or major permanent loss of function unrelated to the natural course of the patient’s illness or underlying condition.

**services** Structural divisions of an organization, its medical staff, or its licensed independent practitioner staff.

**SIPOC process map** A high-level process map that depicts suppliers, inputs, process, outputs, and customers.

**Six Sigma** The measure of variation that achieves 3.4 defects per million opportunities, or 99.999966% acceptability.

**special-cause variation** See variation.
staff As appropriate to their roles and responsibilities, all people who provide care, treatment, and services in the organization, including those receiving pay (for example, permanent, temporary, and part-time personnel, as well as contract employees), volunteers, and health profession students. The definition of staff does not include licensed independent practitioners who are not paid staff or who are not contract employees.

staffing effectiveness The number, competence, and skill mix of staff as related to the provision of needed care, treatment, and services.

stakeholder analysis A tool used to ascertain the level of commitment from key people involved in a process change.

standard A principle of patient safety and quality of care that a well-run organization meets. A standard defines the performance expectations, structures, or processes that must be substantially in place in an organization to enhance the quality of care, treatment, or services.

standard deviation A measure of variability that indicates the spread of a set of observations around the mean.

standard work A tool used to create a logical work flow with a minimum of waste.

suicide The act of ending one’s own life voluntarily and intentionally.

surveillance Systematic method of collecting, consolidating, and analyzing data concerning the frequency or pattern of, and causes or factors associated with, a given disease, injury, or other health condition. Data analysis is followed by the dissemination of that information to those who can improve outcomes. Examples of surveillance data can include ventilator-associated pneumonia, antibiotic prophylaxis, hemodialysis catheter infections, implant infections, surgical site infections, hand hygiene, multi-drug-resistant organisms (MRSA, VRE), equipment sterile processing, vaccinations, urinary tract infections, and health care worker immunization.

survey A key component in the accreditation process, whereby a surveyor(s) conducts an on-site evaluation of an organization’s compliance with Joint Commission or Joint Commission International accreditation requirements.

surveyor For purposes of Joint Commission accreditation, a licensed physician, surgeon, podiatrist, dentist, nurse, physician assistant, administrator, social worker, psychologist, behavioral health care professional, or any other health care professional who meets The Joint Commission’s surveyor selection criteria, evaluates compliance with accreditation requirements, and provides education and consultation regarding compliance with accreditation requirements to surveyed organizations or systems.

tracer methodology A process surveyors use during the on-site survey to analyze an organization’s systems, with particular attention to identified priority focus areas, by following individual patients through the organization’s care process in the sequence experienced by each individual. Depending on the setting, this process may require surveyors to visit multiple care programs and services within an organization or within a single program or service to “trace” the care rendered.

underlying cause The systems or process cause that allows for the proximate cause of an event to occur. Underlying causes may involve special-cause variation, common-cause variation, or both and may or may not be root causes.

utility systems Building systems that provide support to the environment of care, including electrical distribution and emergency power; vertical and horizontal transport; heating, ventilating, and air-conditioning (HVAC); plumbing, boiler, and steam; piped gases; vacuum systems; and communication systems, including data exchange systems.

value stream mapping A tool used to help health care organizations operate successfully by eliminating, or at least minimizing, non-value-added activities—that is, any steps in a process that do not contribute to a patient’s experience of value.
variation  The differences in results obtained in measuring the same phenomenon more than once. Excessive variation frequently leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services. The sources of variation in a process over time can be grouped into two major classes: common causes and special causes. Common-cause variation (also called endogenous-cause variation or systemic-cause variation) in a process is due to the process itself and is produced by interactions of variables of that process inherent in all processes, not a disturbance in the process. It can be removed only by making basic changes in the process. Special-cause variation (also called exogenous-cause variation or extrasytemic cause variation) in performance results from assignable causes. Special-cause variation is intermittent, unpredictable, and unstable. It is not inherently present in a system; rather, it arises from causes that are not part of the system as designed.
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