

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 practice 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 practices reduce variation, reduce risk, and improve quality. Practices 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.

Practices are complex environments that depend on strong leadership 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.

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Sidebar 1. (continued)

- » **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.
- » **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 Institute of Medicine, 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

^{*}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 practice leaders with a proactive approach to maintaining or redesigning 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 practices to improve their ability 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 practice system, at all times, on reducing harm.
2. Assisting health care practices 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 practices about the importance and structure of an integrated patient safety system and helps staff understand the relationship between Joint Commission accreditation and patient safety. It offers approaches and methods that may be adapted by any 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 practices can develop into learning practices
- » Identify the role leaders have to establish a safety culture and ensure staff accountability
- » Explain how practices can continually evaluate the status and progress of their patient safety systems

- » Describe how practices can work to prevent or respond to 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 practice leaders as they work to improve patient safety in their practices

Becoming a Learning Practice

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 practice. *A learning practice is*

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.¹² Practices 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 practice leadership 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

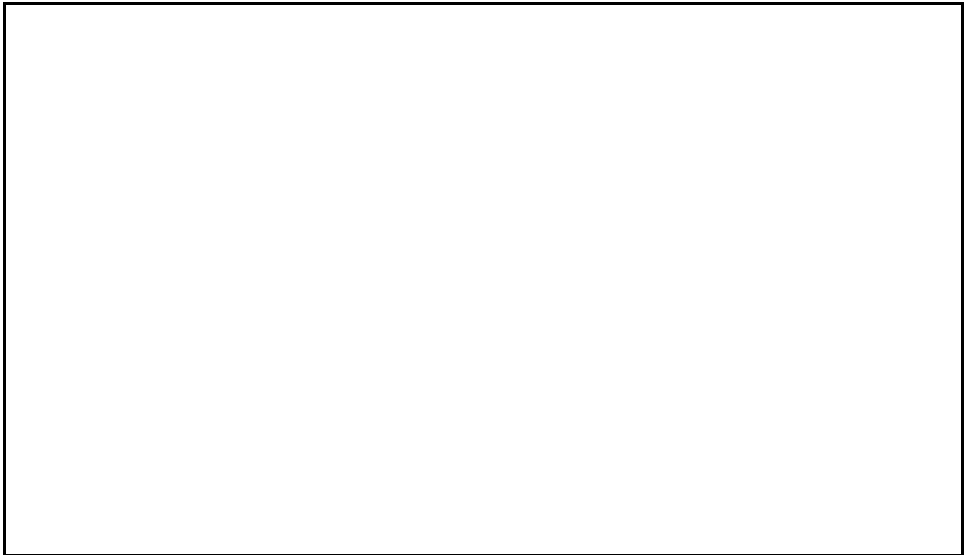


Figure 1. *The Trust-Report-Improve Cycle. In the trust-report-improve cycle, trust promotes reporting, which leads to improvement, which in turn fosters trust.*

Leaders and staff need to address intimidating or unprofessional behaviors within the practice, 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 other ways, such as

- » 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 practices 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

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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, below, 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 practice 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.¹⁻¹⁰

Numerous sources (see references below) are available to assist a practice in creating a formal

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Sidebar 2. (continued)

3. Marx D. How building a 'just culture' helps an organization learn from errors. *OR Manager*. 2003 May;19(5):1, 14–15, 20.
4. Reason J, Hobbs A. *Managing Maintenance Error*. Farnham, Surrey, United Kingdom: Ashgate Publishing, 2003.
5. Vincent C. *Patient Safety*, 2nd ed. Hoboken, NJ: Wiley-Blackwell, 2010.
6. National Patient Safety Agency. Incident Decision Tree. Accessed Jan 10, 2024. <https://>

A number of standards relate to the reporting of safety information, including Performance Improvement (PI) Standard PI.01.01.01, which requires practices to collect data to monitor their performance, and Standard LD.03.02.01, which requires practices to use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

Practices can engage frontline staff in internal reporting in a number of 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

When practices 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 practices 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 requires office-based practices to collect and use data related to certain patient care outcomes and patient harm events. Some key Joint Commission standards related to data collection and use require practices to do the following:

- » Collect information to monitor conditions in the environment (Standard EC.04.01.01)
- » Identify risks for acquiring and transmitting infections (Standard IC.01.03.01)
- » Use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality (Standard LD.03.02.01)
- » Have a practicewide, integrated patient safety program (Standard LD.03.09.01)
- » Evaluate the effectiveness of their medication management system (Standard MM.08.01.01)
- » Collect data to monitor their performance (Standard PI.01.01.01)
- » Improve performance on an ongoing basis (Standard PI.03.01.01)

Effective data analysis can enable practice 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 practice and of effective management of change. When the right data are collected and appropriate analytic techniques are applied, it enables the practice to monitor the performance of a system, detect variation, and identify opportunities to improve. This can help the practice not only understand the current performance of practice 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 a practice determine what has occurred in a system and provides clues as to why the system responded as it did.²⁴ Table 1, following, describes and compares examples of these tools.

Table 1. Defining and Comparing Analytical Tools

Tool	What It Is	When to Use It
Run Chart	A chart that plots points on a graph to show levels of performance over time. A run chart is used to answer questions about whether performance is static or changing and, if it is changing, whether the change is for better or for worse.	<ul style="list-style-type: none"> » When the practice needs to identify variation within a system » When the practice needs a simple and straightforward analysis of a system » As a precursor to an SPC chart
Statistical Process Control (SPC) Chart	A visual representation that tracks progress over time that include an upper and lower control limit based on previous data. Action is taken when a point goes beyond a control limit or points form a pattern or trend.	<ul style="list-style-type: none"> » When the practice needs to identify variation within a system and find indicators of why the variation occurred » When the practice needs a more detailed and in-depth analysis of a system
Capability Chart	An analytical tool that uses upper and lower parameters for acceptable performance of tasks or processes to determine whether a given change in the process is capable of reducing variation in performance.	<ul style="list-style-type: none"> » When the practice needs to determine whether a process will function as expected, according to requirements or specifications

After data has been turned into information, leadership should ensure the following (per the requirements shown):^{26–28}

- » Information is presented in a clear manner (Standard LD.03.04.01)
- » Information is shared with the appropriate groups throughout the practice (from the front line to the leader[s]) (Standards LD.03.04.01, LD.03.09.01)
- » Opportunities for improvement and actions to be taken are communicated (Standards LD.03.05.01, LD.03.07.01)
- » Improvements are celebrated or recognized

A Proactive Approach to Preventing Harm

Proactive risk reduction prevents harm before it reaches the patient. By engaging in proactive risk reduction, a practice can correct process problems to reduce the likelihood of experiencing adverse events. Additional benefits of a proactive approach to patient safety include increased likelihood of the following:

- » Identification of actionable common causes
- » Avoidance of unintended consequences
- » Identification of commonalities across departments/services/units
- » Identification of system solutions

In a proactive risk assessment the practice evaluates a process to see how it could potentially fail, to understand the consequences of such a failure, and to identify parts of the process that need improvement. A proactive risk assessment increases understanding within the practice about the complexities of process design and management—and what could happen if the process fails.

The Joint Commission addresses proactive risk assessments at Standard LD.03.09.01, EP 8, which recommends using the results of proactive risk assessments to improve safety. Practices working to become learning practices are encouraged to exceed this requirement by constantly working to proactively identify risk.

When conducting a proactive risk assessment, practices should prioritize high-risk, high-frequency areas. Areas of risk are identified from internal sources such as ongoing monitoring of the environment, results of previous proactive risk assessments, and results of data collection activities. Risk assessment tools should be accessed from credible external sources such as nationally recognized risk assessment tools and peer review literature.

Hazardous (or unsafe) **000000** /F510.5Tf100Tz000rg23.8199.5Td(review)Tj28.66managemenm

in changing circumstances.[†] A proactive approach to such conditions should include an analysis of the systems and processes in which the hazardous condition is found, with a focus on the climate that preceded the hazardous condition.

A proactive approach to hazardous conditions should include an analysis of the related systems and processes, including the following aspects:²⁹

- » Preconditions. Examples include hazardous (or unsafe) conditions in the environment of care (such as noise, clutter, wet floors, and so forth), inadequate staffing levels (inability to effectively monitor, observe, and provide care, treatment, or services to patients).
- » Supervisory influences. Examples include inadequate supervision, unsafe operations, failure to address a known problem, authorization of activities that are known to be hazardous.
- » Organization influences. Examples include inadequate staffing, organization culture, lack of strategic risk assessment.

A number of tools are available to help practices conduct a proactive risk assessment. One of the best known of these tools is the Failure Modes and Effects Analysis (FMEA). An FMEA is used to prospectively examine how failures could occur during high-risk processes and, ultimately, how to prevent them. The FMEA asks “What if?” to explore what could happen if a failure occurs at particular steps in a process.³⁰

Other tools to consider using for a proactive risk assessment include the following:

- » Institute for Safe Medication Practices Medication Safety Self Assessment[®]. Available for various health care settings, these tools are designed to help reduce medication errors. Visit <https://www.ismp.org/selfassessments/default.asp> for more information.
- » Contingency diagram: The contingency diagram uses brainstorming to generate a list of problems that could arise from generate

[†] Human errors are typically skills based, decision based, or knowledge based, whereas violations could be either routine or exceptional (intentional or negligent). *Routine violations* tend to include habitual “bending of the rules,” often enabled by management. A routine violation may break established rules or policies, and yet be a common practice within an organization. An *exceptional violation* is a willful behavior outside the norm that is not condoned by management, engaged in by others, nor part of the individual’s usual behavior. Source: Diller T, et al. The human factors analysis classification system (HFACS) applied to health care. *Am J Med Qual.* 2014 May–Jun;29(3)181–190.

- » Potential problem analysis (PPA) is a systematic method for determining what could go wrong in a plan under development, rating problem causes according to their likelihood of occurrence and the severity of their consequences. Visit <https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/potential-problem-analysis> for more information.
- » Process decision program chart (PDPC) provides a systematic means of finding errors with a plan while it is being created. After potential issues are found, preventive measures are developed, allowing the problems to either be avoided or a contingency plan to be in place should the error occur. Visit <https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/process-decision-program-chart> for more information.

Sidebar 3 lists strategies for conducting an effective proactive risk assessment, no matter the strategy chosen.

Sidebar 3. Strategies for an Effective Risk Assessment

Regardless of the method chosen for conducting a proactive risk assessment, it should address the following points:

- » Promote a blame-free reporting culture and provide a reporting system to support it.
- » Describe the chosen process (for example, through the use of a flowchart).
- » Identify ways in which the process could break down or fail to perform its desired function, which are often referred to as “failure modes.”
- » Identify the process (for example, through the use of a flowchart) and the failure modes (for example, through the use of a failure mode and effects analysis (FMEA)).

- » *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/reng/>

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