

Actionable Patient Safety Solutions (APSS) #1: **Culture of safety**

How to use this guide

This guide gives actions and resources for creating and sustaining a culture of safety throughout your healthcare organization. In it, you'll find:

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APSS #1: Culture of safety

Executive summary checklist

Achieving and sustaining a culture of safety will require transformational change throughout your healthcare organization. All leaders of your organization, especially the executive leaders and board of directors, must own and lead the changes needed.

The 2 primary leadership activities are to encourage accountability and ensure transparency throughout the organization.

Use this checklist to help you prioritize your actions and measure your organization's progress in each area.

Encourage accountability

- Implement a leadership plan that ensures healthcare governance and senior leadership are committed to, and actively involved in, supporting safety and quality activities
- Build trust:
 - Reject intimidating behavior that suppresses reporting
 - Address concerns in a timely manner
 - Communicate with the staff about improvements and lessons learned
- Set a goal of zero incidents of preventable harm, but make it clear leadership understands that some mistakes are inevitable
 - Tie one-third of hospital executive bonuses each year to the goal of zero. If they do not achieve zero, they do not get that portion of the bonus.
- Ensure leadership and staff can recognize and separate events caused by failures of the system or embedded processes versus events caused by individual malfeasance

Ensure transparency

Create a culture of respect among all parties of the care team, including patients and their families. To do this, embrace a model that:

- Emphasizes teamwork, accountability, and shared purpose
- Ensures an open and transparent culture that encourages staff and patients to:
 - Speak up when they perceive a problem with patient care and to self-report when needed
 - Question in an uninhibited way, even of those with more authority
- Scrutinize the open flow of information
- Create and sustain an environment where providers, patients, and families are actively engaged in open communication, accountability, and support

Create the infrastructure needed to make changes

- Clearly define requirements to maintain trust, accountability, identification of unsafe conditions, strengthening of systems, and continuous assessment and improvement of the safety culture
- Create an infrastructure that provides training, staffing, budget, an electronic reporting system, oversight committees, and regular updates to board level committees. This infrastructure should include a Patient and Family Advisory Committee (PFAC).

- Use a Change Management tool to implement process improvements and support safety behaviors in daily practice. It should ensure acceptance, accountability, and sustainability of the changes.
- Track and record data:
 - Use survey tools such as the free AHRQ Survey on Patient Safety Culture and Safety Attitudes Questionnaire (SAQ) Survey to identify areas for improvement and to track your progress
 - Implement an electronic incident reporting system that allows for anonymous reporting, tracking, trending, and response to aggregate safety data
 - Create a reliable means to capture and analyze good catches and near-misses
- When there is an unexpected outcome, including if a preventable medical error causes patient harm:
 - Address it with open disclosure among the healthcare team, patient, and family
 - Resolve the outcome promptly
- Use the CANDOR (Communication and Optimal Resolution) approach
- Implement thoughtful and memorable internal branding, such as through posters and staff emails, to keep safety expectations and behaviors top-of-mind throughout your organization
- Celebrate successes and the progress towards zero preventable harm
- Use patient stories - in written, video, and in-person formats - to identify gaps and inspire change in your staff

What we know about creating a culture of safety

The problems with patient safety and why they matter

Despite widespread efforts among healthcare organizations to improve patient safety and healthcare quality, preventable patient deaths still happen. Such events cause unnecessary human suffering and waste billions of dollars each year.

Studies show:

- More than 200,000 preventable patient deaths may happen each year in U.S. hospitals alone (Makary & Daniels, 2016; Shojania, & Dixon-Woods, 2017)
- Up to one-third of patients are unintentionally harmed during a hospital stay (James, 2013; Classen et al., 2011)
- Preventable medical harm ranks as the 3rd leading cause of death in the U.S. (Makary & Daniel, 2016)

A combination of continued preventable safety events, growing public vigilance, patient and provider/staff dissatisfaction, and payment systems that penalize poor outcomes all serve 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.

A strong safety culture is associated with reduced adverse events, lower mortality rates, and lower costs.

A closer look at a culture of safety

Organizations that have effectively reduced serious hazards have emphasized “safety culture” as a key factor in promoting performance excellence and reducing patient harm. “Safety culture” is simply defined as the result of 3 things:

- Behaviors that create safe outcomes and are used even when people in authority are not present
- The deeply held convictions of “how things are done around here” that drive the use of safety behaviors
- The workplace experiences, created by leadership, that drive those convictions

In addition, organizations that reflect a culture of safety usually use active Patient and Family engagement and Advisory Committees. (Toffolutti & Stuckler, 2019).

Despite widespread attention to the importance of safety culture, 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). Without an effective safety culture in place, it is nearly impossible for a healthcare organization to fix the safety issues that lead to patient harm.

AHRQ PSNET states that the following are key factors to a culture of safety (Lowthian et al., AHRQ PSNET)

- 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 or near misses without fear of reprimand or punishment

- Encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems
- Organizational commitment of resources to address patient safety concerns

Respect is the essential foundation of a safety culture

Because a Safety Culture is critical to eliminating patient harm, the Patient Safety Movement Foundation's Actionable Patient Safety Solutions (APSS) aim is to create and sustain a culture of safety. An effective and sustained safety culture is driven - fundamentally and foundationally - by a culture of respect. A safety culture will not exist without mutual respect among doctors, nurses, allied healthcare workers, patients, and families.

Respect is essential for effective communication, collaboration, teamwork, and decision-making. These are the safety behaviors that drive safety culture and are critical components of every actionable patient safety solution created by the PSMF.

Hospitals may be the last bastion of unchallenged hierarchical authority. Without respect, the steep authority gradient in healthcare can undermine safe, high quality care delivery.

Effective healthcare is provided by a care team that includes healthcare professionals, the patient, and the family. Team members are accountable to each other for the safe delivery of evidence-based care. Without respect, that level of collegial accountability is impossible.

Respect in healthcare settings 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 attributes of a safety culture

A strong safety culture encourages the care team to identify and reduce risk, as well as to prevent harm. In a poorly defined and implemented culture of safety, staff may conceal errors and fail to learn from them. According to the Institutes 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).

While hierarchies exist in many industries, some high-risk professional industries - such as aviation and nuclear energy - have successfully embraced a model of respect-based teamwork, accountability, and shared purpose to become High Reliability Organizations (HRO's). To reduce risk, they actively include all parties that are responsible for delivering the product/service, and they develop practices and procedures to ensure safe operations.

A culture of safety that fully supports high reliability has 3 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.

The actions of leadership create a positive workplace experience 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
- 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 3 of these vcomponents (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).

In healthcare organizations, there must be transparency:

- Between clinicians and patients - such as disclosure after medical errors
- Among clinicians themselves - such as peer review, the sharing of key safety metrics, and other mechanisms to share information
- Among healthcare organizations - such as regional or national collaboratives
- Of clinicians and organizations with the public - such as public reporting of quality and safety data

Leadership plan

To create a safety culture in your healthcare organization, leaders must take these key actions.

- Governance and senior administrative leadership must commit to learning about performance gaps in your organization. Senior leaders cannot merely be “on board” with patient safety—they must own it.
- Leaders must ensure that the data needed to drive improvement is readily accessible and easy to manage.
- Your board of directors must focus on safety and quality, not just on finances and strategy. Research demonstrates that patient outcomes suffer when boards do not make safety a top priority (Jha & Epstein, 2010).
- Governance, senior administrative leadership, and clinical/safety leadership must close their own performance gap by implementing a proactive, comprehensive safety culture action plan.
 - o Consider strategies such as creating a clinical leadership dyad (with the CMO and CNO) to ensure a joint and consistent approach to safety improvement.
- Healthcare leadership (clinical/safety) must show their commitment by taking an active role, such as to:
 - o Champion process improvement
 - o Give their time, attention, and focus
 - o Remove barriers

- o Provide necessary resources
- o Ensure frontline leaders have a manageable workload that allows them to drive change
- Healthcare leadership must support your organization’s action plan, such as to:
 - o Shape a vision of the future
 - o Provide clearly defined goals
 - o Support staff as they work through improvement initiatives to measure results
 - o Communicate progress towards your goals
- There are many types of leaders within a healthcare organization, and 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, shared accountability and performance must be valued and reflected in compensation plans, job descriptions, and annual performance reviews so that leaders have direct, personal accountability for results
- Use patient stories – in written and video formats – to identify gaps and inspire change in your staff

Change management is a critical element that you must include to sustain any improvements. A change management tool helps prepare and support individuals and teams so they can make organizational changes. For example, start patient safety rounds by an interprofessional group (leadership, physician, pharmacist, nurse, etc.) to help 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 of a change initiative greatly increases the chance of success and sustainability (Ramanujam et al, 2005).

Action plan

These 5 components of a safety culture are necessary to achieve high reliability (Chassin & Loeb, 2013):

1 - Create Trust

- Senior leaders, as well as physician, pharmacist and nurse leaders, can establish a trusting environment among all staff by modeling appropriate behaviors and championing efforts to stop intimidating behaviors
- Implement Patient and Family Advisory committees that have an active presence with the Governing Body and relevant care committees
- Create and maintain an environment where staff feels safe reporting issues and near misses, thus preventing harm from ever reaching a patient. To establish psychological safety for staff:
 - o Recognize that authority gradients and power hierarchies exist in all organizations and may inhibit open communication
 - o Use communication tools, such as TeamSTEPPS, to build an infrastructure that supports near miss reporting and accountability

- o Implement a “non-retaliation” policy for all staff reporting safety concerns
- o Set up an electronic event reporting software that provides options for anonymous reporting and allows anonymous reporting of unsafe conditions without fear of reprisal. Anonymous event reporting will show that leadership is interested in safety issues, not the people reporting them.

2 - Ensure Accountability

- Adopt uniform, equitable, and transparent disciplinary procedures throughout the organization. Ensure staff recognize and act on their shared responsibility for maintaining a culture of safety.
- Implement “Just Culture” policies for peer review and human resources (Duthie, 2015):
 - o This requires a move away from a culture that holds staff to a standard of perfection from the past. At the same time, it allows a “no harm, no foul” attitude when patient outcomes are not affected.
 - o Intentional use of Just Culture requires that actions are separated from decisions. Staff should not be punished for human error, but should always be held accountable for their decisions, regardless of the outcome.
 - o The decisions of all staff should be evaluated by the same standards, regardless of rank

3 - Identify Unsafe Conditions

- Engage and equip front-line colleagues with the tools, structure and support to identify and address unit-based safety concerns through implementation of programs, such as the Comprehensive Unit-based Safety Program (CUSP), that educate staff on the science of safety, how to learn from defects, and how to perform safety assessments (Agency for Healthcare Research and Quality, 2018)
- Encourage staff to “speak up for safety” and recognize and report unsafe conditions and practices before these can harm patients
- Encourage reporting of “near-miss” events
- To encourage a culture of reporting, give feedback to employees and other health care providers who have reported or disclosed errors
- Have an interprofessional team perform safety rounds to identify potentially unsafe conditions
- Encourage integration of retrospective and prospective simulation (when available) to identify latent safety threats (Macrae, 2018; Paige, Fairbanks, & Gaba, 2018)
- Take the next step to address unexpected medical outcomes and preventable harm events
 - o 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 healing and practical and financial support to patients and families harmed by medical errors.
 - o Such programs align with an organization’s business objectives and help preserve its reputation. AHRQ’s CANDOR (Communication and Optimal Resolution) program is a free resource that can help you create a disciplined approach to being transparent after unexpected medical outcomes.
 - o Utilize multidisciplinary debriefing models to conduct post-event analysis and encourage immediate informal debriefs as well as formally facilitated debriefs (Zikhani, 2016)

4 - Strengthen Systems

- Implement a safe and effective reporting system for employees to report safety risks, incidents, and near-miss events. It should be accessible to all, user-friendly, and should not punish those who report.
- Openly share communication / reporting structure for sharing concerns to leadership
- Collect and review data about common causes found when investigating harm events and near-miss events. Use them to identify which systems are most in need of process improvement.
- Build an ongoing, systematic, and mandatory patient safety education program for staff
- Where possible, use system and human factor engineering principles to implement safety strategies such as automation, checklists, and protocols
- Encourage development of a streamlined process for bringing forward and disseminating new evidence-based practice guidelines within an organization.

5 - Assess and Continuously Improve the Safety Culture

- Recognize that employees and providers do not purposefully commit errors and that most errors are failures of complex systems and processes
- Maintain a non-punitive, “blame-free but accountable” philosophy within your organization’s stated standard. Make it clear that both patient and worker events and incidents are preventable.
- Initiate a “Good Catch” program to increase captured events
- Develop comprehensive internal communications plans around safety goals:
 - Thoughtfully, consistently, and openly communicate information about the current state as well as safety performance goals, expectations, and outcomes
 - Use facts and emotions to build staff understanding and commitment
- Build accountability into the job descriptions at all levels of the organization, and evaluate all employees on contributions they make to improve quality and patient safety
- Require staff honesty and cooperation in reporting and helping to fix an adverse event or near-miss. After an event or near-miss:
 - Have staff take part in finding the root cause and be assigned specific performance improvements
 - Take actions to resolve unsafe conditions, then share your actions with staff
- Regularly measure the “culture of safety” using a reliable, validated tool, then:
 - Implement robust, standardized processes for analyzing the root causes of adverse events
 - Share the results openly throughout the organization, including with the board
- Use analysis and process improvement activities to:
 - Reduce variation in patient care delivery systems and processes
 - Undertake specific, measurable actions to improve areas of shortcoming
- To achieve desired results, maintain a results-oriented focus throughout the planning, implementation, evaluation, and sustainment phases

Support the infrastructure needed to create and sustain a safety culture

To create an effective, sustained safety culture, your organization will need:

- A staffing budget that ensures an adequate number of full-time patient safety and quality improvement professionals
- An interprofessional, multidisciplinary comprehensive patient safety program plan, appropriately budgeted and approved through leadership and board channels, that is thoroughly implemented and monitored for success. To ensure accountability, the plan will require regular updates to quality and board-level committees.
- An electronic adverse event reporting software platform and response system that:
 - Provides an anonymous reporting capability
 - Allows leadership to track, trend, and respond to collected safety data
 - Enables the transparent sharing of data through appropriate quality committees
- An internal working group that meets weekly to communicate, review, and resolve issues of concern that crosses departments, such as a Safety Adjudication Committee (SAC). Working group members should include leaders from quality, nursing, risk management, patient safety, patient advocacy, and regulatory areas, a member of the Patient and Family Advisory Committee (PFAC), the chief medical officer, and others as appropriate.
- A multidisciplinary Patient Safety Committee to oversee patient safety activities throughout the organization. It should be accountable to the board and include representatives of all relevant stakeholders, including the PFAC.
- A “Good Catch” program to recognize and reward reporting of near-miss events, stop-the-line behaviors that prevent events, and/or other significant systems issues
- A safety rounding program that collects data from leadership rounding, discerns trends, creates action items, and has a methodology for following up on action items. The rounding program must include executive leadership in the rounding schedule.
- An ongoing, systematic, and mandatory patient safety education program for staff that includes a training plan, certified instructors and coaches, data collection and analysis of its effectiveness, and data-driven training. The multi-channel curriculum, such as the Actionable Patient Safety Solutions (APSS) #17: Patient Safety Curriculum as released by the Patient Safety Movement Foundation, should include:
 - National Patient Safety Awareness Week and World Patient Safety Day
 - Newsletters, emails, and videos
 - Case studies with consideration of utilizing interprofessional examples appropriate for varying skill levels
 - Meetings and huddles
 - Interprofessional, multidisciplinary simulations (where available)
 - Participation in a patient safety organization (PSO) to enhance sharing and learning from safety events
 - Integration of just-in-time training performed by safety coaches or champions
 - Educational videos:
 - I will make a difference: <http://patient.sm/NK2nMB>
 - Safety across the board: <http://patient.sm/aW4Wbu>

Measuring outcomes

Topic:

"Safety is not only the absence of events, it is the presence of resilient processes. In multiple sections, this APSS emphasizes the need for trust, communications and the use of a reporting system for organizational learning. We mention the importance of reporting low threshold "good catches" and "safety rounding data" and also the need for feedback on data collected. To be more proactive and identify precursor conditions and behaviors, other metrics should be considered such as:

- Employee Engagement in reporting by group (e.g. % of staff reporting incidents/good catches each month)
- Low Threshold reporting (e.g. ratio of low severity reports versus high severity)
- Feedback provided to originator (e.g. % of reports discussed in individual feedback or group trend reports)
- Improvements made (e.g. time elapsed since last reportable event and survey scores versus last culture survey)
- Safety Culture training completed for all staff (e.g. % of new hires completing core training, case study reviews etc.)"

If your organization uses 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). An 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 per 10,000 adjusted patient days*

Metric Recommendations:

Direct impact: All patients

Elimination of patient harm: As measured by elimination of serious safety events, sentinel eliminate spaceevents, state reportable events, or hospital acquired conditions (HACs)

Lives spared harm:

Lives spared harm =

(SSE rate_baseline - SSE rate_measurement) x adjusted patient days_measurement

Lives saved:

Lives saved = (SSE mortality rate_baseline - SSE mortality rate_measurement) × adjusted patient days_measurement

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

Notes:

To calculate an “adjusted patient day” accounting for inpatient, outpatient and other miscellaneous workload, the following are weighted: total patient days by inpatient, outpatient, and miscellaneous revenue. The calculation for adjusted patient days is:

$$\frac{\text{Inpatient revenue} + \text{outpatient revenue} + ((\text{miscellaneous revenue}) / (\text{inpatient revenue}))}{x \text{ total patient days}}$$

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.

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.

Workgroup

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