



2015 Comprehensive Accreditation Manual for Hospitals:
The Patient Safety Systems Chapter

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Patient Safety Systems (PS)

Introduction

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. This chapter exemplifies that commitment.

The intent of this “Patient Safety Systems” (PS) chapter is to provide health care organizations with a proactive approach to designing or re-designing 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 health care organizations to improve health care systems to protect patients. The first obligation of health care is to “do no harm.” Therefore this chapter is focused on the following three guiding principles:

1. Aligning existing Joint Commission standards with daily work in order to engage patients and staff throughout the health care system, at all times, on reducing harm.
2. Assisting health care organizations with 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.

Quality* and safety are inextricably linked. *Quality* in health care is the degree to which its processes and results meet or exceed the needs and desires of the people it serves.^{1, 2} Those needs and desires include safety.

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

- Ensuring reliable processes

* The Institute of Medicine defines quality as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. **Source:** Lohr, K., Committee to Design a Strategy for Quality Review and Assurance in Medicare (Eds.). *Medicare: a strategy for quality assurance, Vol. 1*. Washington, DC: IOM, National Academy Press, 1990.

- Decreasing variation and defects (waste)
- Focusing on achieving better 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, harm to patients can be reduced, and the goal is always zero harm. This chapter describes and provides approaches and methods that may be adapted by a health care organization that aims to increase the reliability of its complex systems while making visible and removing the risk of patient harm. Joint Commission-accredited organizations should be continually focused on eliminating systems failures and human errors that may cause harm to patients, families and staff.^{1, 2}

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

Hospitals 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 their patient safety events, including close calls and other system failures that have not yet led to patient harm.

What Does This Chapter Contain?

The “Patient Safety Systems” chapter is intended to help inform and educate hospitals about the importance and structure of an integrated patient safety system. **While this chapter does not include new accreditation requirements, it describes how existing**

requirements can be applied to achieve improved patient safety. It is also intended to help all health care workers understand the relationship between Joint Commission accreditation and patient safety.

This chapter does the following:

- Describes an integrated patient safety system
- Discusses how hospitals can develop into learning organizations
- Explains how hospitals can continually evaluate the status and progress of their patient safety systems
- Describes how hospitals can work to prevent or respond to patient safety events (A sidebar, below, defines key terminology)
- Serves as a framework to guide hospital leaders as they work to improve patient safety in their hospitals
- Contains a list of standards and requirements related to patient safety systems (Those standards and requirements will be scored as usual in their original chapters.)
- Contains references that were used in the development of this chapter

This chapter refers to a number of Joint Commission standards. When a standard cited in this chapter is formatted with the standard number in boldface type followed by a colon (for example: “**Standard RI.01.01.01:**”), the language that follows the colon is the official standard language, verbatim.

Key Terms to Understand

- *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.
- *Sentinel event:*[†] A subcategory of Adverse Events, 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 any of the following:
 - ❑ Death
 - ❑ Permanent harm
 - ❑ Severe temporary harm

[†]For a list of specific patient safety events that are also considered Sentinel Events (SE), see page SE-1 in the “Sentinel Events” chapter of this manual.

- **No-harm event:** A patient safety event that reaches the patient but does not cause harm.
- **Close call** (or “near miss” or “good catch”): A patient safety event that did not reach the patient.
- **Hazardous** (or “unsafe”) **condition(s):** A circumstance (other than a patient’s own disease process or condition) that increases the probability of an adverse event.

Note: Not all patient safety events are preventable. Event analysis is warranted in order to identify weaknesses and whether remedial action is indicated.

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 continuously learn, and thereby enhance their capabilities to create and innovate.³ Learning organizations uphold five principles: team learning, shared visions and goals, a shared mental model (that is, similar ways of thinking), individual commitment to life-long learning, and systems thinking.³ In a learning organization, patient safety events are seen as opportunities for learning and improvement.⁴ 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 hospital 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 hospital leadership.

Leaders, staff, licensed independent practitioners, and patients in a learning organization realize that *every* patient safety event (from minor events to events that cause major harm to patients) must be reported.⁴⁻⁸ When patient safety events are continuously reported, experts within the hospital can define the problem, identify solutions, achieve sustainable results, and disseminate the changes or lessons learned to the rest of the hospital.⁴⁻⁸ In a learning organization, the hospital provides staff with information regarding improvements based on reported concerns. This helps foster trust that encourages further reporting.

The Role of Hospital Leaders in Patient Safety

Hospital leaders provide the foundation for an effective patient safety system by doing the following:⁹

- Promoting learning
- Motivating staff to uphold a fair and just safety culture
- Providing a transparent environment in which quality measures and patient harms are freely shared with staff
- Modeling professional behavior
- Removing intimidating behavior that might prevent safe behaviors
- Providing the resources and training necessary to take on improvement initiatives

For these reasons, many of the standards that are focused on the hospital's patient safety system appear in the Joint Commission's Leadership (LD) standards, including Standard

LD.04.04.05: The hospital has an organizationwide, integrated patient safety program within its performance improvement activities.

Without the support of hospital leaders, hospitalwide 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 leadership managing the change.⁴ Thus, leadership should take on a long-term commitment to transform the hospital.¹⁰

Safety Culture

A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for hospitals striving to become learning organizations. In a strong safety culture, the hospital has an unrelenting commitment to safety and to do no harm. Among the most critical responsibilities of hospital leaders is to establish and maintain a strong safety culture within their hospital. The Joint Commission's standards address safety culture in Standard **LD.03.01.01:** Leaders create and maintain a culture of safety and quality throughout the hospital.

The *safety culture* of a hospital is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization's commitment to quality and patient safety. Hospitals that have a robust safety culture are characterized by communications founded on mutual trust, by shared

perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.¹¹ Organizations will have varying levels of safety culture, but all should be working toward a safety culture that has the following qualities:

- Staff and leaders that value transparency, accountability, and mutual respect.⁴
- Safety as everyone's first priority.⁴
- Behaviors that undermine a culture of safety are not acceptable, and thus should be reported to organizational leadership by staff, patients, and families for the purpose of fostering risk reduction^{4, 10, 12}
- 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.¹⁰ 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.^{10, 13}
- 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.⁶ Staff know that their leaders will not focus on blaming providers involved in errors, but rather focus on the systems issues that contributed to or enabled the patient safety event.^{6, 14}
- By reporting and learning from patient safety events, staff create a learning organization.

A safety culture operates effectively when the hospital fosters a cycle of trust, reporting, and improvement.^{10, 15} In hospitals that have a strong safety culture, health care providers trust their coworkers and leaders to support them when they identify and report a patient safety event.¹⁰ When trust is established, staff are more likely to report patient safety events, and hospitals 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 hospital to improve.¹⁰ In turn, staff see that their reporting contributes to actual improvement, which bolsters their trust. Thus, the trust-report-improve cycle reinforces itself.¹⁰ (*See Figure on page PS-7.*)



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 need to ensure that intimidating or unprofessional behaviors within the hospital are addressed so as not to inhibit others from reporting safety concerns.¹⁶ Leadership 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.¹⁷ 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:^{4, 12, 17}

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

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

These issues are still occurring in hospitals nationwide. Of 4,884 respondents to a 2013 survey by the Institute for Safe Medication Practices, 73% reported encountering negative comments about colleagues or leaders during the previous year. In addition, 68% reported condescending language or demeaning comments or insults; while 77% of respondents said they had encountered reluctance or refusal to answer questions or return calls.¹⁸ Further, 69% report that they had encountered impatience with questions or hanging up the phone.

Nearly 50% of the respondents indicated that intimidating behaviors had affected the way they handle medication order clarifications or questions, including assuming that an order was correct in order to avoid interaction with an intimidating co-worker.¹⁸ Moreover, 11% 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. The respondents included nurses, physicians, pharmacists, and quality/risk management personnel.

Only 50% of respondents indicated that their organizations had clearly defined an effective process for handling disagreements with the safety of an order. This is down from 60% of respondents to a similar ISMP survey conducted in 2003, which suggests that this problem is worsening.¹⁸ 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.^{2, 8} In order to accomplish this, hospitals 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 Leadership standards at **LD.04.04.05**, EP 6: The leaders 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.^{10, 15}

A fair and just culture takes into account that individuals are human, fallible, and capable of mistakes, and 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.^{14, 18, 19} Refer to Standard **LD.04.01.05**, EP 4: 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 that some disciplinary action may then be necessary. (See the sidebar on page PS-9 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.

Assessing Staff Accountability

The aim of a safety culture is not a “blame-free” culture but one that balances learning with accountability. To achieve this, it is essential that leaders assess errors and patterns of behavior in a manner that is applied consistently, with the goal of eliminating behaviors that undermine a culture of safety. There has to exist within the hospital a clear, equitable and transparent process for recognizing and separating blameless errors that fallible humans make daily, from the unsafe or reckless acts that are blameworthy.¹⁻⁷

An appropriate model for this process is the Incident Decision Tree developed by the United Kingdom’s National Patient Safety Agency. The agency adapted this from James Reason’s culpability matrix.⁵ For a consistent process, leaders can adapt the following questions to assess the individual’s culpability in the patient safety event:⁵

- Were the actions intentional? (Deliberate harm test)
 - If the answer to the above question is yes, then were adverse consequences intended?
- Does there appear to be evidence of poor health or substance abuse? (Incapacity test)
 - If yes, then does the individual have a known medical condition?
 - If yes, then is there evidence the individual took an unacceptable risk?
 - If yes, then were there significant mitigating circumstances?
- Did the individual depart from agreed protocols or safe procedures? (Foresight test)
 - If yes, then were the protocols and safe procedures available, workable, intelligible, correct, and in routine use?

- If yes, then is there evidence the individual took an unacceptable risk?
- If yes, then were there significant mitigating circumstances?
- Would another individual coming from the same professional group, possessing comparable qualifications and experience, behave in the same way in similar circumstances? (Substitution test)
- If yes, were there any deficiencies in training, experience, or supervision?
 - If yes, then is there evidence the individual took an unacceptable risk?
 - If yes, then were there significant mitigating circumstances?

Reaching answers to these questions requires an initial investigation into the patient safety event to identify contributing factors. The use of the Incident Decision Tree or other formal decision process can help make determinations of culpability more transparent and fair.⁵

References

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Data Use and Reporting Systems

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

When there is continuous reporting adverse events, close calls, and hazardous conditions, the hospital can analyze the patient safety events, change the process or system to improve safety, and disseminate the changes or lessons learned to the rest of the organization.²¹⁻²⁴

In addition to those mentioned earlier in this chapter, a number of standards relate to the reporting of safety information, including Performance Improvement (PI) Standard **PI.01.01.01**: The hospital collects data to monitor its performance; and **LD.03.02.01**: The hospital uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

Hospitals 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 identifying patient safety events that should be reported
- Provide timely feedback regarding actions taken on patient safety events

Effective Use of Data

Collecting Data

When hospitals 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.²⁵ The effective use of data enables hospitals to identify problems, prioritize issues, develop solutions, and track success.⁹ Objective data can be used to support decisions, influence people to change their behaviors, and to comply with evidence-based care guidelines.^{9, 26}

The Joint Commission and the Centers for Medicare and Medicaid Services (CMS) both require hospitals to collect and use data related to certain patient care outcomes and patient harms. Some key Joint Commission standards related to data collection and use include the following:

- **EC.04.01.01: The hospital collects information to monitor conditions in the environment.****LD.03.02.01:** The hospital uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.
- **IC.01.03.01:** The hospital identifies risks for acquiring and transmitting infections.
- **LD.04.04.05:** The hospital has an organizationwide, integrated patient safety program within its performance improvement activities.

- **MM.08.01.01:** The hospital evaluates the effectiveness of its medication management system.
- **PI.01.01.01:** The hospital collects data to monitor its performance.
- **PI.02.01.03:** The hospital improves its performance on ORYX® accountability measures.
- **PI.03.01.01:** The hospital improves performance on an ongoing basis.
- **PC.03.05.19: For hospitals that use Joint Commission accreditation for deemed status purposes:** The hospital reports deaths associated with the use of restraint and seclusion.

■ **Analyzing Data**

Effective data analysis can enable a hospital 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 hospital to monitor the performance of a system, detect variation, and identify opportunities to improve. This can help the hospital not only understand the current performance of hospital systems but also can help it predict its performance going forward.²³

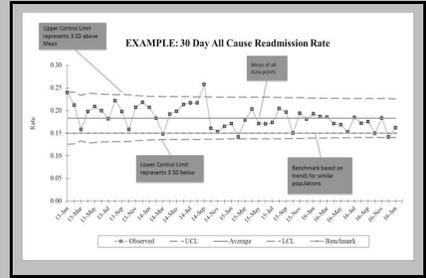
Analyzing data with tools such as run charts, statistical process control (SPC) charts, and capability charts helps a hospital determine what has occurred in a system and provides clues as to why the system responded as it did.²³ Table 1 (below) describes and compares examples of these tools. Please note that several types of SPC charts exist; this discussion focuses on the XmR chart, which is the most commonly used.

Table 1. Defining and Comparing Analytical Tools

Tool	When to Use	Example
Run Chart ¹	<ul style="list-style-type: none"> ■ When the hospital needs to identify variation within a system ■ When the hospital needs a simple and straightforward analysis of a system ■ As a precursor to an SPC chart 	

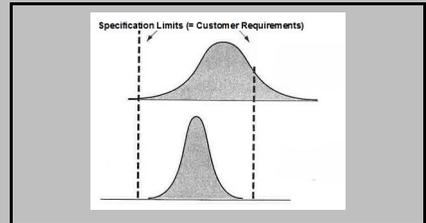
Statistical Process Control Chart

- When the hospital needs to identify variation within a system and find indicators of why the variation occurred
- When the hospital needs a more detailed and in-depth analysis of a system



Capability Chart²

- When the hospital needs to determine whether a process will function as expected, according to requirements or specifications



In the example above, the curve at the top of the chart indicates a process that is only partly capable of meeting requirements. The curve at the bottom of the chart shows a process that is fully capable.

Sources:

1. US Agency for Healthcare Research and Quality. *Advanced Methods in Delivery System Research: Planning, Executing, Analyzing, and Reporting Research on Delivery System Improvement, Webinar #2: Statistical Process Control*. 2013 14 May. Accessed Apr 21, 2014. http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/webinar02/spc_slides.pptx. (Example 2, above).
2. George M, Rowlands D, et al. *The LEAN-Six Sigma Pocket Tool Book*. New York: McGraw-Hill, 2005.

Using Data to Drive Improvement

After data has been turned into information, leadership should ensure the following:²⁷⁻²⁹

- Information is presented in a clear manner (LD.03.04.01, EP 3)
- Information is shared with the appropriate groups throughout the organization (frontline to the board) (LD.03.04.01, LD.04.04.05)
- Opportunities for improvement and actions to be taken are clearly articulated (LD.03.05.01, EP 4; LD.04.04.01)
- Leadership provides staff with the time, resources, and opportunities to participate in improvement efforts as part of daily work (LD.03.01.01, EP 3)
- 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 hospital can correct process problems in order to reduce the likelihood of experiencing adverse events.

In a proactive risk assessment the hospital 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 organization about the complexities of process design and management—and what could happen if the process fails.

When conducting a proactive risk assessment, organizations should prioritize high-risk, high-volume areas. Areas of risk are identified from internal sources such as ongoing monitoring of the environment, results of previous proactive risk assessments, from results of data collection activities. Risk assessment tools should be accessed from credible external sources such as a *Sentinel Event Alert*, nationally recognized risk assessment tools, and peer review literature. Benefits of a proactive approach to patient safety includes 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

Hazardous (or unsafe) conditions provide an opportunity for a hospital to take a proactive approach to reduce harm. Hospitals also 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 conditions 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:³⁰

- **Preconditions.** Examples include hazardous (or unsafe) conditions in the environment of care (such as noise, clutter, wet floors and so forth), inadequate staffing levels, an operator who is impaired or inadequately trained
- **Supervisory influences.** Examples include inadequate supervision, planned inappropriate operations, failure to address a known problem, authorization of activities that are known to be hazardous
- **Organizational influences.** Examples include inadequate staffing, inadequate policies, lack of strategic risk assessment

The Joint Commission requires proactive risk assessments at Standard **LD.04.04.05**, EP 10: At least every 18 months, the hospital selects one high-risk process and conducts a proactive risk assessment. Hospitals should recognize that this standard represents a minimum requirement. Hospitals working to become learning organizations are encouraged to exceed this requirement by constantly working to proactively identify risk.

Strategies for an Effective Risk Assessment

Although several methods could be used to conduct a proactive risk assessment, the following steps comprise one approach:

- 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.”

[‡]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, and not part of the individual’s usual behavior. **Source:** Diller T, Helmrich G, Dunning S, et al. The Human Factors Analysis Classification System (HFACS) applied to health care. *Am J Med Qual.* 2013 Jun 27; 29 (3) 181-190.

- 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.

Tools for Conducting a Proactive Risk Assessment

A number of tools are available to help organizations 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 prevent them. The FMEA asks “What if?” to explore what could happen if a failure occurs at particular steps in a process.³¹

Hospitals have other tools they can consider using in their proactive risk assessment. Some examples include the following:

- Institute for Safe Medication Practices Medication Safety Risk Assessment: This tool is designed to help reduce medication errors. Visit <https://www.ismp.org/communityRx/aroc/> for more information.
- Contingency diagram: The contingency diagram uses brainstorming to generate a list of problems that could arise from a process. Visit <http://healthit.ahrq.gov/health-it-tools-and-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. The problem causes are rated according to their likelihood of occurrence and the severity of their consequences. Visit <http://healthit.ahrq.gov/health-it-tools-and-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 <http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/process-decision-program-chart>.

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 provider's advice.^{32, 33}

A patient-centered approach to care can help hospitals assess and enhance patient activation. Achieving this requires leadership engagement in the effort to establish patient-centered care as a top priority throughout the hospital. This includes adopting the following principles:³⁴

- 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 independent practitioner responsible for the patient's care, or his or her designee, discloses to the patient and family any unanticipated outcomes of care, treatment, and services
- Though 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
- Staffing levels are sufficient, and staff has the necessary tools and skills
- The hospital has a focus on measurement, learning, and improvement
- Staff and licensed independent practitioners must be fully engaged in patient- and family-centered care as demonstrated by their skills, knowledge, and competence in compassionate communication.

Hospitals 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.³⁴

A number of Joint Commission standards address patient rights and provide an excellent starting point for hospitals seeking to improve patient activation. These include the following:

- **Standard RI.01.01.01:** The hospital respects, protects, and promotes patient rights.
- **Standard RI.01.01.03:** The hospital respects the patient's right to receive information in a manner he or she understands.
- **Standard RI.01.02.01:** The hospital respects the patient's right to participate in decisions about his or her own care, treatment, and services.
- **Standard RI.01.03.01:** The hospital honors the patient's right to give or withhold informed consent.
- **Standard RI.01.05.01:** The hospital addresses patient decisions about care, treatment, and services received at the end of life.
- **Standard RI.02.01.01:** The hospital informs the patient about his or her responsibilities related to his or her care, treatment, and services.

Beyond Accreditation: The Joint Commission is Your Patient Safety Partner

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

- *The Sentinel Event Unit:* An internal Joint Commission department that offers hospitals guidance and support when they experience a sentinel event. Organizations can call the Sentinel Event Hotline (630-792-3700) to clarify whether a patient safety event is considered to be a Sentinel Event and is reviewable or to discuss any aspect of the Sentinel Event Policy. The Sentinel Event Unit assesses the thoroughness and credibility of a hospital's comprehensive systematic analysis as well as the action plan to help the hospital prevent the hazardous or unsafe conditions from occurring again.
- *The Joint Commission Center for Transforming Health Care:* A Joint Commission not-for-profit affiliate that offers highly effective, durable solutions to health care's most critical safety and quality problems to help hospitals transform into high reliability organizations. For specific quality and patient problems, the Center's Targeted Solutions Tool™ (TST) guides health care organizations through a step-by-step process to measure their organization's performance, identify barriers to excellence, and direct them to proven solutions. To date, a TST has been developed for each of the following: hand hygiene, hand-off communications, and wrong-site surgery. For more information, visit www.centerfortransforminghealthcare.org.
- *Standards Interpretation Group:* An internal Joint Commission department that helps organizations with their questions about Joint Commission standards. First, organizations can see if other organizations have asked the same question by

accessing the Standards FAQs at www.jointcommission.org/standards_information/jcfaq.aspx. Thereafter, organizations can submit questions about standards to the Standards Interpretation Group by completing an online form at <https://web.jointcommission.org/sigsubmission/sigonlineform.aspx>.

- *National Patient Safety Goals*: The Joint Commission's yearly patient safety requirements based on data obtained from the Joint Commission's Sentinel Event Database and recommended by a panel of patient safety experts. (For a list of the current National Patient Safety Goals, go to 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 Alert*, go to www.jointcommission.org/sentinel_event.)
- *Quick Safety*: Quick Safety is a monthly newsletter that outlines an incident, topic, or trend in health care that could compromise patient safety. http://www.jointcommission.org/quick_safety.aspx?archievey
- *Core Measures Solution Exchange*: Available for accredited or certified organizations through the *Joint Commission Connect Extranet*, organizations can search a database of over two hundred success stories from accredited hospitals that have attained excellent performance on core measures, including accountability measures.
- *Joint Commission Resources*: A Joint Commission not-for-profit affiliate, which produces books and periodicals, holds conferences, and provides consulting services for accreditation and survey readiness. (For more information, go to www.jcrinc.com)
- *Webinars and podcasts*: The Joint Commission and its affiliate, Joint Commission Resources, offer free webinars and podcasts on various accreditation and patient safety topics.
- *Speak Up! Campaign*: 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 www.jointcommission.org/speakup.)
- *Standards BoosterPaks*: Available for accredited or certified organizations through the Joint Commission Connect Extranet, organizations can access boosterpaks that provide detailed information about a single standard or topic area that has been associated with a high volume of inquiries or non-compliance scores. Recent

standards boosterpack topics include restraint and seclusion, management of hazardous waste, environment of care (including standards EC.04.01.01, EC.04.01.03, and EC.04.01.05), and sample collection.

- *Leading Practice Library:* Available for accredited or certified organizations through the *Joint Commission Connect* extranet, organizations can access an online library of solutions to help improve safety. The searchable documents in the library are actual solutions that have been successfully implemented by hospitals and reviewed by Joint Commission standards experts.
- *Joint Commission Web Portals:* Through the Joint Commission website, organizations can access web portals, which provide a repository of resources from The Joint Commission, the Center for Transforming Healthcare, Joint Commission Resources, and Joint Commission International on the following topics:
 - Transitions of care: www.jointcommission.org/toc
 - High reliability: www.jointcommission.org/highreliability
 - Health care-associated infections (HAI): www.jointcommission.org/hai
 - Emergency Management: http://www.jointcommission.org/emergency_management.aspx

Appendix. Key Patient Safety Requirements

A number of Joint Commission standards have been discussed in the "Patient Safety Systems" chapter. However, many Joint Commission requirements address issues related to the design and management of patient safety systems, including the following examples:

APR.09.01.01: The hospital notifies the public it serves about how to contact its hospital management and The Joint Commission to report concerns about patient safety and quality of care.

APR.09.02.01: Any individual who provides care, treatment, and services can report concerns about safety or the quality of care to The Joint Commission without retaliatory action from the hospital.

LD.02.01.01: The mission, vision, and goals of the hospital support the safety and quality of care, treatment, and services.

LD.02.03.01: The governing body, senior managers and leaders of the organized medical staff regularly communicate with each other on issues of safety and quality.

LD.02.04.01: The hospital manages conflict between leadership groups to protect the quality and safety of care.

LD.03.01.01: Leaders create and maintain a culture of safety and quality throughout the hospital.

EP 1. Leaders regularly evaluate the culture of safety and quality using valid and reliable tools.

EP 2. Leaders prioritize and implement changes identified by the evaluation.

EP 3. Leaders provide opportunities for all individuals who work in the hospital to participate in safety and quality initiatives.

EP 4. Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.

EP 5. Leaders create and implement a process for managing behaviors that undermine a culture of safety.

EP 6. Leaders provide education that focuses on safety and quality for all individuals.

EP 7. Leaders establish a team approach among all staff at all levels.

EP 8. All individuals who work in the hospital, including staff and licensed independent practitioners, are able to openly discuss issues of safety and quality.

EP 9. Literature and advisories relevant to patient safety are available to all individuals who work in the hospital.

EP 10. Leaders define how members of the population(s) served can help identify and manage issues of safety and quality within the hospital.

LD.03.02.01: The hospital uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

LD.03.03.01: Leaders use hospital-wide planning to establish structures and processes that focus on safety and quality.

LD.03.04.01: The hospital communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties.

LD.03.05.01: Leaders implement changes in existing processes to improve the performance of the hospital.

LD.03.06.01: Those who work in the hospital are focused on improving safety and quality.

LD.04.01.01: The hospital complies with law and regulation.

LD.04.04.05: The hospital has an organization-wide, integrated patient safety program within its performance improvement activities.

EP 1. The leaders implement a hospital-wide patient safety program.

EP 2. One or more qualified individuals or an interdisciplinary group manages the safety program.

EP 3. The scope of the safety program includes the full range of safety issues, from potential or no-harm errors (sometimes referred to as near misses, close calls, or good catches) to hazardous conditions and Sentinel Events.

EP 4. All departments, programs, and services within the hospital participate in the safety program.

EP 5. As part of the safety program, the leaders create procedures for responding to system or process failures.

EP 6. The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment.

EP 7. The leaders define patient safety event and communicate this definition throughout the organization.

EP 8. The hospital conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the "Sentinel Events" (SE) chapter of this manual.

EP 9. The leaders make support systems available for staff who have been involved in an adverse or sentinel event.

Note: *Support systems recognize that conscientious health care workers who are involved in sentinel events are themselves victims of the event and require support. Support systems provide staff with additional help and support as well as additional resources through the*

human resources function or an employee assistance program. Support systems also focus on the process rather than blaming the involved individuals.

EP 10. At least every 18 months, the hospital selects one high-risk process and conducts a proactive risk assessment.

EP 11. To improve safety and to reduce the risk of medical errors, the hospital analyzes and uses information about system or process failures and the results of proactive risk assessments.

EP 12. The leaders disseminate lessons learned from comprehensive systematic analyses (for example, root cause analyses), system or process failures, and the results of proactive risk assessments to all staff who provide services for the specific situation.

EP 13. At least once a year, the leaders provide governance with written reports on the following:

- All system or process failures
- The number and type of sentinel events
- Whether the patients and the families were informed of the event
- All actions taken to improve safety, both proactively and in response to actual occurrences
- For hospitals that use Joint Commission accreditation for deemed status purposes: The determined number of distinct improvement projects to be conducted annually
- All results of the analyses related to adequacy of staffing

EP 14. The leaders encourage external reporting of significant adverse events, including voluntary reporting programs in addition to mandatory programs.

Note: *Note: Examples of voluntary programs include The Joint Commission Sentinel Event Database and the US Food and Drug Administration (FDA) MedWatch. Mandatory programs are often state initiated.*

PI.01.01.01: The hospital collects data to monitor its performance.

PI.02.01.01: The hospital compiles and analyzes data.

PI.03.01.01: The hospital improves performance on an ongoing basis.

MS.08.01.01: The organized medical staff defines the circumstances requiring monitoring and evaluation of a practitioner's professional performance.

MS.09.01.01: The organized medical staff, pursuant to the medical staff bylaws, evaluates and acts on reported concerns regarding a privileged practitioner's clinical practice and/or competence.

MM.07.01.03: The hospital responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

EP 3. The hospital complies with internal and external reporting requirements for actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

HR.01.05.03: Staff participate in ongoing education and training.

EP 7. Staff participate in education and training that includes information about the need to report unanticipated adverse events and how to report these events. Staff participation is documented.

EP 8. Staff participate in education and training on fall reduction activities. Staff participation is documented.

EP 13. The hospital provides education and training that addresses how to identify early warning signs of a change in a patient's condition and how to respond to a deteriorating patient, including how and when to contact responsible clinicians. Education is provided to staff and licensed independent practitioners who may request assistance and those who may respond to those requests. Participation in this education is documented.

RI.01.01.01: The hospital respects, protects, and promotes patient rights.

EP 29. The hospital prohibits discrimination based on age, race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, and gender identity or expression.

RI.01.02.01: The hospital respects the patient's right to participate in decisions about his or her care, treatment, and services.

EP 21. The hospital informs the patient or surrogate decision-maker about unanticipated outcomes of care, treatment, and services that relate to sentinel events considered reviewable by The Joint Commission.

EP 22. The licensed independent practitioner responsible for managing the patient's care, treatment, and services, or his or her designee, informs the patient about unanticipated outcomes of care, treatment, and services related to sentinel events when the patient is not already aware of the occurrence or when further discussion is needed.

Note: *In settings where there is no licensed independent practitioner, the staff member responsible for managing the care of the patient is responsible for sharing information about such outcomes.*

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