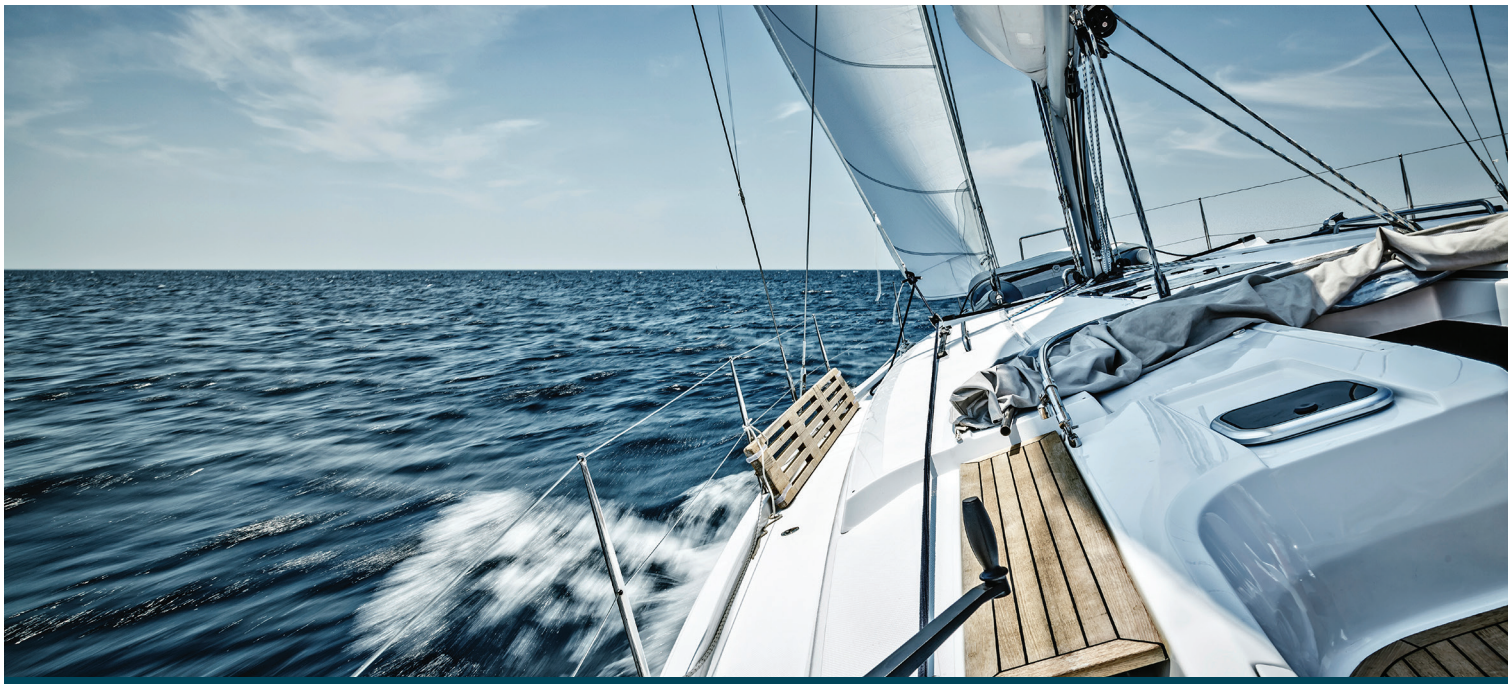

Safety Culture and Risk Reliability in Health Care

EXPLORING THE DYNAMICS OF SAFETY CULTURE AND ORGANIZATIONAL RESILIENCE

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AMC | PSO

ABOUT THIS DOCUMENT

The Academic Medical Center Patient Safety Organization hosted a two-day culture of safety and organizational risk reliability symposium in December 2016, led by notable safety and risk reliability expert Paul LeSage of SG-Collaborative Solutions. Invited attendees included risk managers, patient safety and quality leaders, front line managers, human resources staff, and representatives of senior leadership from AMC PSO member organizations. Key concepts and takeaways are highlighted in this publication.

Background

Since the advent of the 2000 Institute of Medicine report, *To Err is Human,*[1] the healthcare community has made significant efforts to shift the paradigm of seeing medical error as a reason for blame to an opportunity for learning and improvement. From physician offices to large academic medical centers, advances are being made to develop organizational structures and processes that support a "Culture of Safety," or as known in other industries, a "Safety Culture."

Although both terms are frequently used, they lack a single, concrete definition, often described as a set of principles and characteristics. In the guide "Managing Maintenance Error: A Practical Guide," noted human error experts James Reason, PhD, and Alan Hobbs, PhD, define a culture of safety as one that provides highly reliable and safe care, relying on three overarching principles: trust, reporting, and improvement.[2] The Agency for Healthcare Research and Quality (AHRQ) establishes that a culture of safety has these key features:

- acknowledgment of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations;
- a blame-free environment where individuals are able to report errors and near misses without fear of reprimand or punishment;
- encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems; and
- organizational commitment of resources to address safety concerns.[3]

A key element of a safety culture is the concept of having a "Just Culture," a values-supportive model of shared accountability first introduced by David Marx, JD, noted author on organizational management and reliability.[4] In a Just Culture, the goal is to strike the right balance in establishing a blame-free environment that acknowledges our human fallibilities and the role that system deficiencies play in contributing to human error and creating competing priorities. This, coupled with acceptance of personal accountability for individual behavioral choices, helps create a "just" healthcare system that supports rather than stifles safety and the caregivers who make up that system.

Another concept being integrated into healthcare delivery systems is that of organizational and risk reliability. Originally developed through the study of "high reliability organizations" (HRO), reliability can be best defined as, "organizational mindfulness"; a mentality that continuously evaluates the environment with the goal to anticipate and mitigate significant risks or contain unexpected events.[5]

HROs consistently minimize adverse events despite carrying out intrinsically complex and hazardous work.[6] In healthcare, this would be akin to providing safe and effective care, despite the complexities of both the healthcare delivery system and the patients themselves.

Most HROs emerge from "high consequence" industries, where a failure could cause catastrophic consequences, such as death or extensive damage to property. Much like healthcare, they are often complex in their operations and processes. However, this is where the similarities end. Unlike most HROs, healthcare systems or institutions were never designed with resiliency in mind; in addition, healthcare systems do not participate in a single, cross-functional regulatory safety system, such as the FAA in aviation, where safety events can be reported, analyzed, and shared amongst all organizations in a systematic manner. Through conferred federal peer protections, PSO programs may offer opportunities to support healthcare organizations in learning from patient harm events by serving a dual role as both a national convener of stakeholders and a repository of adverse event reports.

High reliability practices integrate the following practices:

- a systems-based approach to minimizing and evaluating risk,
- avoidance of behavioral bias in evaluating and responding to failures (safety events),
- evolution from a rules-based to a risk-based approach,
- a focus on front line operations and involvement of frontline staff in risk reduction activities, and,
- constant, proactive vigilance by all staff to help identify signals of potential and actual risk.

High reliability also requires leadership commitment and alignment across the organization. Additionally, risk mitigation should be based on proactive risk assessment and not be biased by an untoward outcome.

Despite the inherent limitations of traditional healthcare systems from a reliability engineering standpoint, many organizations have embarked on the journey towards achieving higher reliability by integrating key elements of reliability sciences into their operational processes.

Exploring the Dynamics of Safety Culture and Organizational Resiliency

In launching the symposium, the goal of the AMC PSO was to facilitate conversations amongst attendees from the perspective of these key questions:

- Where is safety culture headed?
- How can institutions leverage existing and novel strategies to advance safety culture?
- What is a risk reliable organization?
- How does this compare to "high reliability" organizational models?
- What is missing from current models and how can we fill the gaps?

"The Journey" Presentations

The symposium was framed by presentations from healthcare institutions that had worked collaboratively on a mutual "Journey to a Collaborative Just Culture."

Early learnings on this journey came from AHRQ's Culture of Safety survey results. The results showed a disparity in leadership versus frontline staff perceptions of non-punitive response to error, with leaders rating indicators more favorably than staff. This new awareness helped drive leadership's involvement and commitment to this initiative.

Getting staff to actively submit safety event and near miss reports was also a significant challenge. Fueled by the perception that reports went into a "black hole" with little or no feedback, staff didn't have much interest in taking the time to report minor issues nor 'non-reportable events.' Leaders would need to consider how this initiative could better empower staff and encourage reporting.

Of importance, was the need to clearly define a "culture of safety" relative to norms of behavior. This was relayed by the message that "A culture of safety is a culture where:

- a personal commitment to making care safer is fostered by an environment that encourages curiosity about why errors occur.
- we are encouraged to be open about our errors and the system vulnerabilities we see.
- we feel comfortable speaking up, without fear of punishment."

The element of "Just Culture" was further defined as:

> *A framework for evaluating our systems and behaviors to identify and fix vulnerabilities that guides us in how to respond to behaviors in a fair, just, and collaborative way. The key goal in developing a Just Culture was to move from a "shame and blame" mentality to a "culture of continuous learning."*

In addition, leaders took a realistic look at the scope of resources needed to truly navigate the journey to an improved safety culture and higher reliability. As a result, the message transmitted at the outset of this initiative was clear: this was a long-term, 5–7 year, strategic initiative that would require ongoing leadership support, commitment, resources and, most of all, *patience*.

The first order of action was to develop a new systematic approach to analyzing risk and safety events. Previous methods had focused on first analyzing team or individual behaviors and level of culpability, followed by the identification of possible system-based factors. This fostered a somewhat defensive posture during the root cause analysis (RCA) process, most certainly by those individuals involved in events. The new approach took a more academic, curious approach; the "risk" rather than the "behavior" was the focus. Initial questions centered on how system design, operational policies, and production pressures may have served as drivers and contributors to personal performance and behavioral choices.

This opened the door to creating a positive experience leading to organizational learning. An event algorithm was created to guide teams in conducting this process.

The next step was to bring this methodology to life by integrating it into the organization's human resources, peer review, safety review, and RCA processes. RCAs were replaced by "Collaborative Case Reviews," a non-threatening term.

Collaborative case review teams were developed to help support the new process. Finally, the event reporting system was modified so that staff and managers could simply click a link to request a collaborative case review with submission of an event report. This request could be for services ranging from simple guidance to a full team-facilitated collaborative case review.

A driver of success was the multidisciplinary approach taken by leadership, human resources, quality improvement, and clinical leadership to successfully integrate this approach and methodology across departments. For example, events would be analyzed first from a systems approach before any analysis of employee behavioral choices took place, as the new approach often yielded a different perspective of the employee's choices and behavior, and sometimes revealed that the individual choices were driven by a strong system contributor.

The most comprehensive and resource-intensive focus of this initiative was training. Several levels of training were developed based on staff member role. Training ranged from a short video and introductory presentation (all staff) to two days (champions and advisors).

Tandem efforts supported the development of a risk reliable organization. This work rested on establishing a risk register system by which safety analysts could compile and analyze results in order to identify and communicate significant error rates and trends.

Inherent in their approach to improving safety event reporting were these key assumptions:

- We can only fix what we know about.
- Frontline staff have the most insight into what works… and what doesn't.
- We see only the errors that "break the surface" and result in harm, but
- There is more risk lurking below the surface, which empowered frontline staff can help identify and manage.

By establishing a supportive structure through the creation of a Just Culture Working Group, a Just Culture Advisory Committee, and a Safety Culture Committee, a more comprehensive event reporting process was developed and supported, empowering staff to report.

Efforts were made to streamline the event reporting system and to create feedback loops so that line staff were acknowledged for their efforts and received updates, mitigating perceptions of the "black hole" of event reporting.

At one institution, staff who request a response about follow-up to the safety report now receive an individualized response from the Patient Safety department, in addition to a weekly newsletter entitled, "Last Week in Patient Safety," highlighting a case to the hospital community.

THREE STRIKES: NOT OUT

It was one of those nights every ICU nurse dreads—covering one highly complex patient and then having to admit a fragile, septic 90-year-old with dementia right at shift change! Arlene, the ICU nurse, was working to her limit. When her new admit became highly agitated, Arlene quickly checked the order for Diazepam, opened the Omnicell, glanced at the label and administered an IV bolus.

What Arlene failed to notice was she had actually pulled Diltiazem from the neighboring drawer, not Diazepam.

Five minutes later the alarms sounded; the patient's blood pressure rapidly decreased and the code team was called. Tragically, 20 minutes of resuscitative efforts failed and the patient expired.

An examination of the event revealed the error. On review of the medication administration record (MAR) system, Arlene had made two previous minor medication errors over the past three years. This, combined with the severity of the outcome of this incident, resulted in her immediate dismissal.

During this time, the institution was implementing "Just Culture." A risk-based causal review was done on the case. Data analysis showed this error had occurred several times over the past year: drawer proximity, similar vial types and names and labels were all contributing factors. The system carried risks which, coupled with "production pressures" in the ICU, were seen as contributors to Arlene's error. The team recommended a system fix and staff education on recognizing risks in medication administration. A key point identified in the review noted that the event outcome (death) should not be the determining factor in evaluating causal factors and responses.

When discussed with human resources, it was clear the causal analysis response was not consistent with human resources "three strikes" policy on medication errors and the severity of the outcome (death). Committed to improving its safety culture, leaders realized they needed to develop a model where quality, risk, operations, and human resources aligned their approach policies to support a "Just Culture" by moving away from the old system of punishment to one that is focused on reducing future risk.

Alerts and structural changes were made relative to the storage, dispensing, and administration of the drug. Arlene was rehired, and also educated on medication error prevention and the risks of not asking for help. In the ensuing year no medication errors of this type reoccurred.

Workshop and Convening Highlights

As part of the symposium, a noted safety culture and risk reliability expert led a workshop on the current state of safety culture and risk reliability relative to the healthcare industry.[7] A number of concepts were presented, with some of the more "thought provoking" detailed below.

Taking a "Just Culture" Approach

Current research has moved from individual punitive blame for errors to a more integrated approach that studies systems thinking and its impact on human factors that drive individual choices. Errors are rarely "bad people doing bad things" and are more often the result of individuals exhibiting normal human behaviors while interacting with complex (and often suboptimally designed) systems. This is not to say that the individual is never at fault. With the acknowledgement of the contribution of system and human factors in error, there must also be personal accountability for individual job (task) performance and choices. A punitive approach may be appropriate when an individual demonstrates a conscious disregard of substantial and unjustifiable risk. Using the Just Culture approach to understand where the risk exists and responding in a fair and just fashion helps create psychologically safe environments supportive of error reporting.

Just Culture takes into account system failures that contribute to errors over which an individual may have had no control, as well as how human factors naturally interact within systems.

Proactive Risk Reliability

Covering the expansive field of risk reliability management was beyond the scope of the symposium; however, the importance of proactive risk identification was a key theme. Proactive risk identification involves the ability to actively recognize risks in system design, operational processes, human performance, and behavior.

As noted previously, healthcare systems often lack engineering system design controls found in other highly

technical industries. For this reason, spotting system design flaws can be a productive way to decrease risk. For example, obtaining feedback from frontline staff can be invaluable in evaluating risk, as poor system design usually affects their work the most. Admissions staff will be the first to tell you that confirming required patient demographics is a difficult task when core staff is tasked with processing patient registrations. Most emergency physicians will agree that the ability to have 4–5 patient records open at one time in an EHR creates a risk for wrong patient documentation and computerized physician order entry errors.

Failure Mode & Effects Analysis (FMEA) is another common tool used to proactively assess risk. In FMEA, processes are broken down by steps, with each step evaluated for the likelihood of error and potential outcome severity. Although an effective and systematic strategy, "likelihood" and "outcome" results may be influenced by subjective bias. It is also difficult to calculate the impact of one versus multiple breakdowns in a process. Finally, it is challenging to evaluate human factors such as behavior and choice and their influence on a given process.

More recently, some organizations have explored sociotechnical probabilistic risk assessments (ST-PRA), a highly technical data-driven approach that models combinations of failures, human error, at-risk behaviors, and recovery opportunities through the use of fault trees. Thus, ST-PRA provides insights into the strengths and weaknesses of system design and operations to assist institutions in making risk-informed decisions.

Inherent Error Rates

One of the most thought-provoking concepts presented sought to dispel the notion that institutions can realistically strive for "100% reliable" processes or "zero error." Given the fallibility of humans and technology, there is always a certain level of inherent error.

Robust risk registers and active reporting are used to catalogue "inherent error rates," which can provide leaders with the information to make decisions on what risk levels are acceptable versus non-acceptable. For example, if the rate of an inaccurate diagnostic test result is 0.001%, even if the potential outcome of an error is serious, would this justify the resources necessary to add an additional "double check" on this test? What would be the ability of the double check to actually change this rate? Inherent error rates should be taken into consideration before establishing performance metrics.

Encouraging Event Reporting

As mentioned previously, robust risk registers and event reporting systems are essential for assessing inherent error rates and monitoring trends in patient safety events.

Encouraging staff to "speak up" and report near miss incidents empowers and engages staff, while supporting a safety culture. To ensure near miss reporting achieves its potential, an organization must develop an effective feedback loop to the reporters. Staff training should include the role of near miss reporting in shining a light on inherent error rates, rather than necessarily spurring

visible, immediate action. If staff does not understand the concept of "frequency reporting," they may feel their efforts are wasted.

Another tactic to engage providers and staff in near miss and event reporting is to share the results of analyses and actions related to event reporting. For example, presenting event statistics at departmental meetings is an excellent way to validate and obtain feedback on whether "statistics" match perceived risks. Presenting case reviews is an effective way of combining event statistics with real-life scenarios that staff can relate to. Much like Mortality and Morbidity conferences for physicians, case reviews offer staff the ability to contribute to patient safety.

Safety Event Causal Analysis: Focusing on Risk Vulnerabilities and Contributors

Risk may evolve from multiple sources, each contributing to the overall vulnerability of a process, such as: system design, overt and covert operational priorities or "production pressures," cultural factors, personal performance, and human behavioral factors. When evaluating safety events, the team may want to ask first "What were the key vulnerabilities or 'risks' underlying the event?" Once risks have been identified, the team is encouraged to evaluate each risk in the context of these questions:

- Was there a system design issue that contributed to the event?
- Were there competing priorities that interfered with the ability to follow policies or provide needed care?
- Were personal performance issues involved?
- What behavioral factors contributed to the error?
- What other issues may have contributed to poor choices, at-risk behavior, or even reckless behavior?

Most importantly, causal analysis should be a systematic process. Algorithms can be useful tools in leading teams through this process. Risk reliability algorithms are unique in that they start by identifying the risk and then move to evaluating system design and operational factors that may predispose humans to suboptimal performance and behavioral choices.

There is also a fundamental difference between fault finding exercises and risk-based analysis. Focusing first on the outcome can lead to judgments about personal behavior. In contrast, risk analysis is not focused on the outcome, but rather looks to the risk and evaluates events in the context of the system in which they occurred, for the sole purpose of reducing future risk. It is important for human resources to be aligned with the organization's risk reliability or safety culture approach. As highlighted in "Arlene's Story," disciplinary actions often revolve around the severity of an event outcome, whereas risk-based responses focus on what needs to be done to mitigate future risk and not punishment for bad outcomes.

In the end, a good event causal analysis process, or "collaborative case review," will lead organizations, managers, and teams to make appropriate and specific actionable responses in such a way as to decrease future risk and better ensure safe and effective care.

Organizational Alignment

Organizational alignment is an absolute precursor to instituting any new RCA process that frames how the organization will respond to safety events involving provider or staff performance. First, current policies and procedures across the organization should be in alignment with the safety culture philosophy and causal review process. These policies should be developed and deployed through the shared approach of leaders in quality, patient safety, operations, and human resources.

Silos may also exist between risk management, patient safety, and quality or process improvement. All too often, event investigation results or implementation of action plans are kept within patient safety or risk management. Conversely, some action plans are handed off to quality or process improvement teams to implement with limited follow-up by risk management. For this reason, many healthcare organizations have begun to merge risk, quality, patient safety, process improvement, and even patient advocacy under the same leadership.

Balancing Patient Safety and Production Pressures

Similar to other industries, healthcare is also faced with output demands. While output is not overtly the message communicated in most healthcare settings, pressures to produce are certainly present. For example, while improvements in surgical turnaround times are a commonly celebrated perioperative performance metric, meeting Universal Protocol "time out" compliance may be seen as simply meeting a Joint Commission standard. These covert messages often resonate deeply with staff and may drive behaviors that favor meeting production pressures, rather than safety goals. Understanding these messages and recognizing potential conflicts between production pressure and patient safety goals should lead organizations to examine the relevance of current operational and safety practices and policies and make needed adjustments.

Hierarchical Gradients

Hierarchical gradients, also known as power or authority gradients, are not always thought of as being directly associated with increasing patient safety risk, but they are commonly identified as contributing factors in the analysis of safety event reports.

A common thread in "failure to rescue" cases is the failure of a staff member, trainee, or provider to escalate a concern regarding a patient's condition or treatment before an untoward event occurs. This "failure to escalate" can be due to several factors: 1) reluctance to challenge the opinion of a superior, 2) lack of clear escalation protocols, or 3) a poor safety culture. Hierarchical gradients are often the underlying theme behind these adverse events.

For example, a food service aid may be reluctant to check patient identifiers when delivering a meal if he/she fears interrupting a physical therapist working with a patient; an intern may not challenge a resident's orders despite an ongoing concern that the patient is not responding to treatment; a nurse may not call an on-call physician at 2 AM, uncertain that his/her concerns are justified and

fearful of being angrily dismissed by a physician who has just been "woken up for a non-emergency."

Regardless of credentials, everyone as a member of the care team should feel empowered to speak up about safety concerns. Medical faculty, clinical managers, and team leaders should play a key role in supporting other team members to speak up.

To aid in this process, organizations should consider developing early warning or escalation protocols to provide clear guidance on when and how to escalate concerns through the chain of command.

Examples of escalation protocols include the Boston Children's Hospital's Early Warning Score (CHEWS)[8] and the Modified Early Warning Score (MEWS),[9] developed by the Ysbyty Glan Clwyd (YGC) hospital, located in Rhyl, Denbighshire, central North Wales, as part of the Institute for Healthcare Improvement's Safer Patient Initiative in 2008.

Negative Warnings… or "False Alarms"

We all know the story of the boy who cried wolf, but what happens when an employee calls a Rapid Response Team and the patient is stable? Is the employee actively supported and thanked for escalating his/her concerns, or subtly discouraged from repeating the action?

In reality, there is roughly a 5:1 ratio of negative to positive warnings.[7] With this in mind, leaders should address the meaning of negative warnings as part of safety culture and escalation protocol training. In truth, negative warnings are a positive sign of a strong safety culture and should be treated as such.

One recommendation is to address the prospect of negative warnings in hospital orientation, team training, and simulation models. Also, involving the staff member who initiates the response in post-event debriefings and thanking them for their contribution is an important aspect of supporting safety culture.

Risk Mitigation and Action Strengths

The ultimate goal of a strong safety culture and risk-reliability management system is to enact meaningful change. Stakeholders strive for relevant and lasting accomplishments in patient safety and error prevention. Attaining this goal ultimately rests on the strength of the actions chosen to mitigate risks and support productive change.

Leaders should consider how the strength of actions to decrease risk or improve patient safety contributes to meeting these goals. Table 1 shows a breakdown of action types and strengths, based on a well-known patient safety actions model.[10]

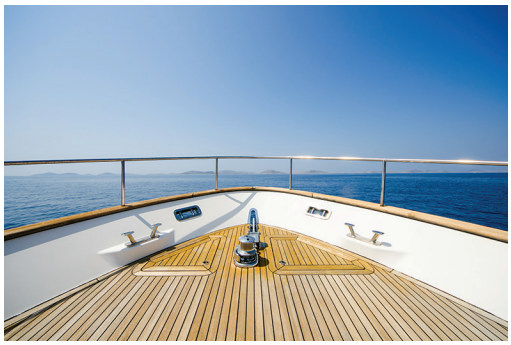
For example, a fundamental response to mitigating human error or performance issues is education; yet education, in itself, rarely leads to lasting change, especially if operational processes or pressures do not support the expected behavior. In contrast, thoughtful system design changes like an EHR decision support algorithm tend to yield higher, lasting benefits.

In determining actions, most leaders recognize there is a balance that needs to be attained between resources and actions. Stronger actions generally require more resources, as they involve major structural or technical changes. For this reason, patient safety should factor into executive level strategic planning activities. Involving executive leadership in quality or patient safety steering committees is a good way to incorporate and align decisions on patient safety initiatives with the institutional strategic plan and resource allocation.

TABLE 1

Action Strengths

ACTION TYPE	EXAMPLES
Strong *system focused*	▪ architectural improvements to the physical or IT environment ▪ improved devices with usability testing ▪ automation
Moderate *system/behaviors focused*	▪ simulation practice ▪ checklist/cognitive aids ▪ eliminate/reduce distractions
Weak *behavior focused*	▪ additional documentation ▪ training/education ▪ revision of policies and procedures



Looking Forward

AMC PSO Convening

In conjunction with the symposium, the AMC PSO held two daily convenings to facilitate reflection and open discussion on principles and ideas presented throughout the day. The AMC PSO uses the convening process to encourage transparent discussion on patient safety and care delivery challenges faced by its members and to set the stage for consensus-based decision-making.

One goal of these convenings was to identify potential areas for future collaboration on safety culture and risk reliability initiatives.

Based on the feedback received during the convening process and from a post-symposium survey, members identified these areas as important considerations for the future:

- Empowering providers and staff to identify risk vulnerabilities and actively report
- Balancing patient safety and operational production pressures
- Managing power gradients (hierarchical issues): Initiatives to build awareness, empowerment and communication strategies
- Designing and implementing a standardized "Collaborative Case Review" RCA methodology
- Brainstorming on how to create stronger action plans with limited resources
- Developing risk registers to better understand inherent error rates.

Conclusion

While the aim of the delivery of healthcare is to provide patients with the safest and most effective possible care, there are inherent risks in healthcare delivery systems that unfortunately lead to error and patient harm.

Recognition of how risks present and evolve, along with a multidisciplinary approach for proper deployment of risk prevention and mitigation strategies, can reduce the severity of outcomes of these types of events.

The AMC PSO is hopeful these strategies offered in this publication will inform and advance your organization's culture of safety and risk reliability efforts.

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About the AMC PSO

In 2009, the Patient Safety and Quality Improvement Act (PSQIA) was enacted to create a culture of safety by providing federal privilege and confidentiality protections for information that is assembled and reported to a PSO, or developed by a PSO, for the conduct of patient safety activities.

The act promotes the sharing of best practices and knowledge to continuously improve the quality of patient care. Before the PSQIA, legal protections for quality activities were limited in scope and existed only at the state level.

The PSQIA encourages voluntary reporting. Identification of common, systemic errors can be achieved more effectively through the aggregation of information reported from providers across the health care delivery system.

In 2010, the Risk Management Foundation of the Harvard Medical Institutions, Inc. formed a component entity, the Academic Medical Center Patient Safety Organization (AMC PSO) to function as a national convener of clinicians and health care organizations to collect, aggregate, and analyze data in a secure environment in an effort to identify and reduce the risks and hazards associated with patient care.

Our objectives:

- Create a bridge between themes driving malpractice activity and factors seen in real-time data with a particular focus on high severity/high significant events seen in root cause analysis (RCA)
- Convene member organizations in response to real-time events and bring context to patient safety issues by providing a secure venue for discussion
- Translate learnings gleaned from our convening sessions and data analyses into focused clinical interventions that can improve quality, reduce costs, and decrease liability
- Reach beyond data reporting and generate actionable responses that can inform the development of best practice recommendations
- Inform institutional patient safety efforts by pinpointing the areas of highest risk and vulnerability to help guide organizational patient safety initiatives

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