Patient Safety Systems (PS)

Quality and Safety in Laboratories

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,

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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 laboratories 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 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 laboratories. While patient safety events may not be completely eliminated, the goal is always zero harm (that is, reducing harm to patients). Joint Commission–accredited laboratories 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 laboratories 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 laboratories 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 health care system, at all times, on reducing harm.
2. Assisting laboratories 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 laboratories 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 laboratories can develop into learning organizations

Identify the role leaders have to establish a safety culture and ensure staff accountability

Explain how laboratories can continually evaluate the status and progress of their patient safety systems

ments 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

Laboratory 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
- Addr0Tog

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.[12] Laboratories 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 laboratory leadership by 7he

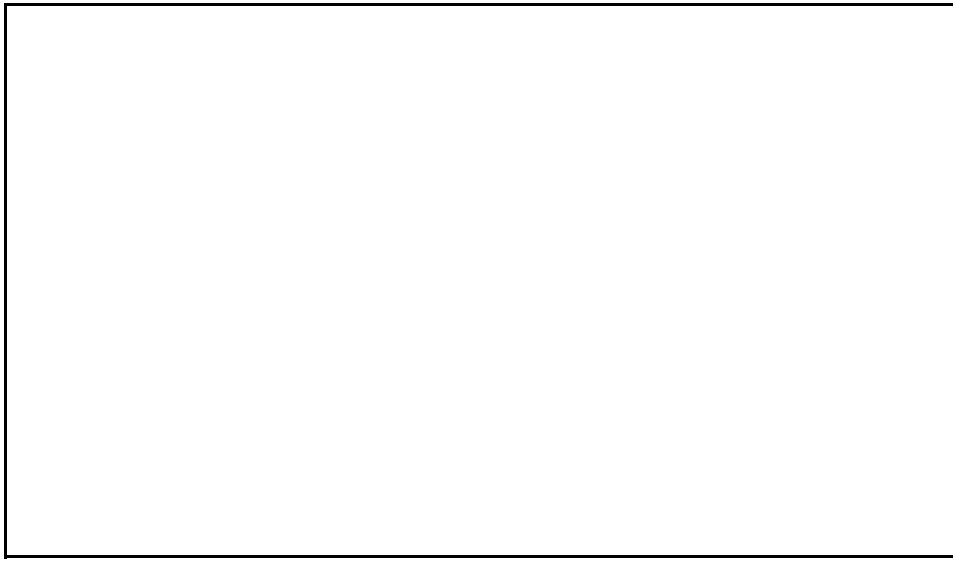


Figure 1. *The Trust-Report-Improve Cycle.*

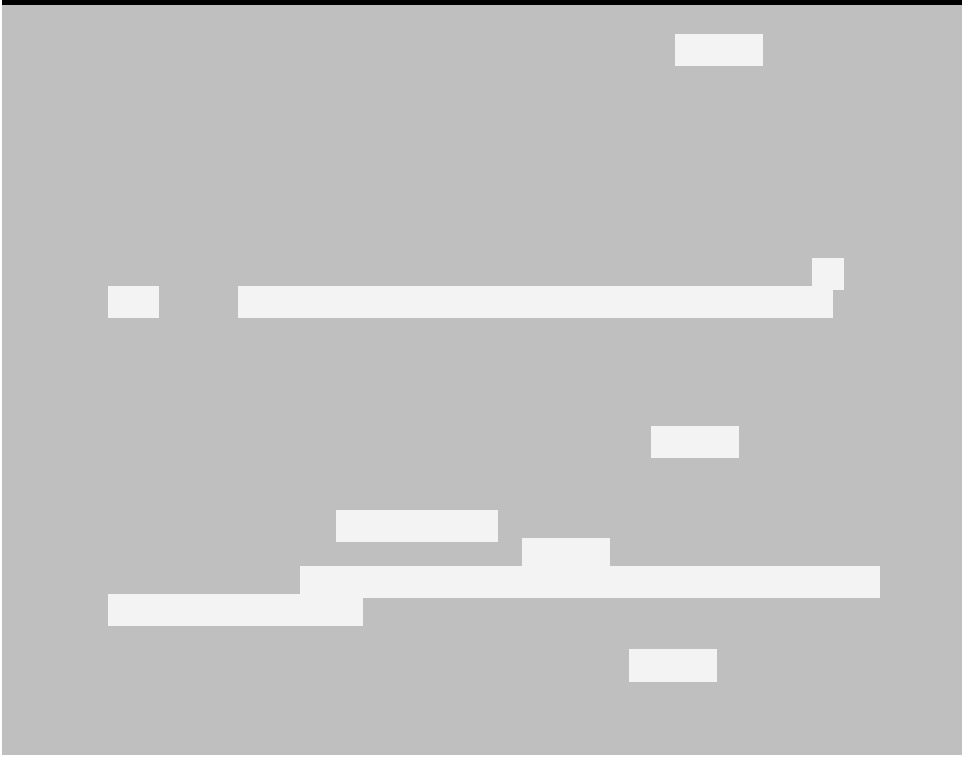
In the trust-report-improve cycle, trust promotes reporting, which leads to improvement, which in turn fosters trust.

Leaders and staff need to address intimidating or unprofessional behaviors within the laboratory, 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 staff member's care
- Refusal to comply with known and generally accepted practice standards, which may prevent other staff from delivering quality care

Sidebar 2.



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

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

Laboratories 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 laboratories 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 laboratories 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 Centers for Medicare & Medicaid Services (CMS) both require laboratories 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 laboratories 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)

Manage safety issues (Standard LD.03.09.01)
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 a laboratory to “diagnose” problems within its

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 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 determine whether a process will function as expected, according to specifications (requirements or targets) When the organization needs to determine how capable their process is for meeting customer specifications (requirements or target)

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 laboratory (from the front line to the board) (Standard LD.03.04.01)
- 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 laboratory 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

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 laboratories 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 a process. Visit https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/contingency-diagram for more information.

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.

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.

Patient- and family-centered care is verifiable, rewarded, and celebrated.

The physician or other licensed practitioner responsible for the patient's care, or the physician's or other 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 laboratory 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.

Laboratories 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]

Beyond Accreditation: The Joint Commission Is Your Patient Safety Partner

To assist laboratories 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 laboratories 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 a laboratory's comprehensive systematic analysis as well as the action plan to help the laboratory 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 laboratories with their questions about Joint Commission standards. First, laboratories can see if other laboratories have had similar questions by accessing the Standards FAQs at https://www.jointcommission.org/standards/standard-faqs/. If you do not find an answer in the FAQs, laboratories 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 http://www.jointcommission.org/standards_information/npsgs.

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 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), laboratories can access web portals with a repository of resources on the following topics:

- Zero Harm
- Emergency Management
- Health Care Workforce Safety and Well-Being
- Infection Prevention and Control
- Suicide Prevention
- Workplace Violence Prevention

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