**Table 1. Defining and Comparing Analytical Tools**

| Tool | What It Is | When to Use It |
|---|---|---|
| Run Chart | A data chart, plotting in time order, used to show the performance of a process over time. It shows both positive and negative patterns, trends, and variation in process. | • When the hospital needs to identify changes and variation within a process<br>• When the hospital needs a simple and straightforward analysis of a process<br>• As a precursor to an SPC chart |
| Statistical Process Control Chart (SPC) | 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 data point goes beyond a control limit or data points form a pattern or trend. | • When the hospital needs to determine if a process is stable, to identify variation within a process, or find indicators of why the variation occurred<br>• When the hospital 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 hospital needs to determine whether a process will function as expected, according to specifications (requirements or targets)<br>• When the hospital needs to determine how capable their process is for meeting customer specifications (requirements or target) |

# Using Data to Drive Improvement

After data have been turned into information, leaders should ensure the following (per the requirements shown)[25–27]:

- Information is presented and shared with the appropriate groups throughout the hospital, from frontline staff to the governing board in a clear manner (**Standards GLD.04.01** and **QPS.01.00**).
- Opportunities for improvement and actions to be taken are communicated (**Standard GLD.04.01**).
- 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 hospital 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 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.

JCI addresses proactive risk assessments at **Standard QPS.04.01, ME 3**, which requires hospitals to select one high-risk process and conduct a proactive risk assessment at least annually. Hospitals should recognize that this standard represents a minimum requirement. Hospitals working to become learning organizations are encouraged to exceed this requirement by constantly identifying risks to proactively address these and reduce the risk of harm (for example, by identifying more than one process to perform a proactive risk assessment, such as low-volume but high-risk processes; or high-volume lower-risk processes, which may carry higher risks via statistical probability).

When conducting a proactive risk assessment, organizations should prioritize high-risk areas, or 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 hospital to take a proactive approach to reduce harm. Hospitals 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.

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 a hospital. 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[28] (*see* "A Fair and Just Safety Culture" section and Sidebar 1).

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[28]:
1. **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, and services to patients).
2. **Supervisory influences:** Examples include inadequate supervision, unsafe operations, failure to address a known problem, and authorization of hazardous activities when alternatives exist.
3. **Organization influences:** Examples include inadequate staffing, organization culture, leadership, lack of strategic risk assessment.

## 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 mode 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.[29] The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones. Failures should be prioritized according to how serious the potential consequences are, how frequently they may occur,

and how easily a failure can be detected.[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 and https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit
- 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.

Strategies for conducting an effective proactive risk assessment, no matter the strategy chosen, should address the following:

- Promote a blame-free **reporting** culture (a blame-free **reporting** culture should be differentiated from the term *blame-free* in relation to *accountability* and *Just Culture* principles) (*see also* Sidebar 1).
- Describe the chosen process (for example, through use of a flowchart).
- Identify ways in which the process could break down or fail to perform its desired function, which are often referred to as "failure modes."
- Identify the 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 comprehensive systematic analysis such as root cause analysis.
- Design or redesign the process and/or the 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 a critical component of 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 hospitals assess and enhance patient activation. Achieving this requires leadership engagement in establishing patient-centered care as a top priority throughout the hospital. 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.