Patient Safety Systems (PS)

Quality and Safety in Health Care

The quality of care and the safety of patients are core values of The Joint Commission accreditation process. This is a commitment The Joint Commission has made to patients, families, health care practitioners, staff, and health care organization leaders.

The ultimate purpose of The Joint Commission's accreditation process is to enhance quality of care and patient safety. Each accreditation requirement, the survey process, the Sentinel Event Policy, and other Joint Commission policies and initiatives are designed to help organizations reduce variation, reduce risk, and improve quality. Organizations should have an integrated approach to patient safety so that safe patient care can be provided for every patient in every care setting and service.

Organizations are complex environments that depend on strong leaders to support an integrated patient safety system that includes the following:

- Safety culture
- Validated methods to improve processes and systems
- Standardized ways for interdisciplinary teams to communicate and collaborate
- Safely integrated technologies

In an integrated patient safety system, staff and leaders work together to eliminate complacency, promote collective mindfulness, treat each other with respect and compassion, and learn from patient safety events, including close calls and other system failures that have not yet led to patient harm. Sidebar 1 defines these and other key terms.

Sidebar 1. Key Terms

- patient safety event An event, incident, or condition that could have resulted or did result in harm to a patient.
- adverse event A patient safety event that resulted in harm to a patient. Adverse events should prompt notification of organization leaders, investigation, and corrective actions. An adverse event may or may not result from an error.

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Sidebar 1. (continued)

- sentinel event A sentinel event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm). Sentinel events are a subcategory of adverse events.
- close call A patient safety event that did not cause harm but posed a risk of harm. Also called *near miss* or *good catch*.
- hazardous condition A circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event. Also called *unsafe condition*.

Quality and safety in health care are inextricably linked. *Quality*, as defined by the National Academy of Medicine (known as the Institute of Medicine until 2015), is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.¹ It is achieved when processes and results meet or exceed the needs and desires of the people it serves.^{2,3} Those needs and desires include safety.

The components of a quality management system should include the following:

- Ensuring reliable processes
- Decreasing variation and defects (waste)
- Focusing on achieving positive measurable outcomes
- Using evidence to ensure that a service is satisfactory

Patient safety emerges as a central aim of quality. *Patient safety*, as defined by the World Health Organization, is the prevention of errors and adverse effects to patients that are associated with health care. Safety is what patients, families, staff, and the public expect from Joint Commission–accredited organizations. While patient safety events may not be completely eliminated, the goal is always zero harm (that is, reducing harm to patients). Joint Commission–accredited organizations should be continually focused on eliminating systems failures and human errors that may cause harm to patients, families, and staff.

^{&#}x27;For a list of specific patient safety events that are also considered sentinel events, *see* the "Sentinel Event Policy" (SE) chapter in E-dition® or the *Comprehensive Accreditation Manual*.

Goals of This Chapter

This "Patient Safety Systems" (PS) chapter provides organization leaders with a proactive approach to designing or maintaining a patient-centered system that aims to improve quality of care and patient safety, an approach that aligns with the Joint Commission's mission and its standards.

The Joint Commission partners with accredited organizations to improve the ability of health care systems to protect patients. The first obligation of health care is to "do no harm." Therefore, this chapter focuses on the following three guiding principles:

- 1. Aligning existing Joint Commission standards with daily work to engage patients and staff throughout the health care system, at all times, on reducing harm.
- 2. Assisting health care organizations to become learning organizations by advancing knowledge, skills, and competence of staff and patients by recommending methods that will improve quality and safety processes.
- 3. Encouraging and recommending proactive quality and patient safety methods that will increase accountability, trust, and knowledge while reducing the impact of fear and blame.

It informs and educates organizations about the importance and structure of an integrated patient safety system and helps health care workers understand the relationship between Joint Commission accreditation and patient safety. It offers approaches and methods that may be adapted by any health care organization that aims to increase the reliability and transparency of its complex systems while removing the risk of patient harm.

The PS chapter refers to specific Joint Commission standards, describing how existing requirements can be applied to achieve improved patient safety. It does not contain any new requirements. Standards cited in this chapter are formatted with the standard number in boldface type (for example, "Standard **RI.01.01.01**") and are accompanied by language that summarizes the standard. For the full text of a standard and its element(s) of performance (EP), please reference E-dition or the *Comprehensive Accreditation Manual*.

Throughout this chapter, we will do the following:

- Discuss how organizations can develop into learning organizations
- Identify the role leaders have to establish a safety culture and ensure staff accountability

- Explain how organizations can continually evaluate the status and progress of their patient safety systems
- Describe how organizations can work to prevent patient safety events with proactive risk assessments
- Highlight the critical component of patient activation and engagement in a patient safety system
- Provide a framework to guide organization leaders as they work to improve patient safety in their organizations

Becoming a Learning Organization

The need for sustainable improvement in patient safety and the quality of care has never been greater. One of the fundamental steps to achieving and sustaining this improvement is to become a learning organization. A *learning organization* is one in which people learn continuously, thereby enhancing their capabilities to create and innovate.⁴ Learning organizations uphold five principles:

- 1. Team learning
- 2. Shared visions and goals
- 3. A shared mental model (that is, similar ways of thinking)
- 4. Individual commitment to lifelong learning
- 5. Systems thinking⁴

In a learning organization, patient safety events are seen as opportunities for learning and improvement.⁵ Therefore, leaders in learning organizations adopt a transparent, nonpunitive approach to reporting so that the organization can *report to learn* and can collectively learn from patient safety events. In order to become a learning organization, an organization must have a fair and just safety culture, a strong reporting system, and a commitment to put that data to work by driving improvement. Each of these require the support and encouragement of organization leaders.

Leaders, staff, licensed practitioners, and patients in a learning organization realize that *every* patient safety event (from close calls to events that cause major harm to patients) must be reported and investigated.⁵⁻⁹ It is impossible to determine if there are practical prevention or mitigation countermeasures available for a patient safety event without first doing an event analysis. An event analysis will identify systems-level vulnerabilities and weaknesses and the possible remedial or corrective actions that can be implemented. When patient safety events are continuously reported, experts within the organization can define the problem, complete a comprehensive systematic analysis, identify

solutions, achieve sustainable results, and disseminate the changes or lessons learned to the rest of the organization.⁵⁻⁹ In a learning organization, the organization provides staff with information regarding improvements based on reported concerns. This helps foster trust that encourages further reporting. (*See* the "Sentinel Event Policy" [SE] chapter for more about comprehensive systematic analyses.)

The Role of Leaders in Patient Safety

Organization leaders provide the foundation for an effective patient safety system by doing the following:¹⁰

- Promoting learning
- Motivating staff to uphold a fair and just safety culture
- Providing a transparent environment in which quality measures and learnings about patient harm events are freely shared with staff
- Modeling professional behavior
- Addressing intimidating behavior that might undermine the safety culture
- Providing the resources and training necessary to take on improvement initiatives

For these reasons, many of the standards that are focused on the organization's patient safety system appear in the Joint Commission's Leadership (LD) standards, including Standard **LD.03.01.01** (which focuses on having a culture of safety).

Without the support of organization leaders, organizationwide changes and improvement initiatives are difficult to achieve. Leadership engagement in patient safety and quality initiatives is imperative because 75% to 80% of all initiatives that require people to change their behaviors fail in the absence of leaders managing the change.⁵ Thus, leaders should take on a long-term commitment to transform the organization.¹¹

Safety Culture

A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for organizations striving to become learning organizations. In a strong safety culture, the organization has an unrelenting commitment to safety and to do no harm. Among the most critical responsibilities of leaders is to establish and maintain a strong safety culture within their organization. The Joint Commission's standards address safety culture in Standard **LD.03.01.01**, which requires leaders to create and maintain a culture of safety and quality throughout the organization. The *safety culture* of an organization is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization's commitment to quality and patient safety. Organizations that have a robust safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.¹¹ Organizations will have varying levels of safety culture, but all should be working toward a safety culture that has the following qualities:

- Staff and leaders that value transparency, accountability, and mutual respect.⁵
- Safety as everyone's first priority.⁵
- Behaviors that undermine a culture of safety are not acceptable, and thus are reported to organization leaders by staff, patients, and families for the purpose of fostering risk reduction.^{5,11,13}
- Collective mindfulness is present, wherein staff realize that systems always have the potential to fail and staff are focused on finding hazardous conditions or close calls at early stages before a patient may be harmed.¹¹ Staff do not view close calls as evidence that the system prevented an error but rather as evidence that the system needs to be further improved to prevent any defects.^{11,14}
- Staff who do not deny or cover up errors but rather want to report errors to learn from mistakes and improve the system flaws that contribute to or enable patient safety events.⁷ Staff know that their leaders will focus not on blaming providers involved in errors but on the systems issues that contributed to or enabled the patient safety event.^{7,15}
- By reporting and learning from patient safety events, staff create a learning organization.

A safety culture operates effectively when the organization fosters a cycle of trust, reporting, and improvement.^{11,16} In organizations that have a strong safety culture, health care providers trust their coworkers and leaders to support them when they identify and report a patient safety event.¹¹ When trust is established, staff are more likely to report patient safety events, and organizations can use these reports to inform their improvement efforts. In the trust-report-improve cycle, leaders foster trust, which enables staff to report, which enables the organization to improve.¹¹ In turn, staff see that their reporting contributes to actual improvement, which bolsters their trust. Thus, the trust-report-improve cycle reinforces itself.¹¹ (*See* Figure 1.)

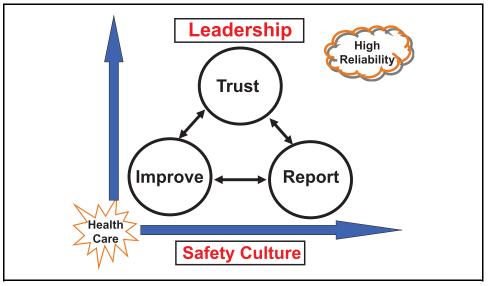


Figure 1. The Trust-Report-Improve Cycle. In the trust-report-improve cycle, trust promotes reporting, which leads to improvement, which in turn fosters trust.

Leaders and staff need to address intimidating or unprofessional behaviors within the organization, so as not to inhibit others from reporting safety concerns.¹⁷ Leaders should both educate staff and hold them accountable for professional behavior. This includes the adoption and promotion of a code of conduct that defines acceptable behavior as well as behaviors that undermine a culture of safety. The Joint Commission's Standard **LD.03.01.01**, EP 4, requires that leaders develop such a code.

Intimidating and disrespectful behaviors disrupt the culture of safety and prevent collaboration, communication, and teamwork, which is required for safe and highly reliable patient care.¹⁸ Disrespect is not limited to outbursts of anger that humiliate a member of the health care team; it can manifest in many forms, including the following:^{5,13,18}

- Inappropriate words (profane, insulting, intimidating, demeaning, humiliating, or abusive language)
- Shaming others for negative outcomes
- Unjustified negative comments or complaints about another provider's care
- Refusal to comply with known and generally accepted practice standards, which may prevent other providers from delivering quality care

- Not working collaboratively or cooperatively with other members of the interdisciplinary team
- Creating rigid or inflexible barriers to requests for assistance or cooperation
- Not responding to requests for assistance or information, not returning pages or calls promptly

These issues are still occurring in organizations nationwide. In a 2021 survey by the Institute for Safe Medication Practices (ISMP), 79% of 1,047 respondents reported personally experiencing disrespectful behaviors during the previous year. In addition, 60% reported witnessing disrespectful behaviors.¹⁹ The respondents included nurses, physicians, pharmacists, and quality/risk management personnel.

Approximately half (51%) of the respondents had asked colleagues to help interpret a medication order or validate its safety to avoid interacting with a particular prescriber.¹⁹ Moreover, 27% said they were aware of a medication error during the previous year in which behavior that undermines a culture of safety was a contributing factor. Nearly 200 events were described, many of which involved high-alert medications (for example, neuromuscular blocking agents, anticoagulants, insulin, chemotherapy) and led to significant delays in care and/or adverse events.

Of the respondents who indicated that their organizations had clearly defined an effective process for handling disagreements with the safety of an order, only 41% said that the process for handling disagreements allows them to bypass a typical chain of command, if necessary.¹⁹ While these data are specific to medication safety, their lessons are broadly applicable: Behaviors that undermine a culture of safety have an adverse effect on quality and patient safety.

A Fair and Just Safety Culture

A fair and just safety culture is needed for staff to trust that they can report patient safety events without being treated punitively.^{3,9} In order to accomplish this, organizations should provide and encourage the use of a standardized reporting process for staff to report patient safety events. Reporting enables both proactive and reactive risk reduction. Proactive risk reduction solves problems before patients are harmed, and reactive risk reduction attempts to prevent the recurrence of problems that have already caused patient harm.^{11,16} A fair and just culture takes into account that individuals are human, fallible, and capable of mistakes, and that they work in systems that are often

flawed. In the most basic terms, a fair and just culture holds individuals accountable for their actions but does not punish individuals for issues attributed to flawed systems or processes.^{15,19,20}

It is important to note that for some actions for which an individual is accountable, the individual should be held culpable and some disciplinary action may then be necessary. (*See* Sidebar 2 for a discussion of tools that can help leaders determine a fair and just response to a patient safety event.) However, staff should never be punished or ostracized for *reporting* the event, close call, hazardous condition, or concern.

Sidebar 2. Assessing Staff Accountability

The aim of a safety culture is not a "blame-free" culture but one that balances organization learning with individual accountability. To achieve this, it is essential that leaders assess errors and patterns of behavior in a consistent manner, with the goal of eliminating behaviors that undermine a culture of safety. There has to exist within the organization a clear, equitable, and transparent process for recognizing and separating the blameless errors that fallible humans make daily from the unsafe or reckless acts that are blameworthy.^{1–8}

Numerous sources (see references below) are available to assist an organization in creating a formal decision process to determine what events should be considered blameworthy and require individual discipline in addition to systems-level corrective actions. The use of a formal process reinforces the culture of safety and demonstrates the organization's commitment to transparency and fairness.

Reaching a determination of staff accountability requires an initial investigation into the patient safety event to identify contributing factors. The use of the Incident Decision Tree (adapted by the United Kingdom's National Patient Safety Agency from James Reason's culpability matrix) or another formal decision process can help make determinations of culpability more transparent and fair.⁵

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Sidebar 2 (continued)

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Data Use and Reporting Systems

An effective culture of safety is evidenced by a robust reporting system and use of measurement to improve. When organizations adopt a transparent, nonpunitive approach to reports of patient safety events or other concerns, the organization begins reporting to learn—and to learn collectively from adverse events, close calls, and hazardous conditions. While this section focuses on data from reported patient safety events, it is but one type of data among many that should be collected and used to drive improvement.

When there is continuous reporting for adverse events, close calls, and hazardous conditions, the organization can analyze the events, change the process or system to improve safety, and disseminate the changes or lessons learned to the rest of the organization.²¹⁻²⁵

Organizations can engage frontline staff in internal reporting in many ways, including the following:

- Create a nonpunitive approach to patient safety event reporting
- Educate staff on and encourage them to identify patient safety events that should be reported
- Provide timely feedback regarding actions taken on reported patient safety events

Effective Use of Data

Collecting Data

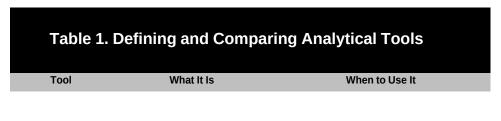
When organizations collect data or measure staff compliance with evidence-based care processes or patient outcomes, they can manage and improve those processes or outcomes and, ultimately, improve patient safety. The effective use of data enables organizations to identify problems, prioritize issues, develop solutions, and track performance to determine success.¹⁰ Objective data can be used to support decisions as well as to influence people to change their behaviors and to comply with evidence-based care guidelines.10,23

The Joint Commission and the US Centers for Medicare & Medicaid Services (CMS) both require organizations to collect and use data related to certain patient care outcomes and patient harm events. Joint Commission standards related to data collection and use require organizations to identify risks for acquiring and transmitting infections (Standard IC.01.03.01).

Analyzing Data

Effective data analysis can enable an organization to "diagnose" problems within its system similar to the way one would diagnose a patient's illness based on symptoms, health history, and other factors. Turning data into information is a critical competency of a learning organization and of effective management of change. When the right data are collected and appropriate analytic techniques are applied, it enables the organization to monitor the performance of a system, detect variation, and identify opportunities to improve. This can help the organization not only understand the current performance of organization systems but also can help it predict its performance going forward.²⁴

Analyzing data with tools such as run charts, statistical process control (SPC) charts, and capability charts helps an organization determine what has occurred in a system and provides clues as to why the system responded as it did.²⁴ Table 1 describes and compares examples of these tools.



Run Chart	A data chart, plotted in time order, used to show the per- formance of a process over time. It shows both positive and negative patterns, trends, and variation in a process.	•	When the organization needs to identify changes and variation within a process When the organization needs a simple and straightforward analysis of a process As a precursor to an SPC chart
Statistical Process Control (SPC) Chart	An advanced data chart, plotted in time order, used to show the performance and stability of a process over time. The chart includes a center line (process mean) and upper and lower control limits (process vari- ation), based on the data plot- ted, that show both positive and negative patterns, trends, and variation in a process. Action is taken when a point goes be- yond a control limit or points form a pattern or trend.	•	When the organization needs to de- termine if a process is stable, to identify variation within a process, or find indicators of why the variation occurred When the organization needs a more detailed and in-depth analysis of a process
Capability Chart	A chart used to assess the capability of a process to meet specifications based on the voice of the customer. The chart shows upper and/or lower specifications (that is, customer requirements or targets).	•	When the organization needs to de- termine whether a process will func- tion as expected, according to specifi- cations (requirements or targets) When the organization needs to de- termine how capable their process is for meeting customer specifications (requirements or target)

Encouraging Patient Activation

To achieve the best outcomes, patients and families must be more actively engaged in decisions about their health care and must have broader access to information and support. Patient activation is inextricably intertwined with patient safety. Activated patients are less likely to experience harm and unnecessary organization readmissions. Patients who are less activated suffer poorer health outcomes and are less likely to follow their provider's advice.^{31,32}

A patient-centered approach to care can help organizations assess and enhance patient activation. Achieving this requires leadership engagement in the effort to establish patient-centered care as a top priority throughout the organization. This includes adopting the following principles:³³

Patient safety guides all decision-making.

- Patients and families are partners at every level of care.
- Patient- and family-centered care is verifiable, rewarded, and celebrated.
- The licensed practitioner responsible for the patient's care, or the licensed practitioner's designee, discloses to the patient and family any unanticipated outcomes of care, treatment, or services.
- Transparent communication when harm occurs. Although Joint Commission standards do not require apology, evidence suggests that patients benefit—and are less likely to pursue litigation—when physicians disclose harm, express sympathy, and apologize.³⁴
- Staffing levels are sufficient, and staff has the necessary tools and skills.
- The organization has a focus on measurement, learning, and improvement.
- Staff and licensed practitioners must be fully engaged in patient- and familycentered care as demonstrated by their skills, knowledge, and competence in compassionate communication.

Organizations can adopt several strategies to support and improve patient activation, including promoting culture change, adopting transitional care models, and leveraging health information technology capabilities.³³

Many Joint Commission standards address patient rights and provide an excellent starting point for organizations seeking to improve patient activation. These standards require that organizations do the following:

- Respect, protect, and promote patient rights (Standard **RI.01.01.01**)
- Respect the patient's right to participate in decisions about their care, treatment, or services (Standard RI.01.02.01)
- Honor the patient's right to give or withhold informed consent (Standard RI.01.03. 01)

Beyond Accreditation: The Joint Commission Is Your Patient Safety Partner

To assist organizations on their journey toward creating highly reliable patient safety systems, The Joint Commission provides many resources, including the following:

Office of Quality and Patient Safety: An internal Joint Commission department that offers organizations guidance and support when an organization experiences a sentinel event or when a safety event is reported that may require analysis or improvement work. The Office of Quality and Patient Safety assesses the thoroughness and credibility of an organization's comprehensive systematic analysis as well as the action plan to help the organization prevent the hazardous or unsafe conditions from occurring again. (*See* the "Sentinel Event Policy" [SE] chapter for more information.)

- Standards Interpretation Group: An internal Joint Commission department that helps organizations with their questions about Joint Commission standards. First, organizations can see if other organizations have had similar questions by accessing the Standards FAQs at https://www.jointcommission.org/standards/standard-faqs/. If an answer cannot be found in the FAQs, organizations can submit questions about standards to the Standards Interpretation Group by clicking on a link to complete an online submission form.
- National Patient Safety Goals: The Joint Commission gathers information about emerging patient safety issues from widely recognized experts and stakeholders to create the National Patient Safety Goals® (NPSG), which are tailored for each accreditation program. These goals focus on significant problems in health care safety and specific actions to prevent them. For a list of the current NPSG, go to the NPSG chapter in E-dition or the *Comprehensive Accreditation Manual* or https://www.jointcommission.org/standards/national-patient-safety-goals.
- Sentinel Event Alert: The Joint Commission's periodic alerts with timely information about similar, frequently reported sentinel events, including root causes, applicable Joint Commission requirements, and suggested actions to prevent a particular sentinel event. (For archives of previously published Sentinel Event Alerts, go to https://www.jointcommission.org/resources/sentinel-event/sentinel-event-alert-newsletters/.)
- *Quick Safety*: Quick Safety is a periodic newsletter that outlines an incident, topic, or trend in health care that could compromise patient safety. (For more information, visit https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/.)
- Joint Commission Resources: A Joint Commission not-for-profit affiliate that produces books and periodicals, holds conferences, provides consulting services, and develops software products for accreditation and survey readiness. (For more information, visit http://www.jcrinc.com.)
- Webinars and podcasts: The Joint Commission and its affiliate, Joint Commission Resources, offer free and fee-based webinars and podcasts on various accreditation and patient safety topics.

- *Speak UpTM program*: The Joint Commission's campaign to educate patients about health care processes and potential safety issues and encourage them to speak up whenever they have questions or concerns about their safety. For more information and patient education resources, go to http://www.jointcommission.org/speakup.
- Joint Commission patient safety portals: Through The Joint Commission website (at http://www.jointcommission.org/resources/patient-safety-topics/), organizations can access web portals with a repository of resources on the following topics:
 - Zero Harm
 - Emergency Management
 - □ Workforce Safety and Well-Being
 - □ Infection Prevention and Control
 - □ Report a Patient Safety Concern or Complaint
 - Suicide Prevention

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