

# Target: Patient Safety

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*The Joint Commission has raised and revised its patient safety standards. Is your facility ready to meet them?*

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Safety in healthcare is not a new concept. Even before the American College of Surgeons formed the Hospital Standardization Program in 1917, healthcare facilities had safety programs in place. These programs aimed to provide a secure and healthy environment in which hazards were minimized for employees, patients, and visitors. When the Joint Commission on Accreditation of Healthcare Organizations took over the accreditation of hospitals in 1951, safe healthcare environments remained a priority.

Due to the public's heightened awareness of medical errors and patient mishaps, the Joint Commission has strengthened its commitment to patient safety. The first step toward adopting a more focused approach to improving patient safety was revising standards to require thorough and systematic investigations of sentinel events in 1996. Minor revisions to encourage patient safety improvements were made in the following years, while lessons learned by other industries involved in safety improvement influenced new standards. The standards have evolved to address what many consider to be the four vital elements of a successful safety program:

- committed and involved people
- supportive culture
- error containment activities
- error reduction activities

In July 2001, new standards covering all four elements took effect.<sup>1</sup> The Joint Commission's mission statement was recently updated to reflect this commitment: "Continuously improve the safety and quality of care provided to the public through the provision of healthcare accreditation and related services that support performance improvement in healthcare organizations." This article describes how healthcare organizations can meet many of these new requirements.

## Make the Commitment

To begin, an organization must make patient safety a visible, organization-wide priority. Because the Joint Commission standards do not specify how an organization is expected to show its commitment to patient safety, it's not necessary to revise mission statements, update values, or issue new goal statements. Surveyors will evaluate leadership's commitment to patient safety through discussions with people in the organization—not by reviewing documents. However, incorporating patient safety into the organization's mission statement or articulating the commitment by developing and disseminating goals statements will help illustrate facility leaders' dedication to improving patient safety (see ["Sample Patient Safety Goal Statement,"](#)). Keep in mind that any mottos or value statements leaders develop must be supported by the staff's attitudes and actions.

## A Part of Performance Improvement

To ensure adequate involvement in patient safety initiatives, organizations should evaluate their current performance improvement structure. Many patient safety activities may already be underway within the facility. Joint Commission standards require that organizations designate an individual or inter-disciplinary group to coordinate patient safety efforts. However, organizations don't need to create a separate patient safety program. Instead, they may simply need to redesign reporting relationships to ensure that the designated individual or group is kept informed of all safety-related measurement results and improvement activities.

A patient safety initiative fits nicely within an organization's performance improvement (PI) plan. The PI plan should be updated to reflect an intensified focus on patient safety and include the person or group responsible for coordinating the initiatives. Where appropriate, the phrase "performance improvement" can be changed to "performance and patient safety improvement." Be sure the PI plan describes the method used for investigating sentinel events (unexpected occurrences involving death or serious physical or psychological injury or risk thereof) and choosing proactive patient safety improvement projects. Many organizations include risk reduction and patient safety as PI program goals.

## Staff Involvement Is Key

Staff members need guidance in what patient safety comprises and why improvements are desirable. Involving clinicians in a root cause analysis of a significant patient incident provides an excellent training experience. As members of the team searching for the underlying cause of a medical accident, clinicians can see how important it is to find the "bad" processes that cause good people to make mistakes. Remember that not everyone can be given the chance to serve on an accident investigation team, so other training opportunities must be offered.

The Joint Commission requires that new and current employees receive a general orientation about the organization's policies and procedures related to patient safety, error reporting, and patient safety program definitions. Specific safety education and training about the patient safety hazards associated with different job responsibilities should also be provided when staff are first hired, when a new hazard is introduced in the workplace, and when there is a change in job assignment.

## Patients: Bystanders No Longer

According to Joint Commission standards, healthcare organizations are required to partner with patients and families to improve the safety of healthcare services. Surveyors are closely evaluating how organizations are involving patients and families in patient safety efforts. Specifically, organizations must gather opinions from patients and their families to determine their perceptions about safety, existing risks, and potential for improvements. Consider adding safety-related questions to inpatient and outpatient patient satisfaction surveys. Questions might include:

- Did staff verify your name prior to administration of medications? (Yes, always/Yes, sometimes/No)
- Did staff wear protective gloves while caring for you? (Yes, always/Yes, sometimes/No)
- Did someone tell you what danger signals about your illness or operation to watch for after you went home? (Yes, completely/Yes, somewhat/No)
- How well was care coordinated among all the people who provided care for you? (Excellent/Very good/Good/ Fair/Poor)
- Did you receive adequate education about your role in the safe delivery of care? (Excellent/Very good/Good/ Fair/Poor)

To illustrate the organization's commitment to partnering with patients and their families, consider adding a statement about the role of patients and families in creating a safe environment in the operating principles or mission and patients' rights materials. Brochures or other educational materials about the patients' and families' roles in safety can be designed and distributed.<sup>2</sup>

## Create a Just Culture

A healthcare organization's culture significantly affects the safety of patients. "Culture" refers to the attitudes of senior leaders that shape staff behavior. The safety culture of an organization is the product of several factors: individual and group values, attitudes, perceptions, competencies, and patterns of behavior. These, in turn, determine an organization's commitment to and the style and proficiency of patient safety management. There are five essential principles of a culture of safety:

- Concern for the safety of patients should be **embedded in the healthcare organization as a whole**. Every staff member needs to assume this responsibility.
- There must be an awareness and understanding of patient safety and an appropriate means of managing issues relating to safety **at all levels** of healthcare services.
- Human fallibility is an inescapable reality. Thus, a mindset of **constant vigilance** is crucial.
- Fear is the enemy of patient safety. An **open and non-punitive environment** in which it is safe to admit and report unintended process variations, especially errors, is fundamental.

- Unintended process variations and adverse events offer an opportunity to **learn** and to **make changes for the better**, not an occasion to punish and forget.

Organization leaders are expected to promote a safe patient culture through words and actions. It is essential that they understand how attitudes at the operational level can affect the patient safety. To determine perceptions about the safety of the work environment, consider conducting a survey of physicians and staff on incident reporting issues, a practice encouraged by the Joint Commission (see [“Staff Survey of Patient Incident Reporting Practices,”](#)).

A keystone of patient safety is an environment that acknowledges the unintentional nature of human error and seeks to learn from mistakes. In this “just” culture, simple errors should not be cause for disciplinary or punitive action.<sup>3</sup> In fact, the threshold for disciplinary action must change. Most organizations will have to rethink their disciplinary policies by answering the following questions:

- When does disciplinary action serve to prevent future events?
- What system of accountability corresponds with the organization’s sense of justice?

As a result, disciplinary action should be used only in the following situations:

- an individual intentionally violates safe practice standards
- an individual commits a reckless act (for example, a caregiver’s action placed a patient at substantial risk, the caregiver understood the risks involved, and the action was not justified given the circumstances)

By providing a safe reporting environment and limiting discipline to individuals who knowingly put patient safety at risk, the organization will realize a critical goal in meeting Joint Commission standards: obtaining the information needed to identify and address underlying system problems that result in adverse patient incidents. The leadership and information management standards of the Joint Commission emphasize the importance of gathering timely and accurate information about patient incidents and hazardous situations.

## Contain Errors Through Analysis

Since 1996 the Joint Commission standards have required organizations to investigate sentinel events. These investigations, known as root cause analyses, aim to identify and resolve underlying system issues that precipitated the event to prevent similar events from occurring in the future.

To meet the Joint Commission’s error containment requirements, organizations should have a defined process for identifying patient incidents that would benefit from a root cause analysis. The risk manager or performance improvement staff may conduct the initial screening of incidents, and administrative or medical staff leaders should make the final decision to conduct a root cause analysis. Because this standard has been in place for several years, most facilities have already conducted several root cause analysis investigations. It’s important not to wait until a serious mishap occurs: incident investigations should be undertaken for near-miss situations also.

## Take a Proactive Approach to Error Reduction

The 2001 changes in the Joint Commission standards expanded requirements for proactive error reduction activities. These activities involve two components:

- ongoing monitoring of critical activities in high-risk patient care processes
- proactive redesign of high-risk processes to reduce the chance that mistakes will harm patients

Patient safety improvements cannot be achieved when an organization acts only on what is learned from yesterday’s mistakes. Again, don’t wait for an undesirable incident to start redesigning patient care processes. Proactive patient safety initiatives are needed to stay ahead of the accidents.

## Take a Measure

For many years, Joint Commission standards have required that organizations measure and analyze the performance of important processes. When significant variation is identified, they need to take appropriate corrective actions. The Joint Commission is currently focusing on critical steps, which are tasks that must be performed properly all (or most) of the time to protect patients from harm. To improve patient safety, organizations are now required to conduct ongoing measurements of critical steps in at least one high-risk process to determine the degree of variation from intended performance (see [“Measures of Critical Tasks in Medication Administration,”](#) for examples in medication administration).

Common high-risk patient care processes that are the focus of nationwide error reduction activities include:

- medication prescribing, dispensing, administration, and monitoring of the events. There are specific medications known to be associated with adverse events. Examples of these “high-alert” medications include:
  - medications with similar names
  - medications with similar packaging
  - medications that are not commonly used or prescribed
  - commonly used medications to which many people are allergic
  - medications requiring testing to ensure proper therapeutic levels
  - insulin, opiates and narcotics, injectable potassium chloride (or phosphate) concentrate, intravenous anticoagulants (heparin), and sodium chloride solutions
- interpretation of diagnostic test results
- restraining of patients
- blood/blood products dispensing, administration, and monitoring of the effects
- security of infants/newborns and other patients at high risk for abduction
- assessment, monitoring, and treatment of high-risk patients (e.g., patients who are confused, suicidal, immuno-suppressed, have multi-system failures, or require complex care)
- intra-operative patient care activities
- use of medical equipment that has been shown to be at risk for human error

In addition, organizations should frequently evaluate pertinent safety measures to identify opportunities for improvement (see [“Common Safety-related Performance Measures,”](#).) Make the results of these measures available to those overseeing the patient safety initiative.

## Redesign High-risk Processes

Redesigning high-risk processes is an important proactive error-reduction activity. Joint Commission standards require organizations to redesign processes known to be problem prone using knowledge-based information, which consists of literature recommendations, guidelines, and safety alerts from national organizations. Be sure your organization has access to common sources of this information, including:

- Food and Drug Administration (FDA) medical device and product-related incident alerts<sup>4</sup>
- medication safety alerts from the Institute for Safe Medication Practices<sup>5</sup>
- reports of medical device safety hazards issued by ECRI, a nonprofit international health services research agency<sup>6</sup>
- Sentinel Event Alerts issued by the Joint Commission<sup>7</sup>
- protocols and educational materials available from the Anesthesia Patient Safety Foundation<sup>8</sup>

Consider maintaining a log of all information that has been acquired and shared with relevant departments, along with actions taken. Surveyors will be looking for evidence that the information is being used to proactively improve patient care so that safety risks are minimized.

## Assess the Risks

Proactive risk assessment is the third error-reduction activity designed to improve the safety of a high-risk process. Unlike a quality improvement project that may focus on improving productivity or process efficiency, a proactive risk assessment focuses on reducing or eliminating the chance of human mistakes. The organization must conduct at least one proactive risk assessment for a high-risk process annually. If your facility is scheduled for a Joint Commission survey after July 1, 2002, it is expected that you will have completed at least one proactive risk assessment.

Several risk assessment techniques have been developed for use in private industries and many of these can be applied to healthcare. The Joint Commission suggests that healthcare organizations use the Failure Mode, Effects, and Criticality Analysis (FMECA) method. This technique promotes systematic thinking about the safety of a patient care process by asking:

- What could go wrong?
- How badly might it go wrong?
- What needs to be done to prevent failures?

The FMECA investigation involves an in-depth analysis of a process conducted by a multidisciplinary team of people familiar with it. The FMECA process begins with the development of a clear understanding of the current process using a flow chart to visualize each step. Next, the team conducts a brainstorming session to create a list of all potential failures for each step. Then, the team determines the criticality score of each potential failure, calculated by considering variables such as the probable frequency of the failure, the amount of harm that might occur, and the likelihood that the failure will be detected before it reaches the patient. Failures with the highest criticality score are those that the team concentrates on preventing.

Once the potential critical failures are better understood, the team redesigns the process to correct problems at their source; in other words, the root causes. It helps to consider the “who, what, where, when, why, and how” of a mistake when trying to unearth the root cause. The team then develops and implements process redesign solutions to prevent the root causes of critical failures. Joint Commission surveyors will expect the team to consider the safety improvement recommendations from external groups when redesigning processes as well as thoroughly test proposed process changes before final implementation.

## The Light at the End of the Tunnel

Patient safety is an important issue for all healthcare organizations, regardless of Joint Commission accreditation. Yet Joint Commission patient safety standards provide a framework for creating a safer healthcare environment. Use a checklist to assess your organization’s compliance with standards related to patient safety (see [“Joint Commission Standards Related to Patient Safety.”](#)). If your organization is not accredited, use the checklist as a guide to creating a safer patient care system in your facility.

Implementing these standards may take some time, but the benefits are obvious. Effective management of safety risks protects the organization’s profitability and avoids the damaging effects of employee turnover. Further, it improves the organization’s reputation with physicians, staff, customers, competitors, other stakeholders, and the community. The most valuable outcome of a patient safety initiative, however, benefits the patients. Meeting these standards reduces injuries, illnesses, and fatalities during the provision of healthcare services while maximizing the well being of the patients.

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## Notes

1. The Joint Commission publishes standards for patient safety in its accreditation manuals for various fields, such as hospitals, home care, and integrated delivery systems. More information on Joint Commission standards and its accreditation manuals can be found online at [www.jcaho.org](http://www.jcaho.org).
2. Two examples of patient education brochures addressing patient safety issues are available on the Internet. Virginians Improving Patient Care and Safety, a coalition of hospitals, healthcare professionals, and health plans, developed a brochure that describes what the public can do to make the healthcare system safer. This brochure is available online at [www.vipcs.org/patients/index.htm](http://www.vipcs.org/patients/index.htm). The Massachusetts Coalition for the Prevention of Medical Errors has created a patient brochure on the subject of medication error prevention. This brochure is available at [www.mhalink.org/publications/docs/consumerguide.pdf](http://www.mhalink.org/publications/docs/consumerguide.pdf).
3. Marx, D. Patient Safety and the ‘Just Culture’: A Primer for Health Care Executives. Columbia University Medical Event Reporting System for Transfusion Medicine, April 2001. Available online at [www.mers-tm.net](http://www.mers-tm.net).
4. The reports received under the FDA’s Medical Devices Reporting Program are available online at [www.fda.gov/cdrh/](http://www.fda.gov/cdrh/). FDA

- medical product alerts can be found on the MedWatch Web site at [www.fda.gov/medwatch/safety.htm](http://www.fda.gov/medwatch/safety.htm). The FDA's Vaccine Adverse Event Reporting System alerts are available online at [www.fda.gov/cber/vaers/vaers.htm](http://www.fda.gov/cber/vaers/vaers.htm).
5. Medication safety alerts can be found on the Institute for Safe Medication Practices Web site at [www.ismp.org](http://www.ismp.org).
6. ECRI Medical Device Safety Reports are available online at [www.mdsr.ecri.org](http://www.mdsr.ecri.org).
7. Sentinel event alerts are posted on the Joint Commission's Web site at [www.jcaho.org](http://www.jcaho.org)
8. These materials are available on the Anesthesia Patient Safety Foundation Web site <http://gasnet.med.yale.edu/apsf/>.

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## Sample Patient Safety Goal Statement

This organization's shared core value of error reduction will be accomplished by:

- creating an environment that encourages responsible reporting of process variations and mistakes in order to fix systems that inhibit patient safety
- establishing priorities that direct resources to the implementation of patient safety improvement initiatives
- identifying, sharing, and implementing safe practices that are known to reduce adverse patient events
- encouraging patients to be aware of their role in maintaining a safe environment
- providing regular patient safety training and education for individuals and groups
- implementing meaningful evaluation of critical activities that affect patient safety

## Staff Survey of Patient Incident Reporting Practices

	Likely			Very Unlikely
How likely would you be to self-report a near miss if the patient was not harmed?	1	2	3	4
How likely would you be to report a colleague's error?	1	2	3	4
How likely is negative treatment if you reported or discussed errors?	1	2	3	4
How likely is support from your supervisor for addressing patient safety problems in your area?	1	2	3	4



## Measures of Critical Tasks in Medication Administration

Critical Tasks	Measures
Provide complete patient identification when ordering medication	Percentage of orders received by pharmacy that lack complete patient identification information
Write orders legibly	Percentage of orders received by pharmacy that are illegible
Review patient allergies before prescribing medications	Percentage of orders received by pharmacy for medication to which patient has a known allergy
Write medication orders that can be accurately interpreted	Percentage of orders received by pharmacy that contain “non-approved” abbreviations or acronyms
Provide patients with complete dosing information	Percentage of take-home medications dispensed that do not have complete dosing information on label
Monitor drug levels for patients on high-alert medications	Percentage of patients receiving theophylline who do not have a theophylline drug level measurement some time during their hospitalization

## Common Safety-Related Performance Measures

<b>Patient Safety</b> <ul style="list-style-type: none"> <li>• medication errors/adverse drug events</li> <li>• nosocomial infections</li> <li>• patient falls</li> <li>• pressure ulcers</li> <li>• transfusion reactions/blood/blood product administration incidents</li> <li>• communicable disease exposures</li> <li>• surgical mishaps</li> <li>• use of restraints</li> <li>• other patient incidents/unexpected clinical events</li> <li>• hazardous conditions</li> <li>• results of patient/family surveys regarding safety</li> </ul>	<b>Worker Safety</b> <ul style="list-style-type: none"> <li>• blood/body fluid exposures</li> <li>• occupational diseases</li> <li>• communicable disease exposures</li> <li>• musculoskeletal injuries</li> <li>• immunization programs</li> <li>• other employee incidents</li> <li>• employee turnover rates</li> </ul>
<b>Visitor Safety</b> <ul style="list-style-type: none"> <li>• visitor incidents</li> </ul>	<b>Environmental Safety</b> <ul style="list-style-type: none"> <li>• product recalls</li> <li>• drug recalls</li> <li>• product/equipment malfunction</li> <li>• air and water quality</li> <li>• security incidents</li> <li>• incidents of workplace violence</li> </ul>

## Joint Commission Standards Related to Patient Safety

	Fully Implemented	Partially Implemented	Implementation Not Yet Begun
<b>Leadership Standards</b>			

LD.1.4. states that the planning process provides for setting performance improvement priorities and adjusts these priorities in response to unanticipated adverse occurrences affecting patients.			
LD.1.8. states that leaders and other relevant personnel collaborate in decision making including a program to measure, assess, and improve performance and patient safety.			
LD.3.2. states that leaders foster a culture that emphasizes cooperation and communication in order to improve patient safety.			
LD.3.4. states that policies and procedures are developed to ensure consistency in the performance of processes. The leaders develop programs to measure the actual performance of processes identified as error prone or high risk, and when variation is identified, take corrective action. At any given time, at least one high-risk process is the subject of an ongoing analysis.			
LD.4.4.-LD.4.4.5 state that leaders allocate adequate resources for improving patient safety including human, information, physical, and financial resources and that they assess the adequacy of these resources.			
LD.4.5. states that leaders must measure and assess their contributions to improving performance and patient safety using the framework described in the Improving Organization Performance chapter.			
LD.5. states that leaders ensure implementation of an integrated patient safety program in the organization.			
LD.5.1. states that leaders define and implement processes for identifying and managing sentinel events.			
LD.5.2. states that leaders define and implement an ongoing, proactive program for identifying and reducing risks in the areas of patient safety and medical errors. This program must include selection of at least one high-risk process annually for a proactive risk assessment.			
LD.5.3. states that leaders ensure that patient safety issues are given a high priority when processes are designed or redesigned.			
<b>Improving Organizational Performance Standards</b>			



PI.2. states that processes must be designed well and must use both internal and external information about potential risks, including sentinel events, in order to minimize risk to patients.			
PI.3.1. states that the organization must collect data to monitor its performance including patient, family, and staff opinions, needs, perceptions of risks, and suggestions for improving patient safety, and staff willingness to report errors. See standard for additional data to be collected.			
PI.4.3. states that undesirable patterns or trends in performance and sentinel events are intensively analyzed. Intense analysis also occurs for those topics chosen by leadership as performance improvement priorities and priorities for proactive reduction in patient risk.			
PI.4.4. states that the organization identifies changes that will lead to improved performance and improved patient safety.			
<b>Management of Information Standards</b>			
IM.1. states that the hospital plans information management processes to meet internal and external needs. The hospital assesses its information management needs based in part on identification of barriers to effective communication among caregivers.			
IM.5. states that the transmission of data and information must be timely and accurate. Specific attention is given to the processes for ensuring accurate, timely, and complete verbal and written communication among caregivers and others involved in data utilization.			
IM.7.2. states that the medical record contains all required information for good patient care including all test results relevant to the management of the patient's condition.			
IM.8. states that the hospital collects and aggregates data to support the delivery of care and operations. This data collection and aggregation function supports performance improvement and reduction of risks to patients.			
IM.9. states that knowledge-based information systems include those describing best practices used to reduce risks.			

<b>Patient Rights and Organization Ethics Standards</b>			
RI.1.2.2. states that patients and families are informed about the outcomes of care, including unanticipated outcomes.			
<b>Patient Education Standards</b>			
PF.3.7. states that the safety of healthcare delivery is enhanced by the involvement of the patient and family as a partner in the healthcare process.			
<b>Continuum of Care Standards</b>			
CC.4.-CC.5. states that the hospital ensures continuity over time among the phases of care to a patient including communication and transfer of information between healthcare professionals in various services and settings essential to a seamless, safe, and effective process.			
<b>Human Resources Standards</b>			
HR.4.-HR.4.2. states that the employee orientation process and ongoing in-service and training programs must emphasize specific job-related aspects of patient safety. These must include ways to report medical errors and definitions such as error, sentinel event, near misses, and hazardous conditions.			

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