Executive Summary Checklist

Achieving a culture of safety in a healthcare organization requires transformational change which is owned and led by the executive leaders of the organization, including the board, encouraging accountability and transparency. Leadership’s primary goal must be to make their hospital a safe haven for patients.

- Address unexpected outcomes with open disclosure and prompt resolution.
- If patient harm results from a preventable medical error, adopt the CANDOR (Communication and Optimal Resolution) Approach: apologize as soon as possible, pay for all care related to the preventable harm, seek a just resolution, and provide ongoing support for patients and families. Clinicians (the “second victims” of patient harm events) may also require attention and support (Lambert et al., 2016).
  1. Create an open and transparent culture that encourages staff to speak up and self-report
  2. Apologize within 30 minutes
  3. No charge for care
  4. Credit card for follow-up care
  5. Incentivize lawyers to settle fast
  6. Do event reviews to avoid reoccurrence
  7. Within 30 days of any event disseminate learning out to the patient, family, hospital system and externally
- Create a standard of care to ensure that clinicians speak with family members to explain what will be changed so this event won’t happen again. Offer family members an opportunity to be involved and witness the change in procedure, etc.
- Create a reliable means to capture and analyze good catches/near-misses. Set a goal that includes aspirations that all errors and incidents are preventable and that zero is the most important goal.
- Implement an electronic adverse event reporting system that allows for anonymous reporting, tracking, trending and response to aggregate safety data.
- Implement thoughtful and memorable internal branding to keep safety expectations and aligned behaviors top of mind throughout an organization.
The Performance Gap

Despite widespread efforts among healthcare organizations to improve patient safety and healthcare quality, preventable patient deaths still occur. It is estimated that there could be over 200,000 preventable patient deaths per year in U.S. hospitals alone, and up to one-third of patients unintentionally harmed during a hospital stay (James, 2013; Classen et al., 2011). Preventable medical harm ranks as the third leading cause of death in the United States (Makary & Daniel, 2016). Such events cause unnecessary human suffering and also waste billions of dollars annually.

The confluence of continued preventable safety events, growing public vigilance, patient and provider/staff dissatisfaction, and payment systems that penalize poor outcomes serves as leverage to change how hospitals address quality and safety. However, even with this strong motivation and focused effort to improve safety and quality, evidence suggests that the risk of harmful error may be increasing.

Respect: The Essential Foundation of Safety Culture

It is not an accident that the Patient Safety Movement Foundation’s first Actionable Patient Safety Solution is “Culture of Safety”. To be more precise, the actionable solution is to create a culture of safety. That culture is informed – fundamentally and foundationally - by a culture of respect. Mutual respect among doctors, nurses, allied healthcare workers, patients and families is essential for effective communication, collaboration, teamwork, and decision-making. Respect is not merely a part of any APSS. Rather, every APSS is derived from a culture of respect.

Hospitals may be the last bastion of unchallenged hierarchical authority. Physicians are ultimately responsible for the outcome of patient care, and that care is dependent on a team that changes every 8 hours for the duration of the patient’s hospital stay. Patients are not generally thought of as a part of their own care team. They are often relegated to a passive role of receiving treatment, with a 3-5-minute window of opportunity to see the doctor once a day.

While hierarchies exist in many industries, some high-risk industries - such as aviation and nuclear energy – have successfully embraced a model of teamwork, accountability, and shared purpose to become High Reliability Organizations (HRO’s). They reduce risk by actively including all parties responsible for delivering the product/service, and by developing practices and procedures to insure safe operations.

Much work in this area has been studied by Dr. Lucian Leape et al in his perspective, “A Culture of Respect, Part 1, The Nature and Causes of Disrespectful Behavior by Physicians”, and “A Culture of Respect, Part 2: Creating a Culture of Respect”. Many of the key themes of safety culture presented here are an outgrowth of that work.

Key Themes of Safety Culture

Organizations that achieve high reliability, that is, to effectively reduce serious hazards well, have emphasized “safety culture” as a key factor in promoting excellence in performance. Despite widespread attention to the importance of safety culture in performance improvement, many healthcare organizations struggle to achieve it. In fact, the lack of safety culture remains a prominent underlying factor in many safety issues faced by healthcare organizations (Chassin & Loeb, 2011).

A strong safety culture promotes the identification and reduction of risk as well as the prevention of harm. A poorly defined and implemented culture of safety may often result in concealment of errors and therefore a failure to learn from them. According to the Institute of Medicine, “the biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm” (Wall, 2000).

“A culture of safety that fully supports high reliability has three central attributes: trust, report, and improve (Institute, 2015). When staff exhibit trust in their peers and leadership, they will routinely recognize and report errors and unsafe conditions. It is the actions of leadership that lead to this trust. Trust is established when the organization eliminates intimidating behavior that suppresses reporting, acts in a timely manner to address staff concerns, and communicates these improvements to the involved staff. Maintaining this trust requires that organizations must hold employees accountable for adhering to the established safety protocols and procedures. There must be a clear, equitable and transparent process for recognizing and separating blameless errors from unsafe or reckless actions that are
blameworthy (Reason & Hobbs, 2003). When all three of these components (trust, report, improve) work well, they will continuously reinforce a culture of safety and high reliability.”

The need for transparency cannot be overemphasized. The National Patient Safety Foundation notes that “…the impact of transparency—the free, uninhibited flow of information that is open to the scrutiny of others—has been far more positive than many had anticipated, and the harms of transparency have been far fewer than many had feared. Yet important obstacles to transparency remain, ranging from concerns that individuals and organizations will be treated unfairly after being transparent, to more practical matters related to identifying appropriate measures on which to be transparent and creating an infrastructure for reporting and disseminating the lessons learned from others’ data” (Chassin & Loeb, 2013).

There are four dimensions to transparency as it relates to healthcare organizations:

1. Transparency between clinicians and patients (illustrated by disclosure after medical errors);
2. Transparency among clinicians themselves (illustrated by peer review and other mechanisms to share information within health care delivery organizations);
3. Transparency of healthcare organizations with one another (illustrated by regional or national collaboratives); and
4. Transparency of both clinicians and organizations with the public (illustrated by public reporting of quality and safety data).

**Leadership Plan**

- Hospital governance and senior administrative leadership must commit to becoming aware of this major performance gap in their own organizations. Senior leaders cannot merely be “on board” with patient safety—they must own it.
- Hospital boards must focus on safety and quality, not just finances and strategy. Research demonstrates that patient outcomes suffer when boards do not make safety a top priority (Jha & Epstein, 2010).
- Hospital governance, senior administrative leadership, and clinical/safety leadership must close their own performance gap by implementing a proactive, comprehensive approach to addressing the culture of safety.
- Healthcare leadership (clinical/safety) must reinforce their commitment by taking an active role in championing process improvement; giving their time, attention and focus; removing barriers, and providing necessary resources.
- Healthcare Leadership must demonstrate their commitment and support by shaping a vision of the future, providing clearly defined goals, supporting staff as they work through improvement initiatives, measuring results, and communicating progress towards goals.
- There are many types of leaders within a healthcare organization, and in order for process improvement to truly be successful, leadership commitment and action are required at all levels. The Board, senior leadership, physicians, pharmacy and nurse directors, managers, unit leaders and patient advocates all have important roles and need to be engaged in specific behaviors that support staff to provide safer care.
- Safety culture and performance must be valued and reflected in compensation plans so that leaders have direct personal accountability for results.

Change management is a critical element that must be included to sustain any improvements. Patient Safety rounds by an interprofessional group (leadership, physician, pharmacist, nurse, etc) will help to reinforce and improve safe patient care. Recognizing the needs and ideas of the people who are part of the process—and who are charged with implementing and sustaining a new solution—is critical in building acceptance and accountability for change. A technical solution without acceptance of the proposed changes will not succeed. Building a strategy for acceptance and accountability for a change initiative greatly increase the opportunity for success and sustainability of improvements.
Practice Plan

The following five components of a safety culture are necessary to achieve high reliability (Chassin & Loeb, 2013):

1. **Trust**
   - Senior leaders, as well as and physician, pharmacist and nurse leaders establish a trusting environment among all staff by modeling appropriate behaviors and champion efforts to eradicate intimidating behaviors.
   - Create and maintain an environment where staff feel safe reporting issues and near misses, thus preventing harm from ever reaching a patient. The first step to establishing psychological safety for staff is to recognize that authority gradients and power hierarchies exist in all organizations, and may inhibit free communication. Implementation of communication tools, such as TeamSTEPPS helps build an infrastructure that supports near miss reporting and accountability.
   - Implement “non retaliation” policy for all staff reporting safety concerns
   - Electronic event reporting software that provides options for anonymous reporting is important as it allows people to report the unsafe condition without fear of reprisal. This also supports Leadership’s contention that they are interested in the safety issue, not the person.

2. **Accountability**
   - There is adoption of uniform, equitable, and transparent disciplinary procedures throughout the organization. All staff recognize and act on their personal accountability for maintaining a culture of safety.
   - Implement “Just Culture” policies for peer review and human resources. This requires a move away from a culture that holds staff to a retrospective standard of perfection, yet simultaneously allows a “no harm, no foul” attitude when patient outcomes are not affected. Intentional use of Just Culture requires that actions are separated from decisions. In other words, associates should not be punished for human error, but should always be held accountable for their decisions, regardless of the outcome. The decisions of all associates should be evaluated by the same standards, regardless of rank (Duthie, 2015).

3. **Identify Unsafe Conditions**
   - Staff recognize and report unsafe conditions and practices before these can harm patients.
   - Encourage reporting of “near miss” events.
   - Encourage a culture of reporting by providing feedback to employees and other health care providers who have reported or disclosed errors
   - Perform patient safety rounds by an interprofessional team to identify potentially unsafe conditions.
   - Communicate results of actions taken to resolve unsafe conditions.

4. **Strengthen Systems**
   - Implement a safe and effective reporting system that is accessible to all, that is user-friendly and non-punitive for employees to report safety risks, incidents, and near miss events.
   - Organizations should aggregate and review common causative factors of their investigations of harm events and near miss events, to identify which systems are most in need of process improvement.
   - Implement safety strategies such as automation, checklists and protocols where possible using system and human factor engineering principles.

5. **Assess and Continuously Improve the Safety Culture**
   - Regularly measure the “culture of safety” using a reliable, validated tool. Share the results transparently throughout the organization and develop improvement plans based on the results.
   - Routinely report safety culture metrics to the Board.
   - Thoughtfully and consistently communicate safety performance goals and expectations.
   - Develop comprehensive internal communications plans around safety goals.
   - Establish a standard that both patient and worker events and incidents are preventable.
   - Personalize the messaging by incorporating facts and emotions to build staff understanding and commitment.
   - Analyze all safety culture measurement data and undertake specific, measurable actions to remedy areas of shortcoming.
   - Maintain a non-punitive philosophy of “blame free” but accountable for practicing within the standard. Accountability should be built into the job descriptions at all levels of the organization, and all employees should be evaluated on contributions made to improve quality and patient safety.
● Require honesty and cooperation in reporting and mitigating any adverse patient event or near miss-including participation in root cause analyses and assigned performance improvement follow up.
● Recognize that employees and providers do not purposefully commit errors and that most errors are failures of complex systems and processes.
● Implement robust, standardized processes for root cause analysis
● Reduce variation in patient care delivery systems and processes through analysis and process improvement activities.

Addressing Unexpected Medical Outcomes and Preventable Harm Events

Organizations with a strong safety culture do not take a “deny and defend” approach after preventable patient harm. A growing body of evidence demonstrates that open disclosure and early resolution programs provide both psychological healings, as well as practical and financial support to patients and families harmed by medical errors. Such programs also align with business objectives of healthcare organizations, and promote reputational preservation. AHRQ’s CANDOR (Communication and Optimal Resolution) program is a free resource that facilitates the creation of a disciplined approach to transparency after unexpected outcomes.

Infrastructure

● Staffing budget to ensure adequate number of full-time patient safety and quality improvement professionals.
● Implementation and ongoing monitoring of a comprehensive patient safety program plan appropriately budgeted and approved by the Board of Trustees.
  ○ Program should be written and approved through leadership and Board channels.
● Electronic adverse event reporting software platform with anonymous reporting capability
  ○ Track, trend and respond to aggregate safety data
  ○ Share data transparently through appropriate quality committees.
● Create an internal working group with quality department leadership, nursing leadership, risk management, patient safety, patient advocacy, regulatory, chief medical officer, and other appropriate members. Meet weekly to communicate, review and resolve issues of concern that cross departments. (eg: Safety Adjudication Committee-SAC).
● Create a multidisciplinary Patient Safety committee, accountable to the board, with representation of all relevant stakeholders to oversee patient safety activities throughout the organization.
● Develop a ‘Good Catch’ program to recognize and reward reporting of near miss or significant systems issues.
● Conduct patient safety rounds which include executive leadership.
● Provide ongoing patient safety education to employees and other health care providers
  ○ National Patient Safety Awareness Week, newsletters, emails
● Develop annual electronic and in-person mandatory training that support patient safety education.
● Provide regular updates to Quality and Board level committees.
● Participation in a Patient Safety Organization (PSO) to enhance sharing and learning from safety events.

Metrics

Topic:
For organizations using the Safety Event Classification system, the following metric specifications apply. If not, consider adapting this model as a template.

Serious Safety Event (SSE) Rate
Rate of Serious Safety Events per 10,000 adjusted patient days (Stockmeier, 2009). A SSE results in harm that ranges from moderate to severe patient harm or death.
Outcome Measure Formula:

**Numerator:** Number of patients with a Serious Safety Event  
**Denominator:** Total number of adjusted patient days  
*Rate is typically displayed as Events/10,000 Adjusted Patient Days*

Metric Recommendations:

**Direct Impact:**  
All Patients

**Lives Spared Harm:**  
\[
\text{Lives Spared Harm} = (\text{SSE Rate}_\text{baseline} - \text{SSE Rate}_\text{measurement}) \times \text{Adjusted Patient Days}_\text{measurement}
\]

**Lives Saved:**  
\[
\text{Lives Saved} = (\text{SSE Mortality Rate}_\text{baseline} - \text{SSE Mortality Rate}_\text{measurement}) \times \text{Adjusted Patient Days}_\text{measurement}
\]

*Mortality SSEs are coded. If the organization codes the severity of their events, this formula could be applied to their data set.*

**Notes:**  
Adjusted patient days weight total patient days by inpatient, outpatient, and miscellaneous revenue to calculate an “adjusted patient day” accounting for inpatient, outpatient and other miscellaneous workload. The calculation for adjusted patient days is:

\[
\left(\frac{\text{Inpatient Revenue} + \text{Outpatient Revenue} + (\text{Miscellaneous Revenue})}{\text{Inpatient Revenue}}\right) \times \text{Total Patient Days}
\]

**Data Collection:**  
Manual chart review of events to determine if an event is a Serious Safety Event.

**Settings:**  
All inpatient and outpatient settings.

**Mortality (will be calculated by the Patient Safety Movement Foundation):**

The PSMF, when available, will use the mortality rates associated with Hospital Acquired Conditions targeted in the Partnership for Patient’s (PfP) grant funded Hospital Engagement Networks (HEN). The program targeted 10 hospital acquired conditions to reduce medical harm and costs of care. “At the outset of the PfP initiative, HHS agencies contributed their expertise to developing a measurement strategy by which to track national progress in patient safety—both in general and specifically related to the preventable HACs being addressed by the PfP. In conjunction with CMS’s overall leadership of the PfP, AHRQ has helped coordinate development and use of the national measurement strategy. The results using this national measurement strategy have been referred to as the “AHRQ National Scorecard,” which provides summary data on the national HAC rate.
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Conflicts of Interest Disclosure

The Patient Safety Movement Foundation partners with as many stakeholders as possible to focus on how to address patient safety challenges. The recommendations in the APSS are developed by workgroups that may include patient safety experts, healthcare technology professionals, hospital leaders, patient advocates, and medical technology industry volunteers. Some of the APSS recommend technologies offered by companies involved in the Patient Safety Movement Foundation that the workgroups have concluded, based on available evidence, are beneficial in addressing the patient safety issues addressed in the APSS. Workgroup members are required to disclose any potential conflicts of interest.
References


