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, staff, and laboratory 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 laboratories reduce variation, reduce risk, and improve quality. Laboratories 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.

Laboratories 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 laboratories 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 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 laboratory 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 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 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 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

- Describe how laboratories 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 laboratory leaders as they work to improve patient safety in their laboratories

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 thinking[4]

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, a laboratory 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 laboratory leaders.

Leaders, staff, 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 laboratory 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 laboratory.[5–9] In a learning organization, the laboratory 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

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
- 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 laboratory'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 laboratory leaders, laboratorywide 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 laboratory.[11]

Safety Culture

A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for laboratories striving to become learning organizations. In a strong safety culture, the laboratory has an unrelenting commitment to safety and to do no harm. Among the most critical responsibilities of laboratory leaders is to establish and maintain a strong safety culture within their laboratory. 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 laboratory.

The *safety culture* of a laboratory is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the laboratory's commitment to quality and patient safety. Laboratories 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.[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 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 those 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 laboratory fosters a cycle of trust, reporting, and improvement.[11,16] In laboratories that have a strong safety culture, health care staff 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 laboratories 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 laboratory 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.)

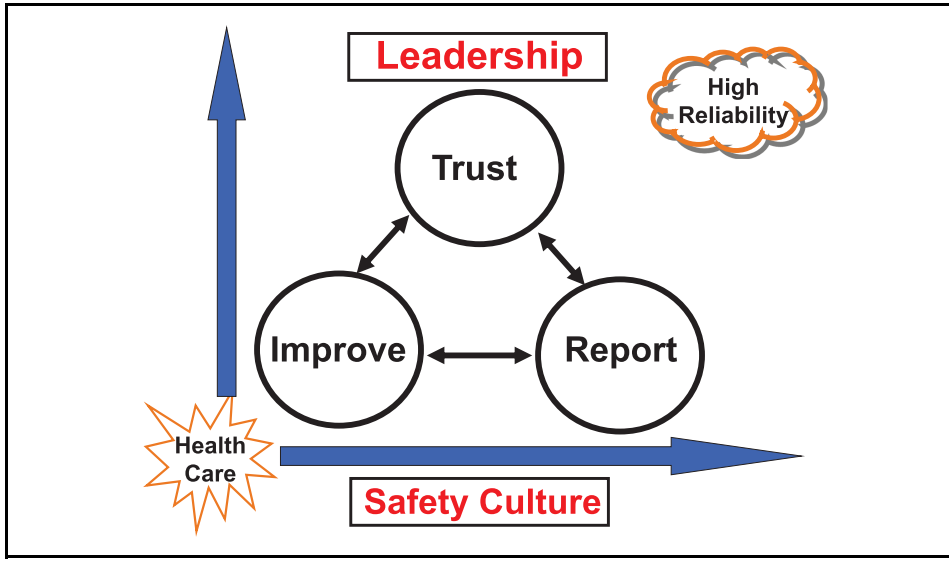

Figure 1. *The Trust-Report-Improve Cycle.*

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 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

- 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 laboratories nationwide. Of 1,047 respondents to a 2021 survey by the Institute for Safe Medication Practices (ISMP), 79% 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, laboratories 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 3, which requires leaders to provide and encourage the use of systems for blame-free reporting of a system or process failure or the results of proactive risk assessments. 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] Standard **LD.03.09.01**, EP 3, 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 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 laboratory 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 a laboratory 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 laboratory'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

1. 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/sentinel-event/sentinel-event-alert-newsletters/sentinel-event-alert-issue-40-behaviors-that-undermine-a-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.
6. National Patient Safety Agency. Incident Decision Tree. Accessed Jan 10, 2024. https://www.ahrq.gov/downloads/pub/advances/vol4/meadows.pdf
7. 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. RCA^2: 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/endorsed-documents-improving-root-cause-analyses-actions-prevent-harm.ashx

Data Use and Reporting Systems

An effective culture of safety is evidenced by a robust reporting system and use of measurement to improve. When laboratories adopt a transparent, nonpunitive approach to reports of patient safety events or other concerns, the laboratory 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 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]

Several 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 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 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 US 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**)

Analyzing Data

Effective data analysis can enable a laboratory 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 laboratory to monitor the performance of a system, detect variation, and identify opportunities to improve. This can help the laboratory not only understand the current performance of laboratory 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 laboratory 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.

Table 1. Defining and Comparing Analytical Tools

Tool	What It Is	When to Use It
Run Chart	A data chart, plotted in time order, used to show the performance 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 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)

Using Data to Drive Improvement

After data has been turned into information, leaders 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

In a proactive risk assessment the laboratory 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 laboratory 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**, which recommends using the results of proactive risk assessments to improve safety. Laboratories working to become learning organizations are encouraged to exceed this requirement by constantly working to proactively identify risk.

When conducting a proactive risk assessment, laboratories 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) conditions also provide an opportunity for a laboratory to take a proactive approach to reduce harm. Laboratories benefit from identifying hazardous conditions while designing any new process that could impact patient safety. A *hazardous condition* is defined as any circumstance that increases the probability of a patient safety event. A hazardous condition may be the result of a human error or violation, may be a design flaw in a system or process, or may arise in a system or process 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, leadership, lack of strategic risk assessment.

[†]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.

Tools for Conducting a Proactive Risk Assessment

Many 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.

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:

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Sidebar 3. *(continued)*

- Promote a blame-free reporting culture and provide a reporting system to support it.
- Describe the chosen process (for example, by using 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 possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
- Prioritize the potential process breakdowns or failures.
- Determine why the prioritized breakdowns or failures could occur, which may involve performing a hypothetical root cause analysis.
- Design or redesign the process and/or underlying systems to minimize the risk of the effects on patients.
- Test and implement the newly designed or redesigned process.
- Monitor the effectiveness of the newly designed or redesigned process.

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 hospital readmissions. Patients who are less activated suffer poorer health outcomes and are less likely to follow their physician's or other licensed practitioner's advice.[31,32]

A patient-centered approach to care can help laboratories assess and enhance patient activation. Achieving this requires leadership engagement in the effort to establish patient-centered care as a top priority throughout the laboratory. 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 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 several 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 portals*: Through The Joint Commission website (at http://www.jointcommission.org/resources/patient-safety-topics/), laboratories 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

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.
7. Agency for Healthcare Research and Quality. *Becoming a High Reliability Organization: Operational Advice for Hospital Leaders*. Rockville, MD: AHRQ, 2008.
8. Fei K, Vlasses FR. Creating a safety culture through the application of reliability science. *J Healthc Qual*. 2008 Nov–Dec;30(6):37–43.
9. Massachusetts Coalition of the Prevention of Medical Errors: When Things Go Wrong: Responding to Adverse Events. Mar 2006. Accessed Jan 10, 2024. http://www.macoalition.org/documents/respondingToAdverseEvents.pdf
10. The Joint Commission. *The Joint Commission Leadership Standards*. Oak Brook, IL: Joint Commission Resources, 2009.
11. Chassin MR, Loeb JM. High-reliability healthcare: Getting there from here. *Milbank Q*. 2013 Sep;91(3):459–490.
12. Advisory Committee on the Safety of Nuclear Installations. Study Group on Human Factors. *Third Report of the ACSNI Health and Safety Commission*. Sudbury, UK: HSE Books, 1993.
13. Leape L, et al. A culture of respect, part 1: The nature and causes of disrespectful behavior by physicians. *Academic Medicine*. 2012 Jul;87(7):1–8.
14. Weick KE, Sutcliffe KM. *Managing the Unexpected*, 2nd ed. San Francisco: Jossey-Bass, 2007.
15. Reason J, Hobbs A. *Managing Maintenance Error: A Practical Guide*. Aldershot, UK: Ashgate, 2003.

16. Association for the Advancement of Medical Instrumentation. *Risk and Reliability in Healthcare and Nuclear Power: Learning from Each Other*. Arlington, VA: Association for the Advancement of Medical Instrumentation, 2013.
17. Reason J. Human error: Models and management. *BMJ*. 2000 Mar 13;320(3):768–770.
18. The Joint Commission: Behaviors that undermine a culture of safety. *Sentinel Event Alert*. 2008 Jul 9. Accessed Jan 11, 2024. https://www.jointcommission.org/resources/patient-safety-topics/sentinel-event/sentinel-event-alert-newsletters/sentinel-event-alert-issue-40-behaviors-that-undermine-a-culture-of-safety/
19. Institute for Safe Medication Practices. Unresolved disrespectful behavior in health care: Practitioners speak up (again)—Part I. *ISMP Medication Safety Alert.* Feb 24, 2022. Accessed Jan 10, 2024. https://www.ismp.org/sites/default/files/attachments/2022-02/Release%20on%20Disrespectful%20Behavior%20Survey%202-25-22.doc
20. Chassin MR, Loeb JM. The ongoing quality journey: Next stop high reliability. *Health Affairs*. 2011 Apr 7;30(4):559–568.
21. Heifetz R, Linsky M. A survival guide for leaders. *Harvard Business Review*. 2002 Jun;1–11.
22. Ontario Hospital Association. *A Guidebook to Patient Safety Leading Practices: 2010*. Toronto: Ontario Hospital Association, 2010.
23. The Joint Commission. The essential role of leadership in developing a safety culture. *Sentinel Event Alert*. Mar 1, 2017. Accessed Jan 11, 2024. https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf
24. Ogrinc GS, et al. *Fundamentals of Health Care Improvement: A Guide to Improving Your Patients' Care*, 2nd ed. Oak Brook, IL: Joint Commission Resources/Institute for Healthcare Improvement, 2012.
25. Agency for Healthcare Research and Quality. *Becoming a High Reliability Organization: Operational Advice for Hospital Leaders*. Rockville, MD: AHRQ, 2008.
26. Nelson EC, et al. Microsystems in health care: Part 2. Creating a rich information environment. *Jt Comm J Qual Patient Saf*. 2003 Jan;29(1):5–15.
27. Nelson EC, et al. Clinical microsystems, part 1. The building blocks of health systems. *Jt Comm J Qual Patient Saf*. 2008 Jul;34(7):367–378.
28. Pardini-Kiely K, et al. Improving and sustaining core measure performance through effective accountability of clinical microsystems in an academic medical center. *Jt Comm J Qual Patient Saf*. 2010 Sep;36(9):387–398.

29. 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.
30. The Joint Commission. *Root Cause Analysis in Health Care: A Joint Commission Guide to Analysis and Corrective Action of Sentinel and Adverse Events,* 7th edition. Oak Brook, IL: Joint Commission Resources, 2020.
31. AARP Public Policy Institute. Beyond 50.09 chronic care: A call to action for health reform. Mar 2009. Accessed Jan 11, 2024. http://www.aarp.org/health/medicare-insurance/info-03-2009/beyond_50_hcr.html
32. Towle A, Godolphin W. Framework for teaching and learning informed shared decision making. *BMJ*. 1999 Sep 18;319(7212):766–771.
33. Hibbard JH, et al. Development of the patient activation measure (PAM): Conceptualizing and measuring activation in patients and consumers. *Health Serv Res*. 2004 Aug;39(4 Pt 1):1005–1026.
34. Kachalia A, et al. Effects of a communication-and-resolution program on hospitals' malpractice claims and costs. *Health Affairs*. 2018 Nov; 37(11). Accessed Jan 11, 2024. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.0720.