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 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.
- 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 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

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- » 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.

^{*}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 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.01.01.01.01") 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

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

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- » 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 (e.g., 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.

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A fair and just safety culture is needed for staff to trust that they can report patient safety events without being treated punitively.³⁹ In order to accomplish this, organizations should provide and encourage the use of a standardized reporting process for staff to report patient safety events. This is also built into the Joint Commission's standards at Standard LD.03.09.01, EP 6, which requires leaders to provide and encourage the use of a system or

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} Standard LD.04.01.05, EP 4, requires that staff are held accountable for their responsibilities.

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 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.¹⁻¹⁰

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

References

 The Joint Commission. Behaviors that undermine a culture of safety. Sentinel Event Alert, No. 40, Jul 9, 2008. Accessed Jan 10, 2024. https://www. jointcommission.org/resources/patient-safety-topics/sentinel-event/sentinelevent-alert-newsletters/sentinel-event-alert-issue-40-behaviors-that-underminea-culture-of-safety/

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Sidebar 2 (continued)

- 2. The Joint Commission. The essential role of leadership in developing a safety culture. *Sentinel Event Alert*. Mar 1, 2017. Accessed Jan 10, 2024. https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf
- 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.
- National Patient Safety Agency. Incident Decision Tree. Accessed Jan 10, 2024. https://www.ahrq.gov/downloads/pub/advances/vol4/meadows.pdf
- Bagian JP, et al. Developing and deploying a patient safety program in a large health care delivery system: You can't fix what you don't know about. *Jt Com J Qual Patient Saf.* 2001 Oct;27(10):522–532.
- 8. National Patient Safety Foundation. RCA²: Improving Root Cause Analyses and Actions to Prevent Harm. Jun 16, 2015. Accessed Jan 10, 2024. https://www.ashp.org/-/media/assets/policy-guidelines/docs/endorsed-documents/en-dorsed-documents-improving-root-cause-analyses-actions-prevent-harm.ashx
- The Joint Commission. Video: Building Your Safety Culture: A Job for Leaders. Chassin M. April 27, 2017. Accessed Jan 10, 2024. https://www.jointcommission.org/resources/news-and-multimedia/video-resources/president-and-ceodiscusses-safety-cultures/
- The Joint Commission. Take 5: Building a Strong Safety Culture A Job For Leaders. Benedicto A. May 10, 2017. Accessed Jan 10, 2024. https://www. jointcommission.org/resources/news-and-multimedia/podcasts/# q=Building%20a%20Strong%20Safety%20Culture

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



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 variation), based on the data plotted, that show both positive and negative patterns, trends, and variation in a process. Action is taken when a point goes beyond a control limit or points form a pattern or trend.

- When the organization needs to determine 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

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[†]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



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, and 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 must be fully engaged in patient- and family-centered care as demonstrated by their skills, knowledge, and competence in compassionate communication.

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

A number of 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 receive information in a manner the patient understands (Standard RI.01.01.03)
- » Respect the patient's right to participate in decisions about their care, treatment, and services (Standard RI.01.02.01)
- Honor the patient's right to give or withhold informed consent (Standard RI.01.03.
 01)
- » Address patient decisions about care, treatment, and services received at the end of

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

- » *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 Up[™] 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 web portals: Through The Joint Commission website (at http://www.jointcommission.org/toc.aspx), organizations can access web portals with a repository of resources on the following topics:
 - j Zero Harm
 - j Emergency Management
 - ; Health Care Workforce Safety and Well-Being
 - i Infection Prevention and Control
 - j Suicide Prevention
 - j Workplace Violence Prevention

References

- 1. Committee to Design a Strategy for Quality Review and Assurance in Medicare, Institute of Medicine. *Medicare: A Strategy for Quality Assurance*, vol. 1. Lohr KN, editor. Washington, DC: The National Academies Press, 1990.
- 2. Juran J, Godfrey A. *Quality Control Handbook*, 6th ed. New York: McGraw-Hill, 2010.
- 3. American Society for Quality. *Glossary and Tables for Statistical Quality Control*, 4th ed. Milwaukee: American Society for Quality Press, 2004.
- 4. Senge PM. *The Fifth Discipline: The Art and Practice of the Learning Organization,* 2nd ed. New York: Doubleday, 2006.
- 5. Leape L, et al. A culture of respect, part 2: Creating a culture of respect. *Academic Medicine*. 2012 Jul;87(7):853–858.
- 6. Wu A, ed. *The Value of Close Calls in Improving Patient Safety: Learning How to Avoid and Mitigate Patient Harm.* Oak Brook, IL: Joint Commission Resources, 2011.



CAMAC Update 1, July 2024

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