Patient Safety
M O V E M E N T
zero preventable deaths by 2020

Actionable Patient Safety Solution (APSS) #1:
CULTURE OF SAFETY

Executive Summary Checklist

Implementing a culture of safety will require an plan to complete the following actionable steps:

☐ Achieving a culture of safety in a healthcare organization requires transformational change which is owned and led by the top leaders of the organization, including the board. Leaders cannot simply be "on board" with patient safety – they must own it.

☐ Transparency regarding the outcomes of care, both within and outside of the organization, facilitates improvement across the continuum of care.

☐ Understanding and implementing Just Culture is essential for transitioning from a culture of shame and blame to one of trust and respect. In a just culture, people are not punished for human errors, but are always held accountable for their decisions.

☐ If patient harm results from a preventable medical error: apologize as soon as possible, pay for all care related to the harm, seek a just resolution, and provide ongoing support for patients, families and providers. Perhaps find a way of including family and clinicians in healing process.

☐ Creation of a reliable means to capture and analyze good catches/near-misses is a key to identifying and addressing processes and systems.

☐ Both safety culture and patient outcomes require continual assessment: "What is measured gets managed."

☐ Create and maintain five components of a safety culture to achieve a high reliability organization
  ● Establish trust
  ● Establish accountability
  ● Identify unsafe conditions
  ● Strengthen systems
  ● Assess and continuously Improve the safety culture

☐ Develop a strong infrastructure ensuring:
  ● Budgets that allow for an adequate number and quality of patient safety professionals
  ● Implementation and ongoing monitoring of a comprehensive patient safety program that is approved by the Board of Trustees.
  ● Creation of an internal working group made up of quality improvement, nursing, risk management, patient safety, patient advocacy and regulatory leaders.
  ● Develop a 'Good Catch' Program to recognize and reward staff for reporting near misses or system issues.
  ● Integration of worker safety and patient safety strategies and resources.

☐ Safety Commitment and goal setting must include aspirations that all errors and incidents are preventable and that zero is the most important goal.

☐ Safety has to be personalized for behaviors to change or be sustained. Alignment of patient safety and worker safety activities is an important consideration for workers to be engaged and for reliability.

☐ Implement an electronic adverse event reporting system that allows for anonymous reporting, tracking, trending and response to aggregate safety data.

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.[1,2] Such events cause unnecessary physical and emotional distress to patients, families, and care providers and also cost the healthcare system billions of dollars annually.

The confluence of continued preventable safety events, growing public vigilance, patient and provider/staff dissatisfaction, and payment systems that penalize bad 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.

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.[3]

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."[4]

"A culture of safety that fully supports high reliability has three central attributes: trust, report, and improve.[5] 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.[6] 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

[1] Classen, D. C., Resar, R., Griffin, F., Federico, F., Frankel, T., Kimmel, N., ... & James, B. C. (2011). Global trigger tool shows that adverse events in hospitals may be ten times greater than previously measured. Health Affairs, 30(4), 581-589.

[2] James, J. T. (2013). A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care. Journal of Patient Safety, 9(3), 122-128.

[3] Chassin, M. R., & Loeb, J. M. (2011). The Ongoing Quality Improvement Journey: Next Stop, High Reliability. Health Affairs, 30(4), 559-568.

[4] Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (Eds.). (2000). To err is human: Building a safer health system (Vol. 6). National Academies Press.

[5] National Patient Safety Foundation's Lucian Leape Institute. (2015). Shining a Light: Safer Health Care Through Transparency. Boston, MA: National Patient Safety Foundation.

[6] Reason, J., & Hobbs, A. (2003). Managing maintenance error: a practical guide (pp. 145-158). Hampshire: Ashgate.

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."[7]

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.[8]
- 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.

Change Management

"Facilitating Change," the change management model The Joint Commission developed, contains four key elements to consider when working through a change initiative to improve a culture of safety.

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[7] Chassin, M. R., & Loeb, J. M. (2013). High- reliability health care: Getting there from here. Milbank Quarterly, 91(3), 459-490.
[8] Jha, A., & Epstein, A. (2010). Hospital governance and the quality of care. Health Affairs, 29(1), 182-187.

Plan the Project:
- Assess the culture for change, define the change, build a strategy, engage the right people, and paint a vision of the future to build a strong foundation for change. This should be done at the outset of the project.

Inspire People:
- Solicit support and active involvement in the plan to improve the safety culture, obtain buy-in and build accountability for the outcomes.
- Identify a leadership group and front-line team members, using multi-disciplinary composition for the culture of safety initiative. This is critical to success.
- Understand where resistance may come from and address it.
- Develop an action plan or strategy to work through any resistance.

Launch the Initiative:
- Align operations and ensure the organization has the capacity to change, not just the ability to change.
- Launch the initiative with clearly identified champions and a clearly communicated vision by leadership.

Support the Change:
- The intention to support change is critical; therefore all leaders within the organization must be a visible part of the safety culture improvement.
- Recognition and reward programs, such as Close Call (or Good Catch!) reporting reward programs, facilitate and support a positive safety culture.
- Frequent communication regarding a positive culture of safety will enhance it.
- Report measurable improvements so that all members of the organization can see the realization of their contributions "fruits of their labor".
- Celebrate success as it relates to improved safety culture (e.g., National Patient Safety Awareness Week).
- Recognize employees who have practiced patient safety and/or promoted a safety culture in their workplace.

Practice Plan

The following five components of a safety culture are necessary to achieve high reliability:[7]

1. Trust
   - Create and maintain an environment where staff feels 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, or ARCC (Ask a question, make a Request, voice a Concern, seek help from the Chain of command) 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.
   - Senior leadership and physician, pharmacist and nurse leaders establish a trusting environment among all staff by modeling appropriate behaviors.
   - Leadership should champion efforts to eradicate intimidating behaviors, and demonstrate those practices as appropriate.
   - Build trust and staff engagement in safety by offering ongoing safety education for workers beyond the workplace. Consistent sharing of safety lessons for workers at home and for their families supports the personalization of safe behaviors as a foundation to safer choices.
2. Accountability
   - Managers at all levels must give high priority to establishing a positive safety culture.

- 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.[9]

3. Identify Unsafe Conditions
- Staff recognize and report unsafe conditions and practices before these can harm patients.
- Encourage reporting of "near miss" events.
- Belief that all employee contributions and concerns about patient safety should be encouraged, valued, respected.
- Encourage a culture of reporting by providing feedback to employees and other health care providers who have reported or disclosed errors
- Ensure early resolution of unsafe conditions.
- Perform patient safety rounds by an interprofessional team to identify potentially unsafe conditions.
- Consider external independent safety observation reviews to avoid the normalization of risk and hazards.
- 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.
- As the safety culture matures, system weaknesses are identified and improved in a proactive manner.
- 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 more robust and standardized processes for root cause analysis, to identify root causes of system failure.
- Commit to full disclosure to patients/families following unanticipated outcomes of care or harm.
- Support employees involved in adverse events by facilitating access to Employee Assistance programs or other programs that address the "second victim" effects of adverse events.

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[9] Duthie, E. A. (2015). Accountability: Challenges to getting it right. Journal of Patient Safety.

- Reduce variation in patient care delivery systems and processes through analysis and process improvement activities.

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.
- Implementation and education for "Just culture" as well as non-retaliation policies.
- Organization policy for disclosure of unanticipated medical outcomes.
- 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).
- Use Root Cause Analysis or other analytical techniques to thoroughly analyze and identify failures in the health care delivery system and develop performance improvements to correct identified systems issues. Action plans should include accountable leaders, timeframes for completion and plan should be monitored at intervals i.e. 3, 6 and 12 months to assure the redesigned systems are controlled.
- 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.

Technology Plan

The recommendations of specific technologies or products herein are those of the Patient Safety Movement Foundation, and do not necessarily represent the opinions of the Joint Commission Center for Transforming Healthcare or its affiliates. The Joint Commission Center for Transforming Healthcare was not consulted on, nor did it participate in the decision or choice of any specific product or technology, and as a matter of policy the Joint Commission Center for Transforming Healthcare does not endorse any specific technologies, equipment, or other products.

Various technology initiatives can support the improvement of a culture of safety and drive better patient outcomes. However, the most commonly cited initiative for creating a culture of safety is a voluntary reporting system.

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.[10] 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/10000 Adjusted Patient Days

Metric Recommendations:

Direct Impact:

All Patients

Lives Spared Harm:

Lives = (SSE Rate $_{baseline}$ - SSE Rate $_{measurement}$) X Adjusted Patient Days $_{baseline}$

Notes:

Adjusted patient days uses inpatient and outpatient revenue and total patient days to calculate a "patient day" for inpatient and outpatient settings that accounts for outpatient workload.

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.[11]

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[10] Throop, C., & Stockmeier, C. (2009). SECSM & SSERSM patient safety measurement system for healthcare. Retrieved from http://hpiresults.com/docs/PatientSafetyMeasurementSystem.pdf

[11] Agency for Healthcare Research and Quality. (2015). Efforts to improve patient safety result in 1.3 million fewer patient harms. Retrieved from http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html

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Version	Primary Author(s)	Description of Version	Date Completed
Version 1		Initial Release	January 2014
Version 2	Lenore Alexander, Paul Alper, Steven Barker, Jim Bialick, Dan Brothman, Karen Curtiss, Leila Entezam, Jackie Gonzalez, Thomas Kallstrom, Ariana Longley, Charles Murphy, Nancy Myers, Anna Noonan, Lori Notowitz, Patricia Roth, Patty Skolnik, Whitney Taylor, Laura Batz Townsend, Michelle Walton, Thomas Zeltner	Workgroup Review	January 2016
Version 3	Michael Ramsay, David Mayer, Ariana Longley, Joe Kiani	Executive Review	April 2016
Version 4	Lenore Alexander, Howard Bergendahl, Ken Rothfield, Steve Barker, Ariana Longley, Michael Ramsay, Joe Kiani	Workgroup and Executive Review	January 2017