CHAPTER 8

IMPROVING PATIENT SAFETY

Learning Objectives

After reading this chapter, you will be able to

- contrast quality management and patient safety,
- recognize measures of patient safety,
- use prospective risk analysis to improve the safety of healthcare processes,
- use root cause analysis to improve patient safety, and
- describe patients' role in reducing adverse events.

Key Words

- Accident
- Adverse event
- Critical failures
- Criticality
- Error
- Failure
- Failure mode and effects analysis (FMEA)
- Failure modes
- Faulty system design
- Hazard analysis
- Hazards
- High-risk activities
- Human factors science
- Incident reports
- Incidents
- Medical errors
- Medication error
- Mistake-proofing
- Near miss
- Organizational culture
- Patient safety
- Patient safety organizations (PSOs)
- Proactive risk assessment
- Reportable events
- Risk
- Risk analysis
- Risk reduction strategies
- Root cause
- Root cause analysis (RCA)
- Safeguards
- Safety
- Sentinel event
- Strategy
- System
- Systems approach
- Vigilant
- Work systems

Although all healthcare professionals espouse the principle "First, do no harm," patients are occasionally harmed by caregivers' actions (or inactions). The Institute of Medicine's (IOM 2000) report *To Err Is Human: Building a Safer Health System* estimated that 44,000 to 98,000 Americans die each year as a result of preventable **medical errors**. IOM calculated the cost of medical errors, in terms of lost income, disability, and healthcare costs, at about $29 billion per year, not to mention the incalculable emotional cost of losing a loved one. The publication caused a public outcry that led to increased attention on **patient safety**.

Medical errors
Preventable adverse events or near misses related to medicine

Patient safety
Actions undertaken by individuals and organizations to protect healthcare recipients from being harmed by the effects of healthcare services; also defined as freedom from accidental or preventable injuries produced by medical care

In 2003, the Agency for Healthcare Research and Quality (AHRQ 2008) began tracking select measures to determine the level of patient safety in the United States. Data from 2005 revealed several opportunities for improvement:

- Adverse drug events in the hospital related to frequently used medications affected 6.89 percent of Medicare patients who received warfarin to 13 percent of Medicare patients who received intravenous heparin.
- A bloodstream infection developed in 1.47 percent of hospitalized Medicare patients who received a central venous catheter.
- A pressure ulcer (patch of deteriorated skin) developed in 20.7 percent of short-stay (30 days or less) nursing home residents.
- Among heart attack patients, the median time from hospital arrival to initiation of thrombolytic (blood thinner) therapy was 43 minutes, well above the national target of 30 minutes set by the American College of Cardiology and the American Heart Association.

8.1 Safety in Healthcare

In the 2001 IOM report *Crossing the Quality Chasm: A New Health System for the 21st Century*, safe healthcare is one of the six dimensions of healthcare quality. Healthcare facilities have had **safety** programs in place for many years. The purpose of these programs is to provide an environment in which **hazards** are eliminated or minimized for employees, staff, patients, and visitors. Safety is promoted via several activities, including risk management, emergency preparedness, hazardous materials management, radiation safety, environmental safety and hygiene, security, and preventive maintenance. Historically, however, there has been no organized, **systems approach** to the prevention of medical errors that cause harm to patients.

Safety
The quality or condition of being safe; freedom from danger, injury, or damage

Hazards
Events, actions, or things that can cause harm

Systems approach
A methodical procedure used to identify factors that cause errors and then reduce or minimize them

The prevention of mistakes in healthcare is not something new but rather something taken for granted. For the most part, it has been entrusted to individuals; the physicians, nurses, technicians, clerical staff, and others who provide care for patients or

Error
An unintended act (either of omission or commission) that produces an undesirable result or significant potential for an undesirable result

Faulty system design
Work system failures that set up individuals who work in that system to fail

Incidents
Events or occurrences that could have led or did lead to undesirable results

Root cause
The most fundamental reason for the occurrence of an actual or a potential event

System
A set of interdependent elements that interact to achieve a common aim

Organizational culture
Prevalent patterns of shared beliefs and values that provide behavioral guidelines or establish norms for conducting business

Work systems
Sets of interdependent elements, both human and nonhuman (e.g., equipment, technologies) that interact to achieve a common aim

support patient care activities have been expected to do the right thing—correctly—every time. When an **error** occurred, the person involved usually was blamed for being careless, incompetent, or thoughtless. Organizations focused on training and hiring competent people, believing they would be less likely to make mistakes. This reliance on healthcare professionals to perform faultlessly was misguided.

While the development of a competent staff is important, poor working conditions can make even the finest professionals prone to error. Investigations of mishaps such as the Three Mile Island and Challenger disasters have found that "accidents are generally the outcome of a chain of events set in motion by **faulty system design** that either induces errors or makes them difficult to detect" (Leape et al. 1995; emphasis added). Faulty system design is also a factor in most medical **incidents**. While an individual may have made a mistake, the **root cause** of that mistake probably lies in the design of the patient care **system**.

Healthcare professionals' activities are influenced by multiple factors, including **organizational culture**, personal attitudes and qualifications, composition of the work group, physical resources, and design of **work systems** and processes. Consider the event described in Critical Concept 8.1. Although the radiology technician erred by not responding to what the patient was saying, this mistake was encouraged by faulty equipment and a departmental procedure that failed to consider the possibility of an equipment malfunction.

CRITICAL CONCEPT 8.1
Patient Care Event Resulting in Patient Harm

A patient tells the radiology technician that she is feeling heat from the X-ray equipment.

The technician dismisses the patient's concerns and continues with the exam because the X-ray procedure states that the machine should be turned off only if the equipment's malfunction warning bulb lights up. Because the mechanical warning system failed, the patient suffers burns.

Accident research in other industries has shown that people's ability to catch and correct mistakes is not infallible (Reason 2001). Even the most explicit procedure or most exacting preventive maintenance schedule cannot eliminate the possibility of human error. Healthcare professionals watch for errors and usually catch and correct them before patients are harmed, but if faulty system design causes numerous little mistakes, healthcare professionals can easily pass over a few without noticing. According to one research study, hospital nurses encounter about one problem per hour that prevents them from continuing their tasks (Tucker and Edmondson 2003). Examples of problems include missing supplies, information, and medications. The nurses must resolve these problems. In systems that are so

problem-prone, even highly competent, **vigilant** nurses are unlikely to catch every error.

Healthcare systems that depend on perfect human performance are fatally flawed. Mistakes can happen to anyone. In general, they result from circumstances beyond the conscious control of the perpetrator. To improve patient safety, systems and processes must be examined to see if changes are needed to reduce the chance that a patient will be harmed. The goal is to lessen the **risk** of errors. If an error does occur, however, reliable safeguards should prevent the mistake from reaching the patient. If the error does reach the patient, response mechanisms should act quickly to reduce the amount of harm to the patient.

LEARNING POINT
Healthcare Safety

Traditionally, healthcare organizations have relied on the people providing patient care to prevent errors. However, processes that rely on perfect human performance are fatally flawed. An organized, systems improvement approach is needed to prevent errors that cause harm to patients.

Patient safety improvement initiatives are an important component of a healthcare organization's overall quality management effort. These initiatives focus primarily on the clinical aspects of patient care, but the same techniques used to protect patients from harm can be applied to any work activity, including billing, patient registration, plant maintenance, and housekeeping. Techniques for preventing human errors are based on **human factors science**, which originated in the military during World War II (Wickens et al. 1997). These techniques have been used for many years in other industries to increase productivity and reduce accidents.

Accident
An unplanned, unexpected event, usually with an adverse consequence

Vigilant
Carefully observant or attentive; on the lookout for possible problems

Risk
The possibility of loss or injury

Human factors science
Study of the interrelationships between humans, the tools they use, and the environment in which they live and work

8.2 Preventing Mistakes

Most mistakes are not intentional but occur because a process is complex. Even simple patient care processes are complex in terms of the variables involved. Consider, for example, the hospital process of obtaining a blood specimen for laboratory testing illustrated in Figure 8.1.

The variables in this process include the method used to order the test (handwritten or electronic), the patient's location, the method used to collect the specimen, the type of vials used to store the blood, the method of laboratory analysis, the manner in which results are reported, and much more. Considering all of these variables, the results are likely to be inaccurate at least some of the time.

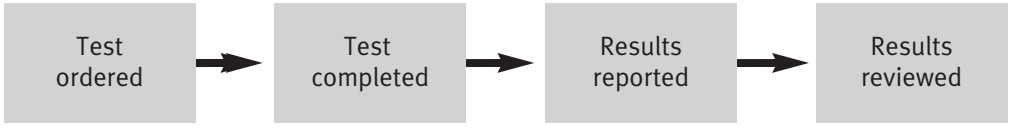


Figure 8.1. High-Level Flowchart of Hospital Laboratory Testing

Mistake-proofing
Improving processes to prevent mistakes or to make mistakes obvious at a glance; also called *error-proofing*

At best, the process can be changed to make errors impossible. We encounter examples of **mistake-proofing** every day. Here are just a few:

- Heating devices that shut off automatically so they are not left on all day
- Circuit breakers that trip when circuits are overloaded
- Computer disks that have overwrite protection
- Lawn mower motors that shut off when the operator lets go of the handle

Safeguards
Physical, human, or administrative controls incorporated into a process to identify and correct errors before a patient is harmed

Unfortunately, elimination of all possible chances for error is not always feasible. In such cases, patient care processes should be redesigned so the chances of harmful errors are minimized. By adding **safeguards** to a process, the likelihood of causing patient harm can be greatly reduced. Table 8.1 provides examples of patient care mistakes and safeguards that catch and correct them before they reach the patient.

Table 8.1. Mistakes and Safeguards That Prevent Patient Harm

Mistake	*Safeguard*
A surgeon starts to close a patient's surgical incision at the completion of an operation for extensive bowel repair, not knowing that a surgical sponge has been left inside the patient.	The scrub nurse does a sponge count and discovers one is missing. The surgeon locates the sponge inside the abdomen and removes it before closing the incision.
A phlebotomist starts to draw blood from the left arm of a patient, not knowing that the patient has just undergone a mastectomy on the left side and should not have blood drawn from that arm.	A red wristband on the patient's left arm alerts the phlebotomist that the left arm should not be used for blood draws.
A hospital dietary worker delivers an unmarked food tray to a patient room. He assumes he is delivering the tray to the correct room because it is the last tray on the cart and the patient in the room is the only patient in the nursing unit who has not received a meal.	A large sign indicating "nothing by mouth" is hung by the patient's bed. The dietary worker sees the sign and does not leave the food tray for the patient.
A physician prescribes a medication without knowing that the patient is allergic to it.	The pharmacist reviews the patient's medication history and discovers the mistake. The pharmacist contacts the physician, and the physician prescribes a different medication.

High-risk activities usually incorporate several safeguards. Figure 8.2 is an illustration of a hospital's medication administration process and errors that could occur at various stages. Notice the reviews along the way that catch and remedy those mistakes. When these safeguards don't work as intended, mistakes can reach the patient. To further safeguard patients, healthcare organizations are adopting many of the error prevention strategies and techniques used in other industries.

High-risk activities
Tasks or processes known to be error-prone or that have potential for causing significant patient harm should an error occur

Patient safety is one component of an organization's quality management activities. The same basic cycle of measurement, assessment, and improvement used in other quality management activities applies to patient safety initiatives. The safety of patient care is measured, the measurement results are assessed, and improvements are made.

LEARNING POINT
Reducing Patient Care Mistakes

Techniques for eliminating and reducing errors that occur in the delivery of patient care are based on human factors science, which has been used for years in other industries to prevent worker accidents.

8.3 Measuring Patient Safety

The purpose of patient safety performance measurement is to discover and fix problems before an **adverse event** occurs. Measures of patient safety are like canaries in coal mines; they warn of risky situations before a mishap occurs. Patient safety measures are no different from other healthcare performance measurements. Many of the measures described in Chapter 3 alert the organization to situations that are a potential safety threat to patients. Examples of patient safety topics and the system-level measures used to assess corresponding performance are shown in Table 8.2.

Adverse event
Any injury caused by medical care

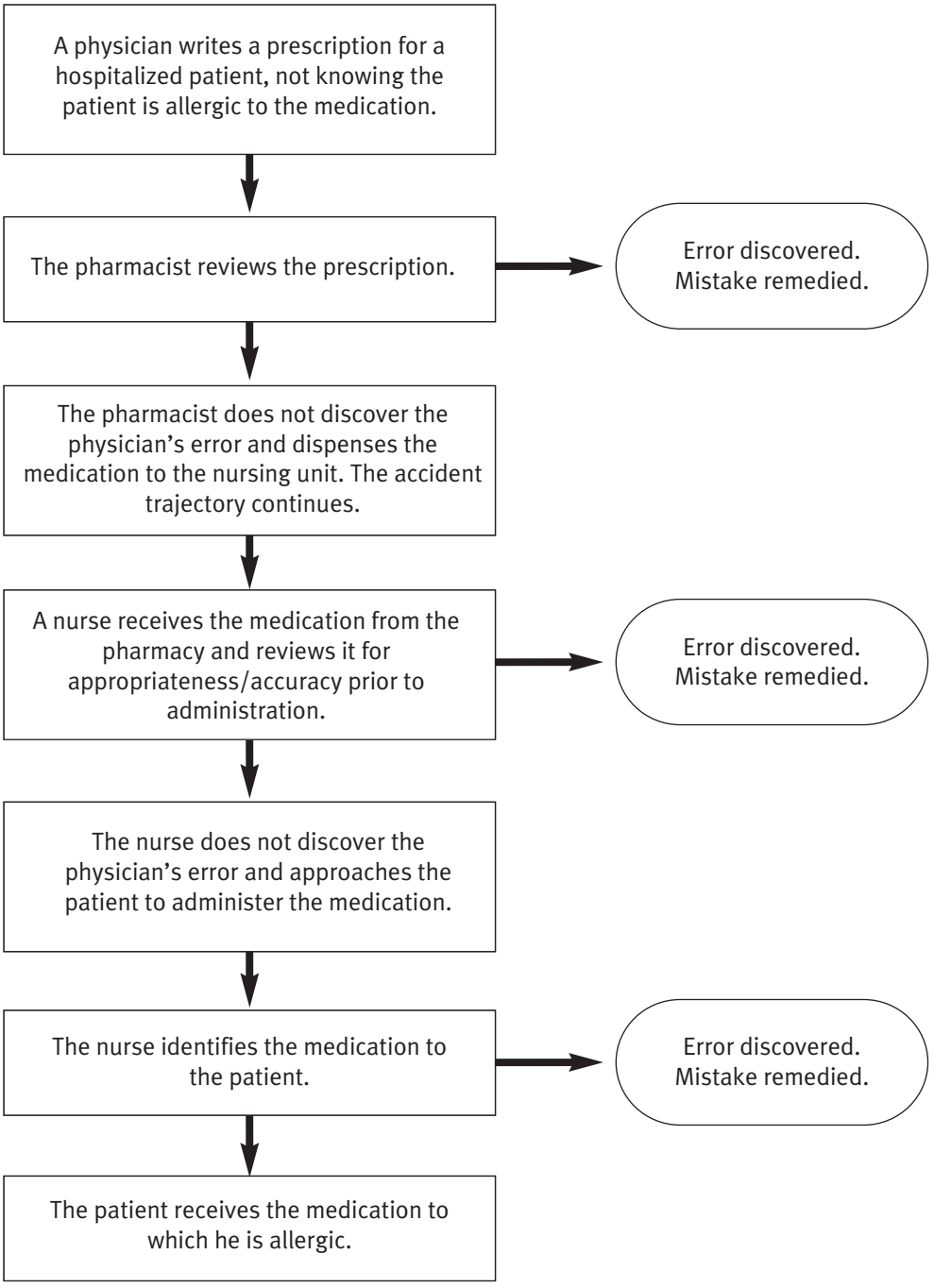
Incident reports, sometimes called *occurrence reports*, are paper or electronic forms used to document potential or actual patient safety concerns. Employees are asked to complete a report whenever a patient is involved in an event that has caused or has the potential to cause injury. The following are examples of **reportable events**:

Incident reports
Instruments (paper or electronic) used to document occurrences that could have led or did lead to undesirable results (An example of an incident report is shown in Figure 8.4.)

- Error that occurs during the delivery of patient care (e.g., medication administration mistake, treatment error)
- Development of a condition seemingly unrelated to a patient's disease (e.g., infection, pressure ulcer)
- Adverse or suspected adverse reactions to a treatment, medication, or blood transfusion
- Serious injury or unexpected death of a patient
- Patient fall

Reportable events
Incidents, situations, or processes that contribute to, or have the potential to contribute to, a patient injury, or that degrade the provider's ability to provide safe patient care

Figure 8.2. Hospital Medication Administration Process



Source: Spath (2001). Used with permission.

Table 8.2. Patient Safety Topics and System-Level Measures

Topic of Interest	*Measure*
How often do patients develop an infection as a result of surgery?	Number of surgical cases in which patients developed an infection following surgery per 100 procedure days
How often do patients develop an infection as a result of a central venous catheter insertion?	Average number of hospital-wide central venous catheter infections per 1,000 catheter line days
How often do patients develop pneumonia as a result of being on a ventilator?	Rate of pneumonia detected per 1,000 ventilator days in the intensive care units
How often do patients have an adverse reaction to a medication?	Average number of adverse drug events per 1,000 doses
How often do patients experience a sentinel event?	Number of sentinel events per 10,000 adjusted patient days*
How often do patients fall?	Number of falls per 10,000 adjusted patient days*
How often do patients experience a medication error?	Number of medication errors per 1,000 doses of medication

* Adjusted patient days is a quantity calculated by the financial department that is based on the sum of inpatient days and financial equivalent patient days, which is determined by applying a formula to outpatient treatments. Therefore, inpatients and outpatients are accommodated in this quantity.

- Malfunction of a medical device resulting in actual or potential patient injury
- Diagnostic or testing problem (e.g., delay in testing or reporting, **failure** to report significant abnormal results, wrong test ordered)

Failure
Compromised function or intended action

An example of a form used to report the circumstances surrounding a patient fall is shown in Figure 8.3. The individual who witnessed, first discovered, or is most familiar with the incident usually completes the report. The reporter does not include his or her judgment on the cause of the event, only facts. The names of witnesses to the event and the employee involved in the incident (if not the reporter) are typically included in the report.

The incident reporting process is not standardized among healthcare organizations. Facilities may define reportable events differently or use different mechanisms to document events. To streamline the reporting process, some organizations have created Web-based incident reporting tools and telephone hotlines.

Prompt identification of patient incidents enables an organization to immediately investigate the circumstances of the incident and, if necessary, modify the process or

FIGURE 8.3.
Patient Fall Incident Report

Patient name: _____ Room # _____ Age: _____ Gender: _____

Admission date: _____ Date of fall: _____ Time of fall: _____

Ask the patient:	
Do you remember falling?	✹ Yes ✹ No (If the patient cannot respond, his or her family may be able to provide information.)
Were you injured?	✹ Yes (How and where?) ✹ No
What were you doing when you fell?	
Other information:	
Was the nurse call light on?	✹ Yes (Include number of minutes call light was on.) ✹ No
The activated call light belonged to:	✹ Patient ✹ Roommate
Contributing factors (Specify all.)	✹ Medication: ✹ Equipment: ✹ Footwear: ✹ Confusion: ✹ Urgency of bladder/bowels: ✹ Environmental issues:
Was the patient following the risk for falls protocol?	✹ Yes ✹ No
Any other information from patient, family, or staff	
Number of hours since last patient assessment	
Has this patient previously fallen during this stay?	✹ Yes ✹ No
Age	
Injury	✹ Yes ✹ No
Did staff witness the fall?	✹ Yes ✹ No
Was the patient identified as at risk for falls?	✹ Yes ✹ No
What fall prevention interventions were used?	
Was the patient physically restrained?	✹ Yes ✹ No

environment to prevent similar occurrences in the future. Incident reports are also used to identify patterns of events that indicate unsafe conditions. Various departments and committees in the organization review these reports on a regular basis. A bar graph of the types of incidents that occurred in a hospital over the course of one month is shown in Figure 8.4.

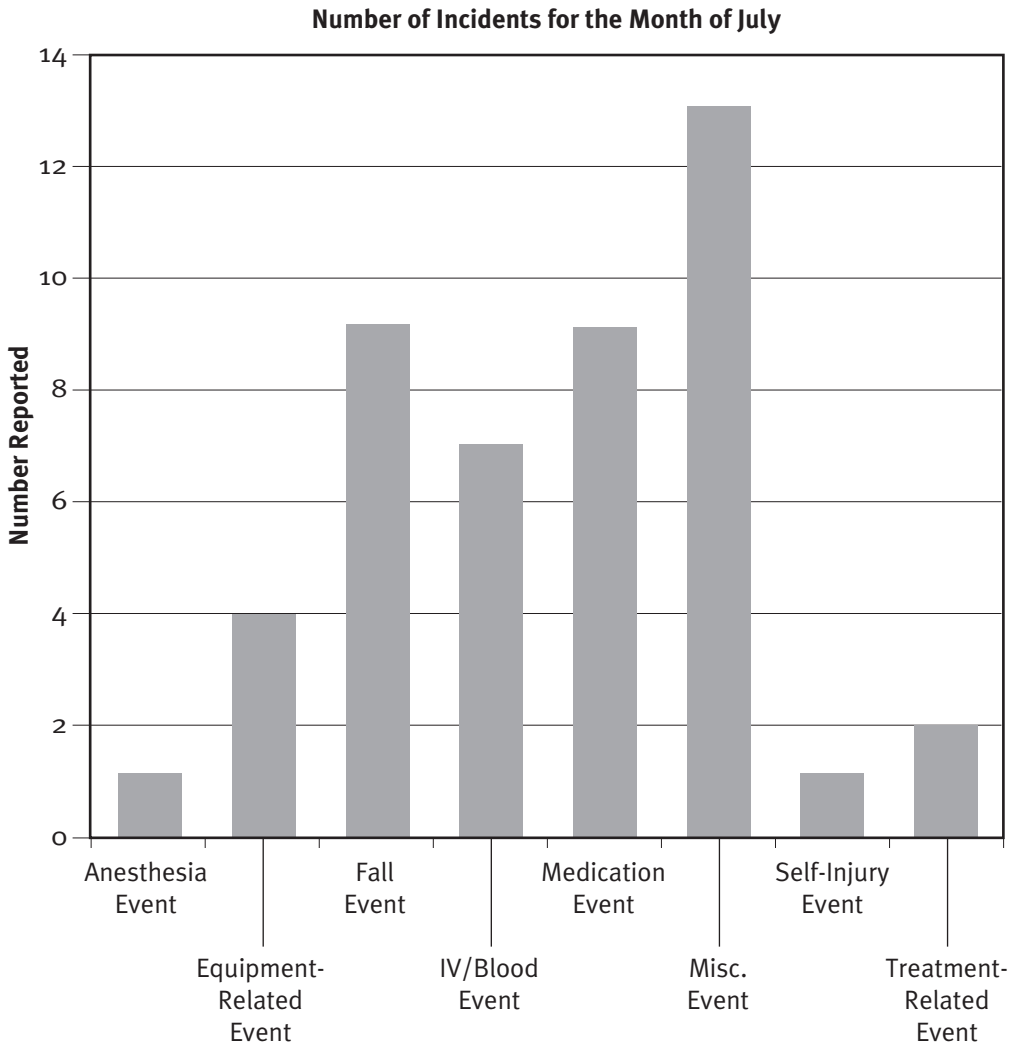


FIGURE 8.4. Bar Graph of Patient Incidents

To ensure that staff members report patient incidents, managers must strive to maintain an environment that encourages people to report mistakes, admit problems, have different opinions, and exchange ideas. Experience has shown that when employees fear reprisal, they are less likely to report patient incidents and the organization thus loses a valuable source of information about patient safety. This finding is consistent with what has been discovered by officials of the NASA Aviation Safety Reporting System and the British Airways Safety Information System. These groups identified the following five practices as important to increasing the quantity and quality of employee incident reports (O'Leary and Chappell 1996):

- Protect people involved against disciplinary proceedings (as far as practical).
- Allow confidential reporting or de-identify the reporter.
- Separate the agency or department collecting and analyzing the reports from those that have the authority to institute disciplinary proceedings and impose sanctions.
- Provide rapid, useful, accessible, and intelligible feedback to the reporting community.
- Make reporting easy.

An increasing number of healthcare facilities are required to report patient incidents to entities outside the organization. More than half of the states have implemented regulations that require healthcare organizations to report certain types of serious incidents to the state health department. Some of these states publicly report the number of each type of incident. More important, state patient incident databases are a means of identifying the underlying causes of risks and hazards in patient care through analysis of events occurring at many facilities. Lessons learned through this analysis are often publicly shared. Several entities that manage state incident reporting systems are listed in the website resources at the end of this chapter.

LEARNING POINT
Safety Measurement

The fundamental principles of performance measurement apply to patient safety. To encourage employees to report events that have caused or have the potential to cause injury to patients, organizations must reassure their staffs that they won't be disciplined for unintentional mistakes.

Ultimately, there will be a national reporting system for patient safety incidents. In 2005, the federal government passed the Patient Safety and Quality Improvement Act (Patient Safety Act), which included plans to develop a national database of patient incident information. The Patient Safety Act made possible the creation of a nationwide network of **patient safety organizations (PSOs)** for the purpose of gathering and analyzing information about patient incidents from providers in all states. To qualify as a PSO, an organization must have expertise in identifying risks and hazards in the delivery of patient care, determining the underlying causes, and implementing corrective and preventive strategies. As of this writing, AHRQ, the federal entity responsible for administering the PSO provisions of the Patient Safety Act, is starting the PSO selection process.

Patient safety organizations (PSOs) Associations that have expertise in identifying risks and hazards in the delivery of patient care, determining the underlying causes, and implementing corrective and preventive strategies

8.4 Improving Patient Safety

Projects aimed at improving patient safety follow the same steps as any other project:

1. Define the improvement goal.
2. Analyze current practices.

3. Design and implement improvements.
4. Measure success.

Any of the models described in Chapter 5 could be used to improve patient safety. For instance, just as rapid cycle improvement (RCI) was used to improve patient satisfaction (Figure 5.4), an outpatient clinic could use RCI to reduce prescription errors.

Two improvement models not described in Chapter 5 are used by healthcare organizations for the explicit purpose of making patient care safer: failure mode and effects analysis and root cause analysis. These patient safety improvement models are described below.

Failure Mode and Effects Analysis

Failure mode and effects analysis (FMEA)
Systematic assessment of a process to identify the location, cause, and consequences of potential failure for the purpose of eliminating or reducing the chance of failure; also called *failure mode, effects, and criticality analysis* (FMECA) and *healthcare failure mode and effects analysis* (HFMEA) (An example of a completed FMEA is shown in Figure 8.7.)

Proactive risk assessment
An improvement model that involves identifying and analyzing potential failures in healthcare processes or services for the purpose of reducing or eliminating risks that are a threat to patient safety

Failure mode and effects analysis (FMEA) is a **proactive risk assessment** technique that involves a close examination of a process to determine where improvements are needed to reduce the likelihood of adverse events (McDermott, Mikulak, and Beauregard 1996). The technique is considered proactive because the improvement project is undertaken to prevent an adverse event. The FMEA technique promotes systematic thinking about the safety of a patient care process in terms of the following questions:

- What could go wrong?
- What will be the result if something goes wrong?
- What needs to be done to prevent a bad result when something does go wrong?

Risk or hazard potential is part of every process. The goal of an FMEA project is to find these hazards and make process changes to reduce the risk of error. FMEA is a formal and systematic assessment process, but individuals informally use FMEA almost every day. Here is an example:

> You want to go to a music concert, expecting to buy a ticket at the door.
> What could go wrong: The concert will be sold out.
> Result: You'll miss the concert, plus you'll be disappointed because you've waited several years for this band to come to your town.
> Prevent the bad result: Buy a ticket in advance.

FMEA has been used to conduct safety system evaluations in manufacturing, aviation, computer software design, and other industries for many years. Now healthcare organizations use the technique to evaluate and improve the safety of patient care activities. Hospitals and skilled nursing facilities accredited by The Joint Commission (2008c, 87; 2008d, 28) are required to periodically conduct prospective risk assessments for patient safety improvement

purposes. The FMEA improvement model is the most common technique used to comply with this standard (American Society for Healthcare Risk Management 2002).

Hazard analysis
The process of collecting and evaluating information on hazards associated with a process

Failure modes
Different ways a process step or task could fail to provide the anticipated result

The six steps of an FMEA project are sequenced similarly to those of the Plan-Do-Study-Act improvement model (see Figure 8.5). FMEA projects are undertaken by a team that has experience with the process under study; it regularly carries out the activities and knows where the potential for error exists. The FMEA project team may also include people who have no experience with the process to gain a different perspective.

An FMEA project begins with the development of a clear understanding of the process. The team develops a flowchart to visualize each of the steps. Next, the team conducts a **hazard analysis**, which involves a brainstorming session to develop a list of all failures that could occur in each step. The first two steps in the process of ordering laboratory tests for hospitalized patients are shown in Figure 8.6. Listed below each step are the **failure modes** or errors that could occur.

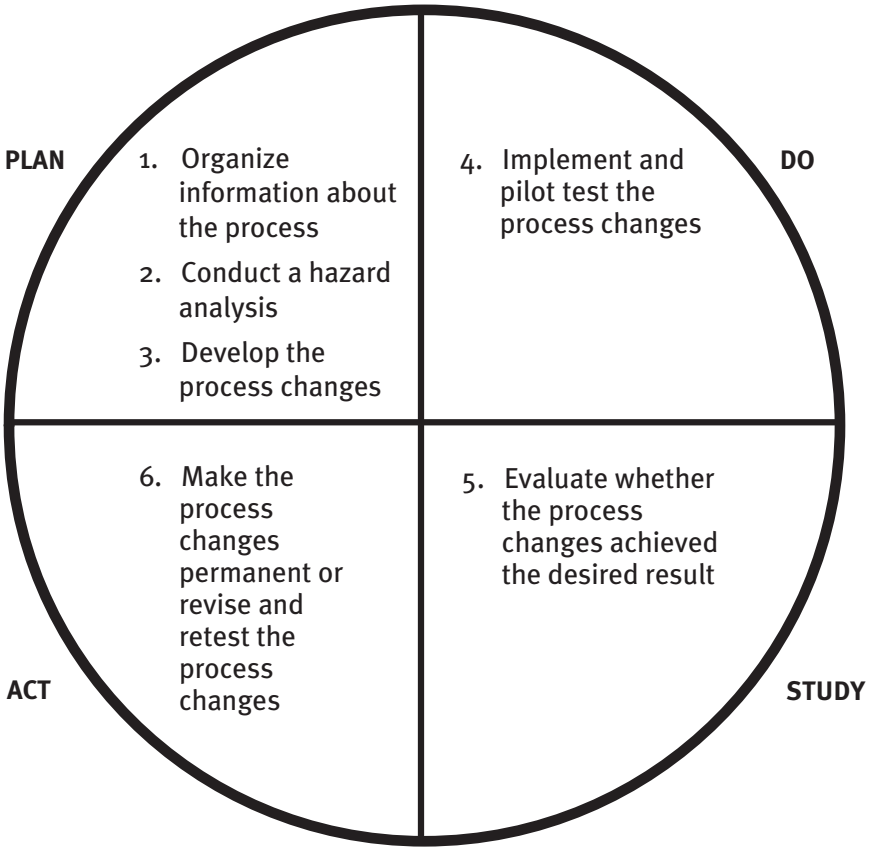


Figure 8.5. FMEA Steps in Relationship to PDSA Cycle

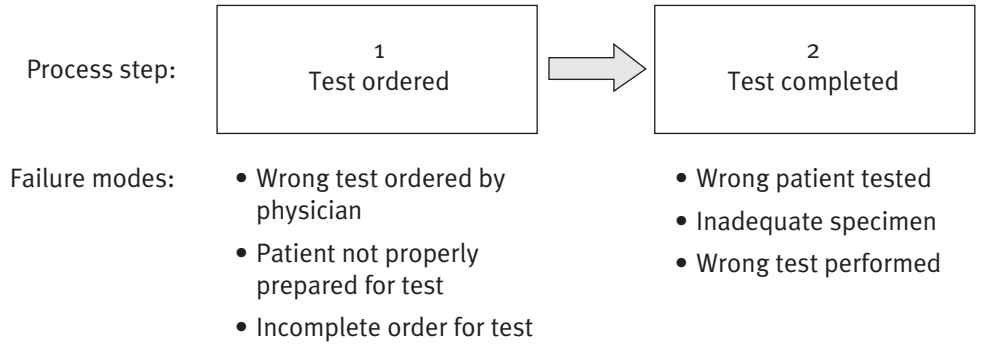


FIGURE 8.6.
First Two Steps in Hospital Laboratory Testing Process and Failure Modes

After all potential failure modes or mistakes have been identified for each step, the team determines the risk or **criticality** of each failure mode to prioritize them for elimination. A criticality score is assigned to each potential failure on the basis of the following criteria:

Criticality
Ranking of potential failures according to their combined influence of severity and frequency and probability of occurrence

- *Frequency*: the probability that the failure will occur
- *Severity*: the degree of harm the patient would experience if the failure occurred
- *Detection*: the likelihood that the failure will be detected before patient harm occurs

Each of these criteria is rated on a scale of one to five, with one as the lowest possible rating and five as the highest. Once the rating process is complete, a criticality score is assigned to each potential failure. This score is calculated by multiplying the frequency score by the severity score by the detection score. Table 8.3 is an FMEA worksheet for the first step in the

TABLE 8.3.
FMEA Worksheet

Step	Potential Failure	Effect	Frequency	Severity	Detection	Criticality Score
Test ordered	Wrong test ordered by physician					
	Patient not properly prepared for test					
	Incomplete order for test					

Critical failures
The most important process failures to prevent, according to criticality scoring results

laboratory test ordering process. After recording in column three the effect the potential failure would have, the team completes the scoring process. The potential failures with the highest criticality scores are considered the **critical failures** most in need of prevention.

Once the critical failures are identified, the team needs to determine what would cause these potential failures so preventive actions can be taken. The following list provides examples of questions the team can ask about the critical failures to discover their root causes:

- Who might experience this problem? Would all the people who do the work experience it or just some of them?
- What is the specific problem? For example, referring to the laboratory ordering process, what information is the physician likely to omit when ordering a test?
- Where might the failure occur? Where would the failure be unlikely to occur?
- When would the problem likely happen (during certain times or days of the week)? When wouldn't the problem happen?
- Why might the failure occur? Why doesn't it occur all the time?
- How many times has the problem occurred in the past? How can the process be changed to eliminate or reduce the chance this problem will occur?

Table 8.4 is an action planning worksheet the team can use to brainstorm ways the process can be changed to reduce the chance of failure, help people perform their jobs correctly, and help people identify and correct the failure before a patient is harmed.

The remaining steps of the FMEA project are the same as those of any improvement project. The process changes are implemented and tested to determine whether the desired results have been achieved. In an FMEA project, the desired result is reduction or elimination of critical failures. If the process changes reduce or eliminate the possibility that the critical failures will occur—the desired result of an FMEA project—they are incorporated into the process. Changes that don't produce the desired result are evaluated to determine why they didn't work, and new process changes are developed and tested.

LEARNING POINT
FMEA

FMEA is a prospective risk assessment technique used to reduce high-risk process failures. The probability and likelihood of detecting a failure is combined with an estimate of the impact of the failure to produce a criticality score. This score helps teams prioritize failures for elimination.

FMEA projects are usually undertaken for processes involving high-risk patient care activities prone to failure; however, they can be used to reduce failure in any process. Figure 8.7 is a completed FMEA for the process of collecting patient demographic and insurance information in a large ambulatory health clinic for women.

Table 8.4. Action Planning Worksheet

	Prevention		*Detection*
Critical Failure	**Reduce the chance for failure**	**Help people perform their jobs correctly**	**Identify and correct the failure before the patient is harmed**
Physician ordered the wrong test			
Patient was not properly prepared for the test			
The order for the test was incomplete			

Members of the FMEA team included the registration area supervisor, two registration clerks, the manager of the patient accounts office, and the patient financial counselor. The clinic business manager served as team leader.

Several variations of the FMEA model described here are being used in healthcare organizations. The Veterans Health Administration created a model called Healthcare Failure Mode and Effects Analysis™ to conduct proactive risk analyses (U.S. Department of Veterans Affairs 2007). Some healthcare organizations use a proactive **risk analysis** model called failure mode, effects, and criticality analysis. All models have similar characteristics.

Risk analysis
The process of defining, analyzing, and quantifying the hazards in a process, which typically results in a plan of action undertaken to prevent the most harmful risks or minimize their consequences

Root Cause Analysis

Root cause analysis (RCA) has been used for many years in other industries. NASA's (2003) use of RCA to investigate the Space Shuttle Columbia disaster is just one example. Safety improvement teams use RCA after an adverse event has occurred to determine system deficiencies that led to the event. The six steps involved in RCA follow the Plan-Do-Study-Act Cycle (Figure 8.8).

Root cause analysis (RCA)
A structured process for identifying the underlying factors that caused an adverse event

Since 1996, organizations accredited by The Joint Commission have been required to conduct an RCA following a sentinel event. A **sentinel event** is an incident in which death or serious harm to a patient occurred. The word *sentinel* reflects the egregiousness of the injury (e.g., surgery performed on the wrong patient) and the likelihood that investigation of the event will reveal serious safety problems (Wachter 2008, 276). The Joint Commission also encourages facilities to conduct an RCA following a near miss. A

Sentinel event
An adverse event involving death or serious physical or psychological injury (or the risk thereof) that signals the need for immediate investigation and response

FIGURE 8.7. FMEA of the Process of Collecting Patient Demographic and Insurance Information

Process Step	Potential Failure Mode	Potential Effect	Severity of Effect	Probability of Failure	Detection of Failure	Criticality Score
Verify patient's mailing address and phone number	Registration clerk does not verify address and phone number.	Billing statement is sent to the wrong address; physician is unable to contact patient if necessary after patient leaves clinic.	4	4	5	80
	Registration clerk enters demographic information incorrectly.	Billing statement is sent to the wrong address; physician is unable to contact patient if necessary after patient leaves clinic.	4	3	5	60
	Patient gives registration clerk incorrect information.	Billing statement is sent to the wrong address; physician is unable to contact patient if necessary after patient leaves clinic.	4	3	5	60
Verify patient's insurance information	Wrong insurance company is billed.	Payment delay	5	3	3	45
	Registration clerk does not perform verification of insurance benefits.	Payment delay	5	4	3	60

Rating Key

Severity rating scale:	*Probability rating scale:*	*Detection rating scale:*
1 = No effect	1 = Highly unlikely/never happened before	1 = Almost certain to be detected and corrected
2 = Minimal effect	2 = Low/relatively few failures	2 = High likelihood of being detected and corrected
3 = Moderate, short-term effect	3 = Moderate/occasional failures	3 = Moderate likelihood of being detected and corrected
4 = Significant, long-term effect	4 = High/repeated failures	4 = Low likelihood of being detected and corrected
5 = Catastrophic effect	5 = Very high/failure almost inevitable	5 = Remote likelihood of being detected and corrected

Critical Failure	Root Causes	Actions Intended to Eliminate/ Reduce Failure or Mitigate Effects	Measures of Success
Registration clerk does not verify address and phone number.	Clerks are not trained and do not receive continuing education on use of address verification capabilities of registration computer system.	• Provide address verification training for registration staff • Educate registration staff on importance of address verification and demonstrate correct way to document that verification was performed	• Percentage of billing statements returned because of invalid address
Registration clerk does not perform verification of insurance benefits.	Management does not hold registration clerks accountable for insurance verification.	• Implement policies and procedures that hold registrars accountable for verification of patient's insurance • Continue to educate registration staff on importance of insurance verification • Implement incentives for registration staff to verify insurance benefits	• Percentage of accounts for which registration clerk does not verify patient insurance benefits • Percentage of accounts with incorrect insurance identification and group numbers • Percentage of accounts billed to wrong insurance company

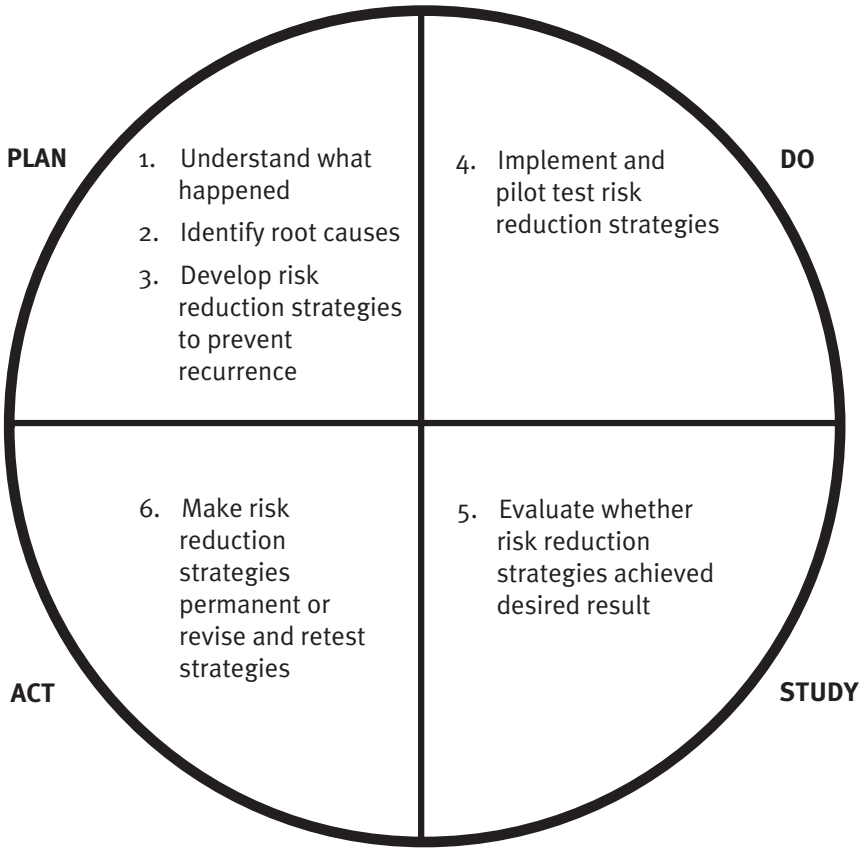


FIGURE 8.8. RCA Steps in Relationship to PDSA Cycle

near miss is an incident that did not result in death or injury but could have; only by chance was the patient not harmed. Since 1996, several states have enacted regulations similar to The Joint Commission's standards. These regulations require healthcare facilities to conduct formal investigations of serious adverse events.

Near miss
Any process variation that does not affect the outcome or result of an adverse event but carries significant chance of an adverse outcome if it were to recur; also known as a ***close call***

Like FMEA, the RCA process is similar to what people do almost every day. For example, a strange sound from my car (a symptom) indicates something is wrong. Symptoms are not the cause of the problem; they are signals that something may be wrong. Turning up the radio to mask the strange sound won't fix the faulty water pump (root cause) causing the sound. My car problem will continue until the root cause is corrected. The same is true for problematic patient care processes. Delivery of the wrong medication to a hospitalized patient (a symptom) signals that something is wrong with the medication administration process. If the people involved in giving medications don't

Medication error
Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer

find and fix the root cause of the mistake, another **medication error** is likely to occur in the future.

RCA begins promptly after a sentinel or adverse event. Like all improvement projects, a team of people is assembled to conduct the investigation. The team comprises people who witnessed the event and people with expertise in the processes involved. In some organizations, managers or senior leaders may also work with the RCA team. Ideally, the team leader is someone who has experience using the RCA investigation technique.

Critical Concept 8.2 is a description of a wrong-site surgery event. An arthroscopy should have been performed on the patient's right knee, but the procedure was done on his left knee. The RCA team for this event comprises the people directly involved in the procedure (surgeon, anesthesiologist, surgical nurses, and surgery scheduling clerk) and the managers of the admission and surgical areas. The team's first task is to determine what happened by collecting and inspecting physical evidence (such as equipment, materials, and safety devices) and reviewing documentary evidence (paper or electronic media). The team also asks the people directly and indirectly involved in the event to provide their perspectives. These discussions may occur in a team meeting, or people may be interviewed individually. Ultimately, the team develops a picture of the event and creates a high-level flowchart to illustrate the steps leading up to it (Figure 8.9).

CRITICAL CONCEPT 8.2
Description of Wrong-Site Surgery Event

A 62-year-old man had an arthroscopy procedure performed on his left knee instead of his right knee. Three weeks prior to the surgery, the orthopedic clinic telephoned the hospital to schedule the man's procedure. At that time, the front office staff in the clinic mistakenly scheduled a left knee arthroscopy (the wrong knee). The surgery scheduling clerk at the hospital faxed a surgery confirmation form to the clinic. Per hospital policy, the clinic is supposed to review the information on the form, verify the accuracy, and fax the signed confirmation back to the hospital. The clinic staff was busy and did not fax the confirmation back.

On the day of the surgery, the patient's paperwork indicated that the surgery was to be performed on his left knee, per the original phone call from the clinic. The surgery schedule, a document used to plan the day's activities in the operating area, also indicated that the patient was to have a left knee arthroscopy. The man was taken to the preoperative holding area, where a nurse spoke with him about his upcoming procedure. Relying only on the surgery schedule, the nurse asked the patient to

CRITICAL CONCEPT 8.2
Description of Wrong-Site Surgery Event

confirm that he was having an arthroscopy on his left knee. The man told the nurse that he had been experiencing pain in both knees and that he'd eventually need procedures on both of them. He thought he was scheduled for surgery on his right knee that day but that perhaps the doctor had decided to operate on his left knee instead. The nurse did not read the history and physical examination report that the patient's doctor brought to the hospital that morning. If she had read this report, she would have noticed that it had right knee surgery scheduled that day.

The anesthesiologist examined the patient in the preoperative holding area. When asked about the procedure, the man was confused about which knee was to be operated on that day. The anesthesiologist wrote 'knee arthroscopy' in his notes in the patient's record. The patient was taken into the operating room, where the surgeon was waiting. The surgeon spoke with the patient about the upcoming procedure on his right knee, and the patient signed a consent form indicating that surgery was to be performed on the right knee that day. The surgeon marked his initials on the man's right knee in ink to designate the surgery site.

The anesthesiologist and scrub nurse readied the room for the procedure. The patient was anesthetized and fell asleep. Thinking the man was having surgery on his left knee, the nurse placed a drape over his right knee, not noticing the surgeon's initials. The left knee was placed in the stirrup and prepped for the procedure. The nurse then asked everyone in the room to confirm that the man was the correct patient and that he was having an arthroscopy on his left knee. Everyone in the room said "yes" except the surgeon, who was busy preparing for the procedure. Distracted, he nodded his head in agreement. The nurse documented on the preoperative checklist that the patient's identity, procedure, and surgery site had been verified.

The surgeon performed the arthroscopy on the knee that had been prepped—the left one. When the patient awoke in the surgical recovery area, he asked the nurse why he felt pain in his left knee and told her the procedure should have been performed on his right knee. The nurse notified the surgeon, who immediately informed the patient and his family about the mistake.

Next, the team looks for the root causes of the event. This step is more involved than the Five Whys tool described in Chapter 6. First, the RCA team determines the causal factors. Causal factors are situations, circumstances, or conditions that collectively,

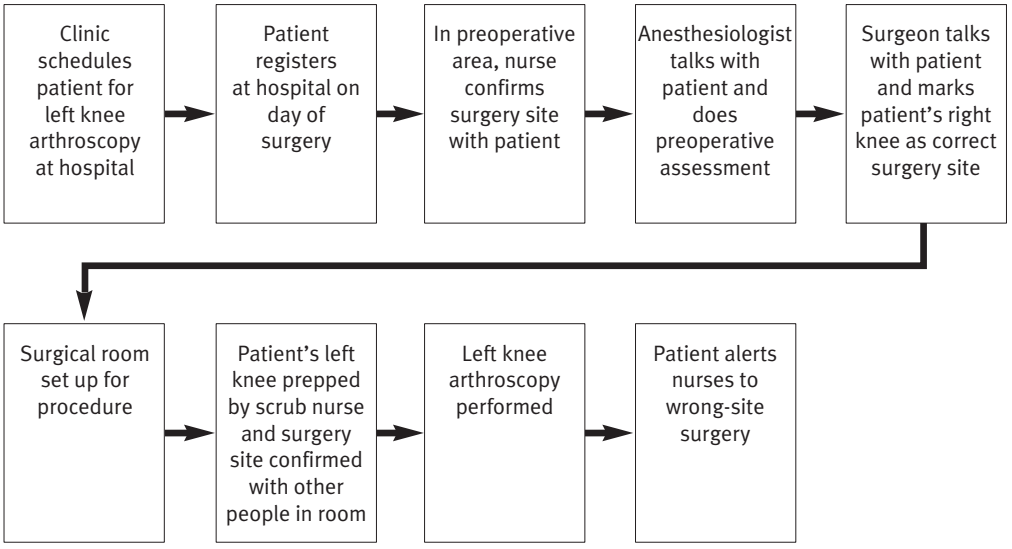


FIGURE 8.9. High-Level Flowchart of Event

with other causes, increased the likelihood of the adverse event. The team identifies several such factors for the wrong-site surgery event:

- The orthopedic clinic phoned the patient's surgery reservation to the hospital. According to procedure, the clinic also should have confirmed the surgery reservation and provided a hard copy of it to the hospital, but it did not. Team discussion reveals that many surgeons' offices don't comply with this step.
- The surgeon failed to provide a copy of the patient's history and physical examination to the hospital at least 72 hours prior to surgery (as required by procedure). Without this document, the admissions and surgery scheduling clerk was unable to double-check the accuracy of the planned surgery prior to the patient's arrival.
- The nurse relied only on what was written on the surgical schedule to confirm the surgery site. The patient's history and physical report (which the surgeon brought to the hospital on the day of the surgery) indicated the patient was to undergo a right knee arthroscopy, but the nurse did not read this report.
- The patient had a history of pain in both knees. The surgeon told him that eventually an arthroscopy would need to be performed on both knees. When the nurse and the anesthesiologist questioned the patient, he appeared confused about which knee was to be operated on that day.

- The surgeon correctly marked the patient's right knee as the surgery site. However, the scrub nurse placed drapes over the right knee and prepared the left knee for the procedure. The nurse had already set her mind to the fact that a left knee arthroscopy was to be performed and didn't notice the surgical site marking on the patient's right knee.
- Prior to starting the arthroscopy, the scrub nurse asked everyone in the room to confirm the left knee as the surgery site. Everyone replied "yes" except the surgeon, who was busy at the time. He just nodded his head in agreement. According to procedure, everyone in the room is supposed to stop what he or she is doing and verbally confirm the correct site.
- The surgeon proceeded with the left knee arthroscopy, not noticing that he was working on the wrong knee.

The team uses a cause and effect diagram like the one in Figure 8.10 to sort the causal factors into problem categories.

Once the team is satisfied that it has identified all causal factors, it identifies the root causes. Root causes are the most fundamental reasons the event occurred. To discover the

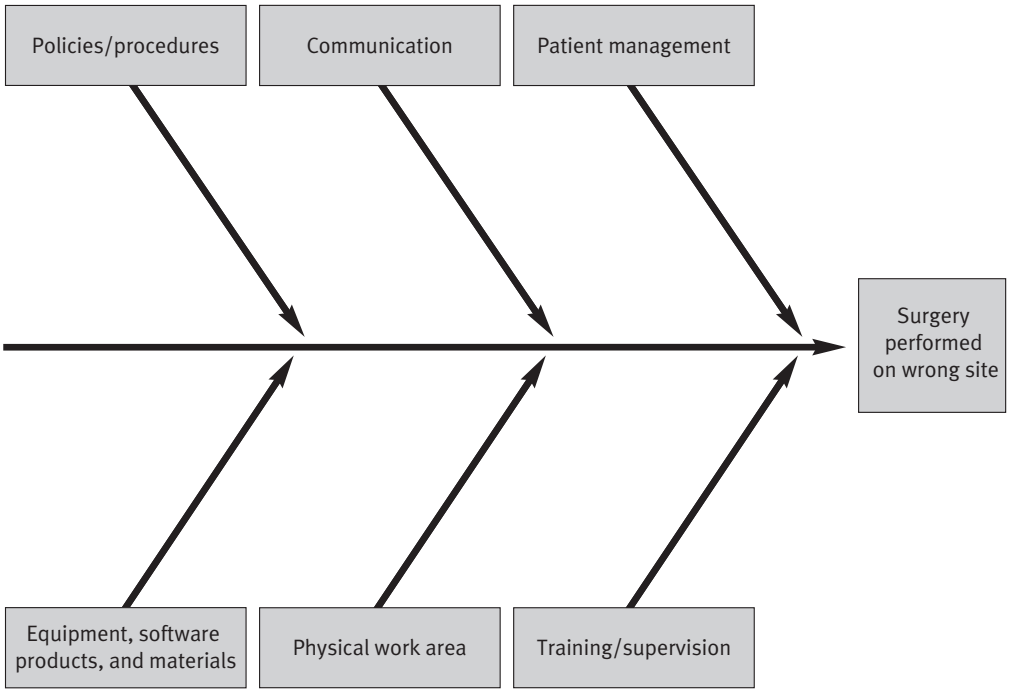


FIGURE 8.10. Cause and Effect Diagram for Wrong-Site Surgery

root causes, the team asks "why" questions about each of the causal factors. For example, why didn't the clinic provide a hard copy of the confirmed surgery reservation as required? Why didn't the nurse double-check the intended procedure by reading through the patient's history and physical report? Why didn't anyone stop to reconfirm the correct surgery site when the patient exhibited confusion about the surgery he was having? Why didn't the scrub nurse notice the surgical site marking on the right knee before covering it up with a drape? This questioning process continues until the team identifies the system problems that underlie the causal factors. System problems take many forms (Vincent 2003):

- Organization and management (e.g., policies and standards, organizational culture, values and priorities)
- Work environment (e.g., staffing levels, workload, skill mix, resource availability, managerial support)
- Team (e.g., communication, team leadership, willingness to seek help)
- Individual staff members (e.g., knowledge and skills, motivation and attitude)
- Task (e.g., availability and use of standardized procedures)

Since January 1995, The Joint Commission has been gathering information on the root causes of sentinel events. As of March 2008, The Joint Commission (2008e) has reviewed 4,977 sentinel events that occurred in accredited healthcare organizations. The most common root cause of sentinel events is inadequate communication between care providers or between care providers and patients/families. Other leading root causes include incorrect assessment of a patient's physical or behavioral condition and inadequate leadership, orientation, or training (The Joint Commission 2008b, 47).

The RCA team involved in investigating the event described in Critical Concept 8.2 determines the following system problems to be the root causes of the wrong-site surgery:

- During the surgery site verification step, members of the surgical team did not actively communicate with each other.
- Management does not ensure that members of the surgical team consistently comply with the standardized surgery site verification procedures.
- Surgeons' offices are not held accountable for not complying with the hospital's surgery scheduling procedures and history and physical exam report requirements.
- Perceived pressure for productivity (the need to start all procedures at the scheduled time) discourages members of the surgical team from interrupting

the process when something unusual occurs (such as a patient expressing confusion about the surgery he is having).

An adverse event usually has no more than four root causes. If the team identifies more than four, questioning should continue until the fundamental reasons are apparent.

Now that the root causes of the sentinel event have been identified, the team develops solutions to prevent such an event from occurring again. The Joint Commission uses the phrase **risk reduction strategies** to describe the actions required to reduce or eliminate root causes. Risk reduction strategies are divided into three broad action categories:

Risk reduction strategies
Actions undertaken to reduce or eliminate the root cause of an adverse event (Examples of risk reduction strategies are found in Table 8.5.)

- Eliminate the chance of failure
- Help people perform their jobs correctly
- Help people identify and correct mistakes before patients are harmed

Examples of strategies in each category are described in Table 8.5.

The remaining steps of the RCA project are the same as those of any improvement project. The risk reduction strategies are implemented and tested to determine whether desired results have been achieved. If the strategies are successful, they are made permanent. Strategies that don't achieve the desired results are evaluated to determine why they didn't work, and new strategies are developed and tested.

LEARNING POINT
Root Cause Analysis

Root cause analysis is an accident investigation technique undertaken to find and fix the fundamental causes of an adverse event. It is similar to any improvement method that follows the steps of the Plan-Do-Study-Act cycle.

FMEA and RCA are not exclusively used for improving the safety of patient care processes. Just as the FMEA improvement model can be used to conduct a prospective risk assessment of any process, the RCA model can be used to investigate the cause of any process failure.

8.5 Patient Engagement in Safety

A patient safety observation by authors of the IOM (1999) report *To Err Is Human* involved the role of patients in preventing medication errors:

> Patients themselves also could provide a major safety check in most hospitals, clinics, and practice. They should know which medications they are taking, their appearance, and their side effects, and they should notify their doctors of medication discrepancies and the occurrence of side effects.

Table 8.5. Action Categories and Risk Reduction Strategies

Action Category	*Examples of Risk Reduction Strategies*
Eliminate the chance of failure	• Change the process to prevent failures • Restructure tasks so that error-inducing behavior is no longer performed • Automate the process to reduce the role of human involvement • Purchase error-proof equipment
Help people perform their jobs correctly	• Create visible displays of acceptable actions • Conduct pre-action inspections using checklists or other reminders • Educate staff and monitor compliance • Standardize the process • Reduce the number of steps in the process, thus reducing the chance of error • Make ergonomic changes (e.g., improve lighting, reduce workplace clutter) • Maintain equipment according to manufacturers' recommendations (e.g., regularly monitor compliance with routine maintenance schedules)
Help people identify and correct mistakes before the patient is harmed	• Train people to better recognize and deal with unusual situations • Create specialized teams of people who are coordinated and prepared to deal with unusual situations

In 2003, the National Quality Forum called for more research regarding the ways providers can facilitate the role of patients in reducing their chance of experiencing a medical error. Since then, a growing body of research suggests patients and their family members can be additional safeguards in the healthcare system (Spath 2008b). Here are just some of the ways patients can make their hospital experience safer:

- Observe/ask caregivers to perform patient identity checks before administration of treatments
- Keep a list of prior medical history, current treatments, and allergies, and share this list with caregivers at admission

- Know how often staff should change wound dressings, and when/how/whom to ask for a dressing change
- Know the type, dosage, and frequency of administration for medications; ask caregivers to explain prescribed medications to verify that they are correct; if incorrect, question the caregiver's decision to administer the medication
- Observe/ask whether caregivers have washed their hands
- Monitor the cleanliness of the equipment and the environment and report problems
- Be informed about the usefulness of changing position in the hospital bed, and ask for position changes if they aren't made as required
- Request help when getting out of bed, or ask for an assistive device (e.g., cane or walker)
- Confirm that caregivers know what the doctor has ordered
- Ask about equipment to understand what different sounds or noises mean; alert caregivers if there appears to be a problem

In 2002, The Joint Commission joined with AHRQ, the American Medical Association, and other national groups to promote involvement of consumers in patient safety efforts. As of this writing, The Joint Commission (2008a, 22) requires accredited organizations to encourage patients' active involvement in their care as a patient safety **strategy**. Caregivers are required to communicate with the patient and family about all aspects of care and encourage them to report concerns about safety.

Strategy
Action designed to lower the risk of failure

Some forward-thinking healthcare organizations are not only sharing information with patients and partnering with them for safety purposes but also including them in advisory groups to solicit safety improvement suggestions. At Dana-Farber Cancer Institute in Boston, patient and family representatives participate in a number of quality and patient safety–related committees (Joint Commission Resources 2006). Likewise, the patient safety oversight committee at Passavant Area Hospital in Jacksonville, Illinois, includes three laypeople from the community. This committee reviews the hospital's patient safety measurement results and discusses solutions to safety problems (Spath 2008a). Dana-Farber and Passavant are two of many organizations embracing consumers as safety partners. Openly

LEARNING POINT
Patient Safety

Patients and family members can promote their safety by speaking up when something appears unsafe or out of the ordinary. In some organizations, patients and family members are involved in internal quality management efforts.

soliciting the consumer perspective on healthcare quality management, including safety improvement, is a relatively new phenomenon gaining in popularity.

Conclusion

For many years, healthcare organizations have relied primarily on people performing their jobs correctly to protect patients from unintended harm. Decades of research, mostly from other industries, has proven that most accidents are caused by capable but fallible people working in dysfunctional systems. Healthcare organizations are now borrowing techniques from other industries and using a systems approach to improve patient safety.

Patient safety is only one dimension of healthcare quality, yet it receives a lot of attention from regulators, purchasers, and accreditation groups. As consumerism in healthcare grows, patients are expecting to take a more active role in safety. Consumers' involvement in safety improvement is becoming a major contributor to healthcare organizations' quality management efforts.

Patient safety includes the same basic quality management components: measurement, assessment, and improvement. Two improvement models, FMEA and RCA, are often used to reduce the chance that harmful mistakes will occur.

Student Discussion Questions

1. Go through the steps of an FMEA project for the process of taking a bath (see Figure 8.11). Use a worksheet like the one in Figure 8.7 to document your ideas.

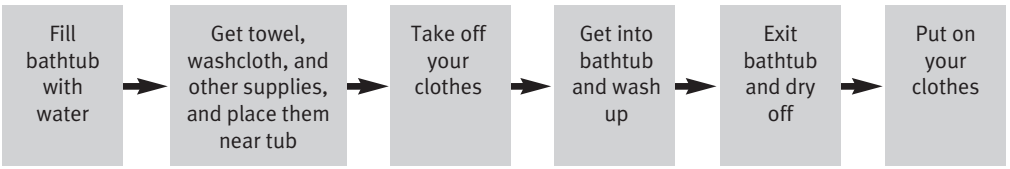


Figure 8.11. Flowchart of Process of Taking a Bath

When completing the FMEA, consider your own bathing experiences and what other people may have told you about their experiences. Be creative; there are no wrong answers.

2. Read the description of the wrong-site surgery event in Critical Concept 8.2 and the root causes identified by the team that conducted the RCA. Conduct a literature and Internet

search for risk reduction strategies aimed at preventing wrong-site surgeries. Which of these strategies would help prevent a similar event from occurring at the hospital described in Critical Concept 8.2?

Websites

- Agency for Healthcare Research and Quality Patient Safety Network
  www.psnet.ahrq.gov
- Consumers Advancing Patient Safety
  www.patientsafety.org
- Grout, J. R. 2007. *Mistake-Proofing the Design of Health Care Processes*. AHRQ Publication No. 07-P0020. Rockville, MD: Agency for Healthcare Research and Quality.
  www.ahrq.gov/qual/mistakeproof
- Maryland Office of Health Care Quality
  www.dhmh.state.md.us/ohcq/index.html
- National Patient Safety Foundation
  www.npsf.org
- Patient safety organizations
  www.pso.ahrq.gov/index.html
- Pennsylvania Patient Safety Authority
  www.psa.state.pa.us
- Safety Leaders Organization sponsored by the Texas Medical Institute of Technology
  www.safetyleaders.org
- VA National Center for Patient Safety
  www.va.gov/ncps/index.html
- Web M&M: A case-based journal and forum on patient safety
  http://webmm.ahrq.gov

References

Agency for Healthcare Research and Quality (AHRQ). 2008. *2007 National Healthcare Quality Report*, Pub. No. 08-0040. Rockville, MD: U.S. Department of Health and Human Services.

American Society for Healthcare Risk Management. 2002. "Strategies and Tips for Maximizing Failure Mode and Effect Analysis in Your Organization." [Online article; retrieved 5/12/09]. www.ashrm.org/ashrm/education/development/monographs/FMEAwhitepaper.pdf.

Institute of Medicine (IOM). 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academies Press.

———. 2000. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press.

———. 1999. "To Err Is Human: Building a Safer Health System; Report Brief." [Online information; retrieved 11/12/08.] http://books.nap.edu/html/to_err_is_human/reportbrief.pdf.

Joint Commission, The. 2008a. *Hospital Accreditation Program, 2009 Chapter: National Patient Safety Goals* (prepublication version). Oakbrook Terrace, IL: The Joint Commission.

———. 2008b. *Improving America's Hospitals: The Joint Commission's Annual Report on Quality and Safety, 2007*. [Online information; retrieved 6/20/08.] www.jointcommissionreport.org/pdf/JC_2007_Annual_Report.pdf.

———. 2008c. *2009 Accreditation Requirements Chapters, Accreditation Program: Hospital* (prepublication version). Oakbrook Terrace, IL: The Joint Commission.

———. 2008d. *2009 Accreditation Requirements Chapters, Accreditation Program: Long Term Care* (prepublication version). Oakbrook Terrace, IL: The Joint Commission.

———. 2008e. "Sentinel Event Statistics: As of March 31, 2008." [Online information; retrieved 6/20/08.] www.jointcommission.org/SentinelEvents/Statistics.

Joint Commission Resources. 2006. "Including Patients in Hospital Management Decisions: Patients Become Partners in the Care Process." *Joint Commission Perspectives on Patient Safety* 6 (1): 9–11.

Leape, L. L., D. W. Bates, D. J. Cullen, J. Cooper, H. J. Demonaco, T. Gallivan, R. Hallisey, J. Ives, N. Laird, G. Laffel, et al. 1995. "Systems Analysis of Adverse Drug Events." *Journal of the American Medical Association* 274 (1): 35–43.

McDermott, R. E., R. J. Mikulak, and M. R. Beauregard. 1996. *The Basics of FMEA*. Portland, OR: Resources Engineering, Inc.

National Aeronautics and Space Administration (NASA). 2003. "Columbia Accident Investigation Board." [Online information; retrieved 11/19/08.] http://caib.nasa.gov.

National Quality Forum. 2003. "Safe Practices for Better Healthcare: A Consensus Report." [Online information; retrieved 2/2/09.] www.ahrq.gov/qual/nqfpract.pdf.

O'Leary, M., and S. L. Chappell. 1996. "Confidential Incident Reporting Systems Create Vital Awareness of Safety Problems." *International Civil Aviation Organization Journal* 51 (8): 11–13.

Reason, J. 2001. "Heroic Compensations: The Benign Face of the Human Factor." *Flight Safety Australia* 6 (1): 29–31.

Spath, P. L. 2008a. "Involving Patients in Safety Improvement." *H&HN OnLine Magazine* [Online article; retrieved 11/10/08.] www.hhnmag.com/hhnmag_app/jsp/articledisplay.jsp?dcrpath=HHNMAG/Article/data/02FEB2008/080219HHN_Online_Spath&domain=HHNMAG.

———. 2008b. "Safety from the Patient's Point of View." In *Engaging Patients as Safety Partners: A Guide for Reducing Errors and Improving Satisfaction*, edited by P. Spath, 1–40. Chicago: Health Forum, Inc.

———. 2001. *The Basics of Patient Safety*. Forest Grove, OR: Brown-Spath & Associates.

Tucker, A. L., and A. C. Edmondson. 2003. "Why Hospitals Don't Learn from Failures: Organizational and Psychological Dynamics That Inhibit System Change." *California Management Review* 45 (2): 55–72.

U.S. Department of Veterans Affairs, VA National Center for Patient Safety. 2007. "Using Healthcare Failure Modes and Effects Analysis™." [Online article; retrieved 11/1/08.] www.va.gov/NCPS/SafetyTopics/HFMEA/HFMEA_JQI.html.

Vincent, C. 2003. "Understanding and Responding to Adverse Events." *New England Journal of Medicine* 348 (11): 1051–56.

Wachter, R. M. 2008. *Understanding Patient Safety*. New York: McGraw-Hill.

Wickens, C. D., J. D. Lee, Y. Liu, and S. E. Gordon-Becker. 1997. *An Introduction to Human Factors Engineering*, 2nd edition. New York: Prentice Hall.