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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 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).

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.
  - 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:
  - Champion process improvement
  - Give their time, attention, and focus
  - Remove barriers
• Provide necessary resources
• 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:
  • Shape a vision of the future
  • Provide clearly defined goals
  • Support staff as they work through improvement initiatives to measure results
  • 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:
  • Recognize that authority gradients and power hierarchies exist in all organizations and may inhibit open communication
  • Use communication tools, such as TeamSTEPPS, to build an infrastructure that supports near miss reporting and accountability
Implement a “non-retaliation” policy for all staff reporting safety concerns
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):
  - 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.
  - 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.
  - 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 condition
- 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
  - 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.
  - 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.
  - 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) x 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:

\[ \text{Inpatient revenue} + \text{outpatient revenue} + \left( \frac{\text{miscellaneous revenue}}{\text{inpatient revenue}} \right) \times \text{total patient days} \]

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.

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

Co-Chairs:
Kenneth Rothfield Medical City Health
Jack Gentry MedStar Health; Patient Advocate

Members:
This list represents all contributors to this document since inception of the Actionable Patient

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<table>
<thead>
<tr>
<th>Name</th>
<th>Organization/Role</th>
</tr>
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<tbody>
<tr>
<td>Lenore Alexander</td>
<td>Leah’s Legacy</td>
</tr>
<tr>
<td>Paul Alper</td>
<td>Next Level Strategies, LLC</td>
</tr>
<tr>
<td>Daniel Baily</td>
<td>Beterra</td>
</tr>
<tr>
<td>Steven J. Barker</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Laura Batz Townsend</td>
<td>Louise H. Batz Patient Safety Foundation</td>
</tr>
<tr>
<td>Michel Bennett</td>
<td>Patient Safety Movement Foundation (formerly)</td>
</tr>
<tr>
<td>Stacy Bennett</td>
<td>HCA Healthcare</td>
</tr>
<tr>
<td>Howard Bergendahl</td>
<td>Bergendahl Institute</td>
</tr>
<tr>
<td>Caroline Bilan</td>
<td>The Compass Health Consultancy</td>
</tr>
<tr>
<td>Laurie Blunk</td>
<td>Advocate</td>
</tr>
<tr>
<td>Mingi Chan-Liao</td>
<td>Taiwan Patient Safety Culture Club</td>
</tr>
<tr>
<td>Jackie Gonzalez</td>
<td>J29 Associates</td>
</tr>
<tr>
<td>Victor B. Grazette</td>
<td>Virginia Hospital Center</td>
</tr>
<tr>
<td>Deborah Grubbe</td>
<td>Dupont</td>
</tr>
<tr>
<td>Julia Hallisy</td>
<td>The Empowered Patient Coalition</td>
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<td>Stephen Harden</td>
<td>LifeWings</td>
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<td>Martin Hatlie</td>
<td>MedStar Health</td>
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<tr>
<td>Diane Hopkins</td>
<td>DuPont Sustainable Solutions</td>
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<td>Stephen Hoyt</td>
<td>PFCC Partners</td>
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<tr>
<td>Thomas Kallstrom</td>
<td>American Association for Respiratory Care</td>
</tr>
<tr>
<td>Mary Kidd</td>
<td>AdventHealth Hendersonville</td>
</tr>
<tr>
<td>Edwin Loftin</td>
<td>Parrish Medical Center</td>
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<tr>
<td>Ariana Longley</td>
<td>Patient Safety Movement Foundation</td>
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<tr>
<td>Jacob Lopez</td>
<td>Patient Safety Movement Foundation (formerly)</td>
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<tr>
<td>Olivia Lounsbury</td>
<td>Patient Safety Movement Foundation</td>
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<td>Tim McDonald</td>
<td>MedStar Health</td>
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<tr>
<td>Lisa Morrise</td>
<td>Consumers Advancing Patient Safety</td>
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<tr>
<td>Charles Murphy</td>
<td>Inova Health System</td>
</tr>
<tr>
<td>Anna Noonan</td>
<td>University of Vermont Medical Center</td>
</tr>
<tr>
<td>Lori Notowitz</td>
<td>University of Vermont Medical Center</td>
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<tr>
<td>Donna Prosser</td>
<td>Prosser Solutions</td>
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<tr>
<td>Kathleen Puri</td>
<td>Fitsi Health, LLC</td>
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<tr>
<td>Patricia Roth</td>
<td>University of California San Francisco (UCSF)</td>
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<td>Rochelle Sandell</td>
<td>Patient Advocate</td>
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</tr>
<tr>
<td>Hannah Schroeder</td>
<td>Hospital Sisters Health System Sacred Heart Hospital</td>
</tr>
<tr>
<td>Bob Silver</td>
<td>Healthsystem University of Utah</td>
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<tr>
<td>Erin Stieber</td>
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How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for hand hygiene. In it, you’ll find:

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APSS #2A: Hand hygiene

Executive summary checklist
The lack of consistent, appropriate hand hygiene in all patient care areas is a “medical error” that results in avoidable infections and deaths. As of January 1, 2018, The Joint Commission began citing individual failures to perform hand hygiene in direct patient care as a deficiency, prompting a Requirement for Improvement (RFI) - meaning that a medical provider’s accreditation is at risk when staff members are seen as noncompliant.

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

Ensure best patient care
☐ Ensure that alcohol-based hand rubs and / or soap and water are available as close to the point of patient care as possible

Create an action plan
☐ Show accountability for performance improvement in your organization and unit leadership levels as part of an Organizational Hand Hygiene Guideline
☐ Establish a multi-disciplinary hand hygiene team responsible for implementation of the Hand Hygiene Guideline, including:
  ☐ Nurses
  ☐ Physicians
  ☐ Infection preventionists
  ☐ Administration
☐ Include mandatory training for all healthcare workers (HCWs) when they are hired and at least once a year. Train all HCWs to:
  ☐ Address indications for the WHO’s 5-moments for hand hygiene
  ☐ Follow hand rubbing and soap and water washing techniques
  ☐ Create signs for hand rubbing (sanitizing) vs. soap and water washing (World Health Organization (WHO) or Center Disease Control (CDC) Guideline)
  ☐ Speak up when fellow HCWs don’t comply
  ☐ Accept reminders to perform hand hygiene.
  ☐ Provide education for patients, family members, and visitors
  ☐ Conduct performance evaluation and give feedback
☐ Include training for patients and family members when they are admitted and encourage them to speak up when a healthcare provider fails to perform hand hygiene before contact
Use data to find areas for improvement

- Hand hygiene compliance must be measured using a validated, electronic system capable of capturing and reporting all hand hygiene events
- These systems have been shown to lead to sustainable improvement, reduced infections and costs, and a positive impact on patient safety culture when compliance rates improve significantly (Bouk et al., 2016; Kelly et al., 2016; Michael et al., 2017; Son et al., 2011)

- Direct Observation (DO) should only be used for:
  - Coaching
  - Performance feedback
  - Obstacle
  - Barrier identification

- There is currently no research to support that either direct observation nor electronic monitoring is better than the other. However, for direct observation it should be emphasized that the training of observers for direct observation is a recommended step.

Engage staff

- Provide performance feedback to unit leadership and frontline staff on a regular basis, using evidence-based behavior change feedback models (Welsh et al., 2012)

- Place reminders in the workplace using:
  - Posters
  - Brochures
  - Leaflets
  - Badges
  - Stickers

- Ensure the messages and reminders are consistent with your organization’s Hand Hygiene guideline

- Use patient stories—in written and video form—to identify gaps and inspire change in your staff
What we know about hand hygiene

Hand hygiene keeps patients safe. While hand hygiene is not the only measure to prevent Healthcare Associated Infections (HAIs), compliance with it alone can significantly enhance patient safety (Kelly et al., 2016). HAIs are preventable infections that patients may get while being treated for another condition, especially when devices such as catheters or ventilators are used. Research shows that microbes causing HAIs are most frequently spread between patients on the hands of healthcare workers. Patients may carry microbes without any obvious signs or symptoms of an infection—colonized or sub clinically-infected. This can happen because microbes have an impressive ability to survive on the hands—sometimes for hours—if hands are not cleaned. The hands of staff can become contaminated even after seemingly ‘clean’ procedures, such as taking a pulse or blood pressure reading, or touching a patient’s hand (World Health Organization, 2009).

We know that healthcare facilities that readily embrace strategies for improving hand hygiene are more open to closer scrutiny of their infection control practices. Therefore, the impact of focusing on hand hygiene can lead to an overall improvement in patient safety across an entire organization (Kelly et al., 2016).

What we know about this safety issue has been typically accomplished by Direct Observation (DO) by human observers known as “secret shoppers”. However, recent research shows that DOs should no longer measure hand hygiene because they can overstate compliance by as much as 300% giving a false sense of security and complacency that blocks the sense of urgency to improve (Srigley et al., 2014; Scheithauer et al., 2009). Further, allowing “secret shoppers” to observe the lack of hand hygiene compliance and do nothing to intervene enables a healthcare worker to provide care with potentially contaminated hands—putting patients at unnecessary risk of harm. The solution is to measure hand hygiene compliance with an evidence-based and validated electronic hand hygiene compliance system.

Center for Medicare & Medicaid Innovation (CMS/CMMI) and their Partnership for Patients are now promoting the deployment of electronic hand hygiene compliance systems to reduce infections and costs to the Hospital Improvement Innovation Networks (HIINs) via their website and a web broadcast. Find more information about HINNs here: http://patient.sm/zNdSRF

Leadership plan

To improve hand hygiene practices and maintain compliance, leaders in your organization must take these key actions:

- Be engaged and model compliant hand hygiene practices
- Foster psychological safety and promote a “just” safety culture. It must be safe for everyone to be able to speak up and “stop the line” when hand hygiene does not occur
- Use DOs for unit based feedback and real-time barrier identification
  - Develop and agree on an action plan to remove the barriers
  - Research suggests that this approach leads to sustainable improvement (Steed, 2016)
- Agree on unit-specific improvement goals and celebrate small successes (Son et al., 2011)
- Engage with your frontline staff and give frequent feedback on performance
- Make hand hygiene compliance improvement part of performance evaluation
  - Report results to senior leadership for facility-wide feedback
• Use patient stories – in written and video form – to identify gaps and inspire change in your staff
  o Curate stories based on your own organization’s culture
  o Use examples that are meaningful, such as from:
    • Patient Safety Movement Foundation
    • Partnering to Heal (Office of Disease and Health Promotion, 2018)

**Action plan**

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.

**Ensure accountability**

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 the acceptance and accountability for change. Building a strategy for acceptance and accountability of a change initiative can increase the opportunity for success and subsequent sustainability of improvements in your organization. “Facilitating Change,” the change management model The Joint Commission developed, contains four key elements to consider when working through a change initiative to address HAIs (See Appendix A).

The Joint Commission Center for Transforming Healthcare Targeted Solutions Tool (TST) provides healthcare organizations with a comprehensive approach to improve hand hygiene compliance. However, when using the tool, measurement should only be done with an evidence-based, validated electronic hand hygiene compliance system. Both electronic monitoring and DOs have been proven to drive sustainable improvement (Steed, 2016; Boyce, 2017).

**Create guidelines**

This involves a proven 4 step process:

1. Identify barriers and obstacles unique to the unit using interventional DO as described above
2. Work with your unit leadership to put in place training and an action plan to remove the barriers
3. Implement training and action plan
4. Measure improvement using:
   a. An evidence-based, validated electronic hand hygiene compliance system
   b. Give appropriate feedback to ensure successes are acknowledged and that remaining barriers and obstacles are addressed (Steed, 2016)

**Provide staff training**

1. Teach staff by modeling and staff to teach-back the concepts
2. Admission nurses teach the concepts with daily reminders by staff nurses
   a. Family and visitors will also be taught
3. Use print and audiovisual materials to strengthen teaching
4. Ensure knowledge and use of approved cleaning agents for computers and other technological equipment
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

Recent research suggests that electronic hand hygiene compliance systems are accurate and reliable (Diller et al., 2014; Pittet et al., 2013) when combined with appropriate staff feedback and multimodal action plans can lead to reduced infections and avoided costs (Kelly et al., 2016; Robinson et al., 2014).

What to look for in an electronic hand hygiene compliance system

An electronic hand hygiene compliance system must:

- Be capable of capturing and reporting all hand hygiene events
- Be able to provide room level soap vs. sanitizer monitoring in the case of C Diff.
  - Giving timely feedback to staff on soap vs. sanitizer use has been shown to reduce C Diff rates (Robinson et al. 2014)
- Include a behavior change framework for how to use the data with front line staff to drive sustainable behavior change
  - The behavior change framework must also inherently foster a “just culture” and promote “psychological safety”
- Have validated accuracy
- Be evidence-based
Measuring outcomes

There is no direct calculation for mortality related to the hand hygiene performed in hospitals. Hospitals would need to link mortality to a healthcare-associated infection rate (ex: APSS 2A-2F). The most commonly accepted metric for measuring a hospital’s compliance is offered below.

Key performance indicators

Key performance indicators you can use within the Hand Hygiene Protocol should be:

- Compliance rates at the Unit, Facility and IDN (Integrated Delivery Network) level plus individual when such technology is employed
- Daily, Weekly, Monthly, Quarterly, Yearly
- HAI rates and changes at the Unit, Facility and IDN level
- Safety Culture Assessment Annually

Based on the WHO “My five moments for hand hygiene” method (Sax et al., 2007; Sax et al., 2009), you can define moments as:

- Before patient contact
- Before aseptic task
- After body fluid exposure
- After patient contact
- After contacts with patient surroundings

Outcome measure formula

You can use the formula to calculate hand hygiene compliance during all 5 moments (Pittet, et al., 2013). You can apply a similar approach if only the Wash In/Wash Out Method is used. However, the “in room” moments provide a high risk of infection (Kelly, et al., 2015) and thus training on, and measurement of all 5 Moments is indicated. The WHO 5 Moments mirror the CDC Guideline so if your facility wants to adhere to CDC Guidelines, either the CDC or WHO 5 Moments need to be the standard of care that is taught, measured, and used for feedback.

**Numerator:** Number of hand hygiene events performed as measured by a validated electronic hand hygiene compliance system

**Denominator:** Number of hand hygiene events required (hand hygiene opportunities or HHOs) based on how the technology software calculates the denominator:

- The denominator could be based on the WHO 5 Moments, Wash In/Wash Out Method or another algorithm depending on the technology system used

Metric recommendations:

Direct impact: All patients

Deploying Use of the Electronic Hand Hygiene Compliance Data - Evidence Based Practice (Son et al., 2011)

1. Share the data with your frontline staff routinely (daily or weekly to start)
2. Empower your unit leadership to identify unit based barriers and obstacles along with action plans to eliminate them
3. Enable your units to establish their own performance improvement goals
4. Measure performance improvement against the goals and celebrate all successes
   a. Use DOs to understand lack of improvement
5. Hold your unit leadership accountable to performance improvement goals and make this part of the performance evaluation process

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup
Co-Chairs
*Paul Alper
Ebony Talley
Carole Moss

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions

Steven J. Barker
Michel Bennett
Naomi Bishop
Jonathan Coe
Alicia Cole
Peter Cox
Maria Daniela DaCosta Pires
Todd Fletcher
Kate Garrett
Helen Haskell
Brook Hossfeld
Lucas Huang
Mert Iseri
Sarah Knowles
Terry Kuzma-Gottron
Jerika Lam

Next Level Strategies, LLC
Kaiser Permanente Woodland Hills Medical Center
Nile’s Project
Patient Safety Movement Foundation; Masimo
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Global Network for Simulation In Healthcare
SwipeSense
University Hospitals Geauga Medical Center
Avardim Technologies
Chapman University School of Pharmacy
<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
</tr>
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<tbody>
<tr>
<td>Emily Leathers</td>
<td>Parrish Medical Center</td>
</tr>
<tr>
<td>Gabriela Leongtez</td>
<td>Gresmex</td>
</tr>
<tr>
<td>Christian John Lillis</td>
<td>Peggy Lillis Foundation</td>
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<tr>
<td>Lori Lioce</td>
<td>Global Network for Simulation In Healthcare</td>
</tr>
<tr>
<td>Edwin Loftin</td>
<td>Parrish Medical Center</td>
</tr>
<tr>
<td>Ariana Longley</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Jacob Lopez</td>
<td>Patient Safety MovementFoundation (formerly)</td>
</tr>
<tr>
<td>Olivia Lounsbury</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Betsy McCaughey</td>
<td>The Committee to Reduce Infection Deaths</td>
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<td>Poiesis Medical</td>
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<td>Armando Nahum</td>
<td>Safe Care Campaign</td>
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<td>Advocate</td>
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<td>Brent D. NiBarger</td>
<td>BioVigil</td>
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<tr>
<td>Anna Noonan</td>
<td>University of Vermont Medical Center</td>
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<tr>
<td>Kate O’Neill</td>
<td>iCareQuality</td>
</tr>
<tr>
<td>Donna Prosser</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Kathy Puri</td>
<td>Fitsi Health</td>
</tr>
<tr>
<td>Caroline Puri Mitchell</td>
<td>Fitsi Health</td>
</tr>
<tr>
<td>Kellie Quinn</td>
<td>Patient Advocate</td>
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<tr>
<td>Julia Rasooly</td>
<td>PuraCath Medical</td>
</tr>
<tr>
<td>Judith Reiss</td>
<td>Education Training Solutions</td>
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<tr>
<td>Yisrael Safeek</td>
<td>SafeCare Group</td>
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<tr>
<td>Rochelle Sandell</td>
<td>Patient Advocate</td>
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<tr>
<td>Sundary Sankaran</td>
<td>Kaiser Permanente</td>
</tr>
<tr>
<td>Steve Spaanbroek</td>
<td>MSL Healthcare Partners, Inc.</td>
</tr>
<tr>
<td>Philip Stahel</td>
<td>Patient Safety Movement Foundation</td>
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<tr>
<td>Jeanine Thomas</td>
<td>MRSA Survivors Network</td>
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<tr>
<td>Greg Wiita</td>
<td>Poiesis Medical</td>
</tr>
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**Metrics Integrity**

Robin Betts                                       Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.*
References


Appendix A

“Facilitating Change,” the change management model The Joint Commission developed, contains four key elements to consider when working through a change initiative to address Healthcare Associated Infections (HAIs).

Plan the Project:

- At the start of project, build a strong foundation for change by:
  - Assessing the culture for change
  - Defining the change
  - Building a strategy
  - Engaging the right people
  - Painting a vision of the future

Inspire People:

- Ask for support and active involvement in the plan to reduce:
  - HAIs
  - Get agreements
  - Build accountability for the outcomes
- Identify a leader for the HAI initiative (this is critical to the success of the project)
- Understand where resistance may come from

Launch the Initiative:

- Align operations and guarantee the organization has the capacity to change, not just the..
ability to change

- Launch the HAI initiative with a clear champion and a clearly communicated vision by leadership

Support the Change:

- All leaders within the organization must be a visible part of the HAI initiative
- Frequent communication regarding all aspects of the HAI initiative will enhance the initiative
- Celebrate success as it relates to a reduction in HAI s or a positive change in HAI organizational culture
- Identify resistance to the HAI initiative as soon as it occurs
Actionable Patient Safety Solutions (APSS) #2B: Catheter-associated urinary tract infections (CAUTI)

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for CAUTI. In it, you’ll find:

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Executive summary checklist

A urinary tract infection (UTI) is an infection involving any part of the urinary system, including urethra, bladder, ureters, and kidney. CAUTIs are a frequent cause of harm and death in patients across hospitals in the U.S. Out of all the reported UTIs that are acquired in hospitals, up to 80% are associated with a urinary catheter—a thin, flexible tube put in a patient’s body to drain the urine from their bladder (Apisarnthanarak et al., 2007).

Use this checklist to help you prioritize your actions and measure your organization’s progress in each area. Prevention of CAUTIs requires the following actions:

☐ Insert urinary catheters only for appropriate indications
☐ Ensure that only properly trained persons perform perineal care
☐ Insert catheters using an aseptic technique and sterile equipment
☐ Monitor patients who have indwelling catheters to reduce the risk of skin breakdown and irritation
☐ Remove catheters as soon as possible
☐ After aseptic insertion, maintain a closed drainage system
☐ Use technology that has shown early success to reduce infections and positively enhance outcomes of patients
☐ Complete a full root cause analysis (RCA) when CAUTIs are identified by the unit where the infection occurred using a multidisciplinary approach including nurses, doctors, and infection prevention specialists
☐ Implement—and share—all learnings from the RCA
☐ Use patient stories – in written and video form – to help teach and inspire change in your staff
What we know about CAUTI

**Catheter-associated urinary tract infections (CAUTI)**

Urinary tract infections are one of the most common healthcare-associated infections (HAI), accounting for up to 40% of infections reported in acute care hospitals (Edwards et al., 2009). Researchers think that catheter-associated urinary tract infections—or CAUTI, for short—develop:

- When a catheter is inserted or placed on a patient
- By capillary action
- When there’s a break in the closed drainage tubing
- By contamination of the collection urine bag

The source of the bacteria that cause CAUTIs may come from:

- Endogenous factors, such as from meatal, rectal, or vaginal colonization or,
- Exogenous factors, usually through contaminated hands of healthcare staff during catheter insertion or when changing the urine collecting system

**The problems with CAUTIs**

Urinary catheters are used in 15-25% of hospitalized patients (Weinstein et al., 1999) and are often placed for inappropriate indications.

There are an estimated 560,000 diagnosed UTIs in United States hospitals each year, with a projected cost of $450 million (Klevens et al., 2007). Out of all the reported UTIs that are acquired in hospitals, up to 80% are associated with a urinary catheter (Apisarnthanarak et al., 2007). Other studies have shown that urinary catheters are used in large numbers in patients where it was not indicated or for longer than clinically necessary (Saint et al., 2000).

A CAUTI increases hospital costs and is associated with increased harm and death (Laupland et al., 2005; Wald and Kramer, 2007; Cope et al., 2009). There are an estimated 13,000 deaths annually caused by CAUTIs (Klevens et al., 2007).

According to a 2008 survey of U.S. hospitals, more than 50% of hospitals did not monitor which patients were catheterized, and 75% did not monitor duration and/or discontinuation (Saint et al., 2008).

**Preventing CAUTIs**

CAUTIs are considered to be a preventable complication of hospitalization by the Centers for Medicare and Medicaid Services. As such, no additional payment is provided to hospitals for CAUTI treatment-related costs.

The Centers for Disease Control and Prevention’s Healthcare Infection Control Practices Advisory Committee (HICPAC) has created prevention strategies for healthcare institutions to adopt and implement (Gould et al., 2010):

- The core strategies are supported by highest levels of scientific evidence and demonstrated feasibility
- The supplemental strategies are supported by less robust evidence and have variable levels of feasibility
Core prevention strategies

- Insert catheters only for medically necessary indications
- Compliance with evidence-based guidelines, such as:
  - Centers for Disease Control and Prevention (CDC) Guideline for Prevention of Catheter-Associated Urinary Tract Infections (2019) recommends removal of catheter as soon as possible postoperatively, preferably within 24 hours, unless there are appropriate indications for continued use.
- Leave catheters in place only as long as needed
- Only properly trained staff can insert and maintain catheters
- Insert catheters using an aseptic technique and sterile equipment
- Maintain a closed drainage system
- Keep urine flow unobstructed
- Follow evidence-based hand hygiene guidelines and appropriate isolation precautions

Supplemental prevention strategies

- Alternatives to indwelling urinary catheterizations, such as:
  - External devices for male or female patients
  - Intermittent catheterization (i.e. straight catheterization)
- Portable ultrasound devices to reduce unnecessary catheterizations

The following practices are not recommended for CAUTI prevention—HICPAC guidelines:

- Complex urinary drainage systems
- Changing catheters or drainage bags at routine, fixed intervals
- Routine antimicrobial prophylaxis
- Cleaning of periurethral area with antiseptics while catheter is in place
- Irrigation of bladder with antimicrobials
- Instillation of antiseptic or antimicrobial solutions into drainage bags
- Routine screening for asymptomatic bacteriuria (ASB)

Leadership plan

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce CAUTIs in your organization.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

Show leadership’s commitment to reducing and preventing CAUTIs

- Leadership commitment and action are required at all levels for successful process improvement
• Hospital governance and senior administrative leadership must champion efforts in raising awareness to prevent and reduce CAUTIs

Create the infrastructure needed to make changes

• Support the design and implementation of standards and training programs on catheter insertion and manipulation
• Address barriers
• Provide resources, such as budgets and staffing
• Assign accountability throughout the organization

Make policy changes

• Implement policies in your organization that aim to:
  a. Decrease the use and duration of use of urinary catheters
     o While there have been multiple attempts to deploy antimicrobial catheters to reduce the rate of infection, there is no literature to support that this technology has made a significant impact
     o Utilize tools such as the National Healthcare Safety Network (NHSN) Standardized Utilization Ratio to track and monitor frequency, and to implement strategies to reduce the use of urinary devices. (CDC, 2016)
  b. Insert catheters only for appropriate indications

Engage staff

• Utilize patient stories - in written and video form - to identify gaps and inspire change in your staff
  o You’ll find examples of impactful stories at:
  o Patient Safety Movement Foundation http://patient.sm/9z4OAH
  o Preventing CAUTI http://patient.sm/0CK2FF

Action plan

Before you implement new preventive measures, you should conduct an evaluation to assess baseline policies and procedures regarding CAUTIs in your institution.

Track and analyze your progress

New policies and practices should be tracked once implemented to ensure adherence and to remove any barriers to effective change.

Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

Consider implementing the following systems of practice or technologies to address CAUTIs in your organization:
### Measuring outcomes

**Topic**

**Catheter-associated urinary tract infections (CAUTI)**

Rate of patients with CAUTI per 1,000 urinary catheter-days - all inpatient units

**Outcome measure formula**

**Numerator:** Catheter-associated urinary tract infections based on CDC NHSN definitions for all inpatient units (CDC, 2015)

**Denominator:** Total number of urinary catheter device-days for all patients that have an urinary catheter in all tracked inpatient locations where an indwelling urinary catheter is defined as a drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a drainage bag.

*Rate is typically displayed as CAUTI/1000 urinary catheter-days

**Metric recommendations**

**Indirect Impact:**
All patients with conditions that lead to temporary or permanent incontinence

**Direct Impact:**
All patients that require a urinary catheter

**Lives Spared Harm:**

\[
Lives = (\text{CAUTI Rate}_{\text{baseline}} - \text{CAUTI Rate}_{\text{measurement}}) \times \text{(Urinary Catheter) days}_{\text{baseline}}
\]

**Lives Saved:**

\[
Lives\ Saved = Lives\ Spared\ Harm \times \text{Mortality Rate}
\]

**Notes**

To meet the NHSN definitions, infections must be validated using the hospital-acquired infection (HAI) standards. Infection rates can be stratified by unit type (CDC, 2020). Infections that were present on admission (POA) are not considered HAI and not counted.

**Data collection:**
CAUTI and urinary catheter-days can be collected through surveillance (at least once...
CAUTI can be displayed as a Standardized Infection Ratios (SIR) using the following formula:

\[ SIR = \frac{\text{Observed CAUTI}}{\text{Expected CAUTI}} \]

Expected infections are calculated by NHSN and available by location (unit type) from the baseline period.

**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 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 (AHRQ, 2013). Catheter Associated Urinary Tract Infections was included in this work with published metric specifications. This is the most current and comprehensive study to date. Based on these data the estimated additional inpatient mortality for Catheter Associated Urinary Tract Infection Events is 0.023 (23 per 1000 events).

**Conflicts of interest disclosure**

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**Workgroup**

**Co-Chairs**

**Ebony Talley**
Kaiser Permanente Woodland Hills Medical Center

**Carole Moss**
Nile’s Project

**Members**

This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions

**Steven J. Barker**
Patient Safety Movement Foundation; Masimo

**Michel Bennett**
Patient Safety Movement Foundation (formerly)
Naomi Bishop
Human-Centered Healthcare Design
Jonathan Coe
Prescient Surgical
Alicia Cole
Alliance for Safety Awareness for Patients (ASAP)
Peter Cox
SickKids
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Geneva University Hospitals
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Resources Global Professionals
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Lucas Huang
Global Network for Simulation In Healthcare
Mert Iseri
SwipeSense
Sarah Knowles
University Hospitals Geauga Medical Center
Terry Kuzma-Gottron
Avadim Technologies
Jerika Lam
Chapman University School of Pharmacy
Emily Leathers
Parrish Medical Center
Gabriela Leongtez
Gresmex
Christian John Lillis
Peggy Lillis Foundation
Lori Lioce
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Kathy Puri
Fitsi Health
Caroline Puri Mitchell
Fitsi Health
Kellie Quinn
Patient Advocate
Julia Rasooly
PuraCath Medical
Judith Reiss
Education Training Solutions
Yisrael Safeek
SafeCare Group
Sundary Sankaran
Kaiser Permanente
Metrics Integrity

Robin Betts  
Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

References


How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for SSI. In it, you’ll find:

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Executive summary checklist

A surgical site infection—or SSI, for short—is an infection that happens after surgery in the part of the body where the surgery took place. Creating evidence-based protocols and engaging staff responsible for preventing and reducing the occurrence of SSIs can greatly impact the frequency of SSIs in your organization.

Post-operative infections at the site of surgery remain a major source of perioperative morbidity and mortality. The perioperative period is the time period of a patient's surgical procedure.

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

Create an action plan to engage staff and use data to find areas for improvement

- Implement evaluation practices and metrics to measure patient outcomes
- Review results of all evaluation activities frequently, including at caregiver education sessions, such as at “grand rounds”
- Educate patients and families on SSI prevention
- Use patient stories - written & in video - to help teach and inspire change in your staff

Implement pre-operative measures

- Administer antimicrobial antibiotic prophylaxis in accordance with evidence-based standards and guidelines (Bratzler et al., 2013)
  - Administer within 1 hour prior to incision (2 hours for vancomycin and fluoroquinolones)
- Administer the appropriate parenteral prophylactic antimicrobial agents before skin incision in all cesarean section procedures (Berríos-Torres et al., 2017)
- Choose the appropriate agents on basis of:
  - Surgical Procedure
  - Most common SSI pathogens for the planned procedure
  - Known allergies or drug reactions of each specific patient
  - Published recommendations
- Don’t remove hair at the operative site unless it will interfere with the surgical procedure
- Use appropriate antiseptic agent and technique for skin preparation, preferably an alcohol containing preparation (Berríos-Torres et al., 2017)
- If appropriate, mechanically prepare patients for colorectal surgery by enema or cathartic agents (Ban et al., 2017)
- Tell patients to stop smoking 4 to 6 weeks before surgery (Ban et al., 2017)
- Implement perioperative glycemic control and use of blood glucose targets levels less than 200 mg/dL in patients with and without diabetes (Berríos-Torres et al., 2017)
- Tell patients to shower or bathe (full body) with soap (antimicrobial or nonantimicrobial) or an antiseptic agent on at least the night before their procedure (Berríos-Torres et al., 2017)
Implement intra-operative measures

- Maintain intra-operative and post-operative normothermia (Ban et al., 2017)
- Re-dose prophylactic antibiotics based on agent half-life or for every 1,500 mL of blood loss (Ban et al., 2017)
- Keep operating room doors closed during surgery, except as needed for passage of equipment, staff, and the patient
- Keep the interior of the operating room at “positive pressure”
- Use an impermeable plastic wound protector after open abdominal surgery, especially colorectal and biliary procedures (Ban et al., 2017)
- Ask staff to change their gloves before closure in colorectal cases (Ban et al., 2017)
- Perform topical irrigation of the incision site, especially in colorectal surgery (Mueller et al., 2015)
- In clean and clean-contaminated procedures, don’t administer additional prophylactic antimicrobial agent doses after the surgical incision is closed in the operating room, even in the presence of a drain (Berríos-Torres et al., 2017)
- For patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation, administer increased FIO2 during surgery (Berríos-Torres et al., 2017)
- Perform intra-operative skin preparation with an alcohol-based antiseptic agent unless contraindicated (Berríos-Torres et al., 2017)
- Do not withhold transfusion of necessary blood products from surgical patients as a means to prevent SSI (Berríos-Torres et al., 2017)
- For prosthetic joint arthroplasty patients in clean and clean-contaminated procedures, do not administer additional antimicrobial prophylaxis doses after the surgical incision is closed in the operating room, even in the presence of a drain (Berríos-Torres et al., 2017)

Implement post-operative measures:

- Protect primary closure incisions with sterile dressing for 24-48 hours post-op
- Stop using antibiotics within 24 hours after the surgery end time–48 hours for cardiac patients–unless signs of infection are present
- Do not apply antimicrobial agents (i.e., ointments, solutions, or powders) to the surgical incision to prevent an SSI (Berríos-Torres et al., 2017)
- For patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation, administer increased FIO2 after extubating in the immediate post-operative period (Berríos-Torres et al., 2017)
What we know about SSIs

An SSI is an infection that happens after surgery in the part of the body where the surgery took place. Most patients who have surgery don’t develop an infection.

Symptoms of an SSI include:

- Redness and pain around the surgical site area
- Drainage of cloudy fluid from the surgical wound
- Fever

Causes of SSIs are sometimes caused by either:

- **Endogenous factors**, such as from the patient’s flora or seeding from a distant site of infection, or,
- **Exogenous factors**, such as from surgical staff, physical environment and ventilation, tools, equipment, and materials in the operating room

The problems with surgical site infections (SSIs)

There are about 300,000 SSIs each year—17% of all Healthcare Associated Infections (HAIs), just second to Urinary Tract Infections (UTI).

- SSIs happen in 2%-5% of patients getting inpatient surgery (CDC, 2010)
- The SSI mortality rate is 3 %, with a 2-11 times higher chance of death when compared to other types of infections
- Seventy-five percent of deaths among patients with SSI are directly attributable to the SSI
- SSI can cause long-lasting disabilities

SSIs can sometimes result in patients spending an additional 7-10 days in the hospital. Healthcare costs can rise up to $3,000-$29,000 for each SSI, depending upon the procedure and pathogen. On a national level, direct and indirect healthcare costs combined can reach up to $10 billion annually (Quicho, 2016). These estimated costs don’t account for the additional costs of:

- Rehospitalization
- Post-discharge outpatient expenses
- The costs of care for long-lasting disabilities

Detecting SSIs is also becoming increasingly challenging due to the lack of standardized methods for post-discharge and outpatient surveillance. This is in part due to an increased number of outpatient surgeries and shorter postoperative inpatient stays. The increasing trend of resistant organisms is presenting another challenge which may threaten the effectiveness of existing recommendations for antimicrobial prophylaxis.

Preventing surgical site infections

Education and awareness of risk factors among healthcare workers, physicians, and nurses followed by the implementation of standardized guidelines can minimize the occurrence of SSIs in hospitals.

Institutions can implement preventive practices, such as:

- Antimicrobial prophylaxis
- Preoperative identification and treatment of existing infections
• Proper site preparation methods
• Maintenance of normothermia in the postoperative period
• Keeping operating room doors closed during surgical procedures

**Leadership plan**

To improve patient health outcomes and prevent SSIs in hospitals, leaders in your organization must take these key actions:

**Show leadership’s commitment to preventing and reducing SSIs**

- Hospital governance and senior administrative leadership must champion efforts in raising awareness around:
  - The high incidence of SSIs
  - The importance of prevention measures

**Create the infrastructure needed to make changes**

- Support the implementation of standards on pre-, intra- and post-operative guidelines
- Address barriers
- Provide resources
- Keep accountability throughout the organization
- Implement evaluation practices to measure outcomes
- Use patient stories—in written and video form—to identify gaps and inspire change in your staff, such as:
  - Alicia Cole video—Patient Safety Movement Foundation [http://patient.sm/CzRYiQ](http://patient.sm/CzRYiQ)

**Action plan**

**Create protocols and ensure accountability in the following areas:**

- Pre-operative skin cleansing
- Pre-operative screening for patients with a higher chance of developing an SSI
- SSI prevention education for patients and their families
- Pre-operative skin antisepsis
- Proper hair removal
- The use of prophylactic antibiotics
- Maintenance of normothermia

**Pre-operative skin cleansing**

- Develop a standardized process for pre-operative skin cleansing. Use the information in Appendix A to verify that the ingredients used are appropriate.
- Educate patients on how to:
  - Apply the CHG before surgery
  - Avoid lotions or deodorants after cleansing

**Pre-operative screening for patients at risk for SSI**

- Create a protocol to conduct nasal Staphylococcus aureus (SA) screening in patients
who will have cardiac and elective orthopedic surgery

• Create a protocol to decolonize SA carriers that includes intranasal Mupirocin

**Educate patients and families on SSI prevention**

Talk to your patients and their families about:

• The negative effects of tobacco use
  o Tell them to stop using tobacco 1 month before and after surgery
• The importance of eating healthy before and after surgery
• In patients with diabetes, the importance of making sure their blood sugar levels are well controlled
• Pre-operative bathing and skin cleansing
• How to identify skin irritation, hypersensitivity, or any skin condition before surgery
• Post-operative wound handling techniques
• Hand hygiene
• The early warning signs of sepsis

**Peri-operative skin antisepsis**

• Use pre-operative skin antisepctic agents—FDA approved or cleared—and approved by your organization’s infection control staff:
  o The purpose of skin antisepctic agents is to significantly lower microorganisms on intact skin
  o Skin antisepctic agents should be used for all pre-operative skin preparation
  o Skin antisepctic agents must contain a non-irritating antimicrobial preparation, be broad spectrum, fast acting, and have a long-lasting effect
• Develop standardized practices—guided by the product insert—for the peri-operative application of skin antisepctic agents
  o These practices ensure that an appropriate therapeutic dose covers and is maintained across the entirety of the skin surface
• Educate peri-operative staff on:
  o The safe application and use of skin antisepctic agents
  o The benefits of skin antisepsics—to reduce the microbial burden on the skin before surgery

**Proper hair removal**

• Remove only hair that interferes with the surgical procedure
• Clip hair at the surgical site using:
  o A single-use hair clipper
  o A clipper with removable head that can be disinfected between patients
• Don’t use razors

**Appropriate timing, selection, and duration of prophylactic antibiotics**

• Create protocols about the appropriate use of prophylactic antibiotics to prevent and reduce infection complications

**Maintenance of normothermia**

• Use warmed forced-air blankets:
1. Preoperatively
2. During surgery
3. In PACU
   - Use warmed fluids for IVs and flushes in surgical sites and openings

**Technology plan**
Technology can help you successfully implement your plan and track outcomes. This section lists technologies that have evidence-based safety benefits. In some cases, it lists the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

<table>
<thead>
<tr>
<th>System or Practice</th>
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</table>
| The Office of the National Coordinator for Health Information Technology (ONC) Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities:  
  • Computerized Provider Order Entry (CPOE)  
  • Drug-drug interaction check  
  • Drug-allergy interaction check  
  • Clinical Decision Support tools (CDS) |  |
| Skin antiseptic activity |  |
| Supportive intra-operative wound protection |  |
| Actively clean and remove infectious contamination from the surgical incision |  |
Measuring outcomes

Topic 1

Colon Surgical Site Infection Rate (Colo SSI):
Rate of patients with a Colon Surgical Site Infection per 100 NHSN colon operative procedures

Outcome Measure Formula:
Numerator: Colon surgical site infections based on CDC NHSN definitions (CDC, 2019)
Denominator: Total number of colon operative procedures based on CDC NHSN definitions
* Rate is typically displayed as SSI/100 Operative Procedures

Metric recommendations
Indirect Impact:
All patients requiring a colon operative procedure

Direct Impact:
All patients requiring a National Healthcare Safety Network (NHSN) colon operative procedure

Lives Spared Harm:
\[
\text{Lives Spared Harm} = (\text{SSI Rate}_\text{baseline} - \text{SSI Rate}_\text{measurement}) \times \text{Operative Procedures}_\text{baseline}
\]

Lives Saved:
\[
\text{Lives Saved} = \text{Spared Harm} \times \text{Mortality Rate}
\]

Notes:
To meet the NHSN definitions, infections must be validated using the hospital acquired infection (HAI) standards.

Data Collection
All NHSN colon operative procedures require infection surveillance for 30 days following the procedure date. Operative procedures are defined by ICD and CPT codes.

Colon SSIs can be displayed as a Standardized Infection Ratios (SIR) using the following formula:

\[
\text{SIR} = \frac{\text{Observed SSI}}{\text{Expected SSI}}
\]

Expected infections are calculated by NHSN and available by location (unit type) from the baseline period.

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 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 (AHRQ, 2015). Based on these data, the estimated additional inpatient mortality for Colo SSI is 0.026 (26 per 1000 events).

**Topic 2**

**Abdominal Hysterectomy Surgical Site Infection Rate (Hyst SSI)**

Rate of patients with an abdominal hysterectomy surgical site infection per 100 NHSN abdominal hysterectomy operative procedures.

**Outcome Measure Formula:**

**Numerator:** Abdominal hysterectomy surgical site infections based on CDC NHSN definitions

**Denominator:** Total number of abdominal hysterectomy operative procedures based on CDC NHSN definitions

* Rate is typically displayed as SSI/100 Operative Procedures

**Metric recommendations**

**Direct Impact:**

All patients requiring a NHSN abdominal hysterectomy operative procedure

**Lives Spared Harm:**

$Lives = (SSI\ Rate_{baseline} - SSI\ Rate_{measurement}) \times Operative\ Procedures_{baseline}$

**Lives Saved:**

$Lives\ Saved = Spared\ Harm \times Mortality\ Rate$

**Notes:**

To meet the NHSN definitions, infections must be validated using the hospital acquired infection (HAI) standards (CDC, 2017).

**Data Collection**

All NHSN abdominal hysterectomy operative procedures require infection surveillance for 30 days following the procedure date. Operative procedures are defined by ICD and CPT codes.

Colon SSIs can be displayed as a Standardized Infection Ratios (SIR) using the following formula:

$SIR = \frac{Observed\ SSI}{Expected\ SSI}$

Expected infections are calculated by NHSN and available by location (unit type) from the baseline period.

**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 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
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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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs
Ebony Talley  
Kaiser Permanente Woodland Hills Medical Center
Carole Moss  
Nile’s Project

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions

Steven J. Barker  
Patient Safety Movement Foundation; Masimo
Michel Bennett  
Patient Safety Movement Foundation (formerly)
Naomi Bishop  
Human-Centered Healthcare Design
Jonathan Coe  
Prescient Surgical
Alicia Cole  
Alliance for Safety Awareness for Patients (ASAP)
Peter Cox  
SickKids
Maria Daniela DaCosta Pires  
Geneva University Hospitals
Todd Fletcher  
Resources Global Professionals
Kate Garrett  
Ciel Medical
Helen Haskell  
Mothers Against Medical Error
Brook Hossfeld  
Sodexo
Lucas Huang  
Global Network for Simulation In Healthcare
Mert Iseri  
SwipeSense
Sarah Knowles  
University Hospitals Geauga Medical Center
Terry Kuzma-Gottron  
Avadim Technologies
Jerika Lam  
Chapman University School of Pharmacy
Emily Leathers  
Parrish Medical Center
Gabriela Leongtez  
Gresmex
Christian John Lillis  
Peggy Lillis Foundation
<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Lori Lioce</td>
<td>Global Network for Simulation In Healthcare</td>
</tr>
<tr>
<td>Edwin Loftin</td>
<td>Parrish Medical Center</td>
</tr>
<tr>
<td>Ariana Longley</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Jacob Lopez</td>
<td>Patient Safety MovementFoundation (formerly)</td>
</tr>
<tr>
<td>Olivia Lounsbury</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Betsy McCaughey</td>
<td>The Committee to Reduce Infection Deaths</td>
</tr>
<tr>
<td>Derek Monk</td>
<td>Poiesis Medical</td>
</tr>
<tr>
<td>Armando Nahum</td>
<td>Safe Care Campaign</td>
</tr>
<tr>
<td>Neesha Nair</td>
<td>Advocate</td>
</tr>
<tr>
<td>Brent D. NiBarger</td>
<td>BioVigil</td>
</tr>
<tr>
<td>Anna Noonan</td>
<td>University of Vermont Medical Center</td>
</tr>
<tr>
<td>Kate O’Neill</td>
<td>iCareQuality</td>
</tr>
<tr>
<td>Donna Prosser</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Kathy Puri</td>
<td>Fitsi Health</td>
</tr>
<tr>
<td>Caroline Puri Mitchell</td>
<td>Fitsi Health</td>
</tr>
<tr>
<td>Kellie Quinn</td>
<td>Patient Advocate</td>
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<tr>
<td>Julia Rasooly</td>
<td>PuraCath Medical</td>
</tr>
<tr>
<td>Judith Reiss</td>
<td>Advocate</td>
</tr>
<tr>
<td>Yisrael Safeek</td>
<td>SafeCare Group</td>
</tr>
<tr>
<td>Sundary Sankaran</td>
<td>Kaiser Permanente</td>
</tr>
<tr>
<td>Steve Spaanbroek</td>
<td>MSL Healthcare Partners, Inc.</td>
</tr>
<tr>
<td>Philip Stahel</td>
<td>Patient Safety Movement Foundation</td>
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<tr>
<td>Jeanine Thomas</td>
<td>MRSA Survivors Network</td>
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<td>Greg Wiita</td>
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References


Appendix A: Active Ingredients in Antiseptic Skin Preparations

In Table 3 below the antiseptic ingredients that are recommended by the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) are described (Jackson, 2018).

Table 3 lists the health care antiseptic active ingredients that have been considered under this rulemaking and shows whether each ingredient is eligible or ineligible for evaluation under the OTC Drug Review for use in health care antiseptics for each of the five specified uses: Patient antiseptic skin preparation, health care personnel hand wash, health care personnel hand rub, surgical hand scrub, and surgical hand rub.

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Patient Antiseptic Skin Preparation</th>
<th>Health Care Personnel Hand Wash</th>
<th>Health Care Personnel Hand Rub</th>
<th>Surgical Hand Scrub</th>
<th>Surgical Hand Rub</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol 60 to 95 percent</td>
<td>Y*</td>
<td>N*</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>Y</td>
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<td>Y</td>
<td>Y</td>
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</tr>
<tr>
<td>Benzethonium chloride</td>
<td>Y</td>
<td>Y</td>
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<td>N</td>
</tr>
<tr>
<td>Chlorhexidine gluconate</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Chloroxylenol</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
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<tr>
<td>Clofucarbam</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Fluorosalan</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
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<tr>
<td>Hexylresorcinol</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
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<td>Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
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<tr>
<td>Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
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<td>N</td>
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<tr>
<td>Iodine tincture United States Pharmacopeia (USP)</td>
<td>Y</td>
<td>N</td>
<td>N</td>
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<tr>
<td>Iodine topical solution USP</td>
<td>Y</td>
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<tr>
<td>Nonylphenoxypoly (ethyleneoxy) ethanoliodine</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
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<tr>
<td>Poloxamer-iodine complex</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Povidone-iodine 5 to 10 percent</td>
<td>Y</td>
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<td>Undecylenol chloride iodine complex</td>
<td>Y</td>
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<tr>
<td>Isopropyl alcohol 70-91.3 percent</td>
<td>Y</td>
<td>N</td>
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<td>Y</td>
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<tr>
<td>Mercufenol chloride</td>
<td>Y</td>
<td>N</td>
<td>N</td>
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Actionable Patient Safety Solutions (APSS) #2D:
Ventilator-associated pneumonia (pedVAP/PVAP)

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for pedVAP/PVAP. In it, you’ll find:

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Ventilator-associated pneumonia (pedVAP/PVAP)

Executive summary checklist

Ventilator-associated pneumonia (VAP)—pedVAP in children and Possible VAP (pVAP) when suspected in adults—is a lung infection that develops in a patient who is on a ventilator. An infection may occur if germs enter through the tube and get into the patient’s lungs (CDC, 2014). VAP is a serious problem in critically-ill patients, resulting in many patient deaths each year.

Use this checklist to help you prioritize your actions and measure your organization’s progress in each area. Prevention of VAP requires the following actions:

Create an action plan

☐ Show leadership’s commitment to support a program to eliminate VAP
☐ Implement evidence-based guidelines to prevent the occurrence of VAP

Ensure best patient care

☐ Prevent aspiration of body secretions, following these protocols:
  ☐ Maintain elevation of head of bed (HOB) between 30-45 degrees
  ☐ Avoid gastric overdistention
  ☐ Prevent unplanned, uncontrolled extubation
    ☐ Patient self extubation
    ☐ Accidental extubation
  ☐ Minimize pooling of secretions above the cuff of endotracheal tube
  ☐ Maintain the endotracheal tube cuff pressure at greater than 20 cmH2O
  ☐ Encourage physical or occupational therapy to help patients get moving
  ☐ Before patients are extubated, ensure they
    ☐ Are conscious and responsive
    ☐ Have undergone readiness testing and weaning

☐ Decrease duration of ventilation:
  ☐ Conduct “sedation vacations”
  ☐ Assess readiness to wean from ventilator daily
  ☐ Conduct spontaneous breathing trials

☐ Reduce colonization of aero-digestive tract:
  ☐ Use non-invasive ventilation methods when possible (i.e., CPAP, BiPap)
  ☐ Use oro-tracheal over naso-tracheal intubation
  ☐ Perform regular oral care with an antiseptic agent (see Appendix A for antiseptic ingredients to consider)
  ☐ Reduce opportunities to introduce pathogens into the airway

☐ Prevent exposure to contaminated equipment:
  ☐ Use sterile water to rinse reusable respiratory equipment
  ☐ Remove condensation from ventilator circuits
  ☐ Change ventilator circuit only when malfunctioning or visibly soiled
  ☐ Store and disinfect respiratory equipment effectively
Measure adherence to VAP prevention practices and consider monitoring compliance:
- Hand Hygiene
- Daily sedation vacation/interruption and assessment of readiness to wean
- Regular antiseptic oral care
- Semi-recumbent position of all eligible patients—head up to 30 degrees

Monitor ventilated patients for:
- Positive cultures
- Temperature chart/log
- Pharmacy reports of antimicrobial use
- Change in respiratory secretions
- If complications arise, list these at the top of the patient’s Electronic Health Record (EHR) problem list

Engage staff and use data to find areas for improvement
- Create an education plan for physicians and nurses to cover key curriculum about the prevention of VAP
- Encourage continuous process improvement through the implementation of:
  - Quality process measures and metrics
  - A monthly display of data results through a dashboard
- Encourage each unit to monitor and perform an event analysis on each VAP infection using a multidisciplinary approach to engage all unit staff
- Complete a full root cause analysis (RCA) for any VAP that is identified—through event analysis—to be associated with patient death
- Implement—and share—all learnings from the RCA
- Utilize patient stories - written and in video - to help teach and inspire change in your staff
What we know about VAP

Ventilator-associated pneumonia
Ventilator-associated pneumonia is a lung infection that develops in a patient who is on a ventilator. Mechanically ventilated hospital patients are usually critically ill and need to be treated in an intensive care unit (ICU).

The infection can develop after 2 days or more of mechanical ventilation and is caused when bacteria reaches the lower respiratory tract via the endotracheal tube or tracheostomy (when doctors put a plastic tube through a patient’s mouth or nose and down their windpipe to help them breathe). When a patient’s airways are not properly maintained, intubation may allow for oral and gastric secretions to enter their lower airways (Amanullah, 2015).

Ventilator associated events (VAE)
In 2011 the Centers for Disease Control’s (CDC) National Healthcare Safety Network (NHSN) expanded the definition of VAP to address limitations in the previous standing surveillance definition. The surveillance definition was expanded to include additional pulmonary conditions indicative of processes that could be identified as or lead to a VAP.

The updated tiered definition—Ventilator Associated Events, or VAE, for short—includes the updated criteria of Possible Ventilator Associated Pneumonia, or PVAP, in adults. The purpose of this definition is for surveillance only and is not meant to be used for clinical identification of pneumonia in a ventilated patient.

The risks with the standard treatment
VAP is the leading cause of death associated with healthcare-associated infections (HAIs) (IHI, 2012). In the US, a multi-state prevalence survey estimated the occurrence of VAP in the US at 49,900 cases annually (Magill, 2014).

Research shows that as many as 28% of patients who receive mechanical ventilation in the hospital will develop VAP—the frequency increases with the duration of mechanical ventilation.

- Unplanned, uncontrolled extubation increases the occurrence of pneumonia from 14% to 30% (DeLassence et al., 2002)
- There are more than 120,000 incidents of unplanned extubation in adult U.S. ICUs yearly—causing more than 36,000 VAPs every year (DeLassence et al., 2002)
- The crude mortality rate for VAP is between 20% and 60%—incidence ranges from 4% to 48% (Cook, 1998; Heyland et al., 1999)

Depending on the type of pneumonia, the mortality rate may vary. Pseudomonas and Acinetobacter are associated with higher mortality rates than other strains of bacteria (Fagon, 1996). It is believed that when antibiotic therapy is delayed or improperly dosed, mortality also increases. These factors are largely preventable.

Patients who acquire VAP have significantly longer durations of mechanical ventilation and a longer stay in the ICU (Rello, 2002). In addition, the development of VAP is associated with a significant rise in healthcare costs and poor economic outcomes.

- VAP is associated with greater than $40,000 in mean hospital charges per patient
Reducing and preventing VAP
Researchers predict that implementing system-wide change and the use of technology to reduce VAP can save up to $1.5 billion per year while significantly improving quality and safety (Scott, 2009).

Leadership plan
Addressing this safety issue will require hospitals and healthcare systems to commit to action in the form of specific leadership, action, and technology plans. Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce VAP infections.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

Show leadership’s commitment to reducing VAP
• Commitment and action are required at all levels for successful process improvement
• Hospital governance and senior administrative leadership must champion efforts in raising awareness to prevent and manage VAP infections safely

Create the infrastructure needed to make changes
• Support the design and implementation of an antimicrobial stewardship program
• Integrate surveillance and metrics to ensure prevention measures are being followed by all staff
• Utilize patient stories - written & in video - to identify gaps and inspire change in your staff

Action plan
Establish and consistently implement VAP prevention guidelines (Coffin, 2008) that focus on:
• Surveillance
• Decreasing the number of days patients spend on a ventilator
• Prevention of aspiration and gastric distention
• Equipment cleansing
• Oral hygiene
• Avoidance of unintended extubation and reintubation

An example of an evidence-based bundle is the Institute for Healthcare Improvement’s How-to Guide: Prevent Ventilator Associated Pneumonia. You can access this guide by visiting the Institute for Healthcare Improvement’s (IHI) website.

Johns Hopkins University’s Armstrong Institute for Patient Safety and Quality has published a Toolkit to Improve Safety of Mechanically Ventilated Patients that includes recommendations on preventing, measuring and tracking outcomes related to VAP. This Toolkit can be accessed online through the John Hopkins Medicine website.

Encourage action with the following practices
• If tolerated by your patient, elevate the head of the bed to between 30 and 45 degrees
• Use Daily Sedation Interruption and Daily Assessment of Readiness to extubate
• Use Deep Venous Thrombosis (DVT) prophylaxis
• Recommend daily oral care
• Follow hand hygiene procedures before and after touching a patient
• Although Peptic Ulcer Disease (PUD) prophylaxis was previously a component of the VAP bundle, recent studies have shown that the increase in gastric pH that results from these medications promotes the growth of bacteria in the upper GI tract, which actually increases the risk for VAP. For this reason, the use of PUD prophylaxis should be based upon each patient’s risk for GI bleed and has been excluded from current recommendations (Hellyer, Ewan, Wilson & Simpson, 2016).

*Unplanned, uncontrolled, self or accidental extubation contributes significantly to the overall occurrence of VAP. Therefore, prevention of unplanned extubation should be a top priority. If you would like to learn more about this topic, please go to The Patient Safety Movement Foundation’s Actionable Patient Safety Solutions (APSS) #8B - Unplanned Extubation.

Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

Consider implementing the following technologies to address VAP in your organization:

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Available Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities:</td>
<td>• Computerized Provider Order Entry (CPOE)</td>
</tr>
<tr>
<td></td>
<td>• Drug-drug interaction check</td>
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<td></td>
<td>• Drug-allergy interaction check</td>
</tr>
<tr>
<td></td>
<td>• Clinical Decision Support tools (CDS)</td>
</tr>
<tr>
<td>Implement endotracheal tubes designed to drain subglottic secretions</td>
<td></td>
</tr>
<tr>
<td>If endotracheal tubes designed to drain subglottic secretions are not available</td>
<td></td>
</tr>
<tr>
<td>Implement oral hygiene products</td>
<td></td>
</tr>
<tr>
<td>Implement electronic surveillance technologies that support antimicrobial stewardship</td>
<td>• In late onset cases of VAP, bacteria is often multidrug resistant, and can have great clinical and economic challenges</td>
</tr>
</tbody>
</table>
Implement Electronic Measurement of hand hygiene compliance

- See APSS #2A to learn more

**Measuring outcomes**

**Topic:**

**Ventilator-associated Pneumonia Rate (VAP)**

Rate of patients on a ventilator for more than 2 calendar days who develop pneumonia while on the ventilator or within 1 day of ventilator removal per 1,000 ventilator-days

**Outcome measure formula:**

**Numerator:** Ventilator-associated pneumonia (VAP) for pediatrics or Possible Ventilator Associated pneumonia for adults (PVAP) infections based on CDC NHSN surveillance definitions for all inpatient units (CDC, 2018).

**Denominator:** Total number of ventilator-days for all patients on a ventilator in all tracked units

* Rate is typically displayed as VAP/1000 ventilator days

**Metric recommendations**

**Indirect Impact:**

All patients with conditions that lead to temporary or permanent ventilation

**Direct Impact:**

All patients that require invasive ventilation.

**Lives Spared Harm:**

\[ \text{Lives} = (\text{VAP Rate}_{\text{baseline}} - \text{VAP Rate}_{\text{measurement}}) \times \text{Ventilator days}_{\text{baseline}} \]

**Notes:**

To meet the NHSN definitions, infections must be validated using the hospital acquired infection (HAI) standards (CDC, 2018). Infection rates can be stratified by unit types further defined by CDC (CDC, 2016). Infections that were present on admission (POA) are not considered HAIs and not counted.

**Data collection**

VAP and ventilator-days can be collected through surveillance (collected at least once per month and reported monthly) or gathered through electronic documentation. Denominators documented electronically must match manual counts (+/- 5%) for a 3 month validation period.

**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 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 (AHRQ, 2019). Based on these data the estimated additional inpatient mortality for Ventilator-associated Pneumonia (VAP) is 0.144 (144 per 1000 events) (AHRQ, 2013).

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs

Ebony Talley
Kaiser Permanente Woodland Hills Medical Center

Carole Moss
Nile’s Project

Members

This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions

Steven J. Barker
Patient Safety Movement Foundation; Masimo

Michel Bennett
Patient Safety Movement Foundation (formerly)

Naomi Bishop
Human-Centered Healthcare Design

Jonathan Coe
Prescient Surgical

Alicia Cole
Alliance for Safety Awareness for Patients (ASAP)

Peter Cox
SickKids

Maria Daniela DaCosta Pires
Geneva University Hospitals

Todd Fletcher
Resources Global Professionals

Kate Garrett
Ciel Medical

Helen Haskell
Mothers Against Medical Error

Brook Hossfeld
Sodexo

Lucas Huang
Global Network for Simulation In Healthcare

Mert Iseri
SwipeSense

Sarah Knowles
University Hospitals Geauga Medical Center

Terry Kuzma-Gottron
Avadim Technologies

Jerika Lam
Chapman University School of Pharmacy

Emily Leathers
Parrish Medical Center
<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Gabriela Leongtez</td>
<td>Gresmex</td>
</tr>
<tr>
<td>Christian John Lillis</td>
<td>Peggy Lillis Foundation</td>
</tr>
<tr>
<td>Lori Lioce</td>
<td>Global Network for Simulation In Healthcare</td>
</tr>
<tr>
<td>Edwin Loftin</td>
<td>Parrish Medical Center</td>
</tr>
<tr>
<td>Ariana Longley</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Jacob Lopez</td>
<td>Patient Safety MovementFoundation (formerly)</td>
</tr>
<tr>
<td>Olivia Lounsbury</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Betsy McCaughey</td>
<td>The Committee to Reduce Infection Deaths</td>
</tr>
<tr>
<td>Derek Monk</td>
<td>Poiesis Medical</td>
</tr>
<tr>
<td>Armando Nahum</td>
<td>Safe Care Campaign</td>
</tr>
<tr>
<td>Neesha Nair</td>
<td>Advocate</td>
</tr>
<tr>
<td>Brent D. NiBarger</td>
<td>BioVigil</td>
</tr>
<tr>
<td>Anna Noonan</td>
<td>University of Vermont Medical Center</td>
</tr>
<tr>
<td>Kate O’Neill</td>
<td>iCareQuality</td>
</tr>
<tr>
<td>Donna Prosser</td>
<td>Patient Safety Movement Foundation</td>
</tr>
<tr>
<td>Kathy Puri</td>
<td>Fitsi Health</td>
</tr>
<tr>
<td>Caroline Puri Mitchell</td>
<td>Fitsi Health</td>
</tr>
<tr>
<td>Kellie Quinn</td>
<td>Patient Advocate</td>
</tr>
<tr>
<td>Julia Rasooly</td>
<td>PuraCath Medical</td>
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<tr>
<td>Judith Reiss</td>
<td>Advocate</td>
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<tr>
<td>Yisrael Safeek</td>
<td>SafeCare Group</td>
</tr>
<tr>
<td>Sundary Sankaran</td>
<td>Kaiser Permanente</td>
</tr>
<tr>
<td>Steve Spaanbroek</td>
<td>MSL Healthcare Partners, Inc.</td>
</tr>
<tr>
<td>Philip Stahel</td>
<td>Patient Safety Movement Foundation</td>
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<tr>
<td>Jeanine Thomas</td>
<td>MRSA Survivors Network</td>
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<tr>
<td>Greg Wiita</td>
<td>Poiesis Medical</td>
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<tr>
<td>Metrics Integrity</td>
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</tr>
<tr>
<td>Robin Betts</td>
<td>Kaiser Permanente, Northern California Region</td>
</tr>
</tbody>
</table>

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

## References


AHRQ. Efforts to Improve Patient Safety Result in 1.3 Million Fewer Patient Harms: Interim Update on 2013 Annual Hospital-Acquired Condition Rate and Estimate of Cost Savings and
paredness, Detection, and Control of Infectious Diseases, Centers for Disease Control and Prevention (2009).


Appendix A: Active Ingredients in Antiseptic Skin Preparations

Table 3 lists the health care antiseptic active ingredients that have been considered under this rulemaking and shows whether each ingredient is eligible or ineligible for evaluation under the OTC Drug Review for use in health care antiseptics for each of the five specified uses: Patient antiseptic skin preparation, health care personnel hand wash, health care personnel hand rub, surgical hand scrub, and surgical hand rub.

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Patient Antiseptic Skin Preparation</th>
<th>Health Care Personnel Hand Wash</th>
<th>Health Care Personnel Hand Rub</th>
<th>Surgical Hand Scrub</th>
<th>Surgical Hand Rub</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol 60 to 95 percent</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Benzethonium chloride</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Chlorhexidine gluconate</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Chloroxylenol</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Clofucarban</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Fluorosalan</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Hexylresorcinol</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Iodine tincture United States Pharmacopeia (USP)</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Iodine topical solution USP</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Nonylphenoxypoly (ethyleneoxy) ethanoliodine</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Poloxamer-iodine complex</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Povidone-iodine 5 to 10 percent</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Undecylenium chloride iodine complex</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Isopropyl alcohol 70-91.3 percent</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Mercufenol chloride</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
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</tbody>
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Courtesy of the Department of Health and Human Services, Food and Drug Administration
Actionable Patient Safety Solutions (APSS) #2E: 
**Clostridioides difficile infection (CDI)**

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for *Clostridioides difficile* infection (CDI). In it, you’ll find:

- Executive summary checklist.......................... 68
- What we know about CDIs................................. 70
- Leadership plan............................................. 71
- Action plan..................................................... 71
- Technology plan.............................................. 73
- Measuring outcomes........................................ 74
- Conflicts of interest disclosure.......................... 75
- Workgroup...................................................... 75
- References..................................................... 77
Clostridioides difficile (also known as C. diff) is an opportunistic bacterium that can cause symptoms ranging from diarrhea to colitis or life-threatening inflammation of the colon (CDC, 2012). C. diff is a spore-forming, Gram-positive anaerobic bacillus bacteria that produces two exotoxins: toxin A and toxin B (CDC, 2012).

Transmission of C. diff is primarily via the fecal-oral route. Patients can become infected with Clostridioides difficile infection (CDI) if they touch items or surfaces that are contaminated with feces and then touch their mouths or other mucous membranes. This issue is especially important in healthcare settings because staff can spread the bacteria to patients or contaminate surfaces using their hands.

Use this checklist to help you prioritize your actions and measure your organization’s progress in each area. Prevention of CDIs requires the following actions:

**Create an action plan**

- Implement an antimicrobial stewardship program to prevent and/or minimize CDI rates in healthcare settings
  - Go to APSS #3B to learn more
- Maintain contact precautions for at minimum 48 hours post resolution of diarrhea, up to the duration of the admission
- Use a laboratory-based alert system for immediate notification of all C. diff positive test results
- Implement technologies that support proper surface cleaning and utilize as part of a defined environmental control best practice program, such as:
  - Bleach Germicidal Wipes
  - UV Light Disinfection System
- Create educational pamphlets for healthcare providers, housekeeping, administration, patients, and families about CDIs

**Ensure best patient care**

- Comply with hand hygiene, as described in APSS #2A:
  - Encourage patient, family, and visitors to practice hand hygiene protocols
  - Remind all healthcare staff to practice hand hygiene protocols
- Use soap and water for hand washing
- Use C. difficile sporicidal agents to clean and disinfect equipment and environment, including equipment that comes into contact with the patient, such as:
  - Blood pressure cuffs
  - Pulse oximeters
  - Other equipment that is not frequently cleaned between patients
Engage staff and use data to find areas for improvement

- Encourage continuous process improvement through the implementation of quality process measures and metrics
- Complete a full root cause analysis (RCA) when CDIs are identified by the unit where the infection occurred using a multidisciplinary approach
- Implement and share all learnings from the RCA
- Utilize patient stories - written and in video - to help teach and inspire change in the healthcare staff and custodial personnel
What we know about CDIs

**Clostridioides difficile infections**

*Clostridioides difficile* (also known as C. diff) is an opportunistic bacterium that can cause symptoms ranging from diarrhea to life-threatening inflammation of the colon.

- C. diff is a spore-forming, Gram-positive anaerobic bacillus that produces two exotoxins: toxin A and toxin B (CDC, 2012)
- It can cause C. difficile-associated diarrhea (CAD), and it accounts for 15-25% of all episodes of CAD
- CDIs can cause many diseases, including:
  - Pseudomembranous colitis
  - Toxic megacolon
  - Perforations of the colon
  - Sepsis and, sometimes, death

**CDI symptoms include:**

- Watery diarrhea
- Fever
- Loss of appetite
- Nausea
- Abdominal pain and tenderness

Some patients have a higher risk of contracting CDIs, including those:

- With antibiotic exposure
- With gastric acid suppressors (e.g., proton pump inhibitors and/or histamine 2 receptor antagonists)
- With immunocompromised status
- Who’ve had gastrointestinal surgery
- Who spend more time in healthcare settings
- Who may have a serious underlying illness
- Who are elderly (65 years and older)

**How is CDI spread?**

*C. diff* is spread among patients through the fecal-oral route. Patients can become infected if they touch items or surfaces that are contaminated with feces and then touch their mouths or other mucous membranes.

In healthcare settings, *C. diff* spores are primarily spread to patients by the hands of healthcare staff who have touched a contaminated surface or item. These spores are not killed by alcohol-based hand sanitizers (Oughton *et al.*, 2009; Jabbar *et al.*, 2010; Gerding *et al.*, 2008).

**Preventing CDI**

The World Health Organization (WHO) recommends that healthcare staff wash their hands with soap and water before and after patient contact (WHO, 2011).
• In about 20% of patients, CDIs go away within 2-3 days of discontinuing the antibiotic to which the patient was previously exposed to
• The infection can be treated with an appropriate course of antibiotics
• After treatment, research suggests that repeating C. diff testing is not recommended if the patients’ symptoms have gone away because they may remain colonized with the bacterium

Leadership plan
Addressing this safety issue will require hospitals and healthcare systems to commit to action in the form of specific leadership, clinical, and technology plans. Hospital governance, senior administrative leadership, clinical leadership, and infection control leadership need to work collaboratively to reduce CDIs.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

Leadership in your organization should be familiar with the differences between C. diff colonization and infection:
  • Clostridioides difficile colonization:
    o Patient doesn’t show clinical symptoms
    o Patient tests positive for C. diff organism and/or its toxin
    o More common than CDI
  • Clostridioides difficile infection:
    o Patient shows clinical symptoms

Show leadership’s commitment to reducing CDI
• Commitment and action are required at all levels for successful process improvement
• Hospital governance and senior administrative leadership must champion efforts in raising awareness to prevent and manage CDIs effectively

Create the infrastructure needed to make changes
• Support the design and implementation of an antimicrobial stewardship program
• Integrate surveillance and metrics to ensure prevention measures are being followed by all staff
• Utilize patient stories - written & in video - to identify gaps and inspire change in the healthcare staff and custodial personnel

Action plan
Create, establish, and consistently implement CDI prevention guidelines that focus on educating:
  • Healthcare providers and custodial personnel
  • Patients and their families

On the following topics:
  • Surveillance
  • Hand hygiene
  • Contact and isolation precautions
Prevention guidelines must also include the establishment of an antimicrobial stewardship program (CDC, 2012; WHO, 2011).

The Association for Professionals in Infection Control and Epidemiology created an evidence-based approach—Guide to Preventing *Clostridioides difficile* Infections. The guide can be accessed online (Carrico, 2013).

CDI prevention can be achieved by acting in the following areas:

**Diagnosing a clostridium difficile infection**

Doctors use laboratory tests to diagnose CDIs, including:

- Stool cultures
- Molecular tests
- Antigen detection for C. diff
- Toxin testing:
  - Tissue culture cytotoxicity assay
  - Enzyme immunoassay

The toxin is very unstable and degrades at room temperature, and may be undetectable within 2 hours after collection of a stool specimen. False-negative results can happen when specimens are not quickly tested or kept refrigerated until testing can be done.

**Track and analyze your progress**

- Implement surveillance
  - Implement a facility-wide CDI surveillance method of both process measures and the infection rates to which the processes are linked

**Use safe, clean equipment**

- Practice standardized hand hygiene (Oughton, 2009; WHO, 2011)
  - Healthcare providers must wash hands with soap and water before putting on and after removing gloves when caring for patients with a CDI
  - No agent, including alcohol-based hand sanitizers, is effective against *C. diff* spores
  - Appropriate use and removal of gloves is essential when caring for patients with diarrhea illnesses
- Take contact and isolation precautions
  - Use Standard Precautions for all patients, regardless of diagnosis
  - Place patients with CDI on Contact Precautions in private rooms when available
  - Perform hand hygiene and put on gown and gloves before entry to the patient’s room
  - Use dedicated equipment, such as a blood pressure cuff, thermometer, and stethoscope
  - Remove gown and gloves and perform hand hygiene before exiting the room
  - Educate the patient and family about precautions and why they are necessary and ensure that visitors are properly attired in personal protective equipment

**Provide staff training**

- Be aware of environmental infection prevention
  - Ensure that staff responsible for environmental cleaning and disinfection have been appropriately trained
Use EPA-approved germicide for routine disinfection during non-outbreak situations (USEPA, 2018)

Ensure that staff allow appropriate germicide contact time

For routine daily cleaning of all patient rooms, address:
- Bed, including bedrails and all patient room furniture
- Bedside commodes and bathrooms, including the sink, floor, tub/shower, and toilet
- High-touch surfaces like call buttons and the TV remote
- All communication devices such as walkie-talkies used by nurses to communicate with the nursing station and staff personal cell phones

**Report outcomes inside your organization**

- Antimicrobial stewardship and CDI
  - Implement a program that supports the thoughtful use of antimicrobial agents (CDC, 2016)
  - Ensure that the program incorporates:
    - A process that monitors and evaluates antimicrobial use
    - Provides feedback to medical staff and leadership
  - Work with the healthcare institution’s Infection Control program to reduce the risks of transmission

**Technology plan**

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

Consider implementing the following technologies to address CDIs in your organization:

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<th>Available Technology</th>
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<td>- High alerts for CDI</td>
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<td>Support proper surface cleaning and utilize as part of a defined environmental control best practice program</td>
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</tr>
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</table>
Support proper hand hygiene and utilize as part of a defined hand hygiene best practice program including:

- product utilization and staff movement tracking
- sensor bracelets
- alcohol sensing technologies

See APSS #2A for a list of hand hygiene technology suppliers

---

**Measuring outcomes**

**Topic**

**Healthcare-associated Clostridioides Difficile Infection (CDI) Rate**
Rate of patients with a healthcare associated CDI per 1,000 patient days

**Outcome measure formula**

**Numerator:** Number of healthcare associated CDI based on CDC National Healthcare Safety Network (NHSN) definitions

**Denominator:** Total number of patient days based on CDC NHSN definitions

* Rate is typically displayed as Infections/1000 Patient Days

**Metric recommendations**

Direct Impact:

All hospitalized patients

Lives Spared Harm:

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

Lives Saved:

\[
\text{Lives Saved} = \text{Spared Harm} \times \text{Mortality Rate}
\]

Notes:

To meet the NHSN definitions, infections must be validated using the hospital acquired infection (HAI) standards (CDC, 2016). Infection rates can be stratified by unit types further defined by CDC. Infections that were present on admission (POA) are not considered HAIs and not counted.

**Data collection**

*C. diff* and patient days can be collected through surveillance (at least once per month) or gathered through electronic documentation. Infections must be monitored according to NHSN surveillance definitions. Denominators documented electronically must match manual counts (+/- 5%) for a 3 month validation period.

**Settings**

Infection Surveillance will occur in any inpatient location where denominator data can be collected, which may include critical/intensive care units, specialty care areas, step-down units,
wards, and chronic care units. Surveillance will NOT be performed in Neonatal Intensive Care Units, Specialty Care Nurseries, babies in Labor, Delivery, Recovery and Postpartum (LDRP) room, or well-baby nurseries. If LDRP locations are being monitored, baby counts must be removed.

**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 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 Partnership for Patients (PfP) initiative, the Department of Human Health Services 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 Hospital-acquired Conditions (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 (AHRQ, 2019). CDI was included in this work, under the “All Other HACs” definition, with published metric specifications. This is the most current and comprehensive study to date. Based on these data the estimated additional inpatient mortality for CDI is 0.045 (45 per 1000 events).

**Conflicts of interest disclosure**

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

**Workgroup**

**Co-Chairs**

**Ebony Talley**
Kaiser Permanente Woodland Hills Medical Center

**Carole Moss**
Nile’s Project

**Members**

This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions

**Steven J. Barker**
Patient Safety Movement Foundation; Masimo

**Michel Bennett**
Patient Safety Movement Foundation (formerly)

**Naomi Bishop**
Human-Centered Healthcare Design

**Jonathan Coe**
Prescient Surgical

**Alicia Cole**
Alliance for Safety Awareness for Patients (ASAP)

**Peter Cox**
SickKids
Maria Daniela DaCosta Pires  
Geneva University Hospitals

Todd Fletcher  
Resources Global Professionals

Kate Garrett  
Ciel Medical

Helen Haskell  
Mothers Against Medical Error

Brook Hossfeld  
Sodexo

Lucas Huang  
Global Network for Simulation In Healthcare

Mert Iseri  
SwipeSense

Sarah Knowles  
University Hospitals Geauga Medical Center

Terry Kuzma-Gottron  
Avadim Technologies

Jerika Lam  
Chapman University School of Pharmacy

Emily Leathers  
Parrish Medical Center

Gabriela Leongtez  
Gresmex

Christian John Lillis  
Peggy Lillis Foundation

Lori Lioce  
Global Network for Simulation In Healthcare

Edwin Loftin  
Parrish Medical Center

Ariana Longley  
Patient Safety Movement Foundation

Jacob Lopez  
Patient Safety MovementFoundation (formerly)

Olivia Lounsbury  
Patient Safety Movement Foundation

Betsy McCaughey  
The Committee to Reduce Infection Deaths

Derek Monk  
Poiesis Medical

Armando Nahum  
Safe Care Campaign

Neesha Nair  
Advocate

Brent D. NiBarger  
BioVigil

Anna Noonan  
University of Vermont Medical Center

Kate O’Neill  
iCareQuality

Donna Prosser  
Patient Safety Movement Foundation

Kathy Puri  
Fitsi Health

Caroline Puri Mitchell  
Fitsi Health

Kellie Quinn  
Patient Advocate

Julia Rasooly  
PuraCath Medical

Judith Reiss  
Advocate

Yisrael Safeek  
SafeCare Group

Sundary Sankaran  
Kaiser Permanente

Steve Spaanbroek  
MSL Healthcare Partners, Inc.

Philip Stahel  
Patient Safety Movement Foundation

Jeanine Thomas  
MRSA Survivors Network

Greg Wiita  
Poiesis Medical

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Metrics Integrity
Robin Betts
Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

References


Effectiveness of Alcohol-Based Hand Rubs for Removal of Clostridium difficile Spores from Hands. Infection Control & Hospital Epidemiology, 31(06), 565-570. doi:10.1086/652772


How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for CLABSI. In it, you’ll find:

Executive summary checklist ......................... 80
What we know about CLABSI ............................ 81
Leadership plan ............................................. 82
Action plan ..................................................... 83
Technology plan .............................................. 88
Measuring outcomes ....................................... 89
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References .................................................... 92
Appendix A ..................................................... 94
Executive summary checklist

Central line-associated bloodstream infections (CLABSI) are a source of serious harm and death in hospitalized patients. A CLABSI is a serious infection that occurs when germs—usually bacteria or viruses—enter the bloodstream through the central line (CDC, 2016).

Use this checklist to help you prioritize your actions and measure your organization’s progress in each area. Prevention of CLABSIs requires the following actions.

Create an action plan

☐ Implement evidence-based guidelines to prevent the occurrence of CLABSIs, including:
  ☐ Insertion
  ☐ Maintenance
  ☐ Standardized access procedures

*If implementing guidelines for all 3 processes simultaneously is not feasible, prioritize interventions based on your institution’s experience.

Ensure best patient care

☐ During insertion of a central catheter, doctors should always:
  ☐ Perform a “time-out”
  ☐ Perform hand hygiene procedures, either by washing hands with conventional soap and water or with alcohol-based hand rubs (ABHR).
  ☐ Prepare clean skin with a >0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives.
  ☐ Place sterile drapes over the entire patient and wear a sterile mask, hat, gown, and gloves
  ☐ Put a sterile dressing over the catheter site after the insertion
  ☐ Standardize a central-line kit based on the needs of your facility, and implement technology that will have a significant return on investment (ROI)
  ☐ Minimize blood sample draws from central access catheters

Engage staff and use data to find areas for improvement

☐ Develop a standardized educational plan for doctors and nurses to cover key curriculum about the insertion and maintenance of central lines

☐ Encourage continuous process improvement through the implementation of quality process measures and metrics

☐ Complete a root cause analysis (RCA) or multidisciplinary review when CLABSIs are identified in the unit where the infection occurred using a multidisciplinary approach including nurses, doctors, and infection prevention professionals.

☐ Implement—and share—all learnings from the RCA

☐ Use patient stories - written & in video - to help teach and inspire change in your staff
What we know about CLABSI

There are more than 700,000 healthcare-associated infections (HAIs) each year in the U.S. resulting in 99,000 deaths and $28-$45 billion in extra health care costs (Klevens et al., 2007) (Scott, 2009). Researchers estimate that up to 41,000 patients in US hospitals acquire central line-associated infections each year (O’Grady et al., 2011).

Researchers think CLABSIs occur due to (Mermel et al., 1991; Kallen, et al., 2009, Haddadin et al., 2019):

- Heavy bacterial colonization at the insertion site
- “Non tunneled” catheter is placed in the arm or leg rather than placement in the chest
- Catheterization lasts longer than 3 days
- Catheter insertion with less stringent barrier precautions significantly increase the risk of a catheter-related infection
- The presence of multiple lumens may increase opportunity for infection
- Host factors including complex, chronic illness, immunocompromised state, prolonged hospitalization

The problems with the standard treatment

While intensive care unit (ICU) patients have the highest chance of acquiring CLABSIs, central venous catheters are becoming increasingly used outside the ICU, exposing more patients to the risk. In fact, recent data suggest that the greatest numbers of patients with central lines are in hospital units outside the ICU, most notably dialysis units (Vonberg et al., 2006; Kallen et al., 2009). While central line use is increasing outside the ICU, since 2008 the Centers for Medicare and Medicaid Services (CMS) has implemented a policy of reduced reimbursement for reasonably preventable hospital-acquired conditions, including CLABSIs. This policy change can represent a significant financial burden to a hospital because increased hospital costs due to CLABSIs can be more than $48,000 per case (AHRQ, 2016).

Preventing CLABSIs

CLABSIs and other HAIs, however, are mostly preventable. Interventions that focus on reducing CLABSIs have resulted in reductions ranging from 38% to 80% (Pronovost, et. al., 2006; Drews, et al., 2019). In one study, researchers observed a 66% decrease in CLABSIs after implementing a multi-component intervention in the ICUs of 67 Michigan hospitals (Pronovost et al., 2006). In another study conducted across 32 hospitals in Pennsylvania, CLABSIs decreased by 68%, following targeted interventions between April 2001 and March 2005 (CDC, 2005). Other studies have shown similar reductions in CLABSIs, saving lives and dramatically reducing costs (Rosenthal et al., 2012; Hong et al., 2013; Gozu et al., 2011).

A variety of guidelines and recommendations have been identified to prevent CLABSIs including those published by:

- The Healthcare Infection Control Practices Advisory Committee (O’Grady et al., 2017)
- The Institute for Healthcare Improvement (IHI, n.d.)
- The Agency for Healthcare Research and Quality (AHRQ, 2014)

These recommendations share the following components to reduce and prevent CLABSIs:

- Implementing a method to detect the true incidence of CLABSI, such as information technology to collect and calculate catheter days
- Providing adequate infrastructure for the intervention including an adequately staffed
infection prevention and control program, and adequate laboratory support for timely processing of samples

- Implementing a catheter insertion and maintenance checklists
- Monitoring the continued need for intravascular access on a daily basis and prompt removal when the catheter is no longer needed
- Measuring unit-specific occurrence of CLABSIs as part of performance evaluations

Researchers estimate that the use of process change and the use of technology to reduce CLABSI can save up to $2.7 billion per year while significantly improving quality and safety (Scott, 2009). Closing the performance gap will require hospitals and healthcare systems to commit to action in the form of specific leadership, action, and technology plans, examples of which are delineated below for utilization or reference. This is provided to assist hospitals in prioritizing their efforts at designing and implementing evidence-based bundles for CLABSI reduction.

**Leadership plan**

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce CLABSIs. To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

**Show leadership’s commitment to reducing CLABSIs**

- Hospital governance and senior administrative leadership must commit to becoming aware of major performance gaps in their own organization
- Hospital governance, senior administrative leadership, and clinical/safety leadership must close their own performance gap by implementing a comprehensive approach
- Healthcare leadership must reinforce their commitment by:
  - Taking an active role in championing process improvement
  - Giving their time, attention, and focus
  - Removing barriers
  - Providing necessary resources
- Leadership must demonstrate their commitment and support by:
  - Shaping a vision of the future
  - Clearly defining goals
  - Embracing and reinforcing a Culture of Safety so that staff feel empowered to actively participate in CLABSI prevention activities
  - Supporting staff as they work through improvement initiatives
  - Measuring results
  - Communicating progress towards goals
- Actions speak louder than words. As role models, leadership must ‘walk the walk’ as well as ‘talk the talk’ when it comes to supporting process improvement across your organization.
- 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, the C-Suite, senior leadership, physicians, directors, managers, and unit leaders all have important roles and need to be engaged
Create the infrastructure needed to make changes

Change management is a critical element that must be included to sustain any improvements. 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 the 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 opportunity for success and sustainability of improvements. “Facilitating Change,” the change management model The Joint Commission developed, contains four key elements to consider when working through a change initiative to address HAIs (go to Appendix A).

In addition to the change management model, leaders must:

- Include fundamentals of change outlined in the National Quality Forum safe practices, including:
  - Awareness
  - Accountability
  - Ability
  - Action
- Meet with the ICU team, infection control staff, quality and safety leaders, nurse educators, and physician champions to:
  - Understand barriers (walk the process)
  - Use 4E grid to develop strategy to:
    - Engage—use stories and show baseline data
    - Educate—teach staff about the evidence
    - Execute—practice change
    - Evaluate—assess feedback performance and view infections as defects
  - Use surveillance data to drive improvement
  - Monitor and provide feedback of compliance with best practices over time
- Utilize patient stories - written & in video - to identify gaps and inspire change in your staff
  - The story of Nora Bostrom, daughter of Claire McCormick and Thomas Bostrom, is an inspiring story about a CLABSI which can be freely viewed: http://patient.sm/Igu4DQ

Action plan

Use of current evidence-based guidelines and/or implementation aids regarding the prevention of CLABSIs:

Insertion

- Create a standardized central line insertion kit or line cart that contains all needed supplies (go to Technology plan to learn more)
- Ensure an insertion checklist is part of your electronic medical record
- Wear sterile clothing (Personal Protective Equipment, PPE)—gowns, mask, gloves, and hair covering and insure that personnel involved in insertion and maintenance of catheters are trained in correct use of PPE
- Cover patients with a sterile drape, except for a very small hole where the central line
• Maintain strict sterile techniques when placing the central line
• Perform hand hygiene procedures, either by washing hands with conventional soap and water or with alcohol-based hand rubs (ABHR)
  o Hand hygiene should be performed before and after palpating catheter insertion sites, as well as before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter (CDC, 2002)
  o Palpation of the insertion site should not be performed after the application of antiseptic, unless an aseptic technique is maintained (O’Grady et al., 2002)
  o Go to APSS #2A Hand Hygiene to learn more
• Use ultrasound guidance for all non-emergent central line placements
• For directly inserted central lines, the internal jugular and subclavian veins are less frequently associated with infections than the femoral vein.
• Perform a “time-out” before commencing the procedure
• Position patient appropriately

Prepare insertion site
• Prepare clean skin with a 0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter insertion and during dressing changes
  o If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives
• Don’t use iodine ointment - Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance
• Following insertion, ensure line aspirates blood to confirm proper catheter placement
• Apply a sterile dressing to the site
• Use a prepackaged or filled insertion cart, tray, or box that contains all the necessary supplies
• Use an insertion checklist with staff empowerment to stop non-emergent procedure:
  o Include a checklist to ensure adherence to proper practices
• Use a full sterile barrier for providers and patients:
  o Use maximal sterile barrier precautions, including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full body drape, for the insertion of CVCs, PICCs, or guidewire exchange
  o Use a sterile sleeve to protect pulmonary artery catheters during insertion
• Provide insertion training for all providers
• Monitor performance and compliance with the insertion bundle on a routine basis
  o A minimum of 20 audits per month is recommended to acquire ample data to assess staff performance

Maintenance
• Perform daily assessments of need for line and remove when no longer needed:
  o Only healthcare personnel who are properly trained should be doing the maintenance on the central line based on a standardized maintenance bundle
- Create a checklist with all required maintenance bundle elements
- Standardize procedures for line access, dressing, cap and tubing changes
- Discuss with the medical team continued necessity of line
- Discuss with the medical team the function of the line and any problems
- Discuss with the medical team the frequency of access and utilization of the line
  - Limit line access by bundling labs
- Document daily discussion of line necessity in the patient's medical record

- Conduct regular assessment of dressing to assure clean/dry/occlusive:
  - Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled
  - Replace dressings used on short-term central venous catheter sites according to CDC or institution's protocol

- Perform daily CHG bathing and linen changes–follow manufacturer recommendations for usage
- Perform weekly safety rounds
- Send monthly data to team and leadership
  - Celebrate successes: post a running tally of CLABSI-free days in your unit where it can be easily seen
  - Use a systematic approach to review all hospital-acquired CLABSI
  - Perform in-depth case reviews when infections do occur: Include members of the Infection Prevention and Control and Infectious Disease teams.
  - Identify the risks that could’ve been avoided and modifications needed moving forward, during timely safety huddles

**Standardized access procedure**
- Go to Hand Hygiene details in APSS #2A
- Use clean (for temporary CVLs) or sterile (for permanent CVLs) gloves when accessing the line
- Scrub the hub:
  - Alcohol (15 second scrub + 15 second dry)
  - CHG (30 second scrub + 30 second dry)
- Follow standardized dressing, cap, and tubing change procedures/timing:
  - Scrub skin around site with CHG for 30 seconds (2 minute for femoral site), followed by complete drying. For patients with contraindication to CGH (allergy), scrub skin with alcohol or povidone-iodine
  - Note: there may be institutional preference for CHG use for infant < 2 months of age
- Change crystalloid tubing no more frequently than every 72 hours
- Change tubing used to administer blood products every 24 hours or more frequently per institutional standard
- Change tubing used for lipid and TPN infusions every 24 hours
- Document date dressing/cap/tubing was changed or is due for change
- Consider when hub of catheter or insertion site are exposed, wear a mask (all providers and assistants), shield patient's face, endotracheal tube (ETT), or trach with mask or
In the pediatric ICU and neonatal ICU*:

- Create a monthly report-out CLABSI and prevention bundle compliance data monthly at team/quality committee and leadership meetings
- Line stability and securement is a challenge in all pediatric patients, but especially in preterm neonates in whom skin integrity is not yet fully developed. Therefore, extra attention to insertion site and dressings is required
- Implement standardized central venous catheter (CVC) practices:
  - Use pediatric-specific insertion and maintenance bundle checklists
  - Daily assessment of need for and functionality of the line, insertion site, securement and dressing with documentation in the medical record
  - For infants receiving parenteral nutrition, create an electronic health record prompt to remove catheter when the threshold for adequate enteral intake has been achieved based on feeding volume
  - 24-hour catheter tubing change for lines used to provide PN or blood products, with access only by, experienced staff and compliance with standard access procedures only
  - Enhanced nursing education and competency for standardized CVC care
  - Educate caretakers (parents, guardians) on best practices and empower them to reinforce compliance with maintenance care standards.
    - Consider creating printed safety sheets or “key” cards using easy-to-understand language that summarize maintenance care elements (See Fig. 1 *Additional information on Pediatric-specific CLABSI prevention is available from the Children’s Hospitals Solutions for Patient Safety National Children’s Network (www.solutionsforpatientsafety.org) a national consortium of more than 135 children’s hospitals committed to improving care and reducing harm in hospitalized children.)

Provide staff training

- Nursing education—care and maintenance bundle
  - “Just in Time” training incorporates immediate feedback to staff at the time of line care
- Enhanced Pediatric and Neonatal ICU nursing education with regular assessment of—enhanced and competency standard for CVC care practices for all staff who handle central lines
- Central Line Simulation Program
  - Develop education for attendings, residents, and nurses
  - Key Curriculum Concepts—reinforcement
    - Hand hygiene
    - Appropriate gowning and gloving
  - Key Curriculum Concepts
    - Standardized central line insertion best practice
      - Ultrasound guided cannulation for all line placement
    - Insertion checklist
Maintaining sterile technique – immediate feedback

- Central Line Navigator documentation
- General Medical Education (GME)
  - MD rounding navigators (removal prompt)
  - Resident infection prevention training
- Evidence-based practice adherence
- Remain current with new literature findings:
  - “Guidelines for the Prevention of Intravascular Catheter-Related Infections” 2011 compendium by the CDC (Miller et al., 2010)
- Patient/Family education document (see Figure 1 below)

![My CVL Plan](image)

**Figure 1**: My/(Child’s) CVL Plan (developed by Hospital for Sick Children, Toronto)

**Quality process measures and metrics**
Monthly CLABSI rate (expressed per 1000 catheter days)

- Complete documentation elements
  - Number of operator attempts per line placement
  - % of patients compliant with daily CHG treatments, site disinfection
  - % insertion with completed checklist
- Bundle compliance - insertion and maintenance to be measured separately. Direct observation by dedicated, trained “champions” is the best practice for generating reliable procedural compliance data.
  - % of line insertions following all bundle components
  - % compliance with standard maintenance bundle during access and/or dressing, cap or tubing change
  - Hospitals can choose to include additional bundle components. Including more than
5 may confuse and overwhelm providers.

- Quality and effectiveness of patient education
  - % of patients/families educated about infection prevention
- Repetitive patterns, trends, or variables
  - Complication rate
  - PICC v. Central Lines
  - Insertion site choice
- Perform a minimum of 20 audits per month. If procedures are fewer than 20, then include all procedures.

**Technology plan**

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: [https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/](https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/)

Consider implementing the following technologies to reduce or prevent CLABSIs in your organization:

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<tr>
<td>• Clinical Decision Support tools (CDS)</td>
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<tr>
<td>A central venous catheterization (CVC) kit to prepare, insert and maintain a safe</td>
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<td>central line.</td>
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<td>• Kits should be custom designed to fit the needs of one hospital or hospital</td>
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<td>system. Input from all relevant stakeholders should be included before finalizing</td>
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<tr>
<td>the kit components. Design with should focus on convenience and usability.</td>
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<td>• Two such kits are used at the University of Vermont Medical Center and have been</td>
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<td>included:</td>
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Measuring outcomes

Topic:

Central line-associated bloodstream infections (CLABSI)
CLABSI is defined by the CDC National Healthcare Safety Network (NHSN) as a primary bloodstream infection (BSI) in a patient that had a central line within the 2 calendar days before the development of the BSI and is not related to an infection at another site.

Outcome measure formula (CLABSI Rate):

Numerator: A laboratory-confirmed bloodstream infection based on the above CDC NHSN definition (CDC, 2016)

Denominator: Device days

Metric recommendations

Indirect Impact:
Any patient with a peripheral or central line will benefit from several of the interventions being instituted

Direct Impact:
All patients that require a central line

Lives Spared Harm:
\[ \text{Lives} = (\text{CLABSI Rate}_{\text{baseline}} - \text{CLABSI Rate}_{\text{measurement}}) \times \text{Line days}_{\text{baseline}} \]

Lives Saved:
\[ \text{Lives Saved} = \text{Lives Spared Harm} \times \text{Mortality Rate} \]

Notes:
To meet the NHSN definitions, infections must be validated using the hospital acquired infection (HAI) standards (CDC, 2016). Infection rates can be stratified by unit types further defined by CDC. Infections that were present on admission (POA) are not considered HAIs and not counted.

Data collection
CLABSI and Line days can be collected through surveillance (at least once per month) or gathered through electronic documentation. Denominators documented electronically must match manual counts (+/- 5%) for a 3-month validation period.

CLABSI can be displayed as a Standardized Infection Ratios (SIR) using the following formula:
SIR = Observed CLABSI/Expected CLABSI

Expected infections are calculated by NHSN and available by location (unit type) from the baseline period.

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

The PSMF will use the mortality rates associated with Hospital Acquired Conditions targeted in the Partnership for Patient’s grant funded Hospital Engagement Networks (HEN), when available. 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 (AHRQ, 2019). Central Line associated bloodstream infections was included in this work with published metric specifications. This is the most current and comprehensive study to date. *Based on these data the estimated additional inpatient mortality for Central Associated Bloodstream Infection Events is 0.185 (185 per 1000 events).*

**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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

**Workgroup**

**Co-Chairs**
- **Ebony Talley**
  - Kaiser Permanente Woodland Hills Medical Center
- **Carole Moss**
  - Nile’s Project

**Members**

This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions

- **Steven J. Barker**
  - Patient Safety Movement Foundation; Masimo
- **Michel Bennett**
  - Patient Safety Movement Foundation (formerly)
- **Naomi Bishop**
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  - SickKids
Maria Daniela DaCosta Pires  
Geneva University Hospitals

Todd Fletcher  
Resources Global Professionals

Kate Garrett  
Ciel Medical

Helen Haskell  
Mothers Against Medical Error

Brook Hossfeld  
Sodexo

Lucas Huang  
Global Network for Simulation In Healthcare

Mert Iseri  
SwipeSense

Sarah Knowles  
University Hospitals Geauga Medical Center

Terry Kuzma-Gottron  
Avadim Technologies

Jerika Lam  
Chapman University School of Pharmacy

Emily Leathers  
Parrish Medical Center

Gabriela Leongtez  
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**References**


CDC. (2016). Instructions for Mapping Patient Care Locations in NHSN.


Miller, M. R., Griswold, M., Harris, J. M., Yenokyan, G., Huskins, W. C., Moss, M., ... Brilli, R. J.


“Facilitating Change,” the change management model developed by The Joint Commission, contains four key elements to consider when working through a change initiative to address Healthcare Associated Infections (HAIs).

Plan the Project:

- At the start of project, build a strong foundation for change by:
  - Assessing the culture for change
  - Defining the change
  - Building a strategy
  - Engaging the right people
  - Painting a vision of the future

Inspire People:

- Ask for support and active involvement in the plan to reduce:
  - HAIs
  - Get agreements
  - Build accountability for the outcomes
- Identify a leader for the HAI initiative (this is critical to the success of the project)
- Understand where resistance may come from

Launch the Initiative:

- Align operations and guarantee the organization has the capacity to change, not just the ability to change
- Launch the HAI initiative with a clear champion and a clearly communicated vision by leadership

Support the Change:

- All leaders within the organization must be a visible part of the HAI initiative
- Frequent communication regarding all aspects of the HAI initiative will enhance the initiative
- Celebrate success as it relates to a reduction in HAIs or a positive change in HAI organizational culture
- Identify resistance to the HAI initiative as soon as it occurs
Actionable Patient Safety Solutions (APSS) #2G:
Non-ventilator hospital-acquired pneumonia

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for NV-HAP. In it, you’ll find:

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Executive summary checklist

Hospital-acquired pneumonia is the #1 hospital-acquired infection, with non-ventilator hospital-acquired pneumonia (NV-HAP) representing over 60% of cases (Magill et al., 2018). An estimated 35 million U.S. patients are at risk of contracting NV-HAP annually (Baker & Quinn 2018, Magill et al., 2014). NV-HAP occurs in all types of hospitals and with all types of patients, even younger, healthier patients and maternity patients (Baker & Quinn, 2018). Therefore, hospital leadership should prioritize efforts to prevent NV-HAP and serious preventable harm and death in hospitalized patients in the United States.
What we know about NV-HAP

- One in every four hospital-acquired infection is pneumonia, the majority (60%) are non-ventilator hospital-acquired pneumonia (NV-HAP) (Magill et al. 2018).
- Associated mortality from NV-HAP ranges from 15 to 30%, far exceeding other hospital-acquired infections’ mortality rates (Davis & Finley, 2012; Micek, Chew, Hampton, & Kollef, 2016; Quinn, et al., 2014; Baker & Quinn, 2018; Giuliano, Baker, & Quinn, 2018).
- Patients who develop NV-HAP are over 8 times more likely to die than their equally matched controls who do not develop NV-HAP (Micek et al., 2016).
- Pneumonia risk can be minimized through preventive measures. (Baker et al. 2019).
- Patients who develop NV-HAP require longer hospital care days often including intensive care. The average length of stay is up to 4 times longer than patients without NV-HAP (Micek et al. 2016; Thompson, Makary, Dorman, & Pronovost, 2006).
- The patient who acquires NV-HAP may require mechanical ventilation and large amounts of broad-spectrum antibiotics. Serious side effects of antibiotics including clostridium difficile and antibiotic resistance may occur.
- Younger patients (<65 years of age) constitute half of all hospital-acquired pneumonia cases, most of which originate outside of the ICU. Hospital-acquired pneumonia has long been associated with the elderly and intensive care units (ICU). But according to a new multicenter nationwide study, NV-HAP occurs across all units in all types of sizes of U.S. hospitals, putting every patient, the young included, at higher risk for developing the infection. (Baker & Quinn, 2018).
- Pneumonia risk can be minimized through preventive measures. Researchers found basic pneumonia prevention measures were not consistently followed; 58.6 percent of patients diagnosed with NV-HAP did not receive oral care; 81.8 percent did not receive incentive spirometry; 67.4 percent did not undergo cough and deep breathing exercises and only 28.7 percent of patients ambulate at least twice in the 24-hours prior to their pneumonia diagnosis. (Baker & Quinn, 2018).

Background and Significance

- Over the past decade, hospital-based quality improvement initiatives have been focused primarily on the prevention of ventilator-associated pneumonia (VAP), resulting in significant decreases in reported cases of VAP (DiBiase et al., 2014). With the reduction in VAP, NV-HAP now has a larger overall impact on patient morbidity, mortality, and cost of care than VAP (Davis and Finley, 2012; Micek, Chew, Hampton, and Kollef, 2016; Giuliano, Baker and Quinn, 2018).

Current data published by the CDC in 2018 now supports HAP as the leading hospital-acquired infection (HAI), with NV-HAP representing at least 60% of the cases (Magill et al., 2018). Review of 2012 data from Pennsylvania Safety Authority supported that NV-HAP occurs on all types of hospital units and had a higher impact on both cost and mortality than VAP (Davis and Finley, 2012). This study was replicated in 2018 with similar findings (Davis and Finley, 2018). The CDC and Pennsylvania studies demonstrate that patient harm from NV-HAP has persisted over time and that little has been done to reduce the incidence.

Analysis of the 2012 National Inpatient Sample dataset demonstrates a NV-HAP incidence of 16...
% a rate of 3.63 per 1,000 patient days, associated mortality of 13.1%, and an actual hospital cost of care of $39,897 (Giuliano, Baker, and Quinn, 2018). When matched with equally sick controls, NV-HAP had an associated mortality of 15.5% vs. 1.6% in the matched cases (Micek, Chew, Hampton, and Kollef, 2016). An international review of the literature found that most HAP occurs outside of the ICU, and requires monitoring and protocols that vary from standard VAP prevention (Di Pasquale et al., 2016). An associated mortality rate of 30% among NV-HAP patients was found by See and colleagues (2016), far exceeding the associated mortality from other iatrogenic harm.

A review of hospitals in Spain found a 28% NV-HAP mortality rate (Sopena et al., 2014). In patients with spinal injury, Kopp found that 47% suffered consequences of NV-HAP and were more likely to die, even 10 years after hospitalization (Kopp et al., 2017). Finally, researchers studying NV-HAP in 21 US hospitals found rates of 0.12-2.28 per 1,000 patient days (1,300 NV-HAP patients). Most NV-HAP infections (70.8%) were acquired outside of the ICU and 18.8% required an unplanned transfer into the ICU (Baker and Quinn, 2018). NV-HAP is a leading cause of healthcare acquired infection in the US, which the CDC already recognized as a top 10 public health concern. Michael Klompas, a leading pneumonia researcher, refers to NV-HAP as the “next frontier in patient safety” (Klompas, 2016).

**Etiology of NV-HAP**

Pneumonia occurs when bacteria move from proximal sites, such as the oral microbiota, into the lung and incite an inflammatory response (Gomes-Filho, Passos, Seixas da Cruz, 2010; Scannapieco, 2013; Scannapieco and Shay, 2014). Researchers have found a critical relationship between oral microflora and HAP (Di Pasquale et al., 2016; Sopena et al., 2014; Scannapieco and Shay, 2014). While HAP can be associated with multiple types of organisms, it is primarily caused by bacteria and viral organisms (Micek, et al., 2016). For example, bacteria found in patients with HAP have been matched with specific flora found in the oral cavity (Gleeson, Maxwell, and Eggli, 1997; Huxley, Viroslov, Gray, and Pierce, 1978; Didilescu, Skaug, Marica, Didilescu, 2005).

During the first 48 hours of hospitalization, especially in the absence of regular oral care, changes occur in an individual’s oral microbiota that are associated with more virulent pneumonia-causing organisms (Abele-Horn, et al., 1997). Respiratory pathogens such as S. aureus, P. aeruginosa, Klebsiella pneumoniae, and Enterobacter cloacae colonize the dental plaque and micro-aspirations contribute to inoculation of virulent organisms into the lungs, even in healthy adults (Gleeson, et al., 1997; Huxley, et al., 1978; Didilescu, et al., 2005). Recognition of this relationship between the oral microbiota and HAP has led to a growing evidence which targets primary source control of HAP through removal of the oral biofilm.

**Prevention Quality Improvement Projects**

Prevention of NV-HAP is a patient safety concern that workgroups have been working on for several years. Provided here are some representative examples of Hospital-acquired pneumonia prevention initiative (HAPPI) successes. In many cases, this success has been led by nurses with integral involvement of the interdisciplinary team (infection prevention, nursing assistants, respiratory therapists, speech-language therapists, physicians, nursing and hospital management, informatics, and supply chain).

**Sutter Health System**

Specialists at Sutter Health launched a study to explore an oral care intervention that would
help prevent hospital-acquired pneumonia. Under the leadership of Barbara Quinn CNS, RN, Director of Professional Excellence and Nursing Practice for Sutter Health System, a hospital pneumonia prevention effort was launched. The focus was on oral biofilm removal through oral care.

Compared to a 2010-2011 baseline, hospital-acquired pneumonia cases declined by 70% from May 2012 through December 2014 (Baker et al. 2019). Results sustained over a 4-year period saved lives and millions in healthcare expenditures (Quinn et al., 2014; Baker & Quinn, 2018).

Statistical process control R and X-bar-charts demonstrate a significant improvement in the number of NV-HAP following each of the intervention periods. Control limits were calculated from the baseline data. Data starting in July 2013 indicates special cause with all the subsequent points below that mean (15.89). The control chart demonstrates 4 operating modes with each phase operating below the baseline mean. Oral care improved from .25 per day to 2.89 times per day (Figure: Statistical process control R and X-bar-charts: International Statistical Classification of Diseases and Related Health Problems (ICD) codes (3 standard deviations).

More information can be found in the reference page below (Baker, Quinn, Ewan, & Giuliano, 2018; Baker & Quinn, 2018; Lagnado, 2018; Quinn & Baker, 2015; Quinn, Baker, Cohen, Stewart, Lima, & Parise, 2014).

The United State’s largest integrated health care system, the Veterans Health Administration (VHA)

The VHA, manages the care of over 8 million Veterans across 153 medical centers. A team at the Salem VA Medical Center (VAMC) led by Shannon Munro, PhD, NP partnered with the HAPPI research team, examined over 12 years of retrospective and prospective data, and found that an oral care regimen significantly reduces the risk of developing NV-HAP, thus shortening hospital stays, reducing direct health care costs, lowering the need for a higher level of care (e.g. intensive care and discharge to long term care), and saving lives.

At the first VA pilot site, the community living center (CLC) units at Salem VAMC, the incidence rate of NV-HAP decreased from 105 cases to 8.3 cases per 1,000 patient days (decreased NV-HAP by 92%) in the first year, yielding an estimated cost avoidance of $1.76 million and 8 lives saved.

The population of the CLC units is primarily composed of elderly Veterans with complicated chronic health problems requiring rehabilitation and long-term care. Veterans on the CLC units were 10.7 times less likely to develop NV-HAP with consistent oral care than patients receiving standard nursing care. The Houston VAMC replicated the practice in 2017 and reduced the rate of NV-HAP in the coronary care unit and step-down unit (165 admissions per month) from 11 cases to 0 cases per 1,000 patient days and saved an estimated hospital cost of $480,000 and two patient lives in six months.

These successful outcomes at the original VA pilot sites led to funding from the VHA Diffusion of Excellence Initiative, VHA Quality Enhancement Research Initiative (QUERI), VHA Office of Strategic Integration, and the Veterans Engineering Resource center to support continued expansion efforts as quality improvement. Across all reporting units in 8 VA hospitals in Virginia, North Carolina, and Texas, a predicted 255 cases were avoided as of July 31, 2019. Should we extrapolate the data, there is a cost avoidance estimate of $10.1M and 46 Veteran lives saved. Nationwide VA deployment is underway in 41 VA hospitals including 122 medical-surgical, ICU, CLC, and mental health units.
The VA established a national Hospital-acquired Pneumonia Prevention by Engaging Nurses (HAPPEN) program and VHA oral care implementation toolkit under the leadership of Dr. Munro. The HAPPEN toolkit is freely available for download here: [http://patient.sm/KuxQkF](http://patient.sm/KuxQkF)

Implementing the inpatient oral care practice ensures all hospitalized Veterans receive oral care by:

- VHA’s patient education materials: [http://patient.sm/N439Tx](http://patient.sm/N439Tx)
- Aetna’s Informational Toolkits

**Sparrow Hospital (Lansing, Michigan)**

With two rounds of grant funding from Delta Dental of Michigan, Sparrow Hospitals developed a nurse-driven oral care protocol (NDOCP) using HAPPI protocol. Variables included age, hospital length of stay, white blood cell count at pneumonia diagnosis, admission type, sex, mortality and presence of confusion for patients with NV-HAP in both the pre and intervention groups, along with compliance to the NDOCP and the incidence NV-HAP.

There were significantly more NV-HAP cases pre-NDOCP than post-NDOCP (95% CI p < .05; pre-52 versus post-26, X²=12.8[df=1], p=.0004). NV-HAP rates were 2.84 per 1,000 discharges (pre- NDOCP) and 1.41 per 1,000 discharges (post-NDOCP). ([Warren et al. 2019)](http://patient.sm/KuxQkF)

**Aetna Insurance**

Sutter Hospital Systems, Kaiser Permanente, and others are not alone in exploring the potential of oral care to prevent pneumonia. Aetna Insurance has also realized that “Oral hygiene is a weapon against infection” their outreach infection prevention strategy Rush to Brush in collaboration with Johnson and Johnson and Colgate Palmolive, empowers their beneficiaries. They provided 36,000 pre-surgical patients with informational toolkits including toothbrush and toothpaste, and mouthwash packaged in a travel pouch prior to their upcoming hospital stay. Aetna reported a 30% reduction in NVHAP cases for patients who received the oral care kits compared to a sample of patients who did not receive the kits. Aetna Rush to Brush Results

**Leadership plan**

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce hospital acquired pneumonia. To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions:

- Show leadership’s commitment to reducing pneumonia
- Hospital governance and senior administrative leadership must commit to becoming aware of major performance gaps in their own organization.
- Hospital governance, senior administrative leadership, clinical/safety leadership must close their own performance gaps by implementing a comprehensive approach.
- Healthcare leadership must reinforce their commitment by: Taking an active role in championing process improvement
  - Giving their time, attention, and focus
  - Removing barriers
Leadership must demonstrate their commitment and support by
- Shaping a vision of the future
- Clearly defining goal
- Supporting staff as they work through improvement initiatives
- Measuring results
- Communication progress towards goals.

**Action plan**

In order to improve NV-HAP rates in your facility the following toolkits are freely available.

1. HAPPI: [http://patient.sm/Vc0gu7](http://patient.sm/Vc0gu7)
2. HAPPEN Toolkit:
   Contact VAHAPPEN@va.gov for information about VA resources including the HAPPEN toolkit. Read more: [https://patient.sm/zJ02io](https://patient.sm/zJ02io)
3. Mouth Care Matters- Improving Oral Care in the UK: [http://patient.sm/C774Ki](http://patient.sm/C774Ki)
   The Mouth Care Matters programme aims to create a healthcare team that is more responsive and personalised for patients and deliver better clinical outcomes, bringing an increased awareness of the importance of good mouth care and how it impacts on general health and quality of life. The initiative is relevant for all people who provide personal care to patients in an acute, care home or community setting. This website is the “hub” for access to all of the training materials, posters, documentation and access to training. We hope that you wish to engage with us on our project, and that you find the materials and links on this website of great value. (cited directly from the Mouth Care Matters web site Mouth Care Matters UK)

**Technology plan**

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: [patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/](http://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/)

Because there are currently no mandates that require hospitals to address NV-HAP, most hospitals do not have electronic health records or data collection to collect process and outcomes measures related to NV-HAP

Consider implementing the following technologies to address NV-HAP in your organization:

<table>
<thead>
<tr>
<th>System or Practice</th>
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<tbody>
<tr>
<td><strong>ONC Meaningful Use Certified EHR system</strong></td>
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<tr>
<td>Electronic Health Record (EHR) System with the following capabilities:</td>
</tr>
<tr>
<td>• Computerized Provider Order Entry (CPOE)</td>
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<td>• Drug-drug interaction check</td>
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<td>• Drug-allergy interaction check</td>
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<tr>
<td>• Clinical Decision Support tools (CDS)</td>
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</table>
Suction Equipment

Information Technology (IT) Systems

- IT is essential to ensure that easy-to-use screens are available for staff to record appropriate interventions (such as type and frequency of oral care, mobility, etc.) from the first launch of the quality improvement project.

Implement Electronic Measurement of Hand Hygiene Compliance (See APPS #2A to learn more)

<table>
<thead>
<tr>
<th>Data Collection Tools</th>
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<tbody>
<tr>
<td>Oral Care Audit Tracker</td>
</tr>
<tr>
<td>NV-HAP Incidence Calculator</td>
</tr>
<tr>
<td>Patient Experience Survey (quality improvement, optional)</td>
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</tbody>
</table>

*Data Collection Tools from the Department of Veterans Affairs only available for individuals who have VA credentials*

**Measuring outcomes**

When considering outcome measures to monitor the success of NV-HAP quality improvement projects, four key factors are helpful to consider:

1. Measure pre-post process measures selected by the implementation committee. For example, type and frequency of oral care and type of mobility.
2. Clearly define cases of NV-HAP. General administrative data (ICD-10) and the CDC
definition (included in the HAPPI toolkit) can be used (See et al. 2016). However, hospitals may set their own definition and data extraction systems provided the definition is consistently applied in pre/post data collection.

3. Collect the pre-post incidence of NV-HAP, patient sociodemographics, units of NV-HAP occurrence, fiscal impact, and discharge disposition as a minimum data set. Hospitals may want to collect more details to guide further interventions.

4. Compare the process implementation data with the outcome data (incidence of NV-HAP)

**Conflicts of interest disclosure**

Baker and Quinn received initial funding for their work (2014) on NV-HAP from Sage Products LLC/ now Stryker. Baker has served as a consultant to Sunstar GUM, an oral care company.

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</table>
Executive summary checklist

Medication errors are major causes of patient harm and death. Medication errors are preventable adverse events resulting from, but not limited to:

- Wrong medication
- Wrong dose
- Wrong route
- Wrong time
- Wrong patient
- Wrong documentation of medication

Ensure best patient care

☐ Create a multidisciplinary team to lead the project, including physicians, nurses, pharmacists, and information technology personnel

☐ Use systematic protocols for medication administration, including checklists for writing and filling prescriptions, drug administration and patient transitions of care, and other quality assurance tools including:

  ☐ Install the latest safety technology to prevent medication errors, such as:
    - Medication Management System
    - A drug library system
    - Other drug dosing solutions such as a solution for calculating IV & SubQ insulin doses
  ☐ Use barcoding for identification in the medication administration process
  ☐ Check patient’s allergy profile before prescribing medication
  ☐ Ensure appropriate training and safe operation of automated infusion technologies
  ☐ Distinguish “look-alike, sound-alike” medications by appropriate labeling, package design, and storage
  ☐ Practice the Six Patient Rights on Medications - all care providers should use this simple checklist: right patient, drug, dose, route, time of administration, and documentation
  ☐ Follow practices to prevent medication errors during transitions of care

Engage staff and use data to find areas for improvement

☐ Use technology to standardize Computerized Provider Order Entry (CPOE), reporting systems and quality assurance reports to audit compliance

☐ Use Clinical Decision Support (CDS) systems where possible (Kane-Gill et al., 2017)

☐ Review monitoring and reporting results at medical staff meetings and education sessions as a part of Continuous Quality Improvement (CQI)

☐ Use patient stories - in written and video form - to identify gaps and inspire change in your staff
What we know about medication errors

Medication errors are a major cause of death. One out of every 2 surgeries has a medication error or an adverse drug event (Nanji et al., 2016). These errors have a global cost of about $42 billion a year (Donaldson et al., 2017).

Preventing medication errors can improve the quality and safety of healthcare and lower costs. It also helps create a safety culture, which is a culture that promotes patient safety and quality of care while reducing preventable risks and harm.

Some types of medication errors are more common or severe. For example:

- Drug infusion pump errors are common and may have serious consequences. Drug infusion pumps are complex and have poorly designed features for the user, which make it difficult for the user to program and use. Patients who get infused medications are often critically ill and taking multiple medications, which further increases the risk of error and adverse events.
- Surgery has high rates of medication errors with a higher severity level (National Quality Forum, 2010). This is due to a high-stress environment and lack of computerized order entry, pharmacy approval processes, or second check by another person prior to giving the medicine.

Preventing medication errors

To reduce medication errors, there are a variety of new approaches that hospitals and healthcare systems can commit to using, such as automated infusion and IV injectable technologies, electronic medical records, and checklists.

Leadership plan

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce medication errors.

Show leadership’s commitment

- Create a medication safety plan that follows the National Quality Forum (NQF) safe practices (National Quality Forum, 2010)
- Educate and empower patients, healthcare professionals, researchers, and insurers
  - Provide information so that leadership and all healthcare professionals fully understand the performance gaps in their own area of care
  - Make sure all clinical/safety leadership endorse the plan to ensure it’s put into place across all providers and systems

Create the infrastructure needed to make changes

- Identify approaches to medication safety that:
  - Have strong evidence that they work to reduce preventable deaths
  - Can be applied in multiple care settings and for multiple patient types
- Set a firm date to begin the safety plan, with measurable outcomes and milestones - “Some is not a number. Soon is not a time.” (Institute for Healthcare Improvement, n.d.)
- Get approval for the plan’s budget from governance boards and leadership
- Use a standardized feedback system to fine-tune the plan over time
Engage staff
• Use patient stories – in written and video form – to teach and inspire change in your staff
• For example, the story of Emily Jerry, daughter of Chris Jerry, is one of many compelling stories that can be viewed and shared for free:
  http://patient.sm/oemrzL
• Preventing Medication Errors video: http://patient.sm/Dtiyi3

Action plan

Provide staff training
• Create a multidisciplinary team that includes physicians, nurses, pharmacists, and information technology personnel
• Assess opportunities to reduce medication errors using a self-assessment process (ISMP Medication Safety Self Assessment for Hospitals, 2011)
• Create and deliver monthly or quarterly education on medication error and patient safety updates

Create protocols
• Create a universal checklist for medication administration that includes:
  o Patient name
  o List of patient’s current medicines
  o Medication to be given and its:
    • Dose
    • Route
    • Timing
    • Documentation
• Systematize tools and practices, including checklists, for:
  o Patient allergy and medication interaction checks on every patient
  o CPOE (Computerized Provider Order Entry)
  o Medication barcoding
  o Patient education and adherence
  o Correct and on-time medication administration (Acute Care Guidelines for Timely Administration of Scheduled Medications, 2011)
• Practice hand hygiene when giving medication as tablets, capsules, and pills by hand, such as wearing gloves instead of using bare hands
• Use standardized order sets where possible
• Review medication labels and redesign as needed (Practices, n.d.)
• Prepare medication in separate, designated rooms to lower interruptions (Huckels-Baumgart et al., 2016)

Follow guidelines and regulations
• Follow the Institute for Safe Medication Processes (ISMP) guidelines for
  o Training and safe use of intravenous infusion pumps
  o Use of medication dispensing cabinets (ISMP, 2011)
Ensure safety during transitions of care

- Consider the following high-risk medication groups:
  1. Opioids
     a. Consider all pain medications over-the-counter (OTC), that can put patients into respiratory depression because of additive somnolence effects
     b. Concern for exceeding the recommended daily maximum dose of acetaminophen
  2. Anti-diabetics (See APSS #3C for more information)
     a. Prior to initiating or resuming metformin, confirm kidney function is appropriate
     b. Adjust insulin based on food intake
  3. Anticoagulation/Antiplatelet
     a. Check and monitor INR levels, renal function, OTC medication use (i.e., NSAIDs)
  4. Antibiotics (see APSS #3B)
     a. Determine appropriate duration of therapy for the infection
     b. Ensure pertinent labs are ordered (i.e., vancomycin and aminoglycoside concentrations)
     c. Obtain a thorough antibiotic history within the past 3 months

- Coordinate appropriate follow up and monitoring, such as:
  o Labs: INR, digoxin levels, electrolytes, blood sugar, antibiotic concentrations, thyroid levels
  o Chronic disease state management, such as heart failure, diabetes, asthma and COPD

- Confirm medication dose for any changes in health status, including changes in:
  o Weight
  o Renal and liver function
  o Functions that could affect the patient's ability to take medications by mouth, injection, or inhalation routes

- Confirm needed medical equipment is ordered, such as a nebulizer, diabetic supplies, and IV antibiotic

- Evaluate for high risk disease states
  o Check patient's compliance with core measures and immunizations when appropriate (Stroke, MI, Heart Failure)
  o Ensure patients receive and are educated on scheduled vaccines (influenza, pneumonia, etc)
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider:

https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

<table>
<thead>
<tr>
<th>System or practice</th>
<th>Available technology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All settings</strong></td>
<td></td>
</tr>
<tr>
<td>ONC Meaningful Use Certified Electronic Health Record (EHR) System with the following capabilities:</td>
<td></td>
</tr>
<tr>
<td>• Computerized Provider Order Entry (CPOE)</td>
<td></td>
</tr>
<tr>
<td>• Drug-drug interaction check</td>
<td></td>
</tr>
<tr>
<td>• Drug-allergy interaction check</td>
<td></td>
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<tr>
<td>• Electronic Prescribing (eRx)</td>
<td></td>
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<tr>
<td>• Electronic Prior Authorization (ePA)</td>
<td></td>
</tr>
<tr>
<td>Electronic Medication Administration Record (eMAR) system with pharmacy and bedside barcoding capabilities</td>
<td></td>
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<tr>
<td>FDA approved clinical decision support solution for medication therapy recommendation</td>
<td></td>
</tr>
<tr>
<td>Infusion pumps that wirelessly communicate data back to the electronic eMAR</td>
<td></td>
</tr>
<tr>
<td>Patient and medication barcoding system</td>
<td></td>
</tr>
<tr>
<td>CPOE simulation tool to quantify the risk of serious adverse drug events (ADEs) with your facility’s current CPOE system (Metzger et al., 2010; Leung et al., 2013)</td>
<td></td>
</tr>
<tr>
<td>Drug libraries</td>
<td></td>
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<tr>
<td>Pharmacy workflow manager</td>
<td></td>
</tr>
</tbody>
</table>
**Surgery environment**

| | IV injectable doses, audible and visual feedback for each syringe attached with measurement of dose, allergy alerts and more accurate and timely wireless documentation to the anesthesia information system |
| | Continuous physiologic monitoring on patients receiving IV medications to provide an early indication of deterioration due to a medication error |

**Pharmacy**

| | Pharmacy robots to reduce safety problems associated with providers drawing up their own medications, and risks associated with contamination from outsourced compounders |
| | Utilize single use injection kits or pre-mixed sterile solutions |

**Other considerations**

| “End-to-end” smart pump system for IV medication infusions |

---

**Measuring outcomes**

**Key performance indicators**

**Adverse drug event:** Adverse drug event (ADE) with harm to patient (Category E or higher on NCC-MERP classification) that is preventable (i.e., not an unknown first-time reaction to a medication).

**Outcome measure formula**

**Numerator:** Number of reported adverse drug events with harm, as defined above, (by class or medication)

**Denominator:** Number of doses administered (by medication or class of medication)

*Rate is typically displayed as ADE with harm/1000 doses given*

**Metric recommendations**

**Indirect impact (preventable rate):** All patients

**Direct impact (non-preventable rate):** All patients prescribed medications
Lives spared harm:
Lives Spared Harm = (ADE Rate baseline - ADE Rate measurement) \times (Doses or Adjusted Patient Days at baseline)

Lives saved:
Lives Saved = (Lives Spared Harm) \times (Mortality Rate)

Notes
Top medication classes and triggers:
1. Opioids
2. Sedatives and hypnotics (including propofol)
3. Anticoagulants
4. Antimicrobials (including antivirals and antifungals)
5. Anti-diabetic medicines (including insulin, and other injectable and oral medications)
6. Injectable medications

Initial or baseline measurement will show ability to capture ADE information, since most are voluntarily reported. Over time, decreases in this rate can show lives spared harm. To ensure that reductions are not due to decreased reporting, a control measure should also be measured:

Control rate calculation
**Numerator:** Number of ALL reported errors and adverse drug reactions (including harm and NOT causing harm or “near misses”)

**Denominator:** Number of doses administered over a time period

Control ADE rate should be consistent or increase with corresponding decrease in ADE with harm.

Data collection
ADE reporting information is based on volunteer reporting and accuracy of people verifying reports, (preferably from pharmacy the medication error reporting and prevention (MERP) program

Medication usage information is usually collected from billing information rather than medication orders (more accurate if patient received the dose or not).

If medication usage information is not available, the denominator could be per 1000 patient days. This can track over time, especially for all ADE reporting, however, will not adjust ADE rate for high or low utilization medications.

Scales
- The Adverse Drug Reaction Probability Scale (Naranjo) determines the causality of an ADR or how likely is the drug the true cause of the ADE (Adverse Drug Reaction Probability Scale (Naranjo) in Drug Induced Liver Injury, n.d.)

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 Patients (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 to track national progress in patient safety—both in general and specifically related to the preventable HACs being addressed by the PfP. Along 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 (AHRQ, 2015). Adverse drug events were included in this work with published metric specifications. This is the most current and comprehensive study to date.

Based on these data the estimated additional inpatient mortality for ADEs is 0.020 (20 per 1000 events).

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, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs
Christopher Jerry  
The Emily Jerry Foundation
Ron Jordan  
Chapman University School of Pharmacy
Jerika Lam  
Chapman University School of Pharmacy

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Hania Alim  
Patient Safety Movement Foundation
Peter Antevy  
Handtevy
Steven Barker  
Patient Safety Movement Foundation;Masimo
*Linda Beneze  
Monarch Medical Technologies
Michel Bennett  
Patient Safety Movement Foundation (formerly)
Laressa Bethishou  
Chapman University School of Pharmacy
Jim Broselow  
eBroselow
John Burnam  
Louise H. Batz Patient Safety Foundation
Mitchell Goldstein  
Loma Linda Medical Center
Kari Hamlin  
Hackensack Medical Center

Helen Haskell  
Mothers Against Medical Error

Soojin Jun  
Quorum Health

Edwin Loftin  
Parrish Medical Center

Ariana Longley  
Patient Safety Movement Foundation

Olivia Lounsbury  
Patient Safety Movement Foundation

Jacob Lopez  
Patient Safety Movement Foundation (formerly)

Anne Lyren  
Children’s Hospitals’ Solutions for Patient Safety

Brendan Miney  
Talis Clinical

Sidney Morice  
Lee Health

Lisa Morrise  
Consumers Advancing Patient Safety

Steve Mullenix  
National Council for Prescription Drug Programs

*Flannery Nangle  
Monarch Medical Technologies

Robert Nickell  
Enovachem

Deborah Pasko  
American Social of Health-System Pharmacists

Donna Prosser  
Patient Safety Movement Foundation

Talia Puzantian  
Keck Graduate Institute

Judith Reiss  
Advocate

Claire Roy  
Patient Safety Movement Foundation

Rochelle Sandell  
Patient Advocate

Enrique Seoane-Vasquez  
Chapman University School of Pharmacy

Alex Shaffer  
Advocate

David Shane Lowry  
Rosalind Franklin University of Medicine and Science

Robin Shannon  
The T System

Deeba Siddiqui  
Hackensack Medical Center

Charles Simmons  
Cedars-Sinai Medical Center

Nat Sims  
Massachusetts General Hospital

Robert Stein  
Keck Graduate Institute

Laura Townsend  
Louise H. Batz Patient Safety Foundation

Kimberly Won  
Chapman University School of Pharmacy

Jason Yamaki  
Chapman University School of Pharmacy

Sun Yang  
Chapman University School of Pharmacy

Metrics integrity

Robin Betts  
Kaiser Permanente, Northern California Region
*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

References


ISMP. Proceedings from the ISMP Summit on the Use of Smart Infusion Pumps: Guidelines for Safe Implementation and Use.


# How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for antimicrobial stewardship. In it, you’ll find:

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<td>References</td>
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APSS #3B: Antimicrobial stewardship

Executive summary checklist
Antimicrobial stewardship is efforts to promote the appropriate use of antimicrobials, including antibiotics, to prevent:

- Spread of infections
- Adverse reaction and adverse drug events
- Superinfections
- Infections that are resistant to antimicrobials
- Poor clinical outcomes

Create an action plan
- Assure commitment from institutional leadership (administration, medicine, pharmacy, nursing, microbiology, and technology) to create and support an Antimicrobial Stewardship Program (ASP)
- Create a multidisciplinary Antimicrobial Stewardship Committee that includes representatives from infectious diseases, pharmacy, infection prevention, information technology, microbiology, nursing, medicine, and surgery.
- Create ways to educate clinicians regarding ASP initiatives and progress
- Have a nurse or pharmacist review allergy history
- Have a pharmacist review all antimicrobial orders.

Engage staff and use data to find areas for improvement
- Identify and educate clinicians with outlying prescribing patterns
- Monitor progress and include the results in staff education
- Use Computerized Provider Order Entry (CPOE) with Clinical Decision Support (CDS) and computer-based surveillance software to provide real-time data at the point of care for ASP initiatives
- Review all antimicrobial orders by a hospital pharmacist, including a review of allergy profiles
- Use practices to reduce medication errors during Transitions of Care
- Use patient stories – in written and video form – to teach and inspire change in your staff
What we know about antimicrobial stewardship

Appropriate use of antimicrobials is a key part of patient safety. Inappropriate use of antimicrobials can have these unwanted effects:

- The pathogen (germ causing infection and disease) becomes resistant to antimicrobials and spreads within the healthcare system and into the community
- The patient may have adverse reactions, superinfections, selection of resistant pathogens, and poor clinical outcomes

Antimicrobials are the only medications where use in one patient can affect how well that medication works in another patient. Contrary to common belief, antimicrobials are not harmless medications. In fact, studies have found antimicrobial use leads to poor outcomes, including:

- 21.6% of adverse drug events (AHRQ, 2018; Shehab et al., 2016)
- 19% of emergency department visits, with most from allergic reactions (2004-2006)
- 3 times higher risks for adverse events than for aspirin, phenytoin, and clopidogrel (Shehab, Patel, Srinivasan and Budnitz, 2008)
- *Clostridioides difficile* (*C. difficile*) colitis, an infection with a high risk of readmission and death

The appropriate use of antimicrobials helps create a safety culture, which is a culture that promotes patient safety and quality of care while reducing preventable risks and harm.

Practicing antimicrobial stewardship

A hospital can create an Antimicrobial Stewardship Program (ASP) committee to align with these standards and recommendations:

- In 2014, the Centers for Disease Control and Prevention (CDC) recommended that all acute care hospitals create Antibiotic Stewardship Programs
- In September 2014, California Governor Jerry Brown approved Senate Bill 1311 that requires all general acute care hospitals in California to create a physician supervised multidisciplinary Antimicrobial Stewardship committee by July 1, 2015 (California Legislative Information, 2014)
- In January 2017, the Joint Commission’s new Medication Management Standard on Antimicrobial Stewardship requires hospitals and critical access hospitals to have an antimicrobial stewardship program in place
- The Centers for Medicare and Medicaid Services will require facilities participating in Medicare and Medicaid to have formal ASPs in place

A successful ASP committee includes the following members:

- Infectious diseases (ID)-trained physician
- Pharmacist, who is preferably ID-trained
- Infection control personnel
- Information technology personnel
- Quality improvement personnel
- Nursing
- Microbiology
- Committed leadership

The goals of the ASP committee are:

- Decrease inappropriate use of antimicrobials and optimize therapy
• Identify and reduce risks of developing, acquiring, and transmitting infections
• Reduce healthcare costs and toxicities with antimicrobials and inappropriate therapy
• Prevent adverse drug events related to antimicrobials
• Improve patient outcomes, such as reduced *C. difficile* rates and reduced hospital length of stay (LOS)

**Leadership plan**

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively for antimicrobial stewardship.

**Show leadership’s commitment to antimicrobial stewardship**

- Make formal statements from administrative level about:
  - Goals of the ASP
  - Support of the ASP
  - Best use of antimicrobials within the hospital
  - Progress of the ASP
- Show support from the senior administration
- Provide financial support

**Create the infrastructure needed to make changes**

- Create the needed system for tracking and measuring antimicrobial use and outcomes
- Follow CDC recommendations on core elements for hospital ASPs:
  - Commitment from institutional leadership (technology, personnel, finance)
  - Accountability of ASP chair or co-chairs
  - A clinician with drug expertise in antimicrobials (e.g., clinical pharmacist with ID training and/or expertise)
  - Actionable program components (e.g., prospective audit, automatic discontinuation orders)
  - Microbial resistance and infection patterns monitoring
  - Reports of and education about ASP findings to hospital staff (physicians, nurses, pharmacists, etc.)

**Engage staff**

- Protect and approve time for hospital personnel from various departments to take part in the ASP
- Train and support hospital personnel
- Use patient stories – in written and video form – to identify gaps and inspire change in your staff

**Action plan**

**Create an Antimicrobial Stewardship Program (ASP)**

- Create a multidisciplinary team that includes:
- ID-trained physician
- ID-trained or clinical pharmacist
- Information technologists (CDC, 2015)
- Nurse

- Choose the type of ASP based on your hospital size, type, and resources:
  - Restriction of antimicrobial utilization based on ASP
  - Prospective audit with feedback to ASP
  - A combination of both

This table shows the types of ASP committees and their pros and cons:

<table>
<thead>
<tr>
<th>Restrictive program ASP</th>
<th>Prospective audit with feedback ASP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is it?</strong>&lt;br&gt;In this program, select antimicrobials are put on formulary restriction for use in only select indications. To dispense a restricted antimicrobial, designated personnel usually an ID physician, ID fellow, or clinical pharmacist would need to approve in order to be dispensed. Some institutions allow a 24 hour time frame for a restricted antimicrobial to be ordered and dispensed after which an ID consult is required to continue the restricted antimicrobial.</td>
<td>In this program, a prospective (hours to days) review of antimicrobial orders takes place for targeted, and in some institutions, non-targeted antimicrobials for appropriateness. If an opportunity is found, the prescriber is contacted and the case discussed. This also allows for feedback to the prescribers, which may affect their prescribing patterns in the future. It is also common to find programs that use a hybrid approach in which audit and feedback are employed along with a restricted formulary.</td>
</tr>
<tr>
<td><strong>Pros</strong>&lt;br&gt;• Offers direct oversight in the use of restricted antimicrobials&lt;br&gt;• Reduces pathogen resistance within the hospital and communities&lt;br&gt;• Reduces hospital LOS&lt;br&gt;• Reduces risks of antimicrobial-related side effects and drug-drug interactions</td>
<td>• Avoids loss of autonomy&lt;br&gt;• Offers the chance to educate prescribers rather than restrict antimicrobial use.&lt;br&gt;• Reduces pathogen resistance within the hospital and community&lt;br&gt;• Many programs will review all antimicrobial antibiotic orders for appropriateness and therapy optimization</td>
</tr>
<tr>
<td>Cons</td>
<td>Compliance is often voluntary (Dellit, 2007)</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------</td>
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<tr>
<td></td>
<td>Requires personnel dedicated to the ASP - most academic and medium- to-large community hospitals have personnel, but smaller hospitals may not have dedicated personnel available</td>
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<tr>
<td></td>
<td>Requires personnel to be available around-the-clock</td>
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<td>Physicians may see this as a loss of autonomy</td>
</tr>
<tr>
<td></td>
<td>Review of appropriateness only occurs with restricted agent, but not for unrestricted agents which can also lead to problems (Dellit, 2007; Goff et al., 2012)</td>
</tr>
</tbody>
</table>
Create pharmacy driven protocols

<table>
<thead>
<tr>
<th>Pharmacy intervention</th>
<th>Rationale</th>
<th>Minimal resources required</th>
<th>Dedicated resources required</th>
</tr>
</thead>
</table>
| Protocols for changes from intravenous (IV) to oral (PO) antibiotic therapy in appropriate situations | • Decrease cost  
• Decrease hospital LOS  
• Reduce line infections | Pharmacist | Clinical stability criteria for IV to PO conversion:  
• Able to tolerate orals  
• Afebrile  
• Stable heart rate  
• Stable respiratory rate  
• Systolic blood pressure >90 mmHg  
• O₂ saturation >90% (O₂ partial pressure >60 mmHg)  
• Functional GI  
• Normal mental status  
• Lab results received identifying pathogen |
| Antimicrobial dosage adjustments in case of organ dysfunction | • Avoid toxicities | Pharmacist |
| Dose optimization [pharmacokinetics (PK)/pharmacodynamics (PD)] to treat pathogens with reduced susceptibility and sensitivity | • Avoid toxicities  
• Optimize PK/PD  
• Improve patient outcomes |  |
| Automatic alerts where therapy might not be needed | • Avoid toxicities  
• Decrease costs | IT |
| Time-sensitive automatic stop orders for specific antimicrobial prescriptions | • Decrease cost  
• Decrease unnecessary antimicrobial use  
• Decrease resistance | IT |
<table>
<thead>
<tr>
<th>Start necessary treatment for patients who should be receiving antimicrobials</th>
<th>The delay of an active antimicrobial increases mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Institution specific ASP guidelines</strong></td>
<td>• Based on antimicrobial resistance patterns at your institution • Align with ASP initiatives • Provide a resource</td>
</tr>
<tr>
<td><strong>Implementation of extended infusion beta-lactams (e.g., piperacillin/tazobactam)</strong></td>
<td>• Maximizes the pharmacodynamic parameter of time above the minimum inhibitory concentration (MIC) • May increase the development of resistance threshold • Has been shown to improve patient outcomes and potentially decreases costs</td>
</tr>
</tbody>
</table>
## Create microbiology lab protocols

<table>
<thead>
<tr>
<th>Microbiology Protocol</th>
<th>Rationale</th>
<th>Minimal resources required</th>
<th>Dedicated resources required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative and location specific antibiogram creation (hospital-specific) once or twice a year, in accordance with the guidelines set forth in the Clinical and Laboratory Standards Institute (CLSI) document M39-A4.</td>
<td>Provides a mechanism for tracking microbial resistance and provides susceptibility data that can be utilized for empiric antimicrobial selection</td>
<td>Microbiology lab</td>
<td></td>
</tr>
<tr>
<td>Regularly adopt CLSI antimicrobial breakpoint updates</td>
<td>Changes to CLSI breakpoints occur almost yearly, and often are due to new PK/PD considerations and/or patient clinical outcomes. Having the most up to date breakpoints used can potentially influence patient outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid diagnostics, such as:</td>
<td>• Decrease time to appropriate antibiotics and antifungals • Decrease unnecessary antimicrobial use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Nucleic Acid Amplification Test (NAAT) based platforms Multiplex PCR • Matrix Assisted Laser Desorption/ Ionization-Time Of Flight (MALDI-TOF)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consider procalcitonin level measurement</td>
<td>• Tissues make procalcitonin during bacterial infection • Decrease unnecessary unneeded antibiotic antimicrobial use • Shortens length of therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automatic testing and reporting of tigecycline and colistin or newer agents if on hospital formulary (ceftazidime/avibactam, meropenem/vaborbactam, eravacycline) for Carbapenem Resistant Enterobacteriaceae (CRE) isolates</td>
<td>• Increase in carbapenem resistance</td>
<td></td>
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</tr>
<tr>
<td>Reporting of minocycline susceptibility for <em>Acinetobacter</em> isolates</td>
<td>• Minocycline susceptibility remains high in most institutions against multi-drug resistant <em>Acinetobacter spp</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cascade microbiology susceptibility reporting/susceptible dose dependent (SDD)</td>
<td>Cascade reporting is a process of withholding susceptibility results from selected categories of antimicrobials that may have negative effects on the hospital antibiogram/resistance rates, or financial cost that do not have a therapeutic advantage over other commonly used antimicrobial agents. For example, if an E. coli strain is isolated from a bloodstream infection and is not susceptible to a first generation cephalosporin but is susceptible to cefotaxime, then other broad spectrum agents such as cefepime, meropenem, or ceftaroline could be withheld and made available.</td>
<td>Microbiology Lab</td>
<td></td>
</tr>
</tbody>
</table>
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider:

https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Available Technology</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: Computerized Provider Order Entry (CPOE) Drug-drug interaction check Drug-allergy interaction check Clinical Decision Support tools (CDS) tools</td>
<td></td>
<td>• Increases in patient safety • Cost savings • Decreases time on ASP activities (Kullar and Goff, 2014; Evans et al., 1998)</td>
</tr>
<tr>
<td>CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Libraries (Metzger et al., 2010; Leung et al., 2013)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy Workflow Manager</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Measuring outcomes

Key performance indicators

Any institution implementing an ASP must be able to measure 3 key variables:
• Antimicrobial use to assess whether interventions lead to changes in use
• Resistance patterns among microorganisms
• Outcomes associated with changes in antibiotic use

For example, metrics that are used to find the impact of the ASP:
• Defined daily doses (DDDs)
• Days of therapy (DOT) of antibiotics per 1000 patient days or
• Days of therapy (DOT) of antibiotics per 1000 patient days. Cost per quality adjusted life-year (QALY) could also be used to measure the cost-effectiveness of the program in preventing specific infections (e.g., bloodstream infections)
• Clostridioides difficile infection (CDI) - but just measuring CDI is not all encompassing (For a playbook to more comprehensively reduce CDI please see APSS #2C)
Standardized Antimicrobial Administration Ratio (SAAR), which the CDC National Healthcare Safety Network (NHSN) provides to institutions that submit their antimicrobial use to NHSN. The standardized antimicrobial administration ratio (SAAR) compares observed to predicted days of antimicrobial therapy. It is calculated using indirect standardization where predicted antimicrobial use days are based on nationally aggregate antimicrobial use data.

**Outcome measure formula**
The calculation is: \( \frac{\text{DDDs}}{\text{patient days}} \times 1000 \). Recent guidelines from the Infectious Disease Society of America, recommend the use of DOT per 1000 patient days over DDD, with DDD being an alternative at institutions that cannot collect DOT data.

**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, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

**Workgroup**

**Co-Chairs**
Christopher Jerry  
The Emily Jerry Foundation
Ron Jordan  
Chapman University School of Pharmacy
Jerika Lam  
Chapman University School of Pharmacy
Jason Yamaki  
Chapman University School of Pharmacy

**Members**
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Hania Alim  
Patient Safety Movement Foundation
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Charles Simmons
Cedars-Sinai Medical Center

Nat Sims
Massachusetts General Hospital

Robert Stein
Keck Graduate Institute

Laura Townsend
Louise H. Batz Patient Safety Foundation

Kimberly Won
Chapman University School of Pharmacy

Sun Yang
Chapman University School of Pharmacy

Metrics Integrity

Robin Betts
Kaiser Permanente, Northern California Region

References


How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for severe hypoglycemia. In it, you’ll find:

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What we know about severe hypoglycemia ............ 137
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Appendix C: Start Now: U-500 regular insulin project .................................................................................. 146
Executive summary checklist

Severe hypoglycemia (SH) is defined as having a low blood glucose level of less than 40 mg/dL and is likely to cause harm to the patient in an inpatient setting (Schwartz et al., 2007). SH causes significant morbidity and occasional mortality in hospitalized patients.

Create an action plan

- Get commitment to reduce SH from hospital administration and medical leadership
- Create a multidisciplinary team that includes physicians, pharmacists, nurses, diabetic educators, medication safety officers, case managers, and long-term healthcare professionals
- Create a systematic approach to reduce SH and use universal best practices

Ensure best patient care

- Educate staff, patients, and caregivers about the early warning signs and symptoms of SH
- Create a system to identify patients taking anti-diabetic medications (sulfonylureas, insulins, etc.) in the Electronic Health Record (EHR)
- Create insulin order sets that can be modified to reduce risks of hypoglycemia
- Coordinate glucose monitoring, automate insulin dose calculations, insulin administration, and meal delivery during changes of shift and times of patient transfer from one unit to another

Engage staff and use data to find areas for improvement

- Use real-time surveillance methods, analysis tools, and point-of-care blood glucose (BG) monitoring and reporting systems
- Continuously monitor the incidence of SH in the hospital, long-term care and skilled nursing facility settings
- Use the results of this monitoring in staff education as a part of Continuous Quality Improvement (CQI)
- Raise institutional awareness of issues through a system that compares the healthcare facilities and nursing units based on performance quality scorecards
What we know about severe hypoglycemia

SH can cause cardiac arrhythmias, seizures, brain damage and death (Griffing, 2016). It is a preventable harm, and addressing it can help create a safety culture, which is a culture that promotes patient safety and quality of care while reducing preventable risks and harm. While hypoglycemia (low blood sugar) is a common problem for many patients with diabetes, it can also occur in non-diabetics in a healthcare setting. In a 2009 survey of 575 hospitals, 5.7% of all point-of-care BG tests showed hypoglycemia ( <70 mg/dL) tests (Swanson et al., 2011).

Causes of hypoglycemia for patients include:

- Too much insulin dose
- Inappropriate timing of insulin or anti-diabetes therapy
- Unaddressed previous hypoglycemia
- Changes in nutritional status and regimen
- Renal and hepatic function changes
- Steroid dose (Deal et al., 2011)
- Failure to monitor BG
- Ineffective communication between physicians, pharmacists, and nurses and other healthcare providers

The diverse nature of potential errors in the treatment of inpatients with SH supports the need for a decision-making model that can be used to predict and prevent SH episodes and improve overall patient safety and outcomes. Research has found that:

- Frequent hypoglycemia is related to increased disease, length of stay, and death, especially in the intensive care units (Elliott, Schafers, McGill and Tobin, 2012)
- Moderate and SH are strongly linked to increased risk of death, especially from distributive shock (NICE-SUGAR Study, 2012) through:
  - Impairment of autonomic function
  - Changes in blood flow and composition
  - White cell activation
  - Vasoconstriction
  - Release of inflammatory mediators and cytokines (Adler et al., 2008; Wright and Frier, 2008)
- Clinicians do not consistently adjust their patient’s anti-diabetic regimens after treatment of hypoglycemia (Boucai, Southern, and Zonszein, 2011; DiNardo, Noschese, Korykowski, and Freeman, 2006)

Preventing SH

Early recognition and management of mild hypoglycemia can prevent SH. For example, adjusting the patient’s anti-diabetic regimens after treatment of hypoglycemia, or place the anti-diabetic medication on hold if the patient is not eating.
Leadership plan

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce SH.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

Show leadership’s commitment to preventing SH

- Create a plan to prevent SH that includes the areas of change outlined in the National Quality Forum Safe Practices for Better Healthcare, including awareness, accountability, ability, and action (National Quality Forum, 2010)
- Clinical and safety leadership should endorse the plan and ensure use across all providers and systems
- Hospital governance and senior administrative leadership (medical, pharmacy, and nursing) must fully understand the safety issue in their own healthcare system

Create the infrastructure needed to make changes

- Hospital governance, senior administrative leadership, and clinical/safety leadership must address SH by implementing a comprehensive approach
- Hospitals should set a goal date for the start of the corrective plan, with measurable quality indicators and milestones
- Governance boards and senior administrative leaders should evaluate specific budget allocations for the plan

Engage staff

- Use patient stories - in written and video form - to teach and inspire change in your staff
  - Find The Patient Safety Movement Foundation stories here: [http://patient.sm/2XvRoX](http://patient.sm/2XvRoX)

Action plan

Ensure accountability

- Create a multidisciplinary team that includes:
  - Physicians
  - Pharmacists
  - Nurses
  - Diabetic educators
  - Medication safety officers
  - Case managers
  - Long-term care professionals

Create protocols and provide staff training

- Create a systematic approach to prevent SH and optimize glycemic management:
  - Identify and prioritize events
  - Raise institutional awareness
    - Compare hospitals and nursing units based on performance quality scorecards
(use harm rate for at-risk patient days: [# of events]/[# of patient days during hospital stay when an anti-diabetic agent is ordered at any time])

- Encourage nurses to enter hypoglycemia into safety event self-reporting site
- Communicate to the hospital leadership board
- Send letters to physicians and providers (from case managers)
- Educate hospital staff, providers, and patients - hospital newsletter and posters made for each hospital/nursing unit listing common risks of hypoglycemia, safer medication alternatives, and solutions to prevent hypoglycemia (e.g., “STOP Hypoglycemia!”)
- Conduct a kick-off reception for SH safety initiative
- Perform frequent monitoring of glucose levels in patients who are at risk

**Use foundational Best Practices and “Just Do Its” (Appendices A and B)**

- Create a Hypoglycemia Task Force for the hospital
- Propose multidisciplinary diabetes safety team at each hospital
- Adopt foundational best practices (literature-based recommendations for all hospitals)
- Start “Just Do Its!” (or “Start Nows”) - these should be safe and reasonable interventions tested internally
- Adopt ISMP recommendations for U-500 insulin precautions (Appendix C)

**Set restrictions for the prescribing of U-500 Regular Insulin to only specialists and under special circumstances in CPOE**

**Create a checklist of precipitating and contributory factors that could lead to hypoglycemia and SH**

**Develop a protocol that provides proactive carbohydrates by a standardized process (e.g., IV dextrose), with scheduled reassessment of BG and nurse-driven adjustments to prevent recurrent hypoglycemia (Griffing, 2016)**

**Track and analyze your progress**

- Investigate SH events and collect causative factors to consider as part of the analysis tool, such as:
  - Insulin stacking
  - Wrong drug, dose, route, patient, or time of administration
  - Insufficient glucose monitoring
  - Basal or long-acting insulin regimen
  - Decreased nutritional intake
  - Event related to outpatient or emergency department medicine administration
  - Event while treating elevated potassium level
  - Glucose trend not recognized
  - High dose sliding scale insulin
  - Home regimen continued during hospitalization
  - Much lower steroid dose
  - Sulfonylurea-related hypoglycemia
  - Insulin administration and food intake not in sync
Point-of-care BG reading not linked to insulin administration
Point-of-care BG reading not in sync with food intake

- A pharmacist and/or nurse reviews analysis tool forms in a timely manner (e.g., at least within 72 hours) for causative factors and communicates findings with physicians
- Collate and report results to Medication Safety Committee and the Pharmacy and Therapeutics Committee
- Identify the interventions (evidence-based and expert opinion) that are used to resolve the most common or most harmful causative factors
- Track the interventions and create customized action plans based on the results

Report outcomes inside your organization and share best practices outside your organization

- Share best practices within hospital and to other hospitals and healthcare facilities
- Share strategies and use informed interventions on targeted floors and at-risk patients

Technology plan

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</tr>
</thead>
<tbody>
<tr>
<td>ONC Meaningful Use Certified Electronic Health Record (EHR) System with the following capabilities:</td>
<td>• Includes all of the following bullet points with significant additional safety features</td>
</tr>
<tr>
<td>• Computerized Provider Order Entry (CPOE)</td>
<td></td>
</tr>
<tr>
<td>• Drug-drug interaction check</td>
<td></td>
</tr>
<tr>
<td>• Drug-allergy interaction check</td>
<td></td>
</tr>
<tr>
<td>• Clinical Decision Support (CDS) tools</td>
<td></td>
</tr>
<tr>
<td>• Restriction settings for the prescribing of U-500 Regular Insulin to only specialists and under special circumstances in CPOE</td>
<td></td>
</tr>
<tr>
<td>Glycemic management CDS for insulin therapy recommendations, based on individual responses to insulin and designed for mitigation of all types of hypoglycemia</td>
<td></td>
</tr>
<tr>
<td>Real-time surveillance method for informatics alerts and triggers for initiation of hypoglycemia prevention protocol</td>
<td>• “High-Risk Sulfonylurea Alert”</td>
</tr>
<tr>
<td></td>
<td>• “Hypoglycemia Risk Alert”</td>
</tr>
</tbody>
</table>
An automated hypoglycemia event analysis tool (to discover local causes of hypoglycemia and guide future interventions)

Point-of-care BG monitoring and reporting systems
  - Quality assurance reports to audit compliance with hypoglycemia
  - management goals and restriction of insulin use

Automated triggers for most common precipitating or contributory factors of hypoglycemia; and an electronic tracking system for SH events, interventions used, and clinical outcomes

A results dashboard for each nursing unit within the hospital and Best Practices used to resolve the hypoglycemic event(s)

FDA approved glycemic management CDS for insulin therapy recommendation, based on individual patient’s response to insulin and designed for relief of all types of hypoglycemia

CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE

Drug libraries in EHR systems
  - Injectables, or comparable systems

Pharmacy Workflow Manager

### Measuring outcomes

**Topic 1 - Glycemic control of severe hypoglycemia** Rate of SH events (<40 mg/dL) within 12 hours of administration of insulin, or within 24 hours of administration of an anti-diabetic medication other than insulin, and no subsequent glucose value >80 mg/dL within five minutes of the low glucose event.

**Outcome Measure Formula:**

Harm rate for at-risk patient days: (# of events) / (# of patient days during hospital stay when an anti-diabetic medication is ordered at any time)

**Numerator:** Number of reported adverse drug events with harm, (as defined above) - (by class or medication)

**Denominator:** Number of doses administered (by medication or class of medication)

**Metric recommendations**

**Indirect Impact (preventable rate):** All patients

**Direct Impact (non-preventable rate):** All patients prescribed medications that could cause hypoglycemia
Lives Spared Harm:
Lives Spared Harm = (ADE Rate \textit{baseline} - ADE Rate \textit{measurement}) \times (\text{Doses or Adjusted Patient Days at \textit{baseline}})

Lives Saved:
Lives Saved = (\text{Lives Spared Harm}) \times (\text{Mortality Rate})

Notes:
Top medication classes and triggers:
1. Insulins
2. Sulfonylureas
3. Fluoroquinolones
4. Beta blockers
5. Inappropriate timing of insulin or anti-diabetes therapy
6. Unaddressed previous hypoglycemia
7. Changes in nutritional status and regimen
8. Renal and hepatic function\text{Creatinine clearance changes}
9. Steroid dose (Deal et al., 2011)
10. Failure to monitor BG

Failure to monitor BG

Data Collection

SH reporting information is based on volunteer reporting and accuracy of people verifying reports, (preferably from pharmacy and the medication errors reporting and prevention (MERP) program, MERP).

Anti-diabetic medication usage information is usually collected from billing information rather than medication orders (more accurate if patient received the dose or not).

Conflicts of interest disclosure

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Christopher Jerry \hspace{1cm} The Emily Jerry Foundation
Members:
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

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National Council for Prescription Drug Programs

*Flannery Nangle
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Charles Simmons
Cedars-Sinai Medical Center

Nat Sims
Massachusetts General Hospital
**Metrics Integrity:**

**Robin Betts**
Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.*

## References


Schwartz, A. V., Vittinghoff, E., Sellmeyer, D. E., Feingold, K. R., Rekeneire, N. D., Strotmeyer, E. S., ... Harris, T. B. (2007). Diabetes-Related Complications, Glycemic Control, and Falls in Older
Appendix A: Summary of Foundational Best Practices (Moghisii et al., 2009)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raise awareness of hypoglycemia</td>
<td>Initiatives to raise awareness on preventable harm have improved patient care</td>
</tr>
<tr>
<td>Real time analysis (48 hours)</td>
<td>• Pharmacy surveillance system provides information of when and where these events occur, but not why they occur</td>
</tr>
<tr>
<td></td>
<td>• Many hospitals have lowered harm rate using real time analysis</td>
</tr>
<tr>
<td>Create and use diabetes management team</td>
<td>AACE/ADA (American Association of Clinical Endocrinologists/American Diabetes Association) noted that a multidisciplinary steering committee of local diabetic experts can create reasonable and achievable glycemic management goals</td>
</tr>
<tr>
<td>Provide prescriber with tools to use as a dosing guide</td>
<td>• AACE/ADA suggests a systems approach for management of inpatient glycemic control</td>
</tr>
<tr>
<td></td>
<td>• Can create reasonable and achievable glycemic management goals</td>
</tr>
<tr>
<td>Nursing education process</td>
<td>• AACE/ADA noted a lack of ownership in diabetes care due to insufficient knowledge or confidence in diabetes management</td>
</tr>
<tr>
<td></td>
<td>• Ongoing education and training can improve care</td>
</tr>
</tbody>
</table>
Insulin dose timing coincide with food intake

- AACE/ADA noted many hospitals don’t coordination meal delivery and prandial insulin administration
- A systems approach can promote the coordination of glucose monitoring, insulin administration, and meal delivery, particularly during change of shifts and times of patient transfer

Improve point-of-care BG testing glucose testing with the insulin administration time

- AACE/ADA stated that bedside BG monitoring with use of POC glucose meters should be performed before meals and at bedtime in most in-patients who are eating usual meals
- Avoids routine use of correction insulin at bedtime

Use glucose management software

- Reduces hypoglycemic events

**Appendix B: Just Do Its! recommendations (Milligan et al., 2014)**

<table>
<thead>
<tr>
<th>Just Do It!</th>
<th>Modify insulin order set to hold insulin only with physician order</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Modify insulin order set to match pending electronic order set to reduce doses of bedtime sliding scale (30% reduction)</td>
</tr>
<tr>
<td></td>
<td>Modify insulin order set to avoid routine correction insulin at specific times (e.g., 0200 and 0400)</td>
</tr>
<tr>
<td></td>
<td>Modify insulin order set to match pending electronic order set to state: Notify physician when hypoglycemic event occurs (2 levels &lt;70 mg/dL or 1 level &lt;50 mg/dL, or &gt;300 mg/dL)</td>
</tr>
<tr>
<td></td>
<td>Add Pharmacist and Endocrinologist on diabetes management team</td>
</tr>
</tbody>
</table>

**Appendix C: Start Now: U-500 regular insulin project**

**Scope**
Create guidelines for injectable U-500 insulin to reduce ADE preventable harm. U-500 insulin is an uncommon concentration, which can cause serious harm if given with syringes designed for U-100 insulin.

**Preventable Harm**
Risk potential and risk severity are both high
Resources
Pharmacist(s) and nurse(s)

Goals:
- Create standard “High Alert” or “High Hazard Medication” or restrictions for U-500 insulin at all hospitals to prevent improper dosing and harm related to hypoglycemia
- Create policy that will safeguard or restrict the use of U-500 to specialists and special circumstances

Risks and barriers
- Hospitals that do not have the medication on their formulary have not addressed patients who may use it from home
- Hospitals feel that the medication not on their formulary will protect them from ADEs - but non-formulary medications do not equal to no-risk of ADE
Actionable Patient Safety Solutions (APSS) #3D: Pediatric adverse drug events

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for reducing pediatric adverse drug events (pADEs). In it, you’ll find:

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What we know about pediatric adverse drug events........................................ 151
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Action plan ............................................................. 153
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Measuring outcomes .............................................. 157
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Workgroup ............................................................ 158
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Executive summary checklist

Pediatric adverse drug events (pADEs) are harm and injury caused by medication in children. During 2008 to 2012, the Institute for Safe Medication Practices (ISMP) reported there were over 45,000 adverse drug events (ADEs) in children less than 18 years old and 64% of the ADEs (29,298) involved a serious injury, including:

- 2,935 (6%) deaths
- 10,032 (22%) hospitalizations
- 1,430 (3%) life threatening cases
- 816 (2%) cases of disability (ISMP, 2014)

Create an action plan

- Create a multidisciplinary team specialized in neonatal and pediatric medication, nursing, and pharmacy that reports regularly to executive leadership
- Use a software program to identify, detect, and report pADEs with analysis of the incidence and characteristics of pADEs and the near-misses
- Set up a closed loop medication administration system with an electronic medication administration record (eMAR) and barcoding, or other technology with computerized provider order entry (CPOE)
- Collaborate in pADE reduction among all hospital systems during inpatient care and transitions of care

Ensure best patient care

- Standardize order sets and protocols for each admitting diagnosis
- Use a CPOE with decision support systems (DSS) including medication reconciliation, allergy checking, interaction checking, and dose range checking with alerts
- Use a double-check process of medication verification before dispensing high-risk medications
- Ensure open communication and standardize medication handoffs between healthcare teams at shift changes
- Use ‘smart’ drug infusion pumps with drug libraries that include pediatric standardized medication amounts for all weight ranges

Engage staff and use data to find areas for improvement

- Use pediatric-specific technologies to assure that basic resources to treat acutely ill or injured children are present 24/7
- Ensure that the healthcare team reviews and understands the FDA Safety Communication: “Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences”
- Use Continuous Quality Improvement (CQI) software from infusion pump manufacturers to routinely monitor drug library parameters and report the frequency of command overrides and alerts
- Use patient stories - in written and video form – to teach and inspire change in your staff
What we know about pediatric adverse drug events

Preventing ADEs in pediatric patients poses unique challenges because children are particularly vulnerable to adverse outcomes from medication errors (preventable adverse events due to wrong medication use). However, it can create a safety culture, which is a culture that promotes patient safety and quality of care while reducing preventable risks and harm.

Children are especially vulnerable to pADEs due to these factors:
- The need for weight-based drug dosing involving multiple calculations
- Series dilution of stock medication solutions
- Immature renal and hepatic functions
- Limited ability to communicate side effects (Kaushal, 2001; Poole and Carleton, 2008)
- Some medications do not have an FDA-specific indication for children - more than 70% of the medications used in pediatrics have not been studied in age-specific populations to assess patient safety (Poole and Carleton, 2008; Lindell-Osuagwu et al., 2009)

Problems with the standard treatment

Most medications used in the care of children are made and packaged primarily for adults. There are limited dosage forms and amounts for newborns, infants, and children. Therefore, healthcare professionals must often prepare medications in different volumes or amounts for pediatric patients. Also, if an infusion pump is needed, they must provide an infusion rate that is acceptable and within pump capabilities. When medications are not prepared in the pharmacy, calculation errors and admixtures that do not account stability, compatibility, and bioavailability data may pose additional challenges (Joint Commission, 2008).

Studies show that:
- Medication errors in pediatrics are up to 3 times more likely to have a potential pADE compared to those in adults (Kaushal, 2001; Fortescue et al., 2003)
- Compared to other pediatric patient groups, the neonatal ICU patient group has the highest error and potential pADE rate
- pADE rates in hospitalized children are as high as 19.1 per 1000 patient-days (Stockwell et al., 2018)
- 22% of all pADEs could be prevented and 17.8% could have been identified earlier (Takata et al., 2008)
- pADE rates were substantially higher in teaching hospitals, as well as in patients with more chronic conditions (Stockwell et al., 2018).

Preventing pediatric adverse drug events (pADEs)

In 2001, the ISMP and the Pediatric Pharmacy Advocacy Group (PPAG) collaborated to produce the nation’s first set of guidelines to reduce pediatric medication errors (ISMP, 2018). The American Academy of Pediatrics (AAP) has also taken a lead in making recommendations to reduce errors (AAP, 2003).

To reduce medication errors and preventable pADEs, all healthcare professionals, hospitals, and healthcare systems need to create specific leadership, action, and technology plans. This is especially important for community and rural hospitals, which usually treat a low number of pediatric patients. The limited experience, infrastructure deficiency, and highly variable
training in pediatric prescribing and pharmacotherapy may place patients at increased risk of medication errors (Benjamin et al., 2018; Marcin JP et al., 2007; Dharmar M et al., 2013).

**The evidence for reducing pADEs**

Research has found that use of an ADE trigger tool that is aligned with clinical protocols specific for a medication can:

- Ensure more patient safety events compared to voluntary reporting (Burch, 2011; Call et al., 2014)
- Identify ADEs and reduce the frequency for hospitalized pediatric populations (Takata et al., 2008)
- Global Assessment of Pediatric Patient Safety (GAPPS) Trigger Tool developed by the Center of Excellence for Pediatric Quality Measurement (CEPQM) consists of both the manual approach and the automated approach (for automated screens of EHRs).
  - The GAPPS Trigger Tool is shown to reliably identify pADEs and can be used for monitoring quality improvement in healthcare facilities (Landrigan et al., 2016).

Studies in pediatrics have found a decrease in both prescribing errors and ADEs after using technology, including:

- Electronic Health Records (EHR)
- Computerized provider order entry (CPOE) system (York et al., 2019)
- Barcode medication administration (BCMA)
- Bar code assisted medication preparation system (BCMP)
- Smart pump infusion technology (Manias, 2014)

**Leadership plan**

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce pADEs.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

**Show leadership’s commitment to pADEs**

- The hospital board, executives, and other senior administrative leadership (medicine, pharmacy, and nursing) must fully understand the performance gaps (the difference between the safety measurements and the ideal) in reducing pADEs at their own healthcare systems
- Leaders should endorse a comprehensive pADE reduction action plan and ensure it’s applied across all providers and systems
- Create a clear metric and goal to make pADE reduction a strategic priority - include the metric and goal on the hospital-wide dashboard reviewed by the board and senior executives
- Invest and assign funds to:
  - Create and maintain continuous education programs for healthcare providers about pediatric clinical updates, high alert medications, pADEs monitoring, and proper use of drug infusion pumps (Manias et al., 2014; Cimino et al., 2004; Keiffer et al., 2015; Stump, 2000; Wolf, 2016).
  - Support clinical and research programs to create “Best Practices” in pediatric medicine
Engage staff
- Promote communication among all disciplines involved in pediatric patient care, including pharmacy staff, patients, and families (Fortescue, et al., 2003)
- Use patient stories – in written and video form – to teach and inspire change in your staff

Make policy changes
- Review pADE data at least monthly (Stump, 2000) – create a committee or task force to review the reported data at the hospital and unit levels, create strategies for improvement, analyze barriers, and report to executive leadership
- Expect a root cause analysis of all pADEs that involve serious patient harm that includes:
  - Root cause of the medication error
  - Feedback to the individual linked to the error
  - Time-bound and evidence-based changes to avoid similar pADEs
  - Sharing of lessons learned (Stump, 2000)
- Support lessons learned programs to raise awareness about pADE events, risks, and improvement efforts among providers
- Assess staff and ensure an adequate number of medical, nursing, and pharmacy staff specially trained to prescribe, prepare, dispense, and give medications to children (ISMP, 2018; Catlin, 2004)

Create the infrastructure needed to make changes
- Encourage and support the use of a simple, real-time pADE reporting system (Stump, 2000)
- Consider opportunities for collaboration in pADE reduction both among and outside of the pediatric hospital system, such as:
  - The Exploring the Current Landscape of Intravenous Infusion Practices and Errors (ECLIPSE)
  - FDA-ASHP Standardize for Safety (S4S) Initiatives
  - Ohio Children’s Hospitals’ Solutions for Patient Safety (OCHSPS) (Blandford et al., 2016)
- Use and share technology that supports community practitioners as they treat and transfer infants and children

Action plan

Ensure accountability
- Create and maintain a pediatric formulary system with policies for medication evaluation, selection, and use (Joint Commission, 2008; ISMP, 2018)
- Create a smart infusion pump drug library with support for intravenous therapy for pediatric patients (Manrique-Rodriguez et al., 2012)
- Create a pediatric multidisciplinary team to:
  - Achieve hospital-wide pADE reduction goals
  - Monitor pADE metrics
  - Ensure outstanding event reporting systems, root cause analyses, lessons learned processes and improvement strategies for pADE reduction
- Benchmark the adequacy of the features of the individual hospital’s medication safety practices and clinical information systems against the proven best practices, identify gaps, and make recommendations.

- Ensure adequate pharmacy services for pediatric patients to reduce medication errors and ADEs (Manias et al., 2014) based on strategies proposed by the American College of Clinical Pharmacy (ACCP) and the Pediatric Pharmacy Advocacy Group (PPAG) (Bhatt-Mehta et al., 2013), and the guidelines for providing pediatric pharmacy services in hospital and health systems developed by American Society of Health-System Pharmacists (ASHP)-PPAG (Eiland et al., 2018):
  - Elevate the minimum expectations for pharmacists entering pediatric practice
  - Standard pediatric pharmacy education
  - Expand the current number of pediatric clinical pharmacists
  - Create an infrastructure for training of pediatric clinical pharmacists and healthcare professionals.
  - When possible, 24-hour pharmacy services should be available for the pediatric population, especially in specialized, high-risk units (e.g., pediatric intensive care units, neonatal ICU, hematology-oncology unit, operating rooms, and emergency department).

- Create pharmacist-driven processes, such as:
  - Admission medication histories and reconciliation process for pediatric patients (Provine, Simmons, and Bhagat, et al., 2014)
  - Discharge prescription review program, led by a clinical pharmacist (with pediatric training preferred), to ensure the doses are the same with those prepared in the hospital (Christiansen, Hilmas, Morgan, and Shepardson, et al., 2008)
  - A double- and triple-check system for high alert medications to ensure the “5 Rights”, appropriate medication selection, accurate excipients, dose, and concentrations of liquid medication prior to compounding and dispensing them
  - Managing drug product shortages including development of strategies for identifying alternative therapies, working with suppliers, collaborating with physicians and other healthcare providers as well as the Pharmacy and Therapeutics P&T committee for specific clinical changes affecting pediatric patient care (Eiland et al., 2018). For more information about mitigating drug shortages please refer to APSS #3F: Drug Shortages.

- Standardize equipment and measurement systems throughout the institution, such as smart infusion pumps and weight scales for pediatric patients (Stucky, E.R., 2003)

- Ensure best practices are used for syringe pumps with medications that require low infusion rates (<5 mL per hour) (USFDA, 2016)

### Create protocols

- Prevent timing errors in medication administration by:
  - Using a standard number of days in all pediatric protocols for treatment start date, such as Day 0 or Day 1 (Joint Commission, 2008)
  - Standardizing and limiting the number of concentrations and dosage strengths of high alert medications to the minimum needed (Joint Commission, 2008; Irwin et al., 2008; Hilmas, Sowan, Gaffoor, and Vaidya, 2009; Murray et al., 2014; Larsen et al., 2005)

- Weigh and record all pediatric patients in kilograms only at the time of admission, or as
soon as possible (i.e., within four hours of admission) in an emergency situation - weight is used to calculate most dosing for children (Joint Commission, 2008)

• List high alert medications for pediatric patients based on your types of pediatric population, infrastructure, and unique features (Doherty and Donnell, 2012; Glanzmann, Frey, Meier, and Vonbach, et al., 2015)

• Create age-related treatment algorithms to guide providers to the correct dose for the child’s age

• Use reliable references and protocols to standardize pediatric medication therapies

• Create CPOE order sets to help standardize care and medication therapy for specific pediatric disease states with embedded dosing range maximums (Potts et al., 2003)

• Embed a pediatric trigger toolkit in the CPOE as an alert system for prescribers when medications are ordered out of range, or are duplicate therapies (Takata, 2008; Burch, 2011; Call, 2014) – it should electronically identify high risk medications based on the therapeutic levels, doses, and pADEs

• Create a smooth and effective communication process for hand-offs (e.g. using a checklist) upon patient transfer to a different unit within the hospital, and upon the transitions of care within and outside clinical settings (Robins and Dai, 2015; Halsymami et al., 2006; Manias et al., 2015; Manias et al., 2009; Apker, Mallack, and Gibson, 2007

Provide training in pediatric medication safety

• Create and integrate dedicated training in pediatric medication safety in the core curricula of professional training programs in medical, nursing, and pharmacy schools (Mueller et al., 2019; Benjamin et al., 2018; Szymusiak et al., 2018). For more on the curriculum training, see APSS #17)

• Create specialty training for all practitioners involved in the care of pediatric patients, as well as continuous education programs for healthcare providers to stay current in medications and treatment of pediatric conditions, and be familiar with the ongoing pADE tracking and reporting systems (Joint Commission, 2008; ISMP, 2003)

• Create a team of experts (e.g., physician, pharmacist, and nurse) to train healthcare providers at their hospital on how to use the smart infusion pumps with customized pediatric drug libraries (Manrique-Rodriguez et al., 2012b)

• Have a dedicated pharmacist who is specifically trained or certified in pediatrics pharmacy practice to oversee the pharmacotherapy of pediatric patients

• Create an education forum for community healthcare providers (e.g., physicians, pharmacists, and nurses) about appropriate prescribing and dispensing medications for pediatric patients (Benavides, Huynh, Morgan, and Briars, 2011)

• Have all staff and caregivers who use programmable syringe pumps review and understand the FDA Safety Communication: “Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences” (FDA, 2016) - use Massachusetts General Hospital eLearning modules on this topic, that are free at http://patient.sm/PGP6Zu

Track and analyze your progress

• Take part in and track the progress of the FDA-ASHP Standardize for Safety Initiative

• Evaluate clinical guidelines and protocols on a routine basis for sustainability and safety,
especially when there is limited safety and efficacy data in the pediatric population.

- Use Continuous Quality Improvement (CQI) software from infusion pump manufacturers to routinely track drug library parameters and to report the frequency of command overrides and alerts triggered for unsafe practices (Ohashi, 2013; Bergon-Sendin, 2015)
- Analyze and respond to identified issues from smart pump data

**Report outcomes inside your organization and share best practices outside your organization**

- Collaborate in a multidisciplinary team (e.g., physicians, pharmacists, and nurses) to promote and endorse accountability and responsibility in reporting pADEs from all healthcare providers (Crowther, Buck, McCarthy, and Barton, 2011; Stratton, Blegen, Pepper, and Vaughn, 2004)
- Work with the multidisciplinary healthcare team to create, improve, and optimize reporting systems to identify, target, track, and monitor pADEs
- Create real-time surveillance systems to identify high risk/high alert medications and avoid pADEs
- Share pediatric-specific assistive technologies such as eBroselow (or equivalent) to assure that basic capabilities to stabilize and treat acutely ill or injured children are present 24/7 throughout all environments of care (Damhoff, Kuhn, and Baker-Justice, 2014)

**Technology plan**

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider:

http://patient.sm/2sopQK

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Available Technology</th>
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<tbody>
<tr>
<td>ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following abilities:</td>
<td></td>
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<tr>
<td>- Computerized Provider Order Entry (CPOE)</td>
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<td>- Drug-drug interaction check</td>
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<tr>
<td>- Drug-allergy interaction check</td>
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<tr>
<td>- Clinical Decision Support tools (CDS)</td>
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<tr>
<td>Standardized measuring tools for liquid pediatric oral medication</td>
<td>• Oral syringes with better accuracy (Yin et al., 2016)</td>
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<tr>
<td></td>
<td>• Provide measuring tools closely matched to prescribed dose (Yin, et al., 2017)</td>
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</table>
Enhance the accessibility of tertiary care for children, especially in rural and underserved areas

- Using telemedicine consultations in rural ED to reduce physician-related ED medication errors and to improve patient safety among seriously ill and injured children (Dharmar et al., 2013; Yang et al., 2015)
  - Secure electronic communications, information exchange, or other methods that meet applicable state and federal requirements.
- Implementing a telepharmacy services to provide round-the-clock medication order review by pharmacists to reduce prescribing errors (Wakefield, Ward, Loes, O’Brien, & Sperry, 2010)

Bar coded medication process for pediatric medication products (e.g., multi-dose or unit-dose vials, compounded, and/or repackaged) (ASHP, 2013.; Eiland et al., 2018)

- Use a bar code assisted medication preparation system (BCMP) for intravenous sterile compounding in pharmacy,
- Use an electronic aid to help those who compound parenteral medications on their own to standardized concentrations for fluid balance considerations for small patients and patients with fluid restriction (Damhoff, Kuhn, and Baker-Justice, et al., 2014)
- Assure correct source vial identification, container preparation, and Joint Commission-compliant labeling of drugs given by IV push or infusion in the perioperative environment (Nanji, 2016).

Measuring outcomes
The most appropriate metric is the measure of adverse drug events. For more on this measurement, see APSS #3A.

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.
Workgroup

Co-Chairs
Ron Jordan
Chapman University School of Pharmacy
Jerika Lam
Chapman University School of Pharmacy
Nathaniel Sims
Massachusetts General Hospital
Sun (Coco) Yang
Chapman University School of Pharmacy
Christopher Jerry
The Emily Jerry Foundation

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Hania Alim
Patient Safety Movement Foundation
Peter Antevy
Handtevy
Steven Barker
Masimo; Patient Safety Movement Foundation
*Linda Beneze
Monarch Medical Technologies
Michel Bennett
Patient Safety Movement Foundation (formerly)
Laressa Bethishou
Chapman University School of Pharmacy
*Jim Broselow
eBroselow
John Burnam
Louise H. Batz Patient Safety Foundation
Mitchell Goldstein
Loma Linda Medical Center
Kari Hamlin
Hackensack Medical Center
Helen Haskell
Mothers Against Medical Error
Soojin Jun
Quorum Health
Edwin Loftin
Parrish Medical Center
Ariana Longley
Patient Safety Movement Foundation
Jacob Lopez
Patient Safety Movement Foundation (formerly)
Olivia Lounsbury
Patient Safety Movement Foundation
Anne Lyren
Children’s Hospitals’ Solutions for Patient Safety
Brendan Miney
Talis Clinical
Sidney Morice
Lee Health
Lisa Morrise
Consumers Advancing Patient Safety
Steve Mullenix
National Council for Prescription Drug Programs
*Flannery Nangle
Monarch Medical Technologies
Donna Prosser
Patient Safety Movement Foundation
Talia Puzantian
Keck Graduate Institute
Judith Reiss
Advocate
Claire Roy
Patient Safety Movement Foundation
Rochelle Sandell
Patient Advocate
Metrics integrity

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

References


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This guide gives actions and resources for creating and sustaining safe practices for medicine administration. In it, you’ll find:

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APSS #3E: Standardize and safeguard medicine administration

Executive summary checklist

Healthcare providers need to safely and quickly deliver medication to their patients. While this is a reasonable and universal expectation, it is also a continuing challenge to healthcare providers. Medication errors, including wrong drug, dose, time, route of administration, or patient, cause serious patient harm and deaths every year. Standardizing and safeguarding medication administration helps create a safety culture, which is a culture that promotes patient safety and quality of care while reducing preventable deaths and harm.

Create an action plan

☐ Create a multidisciplinary team of physicians, nurses, pharmacists, other healthcare providers, and administration

Ensure best patient care

☐ Use the potential of the newest, barcode-enabled, mobile medication safety tools
☐ Educate staff about and use of a universal checklist for all medication administration
☐ Follow protocols to create a “mobile medication medicine safety system” that:
  ☐ Works everywhere within your healthcare facility
  ☐ Works when offline, such as during natural and man-made disasters, military, transport, and remote situations
  ☐ Has basic documentation functionalities that work with existing electronic systems and electronic medical records (EMR)
  ☐ Is supplemented with barcode access points that eliminate the need for math or memorization at acute ordering, medication preparation, and delivery
  ☐ Can be integrated into your systemic response to acute medication shortages
☐ Use patient stories – in written and video form – to teach and inspire change in your staff
What we know about medication administration

Medication administration can lead to medication errors. As mentioned in the Actionable Patient Safety Solutions #3A on “Medication Errors”, medication errors are preventable adverse events due to wrong medicine use and are a major cause of death in the United States (Lam et al., 2017). One in 20 surgery-related medication administrations, and one in every two surgeries, resulted in a medication error or an adverse drug event (harm and injury caused by medicine) (Nanji et al., 2016).

Most medication errors result from faulty systems and poorly designed processes, instead of poor practices or incompetent practitioners (Palmieri et al., 2008). Research has found that:

- Children have a higher risk of medication errors than adults because there is no standardized dose for different patient sizes and age
- About 35% of pediatric patients receive the wrong dose from emergency department providers (Kaufmann, Laschat, and Wappler, 2012)
- There are 10 times more mathematical errors due to incorrect calculations for children than adults

Preventing medication errors

A standardized system for medication administration can reduce incorrect calculation errors and miscalculation in the absence of the electronic health record (EHR). There are a variety of approaches to standardize medication administration including:

- Automated infusion and IV injectable technologies
- Checklists
- Predictive algorithms

Leadership plan

Hospital governance, senior administrative leadership, clinical leadership, and safety and risk management leadership need to work collaboratively to standardize medication administration. To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

Show leadership’s commitment to standardized medication administration

- National and international governments, hospital leadership, and emergency response leadership must use a comprehensive approach that applies at all levels of medical sophistication
- Use a process that includes:
  - Those outlined in the National Quality Forum (NQF) safe practices and an understanding of applicable practices internationally (Meyer et al., 2010)
  - Evidence-based effectiveness to reduce preventable harm and death
  - Generalizable processes to national and international venues, in first and third world settings
  - Reductions in preventable death and disability when applied
Create the infrastructure needed to make changes
- Provide information to assist healthcare professionals when the EHR is not available
- Set measurable quality indicators, benchmarks, and goals
- Provide budget amounts that are matched to available resources
- Get broad implementation across all providers and systems in target areas
- Create a feedback mechanism for continuous quality improvement

Engage staff
- Use patient stories - in written and video form - to teach and inspire change in your staff

Action plan

Ensure accountability
- Create a multidisciplinary team which includes physicians, nurses, pharmacists, respiratory therapists, laboratory personnel, and information technology (IT) personnel

Create protocols and provide staff training
- Create education and training about:
  - A mobile app or platform that can help standardize and safeguard medication administration
  - The capabilities of the app or platform
  - How to use the app or platform in various healthcare settings
- Collaborate with IT to:
  - Integrate a mobile app or platform into the hospital’s IT infrastructure
  - Use a synchronous communication pathway for recording medication administration: medication, dose, date, time, route of administration (ROA), and patient
  - If you are a resource-limited community and healthcare center, create a copy of the medication administration log book from the mobile app (drug, dose, time of administration, ROA, and patient) and transfer a hardcopy of the log book into the patient’s medical chart
- Create a backup documentation system for when electronic systems are down/offline from the mobile app and related software
  - Review and keep documentation current

Report outcomes inside your organization and share best practices outside your organization
- Collaborate with IT and pharmacy to locally, regionally, nationally, and internationally synchronize medication shortages with alternative medications that have:
  - Similar mechanism of action
  - Compatibilities
  - FDA-approved indications
- Partner with the American Society of Health-System Pharmacists (ASHP), University of Utah medication teams, and international organizations about medication shortages and alternatives
• Get rid of information silos about medication shortage information through the above points

**Technology plan**

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[http://patient.sm/2sopQK](http://patient.sm/2sopQK)

<table>
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<th>System or practice</th>
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<td>Mobile app platform designed to address medicine and knowledge shortages in serious situations and resource-limited settings (e.g. disaster or remote, third-world triaging clinical circumstance). The mobile app platform should:</td>
<td>• Drug Shortages (app by the FDA)</td>
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<tr>
<td>• Have wireless capability</td>
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<tr>
<td>• Work offline</td>
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<tr>
<td>• Synchronize the downtime data back into the EHR when the system goes back online</td>
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<tr>
<td>• Include basic documentation functionalities, such as time-stamped text logs, that work with existing electronic systems</td>
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<tr>
<td>• Be capable of synchronizing medication shortages with compatible alternative medications</td>
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<tr>
<td>• Provide relevant medication information (weight, drug, drug concentration, ROA, and indication)</td>
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<td>• Be manufacturer and EHR agnostic</td>
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<tr>
<td>• Be a knowledge-based mobile tool for checking medications and indications</td>
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<td>• Provide updated information and alerts about medication shortages</td>
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<td>• Have free access for all users</td>
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Measuring outcomes
The measure of adverse drug events. See APSS #3A for more information.

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*Jim Broselow  
edBroselow
Mitchell Goldstein  
Loma Linda Medical Center
Ron Jordan  
Chapman University School of Pharmacy
Christopher Jerry  
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Members
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Olivia Lounsbury  
Patient Safety Movement Foundation
Anne Lyren  
Children’s Hospitals’ Solutions for Patient Safety
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Sidney Morice Lee Health
Lisa Morrise Consumers Advancing Patient Safety
Steve Mullenix National Council for Prescription Drug Programs
*Flannery Nangle Monarch Medical Technologies
Robert Nickell Enovachem
Deborah Pasko American Social of Health-System Pharmacists
Donna Prosser Patient Safety Movement Foundation
Talia Puzantian Keck Graduate Institute
Judith Reiss Advocate
Claire Roy Patient Safety Movement Foundation
Rochelle Sandell Patient Advocate
Enrique Seoane-Vasquez Chapman University School of Pharmacy
Alex Shaffer Advocate
David Shane Lowry Rosalind Franklin University of Medicine and Science
Robin Shannon The T System
Deeba Siddiqui Hackensack Medical Center
Charles Simmons Cedars-Sinai Medical Center
Nathaniel Sims Massachusetts General Hospital
Robert Stein Keck Graduate Institute
Laura Townsend Louise H. Batz Patient Safety Foundation
Kimberly Won Chapman University School of Pharmacy
Jason Yamaki Chapman University School of Pharmacy

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

Metrics Integrity:
Robin Betts Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.


How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for drug shortages. In it, you’ll find:

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Executive summary checklist

Drug shortages are a growing threat worldwide. A drug shortage is a situation in which the total supply of all clinically interchangeable versions of a drug is too low to meet the current or projected demand for use.

- Senior leadership recognize that drug shortages must be treated as a preventable adverse drug event (harm and injury caused by medicine)
- Commit to monitor, prevent, and mitigate drug shortages as outlined by the National Quality Forum (NQF)
- Work on legislation to regulate kickbacks to Group Purchasing Organizations (GPO) from pharmaceutical companies
- Use an effective monitoring and screening system to rapidly identify and mitigate the effects of drug shortages
- Create a rapid response intervention based on the 2018 ASHP Guidelines on Managing Drug Product Shortages (Fox, 2018).
- Review all drug shortages and their impact on patient safety biannually
- Use biannual review to create an improvement plan and as a learning opportunity
What we know about drug shortages

Drug shortages are recurring problem for the US healthcare system (Fox & Tyler, 2003; Baumer & Clark et al., 2004; Kumar, 2006) and around the world (Bochenek, et al., 2018; Iacobucci, 2017; De Weerdt & De Rijdt et al., 2017). The World Health Organization also considers drug shortages as a global problem and has discussed the need for a global notification system (Jarosawski, Azaiez, Korchagina, and Toumi, 2016). Drug shortages happen with all therapeutic classes including:

- Therapeutic products
- Preventive products
- Diagnostic products (Fox, et al., 2009)
- Routinely recommended vaccines (CDC, 2004; CDC, 2002; CDC, 2000; CDC, 2017)
- Biologics (CDC, 2017)
- Parenteral nutrition (Ziesenitz, et al., 2017)
- Saline water (Holcombe, et al., 2017)
- Orphan drugs (Donaldson & Goodchild, 2017)

As of August 28, 2019, the following drug shortages were reported:

- The US Food and Drug Administration (FDA) reported 117 drugs in shortage, including small volume parenteral solutions, electrolytes, sterile water for injection, anesthetics, opioids, and antibiotics, among other drugs
- The European Medicines Agency (EMA) reported 6 drugs in shortage – however, the EMA only reports drug shortages approved using the European centralized system and most shortages are dealt with at a national level. For example, the UK reported 16 new drug shortages in the period January 1-August 28, 2019

The problems with drug shortages

Shortages of drugs, vaccines, and other biological products have an adverse effect on patient outcomes and healthcare costs (Steinbrook, 2009; Hampton, 2007; Kumar, 2006; National Vaccine Advisory Committee, 2003). Current trends show an increase in the health and economic impacts of shortages (Fox & Tyler, 2003; Eggertson, 2010). Pharmaceutical shortages may have a profound effect on patient outcomes (Fox, Tyler, and Caravati, 2002; Hampton, 2007; National Vaccine Advisory Committee, 2003; Lukmanji & Sauro, 2018; Omorodion, et al., 2017).

- Patients may stop the use of an essential product, miss doses, or defer use until the shortage ends (Phuong, et al., 2019; Kumar, 2006; Dorsey, et al., 2009)
- Medicine changes due to pharmaceutical shortages can increase prescribing, dispensing, administration errors, and reduce patient adherence (Fox & Tyler, 2003; Baumer & Clark et al., 2004; Pendergrast, Sher, and Callum, 2004)
- Drug shortages can suddenly change formularies, clinical practice, and clinical decision-support systems, resulting in the disruption of patient care
- Vulnerable populations, including the elderly and patients with rare diseases, bear the highest clinical burden of shortages
- Drug shortages significantly increase drug prices and other healthcare costs (Flannery, et al., 2017; Fox and Tyler, 2017; Alevizakos, et al., 2016; Iacobucci, 2017)
- Patients often need to switch to more expensive alternatives (Kumar, 2006; Dorsey, et al., 2009; Pendergrast, Sher, and Callum, 2005; Hampton, 2007; Hendricks and Singha,
Shortages can have negative effects on the financial performance of the industry (Fox). They also create an economic burden to public health programs and health care professionals and providers related to the cost of:
- Tracking inventories
- Complying with recommendations
- Recalling patients when the product is available (Baumer and Clark, 2004; Traynor, 2010)

Stockpiling and other procurement strategies that often follow the reporting of a shortage may amplify its health and cost effect.

**Preventing drug shortages**
Currently, hospitals lack a standardized methodology to assess the incidence and prevalence, causes, predictors, and effects of drug shortages.

Public and private pharmaceutical shortage programs take a short-term approach, reacting to shortage outbreaks rather than anticipating them. Recent shortage outbreaks justify the need for prevention. Once a shortage happens, mitigation strategies are difficult, costly and fail to address the health and economic effects of the shortage (Baumer and Clark, 2004; Pendergrast, Sher, and Callum, 2005; Kumar, 2006).

In the US, the FDA Safety and Innovation Act (FDASIA) of 2012 requires that manufacturers provide early notification to the FDA of a permanent discontinuance or a temporary interruption of manufacturing of certain medically important prescription drugs. Early notification from manufacturers about possible shortages has enabled FDA to work with manufacturers to restore production of many life saving therapies. If notified of a potential disruption in production, the FDA can help to prevent or mitigate a shortage if other manufacturers are able to increase production by:
- Expediting inspections and reviews of submissions
- Exercising temporary enforcement discretion for new sources of medically necessary drugs
- Working with manufacturers to ensure investigation into the root cause of shortages
- Reviewing possible risk mitigation measures for the remaining inventory

Group Purchasing Organizations (GPOs) could increase the risk of drug shortages (Bruhn, Fracica, and Makary, 2018). Hospital contracts with GPOs should include provisions aiming to reduce the risk of drug shortages. GPOs are excluded from the Social Security Act anti-kickback statute and are allowed to obtain undisclosed fees paid by pharmaceutical companies in exchange of exclusionary contracts. As a result, GPOs have been credited to favor suppliers that pay the largest fees instead of negotiating contracts that lower the risk of market supply disruptions (Kantarjian, 2014).

The EMA and the Heads of Medicines Agencies (HMA) of the European Union created the Task Force on the Availability of Authorised Medicines for Human and Veterinary Use in December 2016 to provide support and advice to tackle disruptions in the supply of human and veterinary medicines and ensure their continued availability. The Task Force priorities include:
- Looking at ways to minimize supply disruptions and avoid shortages
- Facilitating approval and marketing of medicines using the existing regulatory framework
- Developing strategies to improve prevention and management of shortages caused by...
disruptions in the supply chain

- Encouraging best practices within the pharmaceutical industry to prevent shortages
- Improving the sharing of information and best practices among EU regulatory authorities to better coordinate actions across the EU
- Fostering collaboration with stakeholders and enhancing communication of supply problems to EU citizens

The Task Force has released guidance for reporting drug shortages (HMA & EMA, 2019) and for communicating drug availability issues (HMA & EMA, 2019b).

**Leadership plan**

Hospital governance, senior administrative leadership, clinical leadership, and safety and risk management leadership need to work collaboratively to reduce drug shortages.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

**Show leadership’s commitment to reducing drug shortages**

- Hospital governance, senior administrative leadership, and clinical and safety leadership must commit to a comprehensive approach to monitoring, preventing, and mitigating the effects of drug shortages. The approach must include:
  - Fundamentals of change outlined in the National Quality Forum (NQF) endorsed set of safe practices
  - Creation of GPO resources and networks
  - Establishment of 503B relationships
- Treat drug shortages as preventable adverse drug events, and a drug shortage leadership plan should be included as part of the medication errors leadership plan (APSS #3A Medication Errors)
- Work on legislation to regulate kickbacks from GPOs
- Hospital governance should provide the resources needed to implement the drug shortage monitoring, prevention, and mitigation plan

**Action plan**

**Ensure accountability**

- Create an interdisciplinary healthcare team to design and implement a drug shortage prevention and mitigation plan, and assess the risk of drug shortages and their potential effect on patient care
- Create a surveillance system to rapidly identify drug shortages and respond with interventions to mitigate the effect of drug shortages. The surveillance system should include continuous real-time monitoring and assessment of drug shortages reported by:
  - The US Food and Drug Administration (FDA)
  - The American Society of Health-System Pharmacists (ASHP)
  - Pharmaceutical companies and suppliers
- Create a technology system to provide real-time report of the drug inventory in the hospital, impact analysis, and internal resources that are available for compounding and repackaging
• Use the informatics or information technology team need to develop a streamlined process to accommodate drug changes in the electronic health record system, barcode validation, and the infusion pump library

• Negotiate with GPOs, wholesalers, and pharmaceutical companies’ contractual clauses to:
  o Set up prevention programs
  o Reduce the incidence and duration of shortages
  o Establish responsibilities for the effects of drug shortages

**Find areas for improvement**

• Review all drug shortages and their impact on patient care and health outcomes for opportunities to learn and enhance planning.
• Formally assess opportunities to reduce the incidence of drug shortages with a comprehensive self-assessment process.
• The self-assessment must identify risk factors for drug shortages including:
  • Purchasing strategies
  • Inventory management
  • Formulary management
  • Drug use strategies

**Create protocols and provide staff training**

• Understand the medicine safety gaps actually and potentially caused by drug shortages included in one’s formulary
• Consider the risk of drug shortages as one of the factors in drug formulary decision-making
• Promote adequate inventory practices for prevention and mitigation of drug shortages
• Create a process for rapid response interventions to mitigate the effect of drug shortages according to the 2018 ASHP Guidelines on Managing Drug Product Shortages (Fox and McLaughlin, 2018).

• The process for managing drug shortages should include:
  o Assess the details and potential duration of the shortage
  o Assess and manage inventory hand and potential drug supply sources
  o Approve alternative therapies
  o Define alternative clinical pathways for care of patients affected by drug shortages
  o Address ethical considerations related to the allocation of drugs in short supply
  o Communicate with staff, patients, the FDA, and the AHSP
Technology plan
These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider:
patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

<table>
<thead>
<tr>
<th>System or practice</th>
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<td>All settings</td>
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<td>ONC Meaningful Use Certified EHR system</td>
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<td>• Computerized Provider Order Entry (CPOE)</td>
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<td>• Electronic Prescribing (eRx)</td>
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<td>• Electronic Prior Authorization (ePA)</td>
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<td>Electronic Medication Administration Record</td>
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<td>(eMAR) system with pharmacy and bedside</td>
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<td>barcoding capabilities</td>
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<td>FDA-approved clinical decision support</td>
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<td>solution for medication therapy recommendations</td>
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<td>Infusion pumps that wirelessly communicate</td>
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<td>data back to the electronic eMAR</td>
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<td>Patient and medication barcoding system</td>
<td>• Single Use Injection Vials and Kits</td>
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<td>CPOE simulation tool to quantify the risk</td>
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<td>of serious ADEs with one’s current system</td>
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<td>CPOE (Metzger, Welebob, Bates, Lipsitz, &amp;</td>
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<td>Classen, 2010).</td>
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<td>Drug libraries</td>
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Drug libraries

Pharmacy Workflow Manager
Surgery environment

- IV injectable doses
- Audible and visual feedback for each syringe attached with measurement of dose
- Allergy alerts
- More accurate and timely wireless documentation to the anesthesia information system

Pharmacy environment

Pharmacy robots to reduce safety problems associated with providers drawing up their own medication stations, and risks associated with contamination from outsourced compounders.

Utilize Single Use Injection Kits or Pre-mixed sterile solutions

Other considerations

“End-to-end” smart pump system, or other electronic pump systems

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs

Ron Jordan
Enrique Seoane-Vazquez
Christopher Jerry

Chapman University School of Pharmacy
Chapman University School of Pharmacy
The Emily Jerry Foundation
Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

**Hania Alim**  Patient Safety Movement Foundation
**Peter Antevy**  Handtevy
**Steven Barker**  Masimo; Patient Safety Movement Foundation
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**Laressa Bethishou**  Chapman University School of Pharmacy
**Jim Broselow**  eBrosel
**John Burnam**  Louise H. Batz Patient Safety Foundation
**Mitchell Goldstein**  Loma Linda Medical Center
**Kari Hamlin**  Hackensack Medical Center
**Helen Haskell**  Mothers Against Medical Error
**Soojin Jun**  Quorum Health
**Edwin Loftin**  Parrish Medical Center
**Ariana Longley**  Patient Safety Movement Foundation
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**Enrique Seoane-Vasquez**  Chapman University School of Pharmacy
**Alex Shaffer**  Advocate
**David Shane Lowry**  Rosalind Franklin University of Medicine and Science
**Robin Shannon**  The T System
**Deeba Siddiqui**  Hackensack Medical Center
**Charles Simmons**  Cedars-Sinai Medical Center
**Nats Sims**  Massachusetts General Hospital
**References**


Actionable Patient Safety Solutions (APSS) #3G: Opioid safety stewardship

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for drug shortages. In it, you’ll find:

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APSS #3F: Drug shortages

Executive summary checklist

The current opioid crisis is a public health and patient safety issue that is devastating the United States, and one that negatively impacts patients, families, communities, healthcare professionals, and healthcare organizations. The management of acute and chronic pain can be complex. Prescription opioids, when used appropriately, can be an important component of pain management. However, due to significant patient safety issues, risks including misuse, OUD (addiction and dependence), overdose and death must be considered along with their potential benefits. A multimodal pain treatment approach is required to ensure legitimate access to opioids while also preventing diversion and misuse or abuse. This multimodal approach must enhance the safety of opioid use, involve clinicians, patients, and families in the creation of safe pain treatment plans, and coordinate strategies to promote harm reduction and educate patients on opioid safety.

Create an action plan

☐ Provide opioid safety education, training, and support for healthcare professionals, patients, and their families

☐ Share safe pain management practices, including the use of a comprehensive pain assessment, with other organizations

☐ Create a highly functional multidisciplinary team that will provide appropriate and effective patient-centered pain management to reduce the risk of opioid-related harm via five plans (assessment, management, overdose prevention, opioid use disorder and harm reduction)

Ensure best patient care

☐ Develop effective systems of care that focus on patient- and family-centered pain assessment, management, and monitoring

☐ Support programs to promote healthcare and public forums to address the opioid crisis and offer harm reduction resources

☐ Integrate state-level prescription drug monitoring programs (PDMPs) with electronic health records to monitor opioid prescribing and clinical practices to improve safe prescribing practices

☐ Integrate prescribing protocols, order sets, and specific care plans to prioritize safe pain management and to prevent drug diversion
What we know about opioid safety

Mortality and mortality associated with opioids have reached a crisis point in the United States (US). Between 1999 and 2017, the age-adjusted drug overdose mortality rate more than tripled from 6.1 to 21.7 deaths per 100,000 Americans (Hedegaard, Minino, and Warner, 2018). Opioids are currently responsible for nearly 70% of overdose deaths, with approximately 48,000 opioid deaths in the US in 2017 (over 130 deaths per day) (Ahmad, et al., 2019). More specifically, synthetic opioids such as illicitly manufactured fentanyl are currently the main driver of drug overdose deaths with a 45% increase in overdose death rate from 2016 to 2017 (Hedegaard, Minino, and Warner, 2018). While deaths involving prescription opioids remained stable in that time frame, they remained high, with approximately 46 Americans dying each day from prescription opioid overdose (Scholl, et al., 2018). Although prescribing rates of opioids have slowly declined over the past several years, the amount of opioids in morphine milligram equivalents (MME) prescribed per person is approximately three times higher than it was in 1999, and there were still nearly 58 opioid prescriptions written for every 100 Americans in 2017 (“Opioid prescribing rates”).

Prescription opioid use has been associated with illicit opioid use with data showing that 4-6% of those who misused prescription opioids switched to heroin and 80% of heroin users first misused prescription opioids (Muhuri, Gfroerer, and Davies, 2013; Cicero, Ellis, Surratt, and Kurtz, 2014; Carlson, Nahhas, Martins, and Daniulaityte, 2016; Cicero, Ellis, and Kasper, 2017). National survey data from 2017 on drug use found that nearly 2.5 million Americans have an opioid use disorder (OUD) associated with prescription and/or illicit opioids. The US Preventive Services Task Force recently issued a draft statement recommending that primary care providers screen adults for illicit drug use (US Preventive Services Task Force). For screening to be effective, appropriate diagnostic assessment, effective treatment and appropriate care must be available, offered or referred. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), fewer than 80% of patients with opioid use disorder have received treatment (“Medications for opioid use disorder save lives”, 2019).

There are currently a number of guidelines and consensus statements recommending pain management strategies, however there remains variability among clinicians in how these are implemented. Many factors have led to the suboptimal state of opioid pain management, including misalignment between the clinicians’ perceptions of their patients’ pain compared to the actual pain that their patients are experiencing, lack of an effective coordination between the clinical practice guidelines, limited harm reduction resources made available in community, and competing interests from the leadership and healthcare organizations that affect patient safety and quality issues. The commitment from hospitals and healthcare systems to the leadership, action, and technology plans will advance the opioid safety policies and protocols, as well as ensure a patient safety environment and culture.

Leadership plan

Commitment from the hospital leadership, senior administration, and community key stakeholders is required to improve patient care and prevent opioid-related harm and death. Formal statements made at the administrative level in support of an opioid safety program implementation and advancement should be clear and consistent, so that healthcare professionals will know and understand the importance of the program’s goals and strategies. Several approaches that the hospital and community leadership should endorse to optimally support the opioid safety program include the following:
- Financial support for programs that promote, improve, and optimize opioid safety
- Provision of opioid safety education, training, and support for healthcare professionals, patients, and their families
- Formal statements supporting the opioid safety program and the optimal use of opioids for pain management
- Provision of necessary infrastructure for safe opioid prescribing systems, monitoring of opioid prescribing, opioid and nonopioid pain medication use, and patient pain improvement outcomes
- Creation of a safe environment and quality improvement process to identify and assist clinicians with uncommon prescribing patterns and pharmacists with unusual dispensing patterns, to receive support and education to improve
- Coordination of collaborative efforts to promote “Best Practices” in opioid safety across healthcare systems and the communities
- Sharing safe pain management practices, including the use of a comprehensive pain assessment, with other organizations
- Development of effective systems of care that focus on patient- and family-centered pain assessment, management, and monitoring
- Provision of evidence-based systematic strategies to
  - Incorporate nonpharmacological approaches and nonopioid medications to manage pain
  - Prevent and manage opioid-related harm including OUD
  - Prevent and manage opioid overdoses
- Support programs to promote healthcare and public forums to address the opioid crisis and offer harm reduction resources
- Engagement with legislators and third-party payers to implement policies that
- Ensure appropriate opioid prescribing
- Allow access to medication-assisted treatment (MAT) and naloxone
- Promote the availability of safe disposal of needles and syringes

**Action plan**

There is an opportunity to improve patient care and opioid safety when each healthcare organization implements a highly functional multidisciplinary team that comprises of physicians, pharmacists, clinical experts in pain, nurses, therapists, social workers, and case managers. The goals of this team should focus on providing appropriate and effective patient-centered pain management to reduce the risk of opioid-related harm. The team can advance opioid safety in the following ways:

**Assessment plan**

- Develop policies and protocols to measure and assess the effectiveness of interventions for managing pain
- Develop policies to identify patients at risk for an accidental opioid overdose
- Develop policies for screening opioid naive individuals who may be at greater risk for an opioid overdose and require closer monitoring (e.g., sleep apnea, living at high altitudes, etc.). (Refer to APSS #4 for monitoring of opioid-induced respiratory depression)
- Incorporate pharmacogenomic testing for CYP2D6 isoenzyme to determine appropriate
opioid dose for pain management

- Create a streamlined workflow process whereby patients receiving opioids are monitored closely and
  - Assessed for improvement
  - Assessed for whether opioid tapering is appropriate
  - Assessed for a switch to alternative interventions to manage pain (pharmacologic or nonpharmacologic)
  - Assessed for risk of an accidental opioid overdose

Management plan

- Design and implement pain management safety standards and programs by using evidence-based resources and “Best Practices” models
- Develop an Opioid Stewardship program and work with pain specialists (if available)
- Identify and apply relevant innovations in organization-wide approaches to appropriate pain management while ensuring opioid safety
- Create safe and effective pain treatment strategies for different patient populations (e.g., pediatrics, elderly, pregnant, cancer patients, mental health, autoimmune diseases, and those with a history of OUD or addiction)
- Ensure that pain management policies and protocols complement guidelines and are specific to the patient population served by the healthcare system
- Implement continuous improvement activities to ensure that current practice policies and protocols are relevant and sustainable
- Practice patient-centered care by including patients and/or families in the pain treatment and management strategies
- Address essential gaps in pain management and patient care
- Communicate with the hospital and community leadership about “Best Practices” for pain management policies and programs

Overdose prevention plan

- Develop protocols to taper opioids in appropriate patients (DHHS).
- Develop protocols to identify patients at risk for overdose, implement strategies to reduce overdose risk, and provide overdose prevention education to patients and/or families
- Engage with professional accrediting bodies and community leadership to allow pharmacists to offer naloxone without prescription
Opioid Use Disorder (OUD) plan

- Implement effective screening strategies to identify individuals with OUD
- Create a culture of empathic treatment with non-stigmatizing communication with the understanding that OUD is a disease rather than a character flaw
- Engage with healthcare and community leadership to promote the certification of MAT prescribing for OUD for frontline clinicians who manage and treat pain (“Medication-Assisted Treatment (MAT)”, 2019; “Overview of Medication Assisted Treatment”, 2019).
- Develop and support 24/7 access and referral to treatment for substance use disorders, including MAT

Harm reduction plan

- Develop and employ harm reduction strategies, especially in people who inject drugs (PWID), including education around safety and risk mitigation, syringe access, safe syringe disposal, and point-of-care testing for human immunodeficiency virus (HIV) and hepatitis C virus (HCV)
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider:

http://patient.sm/2sopQK

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<tr>
<td>Integrate state-level prescription drug monitoring programs (PDMPs) with electronic health records to monitor opioid prescribing and clinical practices to improve safe prescribing practices</td>
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<tr>
<td>Create technology tools that will consistently measure pain and improvement outcomes across healthcare systems</td>
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<tr>
<td>Create a dashboard of validated pain metrics (operational, processes, and outcomes) that aligns with the organization’s approach to implement and adhere to accreditation standards and state laws</td>
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<tr>
<td>Integrate prescribing protocols, order sets, and specific care plans to prioritize safe pain management and to prevent drug diversion</td>
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<tr>
<td>Create a communication alert mechanism in the electronic medical records to identify patients at risk for an overdose and alert the pharmacist and clinician to offer naloxone and/or referral pain management and/or substance use disorder treatment teams</td>
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<tr>
<td>Develop a system to track and monitor prescribing patterns and other relevant metrics for pain management at the clinical unit, department, health-system and organizational levels</td>
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<tr>
<td>Create a system to optimize prescribing, treatment, monitoring, referrals, and communication across the health system and into the community</td>
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<tr>
<td>Develop a smartphone application and technology resource list for clinicians to manage their patients’ pain</td>
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<tr>
<td>Develop and distribute multimedia videos utilizing patients speaking to their peers about harm reduction, adverse effects, risks, and consequences of misusing opioid medications (Joint Commission’s “Speak Up: About Your Pain” animated videos for patients).</td>
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Measuring Outcomes

Pain Management
Rate of opioid usage = [# of opioid doses (MME) used / # of days supplied]

Measure the percentage of short-acting vs. long-acting opioids prescribed per patient

Measure the # of alternative pain medications prescribed vs. opioid medication prescribed

Measure the percentage of opioid prescriptions in combination with CNS depressants (benzodiazepines, gabapentoids, muscle relaxants, etc.)

Patient’s dose of opioid medication (MME) versus everyone’s (mean MME of individual prescriber vs. mean for dept/institution and/or goal mean)
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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

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Alex Shaffer  Advocate
David Shane Lowry  Rosalind Franklin University of Medicine and Science
Robin Shannon  The T System
Deeba Siddiqui  Hackensack Medical Center
Charles Simmons  Cedars-Sinai Medical Center
Nats Sims  Massachusetts General Hospital
Robert Stein  Keck Graduate Institute
Laura Townsend  Louise H. Batz Patient Safety Foundation
Kimberly Won  Chapman University School of Pharmacy
Jason Yamaki  Chapman University School of Pharmacy
Sun Yang  Chapman University School of Pharmacy

Metrics Integrity:
Robin Betts  Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.
References


Actionable Patient Safety Solutions (APSS) #4: Monitoring for opioid-induced respiratory depression

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for monitoring for opioid-induced respiratory depression. In it, you’ll find:

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Executive summary checklist

Opioid-induced respiratory depression is a leading cause of preventable patient death (Weinger) and causes serious patient harm.

To create a culture of safety and prevent serious harm, health care providers must take steps to prevent opioid-induced respiratory depression and carefully monitor a patient if it happens.

Create an action plan

- Find and prioritize factors in common with serious preventable events:
  - Review all reported patient deaths and serious patient harm events over the previous 24 months for patients given opioids and opioids with sedatives, such as benzodiazepines
  - Review all closed malpractice claims related to opioid-induced respiratory depression
  - Monitor and review all patients given naloxone
- Develop an action plan for your institution based on the data collected from serious preventable events and the strategies within this APSS:
  - Include guidelines for continuous electronic monitoring to notify staff of significant changes in a patient’s respiratory condition, and ensure that staff respond correctly and promptly
  - Appoint a staff “champion” to be in charge of your plan’s implementation, education, and evaluation
  - Provide the resources necessary to implement your action plan
- Educate all staff, patients, and family members on the common contributing factors leading to opioid-induced respiratory depression and side effects of opioids and sedatives
- Continue to report and assess both near-misses and patient harm events for more opportunities to learn and improve
- Use written and recorded patient stories to help staff find gaps between their care and a patient’s experience
- Complete a community needs assessment and act on overused opioids within substance abuse and mental health
- Create a community based approach to alternatives to opioids to opioids when appropriate

Ensure best patient care

- Use continuous electronic monitoring in all hospital units where patients receive opioids:
  - Include continuous monitoring of blood oxygen levels in your care standard, which should include motion and low perfusion pulse oximetry
  - Monitor respiratory rate in patients receiving oxygen with either continuous capnography or acoustic respiration rate monitoring
  - Use a system to alert staff early if a patient’s health is deteriorating, and set an escalation plan to include another staff member
Lower alarm fatigue for staff by setting proper respiratory rate (RR), pulse rate (PR), SpO2, and apnea alarms based on the patient’s risk

Develop a pain management program that uses various methods, including non-opioid adjuncts, Opioid Free Analgesia (OFA), and safe opioid tapering protocols
What we know about opioid-induced respiratory depression

Opioid induced respiratory depression is a serious patient safety issue and only a multidisciplinary approach can improve outcomes. It is a problem that involves the emergency department, hospitalization floor, operating room, postanesthesia care unit, intensive care unit and even home care facilities, and all the professionals involved in those areas.

When a patient has somnolence or appears to be sedated is at high risk to develop OIVI. If not on continuous monitoring this needs to applied immediately and/or the patient transferred to an area where continuous monitoring can occur. OIVI has been reported within 15 minutes of a nursing check (Lee et al 2015). The critical time period for use of continuous monitoring is the first 24 hours postoperatively as demonstrated by the Closed Claims Project that revealed that 88% of events occurred in that time frame. (Lee et al 2015). Regular visits by nurse, medical or administrative staff can trigger alarms about the risk of OIVI, and assessments should include blood pressure, temperature, pulse, respiratory rate, pain level, respiratory status, and especially sedation level. These visits cannot replace continual monitoring.

A greater emphasis on monitoring the first 24 hours is likely to be helpful in reducing adverse events from opioids.

Patients receiving opioids in the hospital have almost twice the incidence of cardiac arrest compared to other patients (Overdyk et al., 2016). The cost associated with respiratory failure after surgery alone in the U.S. Healthcare System is $2 billion (Reed, May, Nicholas, Taylor, & Brown, 2011).

Improper monitoring can lead to opioid-induced respiratory depression

While opioid use is safe for most patients, opioid analgesics are associated with adverse effects, including respiratory depression in many post-surgical patients (Vila et al., 2005; Jarzyna et al., 2011).

Adverse effects associated with opioids not only include the above mentioned respiratory depression, but also hyperalgesia, early development of tolerance and dependence, ileus (inability of the intestine to move food or waste), nausea and vomiting, and delayed recovery (Kane-Gill et al., 2014).

Administration of supplemental oxygen complicates the monitoring issue because it can delay detection of depression ventilation and further impair hypoxic respiratory drive. Another challenge is to accurately measure the incidence of OIVI, because without sequential acquired measures any new monitoring system or protocol can’t be evaluated. There are some surrogates for identifying respiratory depression, like: Hypercapnic hypoventilation, Hypopnea, Decreased ventilatory rate, Hypoxemia and others. After the Institute of Medicine (IOM) described failure to rescue as a key issue in healthcare quality in 2001, they identified it as a key area for improvement in patient safety (“Crossing the Quality Chasm: A New Health System for the 21st Century”, 2001).

A decade later, a study looked at patient safety indicators for 40 million hospitalized patients and concluded that many deaths and permanent disabilities could still be avoided if healthcare systems adopted safe practices and put systems in place that help patient safety (Reed, et al., 2011).

Reports by hospitals to the Joint Commission’s Sentinel Event database (2004-2011) show that the causes of opioid-related adverse events and deaths include:
• 47% from dosing errors
• 29% related to improper monitoring of the patient
• 11% related to other factors including excessive dosing, medication interactions, and adverse drug reactions

This document focuses on the 29% of patients that were improperly monitored.

In-hospital mortality after surgery is higher than expected and has multiple factors that institutions can address systematically (Pearse et al., 2012). This document provides solutions to reduce postoperative opioid-induced respiratory depression, including:
  • Properly monitor and identify patients at risk for “failure to rescue”
  • Create systems to notify staff of important changes in patient condition
  • Ensure proper pain management and opioid dosing
  • Use automated decision support to ensure staff use the right therapy at the right time

**Proper monitoring can prevent opioid-induced respiratory depression**

In 2011, the Anesthesia Patient Safety Foundation recommended continuous monitoring for all patients receiving parenteral (usually administered Intravenously) opioids, and using a system to notify caregivers when alarming conditions occur (Weinger).

In August 2012, the Joint Commission issued a sentinel event alert (a change in policy based on death or serious harm to a patient), urging all healthcare systems to introduce measures to improve safety for patients receiving opioids, including systematic protocols to assess pain and proper opioid dosing, as well as continuous monitoring of oxygenation and ventilation (Joint Commission, 2012). In 2014, the Center for Medicare and Medicaid Services (CMS) clarified the surgical services Condition of Participation (CoP) for hospitals to have adequate provisions for immediate postoperative care and to emphasize the need for monitoring after surgery for patients receiving parenteral opioid medications, regardless of where they are in the hospital (Centers for Medicare & Medicaid Services, 2014).

**The evidence for proper monitoring**

Research has studied the development of early warning systems (EWS) and validated EWS in Europe and Australia (Alam et al., 2014; Ludikhuize, Smorenburg, De Rooji, and De Jonge, 2012; Fullerton et al., 2012; Smith et al., 2013). Your institution can easily incorporate the technology to support EWS, such as remotely monitoring discharged patients. Recently newer EWS have been developed, like NEWS and NEWS 2, which improve sensitivity and specificity to activate Fast Response Teams (FRT (RCP London, 2017)

A landmark study published in January, 2010 by Dartmouth-Hitchcock Medical Center demonstrated that clinicians using motion-resistant and low perfusion pulse oximetry and remote monitoring and clinician notification system identified patient distress earlier, which decreased rapid response team activations by 65%, ICU transfers by 48%, and reduce ICU days by 135 days annually (Taenzer, Pyke, McGrath, and Blike, 2010).

A follow-up report by Dartmouth in 2012 reported that, since December, 2007, no patients have died or had serious brain injuries as a result of respiratory depression from opioids. In addition, expanding monitoring to all general and thoracic vascular post-surgical units produced similar results to those seen in the original orthopedic unit (Taenzer). They also reported savings of $58,459 saved per patient who was not transferred to the ICU from the original orthopedic unit ($76,044 vs. $17,585), equating to $1.48 million in annual savings.
opportunity cost savings in this one unit alone.

In spite of the calls to address failure to rescue for postoperative respiratory depression, pain assessment and opioid dosing approaches are still variable, and a high percentage of post-surgical patients on parenteral opioids are not continuously monitored. A combined approach with clinical skills and technology helps to provide additional information for detection of respiratory depression. The lack of a systematic approach to prevent failure to rescue from postoperative respiratory depression poses significant patient safety, quality, and cost of care implications. Healthcare institutions must commit to action with specific leadership, action, and technology plans to close their performance gap on this issue.

In the future no patients will be harmed by postoperative OIVI. We need to make the commitment to provide safe prescription, to reach for alternative analgesics, and to use technology and clinical skills to monitor every patient with opioid analgesia.

**Leadership plan**

- Hospital governance, senior administrative leadership, and clinical/safety leadership should close their performance gap through a comprehensive approach that addresses the problem
- Hospital governance and senior administrative leadership should commit to be aware of this major performance gap in their healthcare system
- Clinical/safety leadership should:
  - Endorse the plan
  - Drive implementation across their institution
  - Include fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action (National Quality Forum, 2010)
  - Set measurable quality indicators
  - Set a goal date to implement the plan
  - Have hospital governance and senior administrative leadership evaluate the budget
- Use patient stories – in written and video form – to find gaps and inspire change in your staff

**Action plan**

Create protocols for opioid treatment (refer to APSS #3G: Opioid Safety Stewardship)

- Assess pain management protocols and standardized order sets where possible
- Create standard transfer protocols from surgery and intensive care unit to postoperative general floor unit
- Use a tapering protocol for opioid and/or combination of opioids with sedatives based on patient’s alertness, respiratory rate, and pain control
- Store naloxone in every Code Blue crash cart tray on every hospital unit
- Create standard workflows for continuous monitoring from patient admits through discharges

Use opioid alternatives in your pain management protocols (refer to APSS #3G: Opioid Safety Stewardship)
• Enact opioid-free analgesia (OFA) protocols as routine surgical/anesthesia practice as recommended by the Enhanced Recovery After Surgery (ERAS) organizations – evidence shows less cancer recurrence if cancer surgeries use OFA protocols

• Include the following alternatives in your protocols: multimodal therapy with regional anesthetic blocks (such as TAP Blocks with liposomal bupivacaine), non-steroids - acetaminophen, low dose ketamine, dexmedetomidine, intravenous lidocaine, and intravenous magnesium (ASA, 2016)

Create protocols for continuous electronic monitoring
• Improve electronic detection of deteriorating patients and the early notification of the caregivers, including the prevention of adverse events due to respiratory depression from pain medications

• Continuous oxygenation and/or respiratory monitoring (not spot check monitoring) with pulse oximetry through an adhesive sensor. Ideally use pulse oximetry with measure through motion and low perfusion technology

• Use a remote notification system with an alarm to notify the care provider

• Use a system of alarm escalation if the primary nurse does not respond promptly

• Set respiratory rate (RR), pulse rate (PR), and blood oxygen (SpO2) alarms to reduce alarm fatigue, based on your specific patient population. Examples:
  o For most adults:
    • Set RR alarm for below 6 and above 30 breaths per minute
    • Set PR alarm for below 40 and above 100 beats per minute (Taenzer, Pyke, McGrath, and Blike, 2010).
  o For children (use clinical judgement appropriate for age):
    • Set SpO2 alarm for below 84% (McGrath, Pyke, and Taenzer, 2016)

• Use continuous ventilation monitoring (such as capnography or respiratory acoustic rate monitoring) for reduced respiratory rate in patients on supplemental oxygen

• Continuous electronic monitoring systems should use multiple physiologic measures in the form of an index to help identify clinically significant changes earlier and more reliability

Update rapid response team protocols
• Use rapid response teams and a protocol for starting a rapid response call for postoperative respiratory depression (Alam, et al., 2014)

• Allow families to ask the nurse to activate the rapid response system. Educate families about this option (Brady et al., 2014)

• Consider using proactive rounding on high-risk patients by resource nurses with critical care training (Hueckel et al., 2006)

Technology plan
These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: http://patient.sm/dgQogJ
Consider using the following technologies:

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<td>CCHIT-certified EHR systems</td>
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<td>with the following capabilities:</td>
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<td>• Drug-drug interaction check</td>
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<td>• Drug-allergy interaction check</td>
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<td>• Clinical Decision Support tools (CDS)</td>
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<td><strong>Continuous pulse oximetry</strong></td>
<td>Adhesive pulse oximetry sensor connected with pulse oximetry technology proven to</td>
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<tr>
<td>• direct surveillance of patients</td>
<td>measure-through-motion and low perfusion to avoid false alarms and detect true physiologic events</td>
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<td><strong>Continuous respiratory rate monitoring</strong></td>
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<td>• Ability to accurately measure changes in respiratory rate and cessation of</td>
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<tr>
<td>breathing with optimal patient tolerance and staff ease of use in order to</td>
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<td>avoid false alarms, with added importance in care areas without minimal direct</td>
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<td>surveillance of patients</td>
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<td><strong>Remote monitoring and notification system</strong></td>
<td>Multi-parameter monitoring system which includes direct clinician alert through</td>
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<td>• Remote monitoring with direct clinician alert capability compatible with</td>
<td>dedicated paging systems or existing hospital mobile device notification system.</td>
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<td>recommended pulse</td>
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<td><strong>Network</strong></td>
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<td>• Medical-grade wireless network suitable to permit reliable, continuous remote</td>
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<td>monitoring and documentation during ambulation and/or transport</td>
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<td>• Alternatively, use a wired network which allows surveillance of patients while</td>
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<td>they are in bed, but not while they are in an ambulance</td>
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Measuring outcomes

Key performance indicator
If your organization uses the Safety Event Classification system, the following metric specifications apply (If not, consider adapting this model as a template):

Rate of patients with postoperative respiratory failure per 1,000 elective surgical discharges for patients 18 years and older as defined by the Agency for Healthcare Quality and Research (AHRQ)

Outcome measure formula

Numerator: Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with either:
- Any secondary ICD-10-CM diagnosis code for acute respiratory failure
- Any listed ICD-10-PCS procedure codes for:
  - A mechanical ventilation for 96 consecutive hours or more that occurs 0 or more days after the first major operating room procedure code (based on days from admission to procedure)
    - A mechanical ventilation for less than 96 consecutive hours (or undetermined) that occurs 2 or more days after the first major operating room procedure code (based on days from admission to procedure)
    - A reintubation that occurs 1 or more days after the first major operating room procedure code (based on days from admission to procedure)
    - Narcan use

Denominator: Elective surgical discharges, for patients ages 18 years and older, with any-listed ICD-10-PCS procedure codes for an operating room procedure. Elective surgical discharges are defined by specific DRG or MS-DRG codes with admission type recorded as elective.

Exclude cases:
- Where the only operating room procedure is tracheostomy
- Where a procedure for tracheostomy occurs before the first operating room procedure (If day of procedure is not available in the input data file, the rate may be slightly lower than if the information was available).
- With missing gender, age, quarter, year, or principal diagnosis
- With a principal ICD-10-CM diagnosis code (or secondary diagnosis present on admission) for acute respiratory failure (see above)
- With any listed ICD-10-CM diagnosis codes for:
  - Neuromuscular disorder
  - Degenerative neurological disorder
- With any listed ICD-10-PCS procedure codes:
  - That involve the face (when appropriate) and any-listed ICD-10-CM diagnosis codes for craniofacial anomalies
  - For laryngeal or pharyngeal, nose, mouth, or pharynx surgery
  - For esophageal resection
  - For lung cancer
- MDC 4 (diseases/disorders of respiratory system)
Metric recommendations

Direct Impact: All elective surgical patients

Lives Spared Harm:
\[ \text{Lives Spared Harm} = (\text{PSI #11 Rate baseline} - \text{PSI #11 Rate measurement}) \times \text{Elective Surgical Discharges baseline} \]

Notes
For detailed information regarding specific diagnosis codes and DRGs for inclusion, please see AHRQ’s PSI #11 Specification document.

Data collection
Collect data through coding documentation.

Mortality (Patient Safety Movement Foundation will calculate):
The PSMF, when available, will use the mortality rates associated with Hospital Acquired Conditions targeted in the Partnership for Patient’s 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 (AHRQ, 2019).

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs
*Michael Ramsay  
Baylor Research Institute
Lenore Alexander  
Leah’s Legacy

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.
Ernesto Arriaga  
San Ángel Inn Sur Hospital

*Steven J. Barker  
Patient Safety Movement Foundation; Masimo

*Michael Becker  
Masimo

Michel Bennett  
Patient Safety Movement Foundation (formerly)

Thomas Corlett  
Ehlers-Danlos Inspiration Community

Victor Grazette  
Virginia Hospital Center

Edwin Hanson  
Kedren

Helen Haskell  
Consumers Advancing Patient Safety

Sherry Henricks  
Henricks Coaching & Consulting LLC

Kelley Jager-Jackson  
Masimo (formerly)

Ariana Longley  
Patient Safety Movement Foundation

Jacob Lopez  
Patient Safety Movement Foundation

Olivia Lounsbury  
Patient Safety Movement Foundation

*Michael I. Mestek  
Medtronic

Tim O’Malley  
EarlySense

Donna Prosser  
Patient Safety Movement Foundation

Patricia Roth  
University of California, San Francisco

Kenneth Rothfield  
Medical City Health

George Shapiro  
Anesthesia Patient Safety Foundation

Michael Wong  
Physician-Patient Alliance for Health & Safety

Metrics integrity

Robin Betts  
Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

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How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for patient blood management. In it, you’ll find:

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APSS #5: Patient blood management

**Executive summary checklist**

Patient Blood Management (PBM) is the timely application of evidence-based medical and surgical concepts designed to manage anemia. Optimize hemostasis and minimize blood loss in order to improve patient outcomes. PBM strives to return to the ‘medical model’ where the clinician identifies the disease first and then looks for the appropriate treatment. Errors in the use of blood components are a significant cause of hospital patient morbidity and mortality (Meybohm et al., 2017).

Use this checklist to help prioritize your actions and measure your institution’s progress.

**Ensure accountability**

- Establish a Patient Blood Management Committee and appoint an MD to be responsible and accountable for leading this group
- Prepare and deliver a monthly report to senior healthcare leadership on system-wide blood components usage
- Develop a Patient Blood Management education program for any staff involved with blood transfusions
- Constantly check the success of the Patient Blood Management program and use these results in medical staff educational sessions as a part of Continuous Quality Improvement (CQI)
- Use patient stories – in written and video form – to identify gaps and inspire change in your staff

**Establish PBM protocols**

- Use interdisciplinary and conservative blood management practices, including:
  - Minimize unnecessary laboratory tests
  - Minimize how often providers draw blood, as well as the amount drawn
  - Minimize discarded dead space blood volumes (the volume of blood from within a catheter that a staff discards to reach a clean blood sample)
  - Use a consistent protocol to manage platelet inhibitors (and other anticoagulants) before surgery
- Integrate proven technology for bloodwork to improve patient care, such as:
  - Continuous, non-invasive hemoglobin monitoring
  - Dynamic volume assessments to determine plasma volume
  - Red cell recovery technology in the operating room
- Before surgery, providers should test for and treat anemia in a patient when possible, including checking patient hemoglobin levels to identify who may need a blood transfusion
- Set a single unit transfusion policy for non-bleeding patients who need a transfusion and advocate for more restrictive transfusion practices
- Record hemoglobin levels before and after each blood transfusion
- Minimize transfusion with proper anemia treatment tailored to the cause of the anemia (such as intravenous iron or erythropoietin stimulating agents (ESAs))
What is patient blood management?

Patient Blood Management (PBM) is the use of properly timed, evidence-based practices when managing anemia in patients. The causes of anemia include blood loss, problems with red blood cell formation, and malnutrition.

While healthcare providers normally use blood transfusions to treat anemia, these often don’t treat the underlying cause and introduce risk of error each time a patient receives a transfusion. Errors in the use of blood components are a significant cause of hospital patient harm and death (Meybohm et al., 2017).

To lower this risk for patients, healthcare institutions should:

- Find the cause of anemia in a patient and use the proper treatment
- Improve practices to reach hemostasis (stop patient bleeding)

These will lower the need for transfusions, the risks of errors they present, and the preventable patient deaths connected to this issue.

What we know about patient blood management

Anemia is a worldwide problem

The usual symptoms of anemia include feeling weak, tired, and having problems concentrating. Healthcare providers often overlook or ignore anemia since these symptoms are vague and a part of daily life for many people.

However, anemia is the most common blood disorder worldwide, affecting around 1 in 3 people across the globe (Kassebaum et al., 2014). This is especially true for women of childbearing age - around 500 million women worldwide in this group have anemia (Friedman et al., 2012).

Patients in both developing countries and the industrialized world experience anemia and it's the source for 68.3 million years lived with disability (YLD) and 8.8% of all ailments worldwide (McLean et al., 2009). Being a worldwide epidemic with significant consequences (Kassebaum et al., 2014), anemia requires prompt evaluation and treatment (Meybohm et al., 2017).

Anemia increases surgery risks

Recent studies show that anemia can have a serious impact on surgical outcomes making it an independent risk factor for patients. Musallam and colleagues looked back at data including 227,425 patients undergoing any kind of non-cardiac surgery:

- Non-anemic patients had a 30-day mortality rate of 0.78% (over 158,000 patients)
- In contrast, patients with only mild anemia (Hb level of 10-13 g/dL in men and 10-12 g/dL in women) had a mortality rate 4.5 times higher than non-anemic patients (3.52% in over 57,000 patients)
- When patients were severely anemic (Hb level below 10 g/dL) their 30-day mortality rate increased to 13 times more than non-anemic patients (more than 11,000 patients).

(Musallam et al., 2011)

A separate study looked at medical reports of more than 39,000 patients confirming the association between mild anemia and increased death (+20% in multivariate models), longer
stays at hospitals, and a greater need for intensive care (Baron et al., 2014). Longer hospital stays are associated with greater cost and greater risk for other healthcare-associated conditions like falls and healthcare-associated infections (HAIs).

**The risks of blood transfusions**

Healthcare providers often give red blood cell (RBC) transfusions to patients with anemia to raise their oxygen carrying capacity. Yet many RBC transfusions are overused and may cause undue risk or harm. The Institute of Medicine (IOM) defines overuse as “in circumstances where the likelihood of benefit is negligible or zero, and therefore the patient is exposed to the risk of harm”. Often, healthcare institutions aren’t aware of the serious impact this overuse has on safety of patients or the resource savings of avoiding RBC overuse.

1 in 10 in-patients receive at least 1 unit of blood, making RBC transfusion one of the most common procedures for hospitals in the U.S. and Europe (Cost et al., 2009). However, laboratory hemoglobin values, a primary indicator for RBC transfusions, are only checked on occasion and often delayed - leading to transfusion decisions without knowing if they will help (Frank, er al., 2012). If a patient has their blood drawn too often for lab tests, it can even lead to anemia or make it worse (Ranasinghe and Freeman, 2014; Salisbury et al., 2011).

**The evidence for PBM**

The PBM was officially established under the Wolff Center in 2013. Over the past 5 years, their PBM strategy has resulted in significant blood and blood product procurement and services cost reductions ($10M), while increasing patient safety (Patient Safety Movement Award 2015). The University of Pittsburg Medical Center (UPMC) PBM program is nationally and internationally recognized as a model of excellence in blood management. (Figure 1)

![Blood Product Purchases 2012-2017](image)

**Figure 1**: The reduction in blood product used over the last 5 years at the Wolff Center, which reduced costs by $10M by implementing the 6-point strategy for PBM

The largest multicenter trial (almost 130,000 patients) in the world shows that integrating PBM greatly reduces the amount of transfused blood, costs, and kidney damage. Overall, the implementation of PBM is safe and effective (Meybohm et al., 2016).

Technology to support laboratory hemoglobin measurements, such as noninvasive and continuous hemoglobin monitoring, can give clinicians more real-time trending information to
determine if hemoglobin values are changing, which permits clinicians to make more informed and early RBC transfusion decisions.

Hospitals with robust PBM programs commit, not only to reduce transfusion as a safety measure, but also to recognize and incorporate the diagnosis and proper treatment of anemia. A careful assessment of the patient’s condition includes finding the cause of their anemia and should direct the clinician to employ the best and safest intervention.

Research shows that fewer RBC transfusions through process changes and using technology can save the U.S. healthcare system more than $5 billion per year, while greatly improving quality and safety (Masimo Corp, 2012). Healthcare institutions must commit to action with specific leadership, action, and technology plans to close their performance gap on this issue.

**Leadership plan**

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to increase awareness of anemia and minimize its risks (Meybohm et al., 2017; Shander, Isbister, and Gombotz, 2016; Moskowitz et al., 2010; Leahy et al., 2014; Theusinger et al., 2014; Freedman, 2014; Oliver, Griffin, Hannon, and Marques, 2014):

- Hospital governance, senior administrative leadership, and clinical/safety leadership should close their institution’s performance gap with a plan that includes:
  - A comprehensive approach
  - A timeline with defined deliverables to implement the plan
  - Measurable quality indicators
- Governance boards and senior administrative leaders should evaluate and approve the resources needed for the plan
- Clinical/safety leadership should endorse the plan and drive implementation across all providers and systems
- Include changes in the plan outlined in the National Quality Forum (NQF) safe practices, including awareness, accountability, ability, and action (National Quality Forum, 2010)
- Identify a physician champion for the PBM program who is a thought leader within the organization to help drive change among providers
- Utilize patient stories - in written and video form - to identify gaps and inspire change in your staff

**Action plan**

**Ensure accountability**

- Establish a PBM Committee and appoint a leader to be responsible and accountable for its actions. This committee and leader should:
  - Communicate early with key stakeholders
  - Set up a complete plan for anemia management
  - Set measurable goals and outcomes for individuals and departments
- Develop a broad education program that targets healthcare staff and focuses on the PBM program’s goals, structure, and scope:
  - Consider an online course and “Patient Blood Management certificate”
Create PBM protocols

- Cooperate with all stakeholders to set guidelines, checklists, SOP’s, and transfusion thresholds for anemia therapy
- Use proactive review instead of the more common retroactive review
- Establish both out-patient and in-patient systems to address anemia
- Set protocols for lab work that incorporate (Goodnough and Shander, 2013):
  - Fewer unneeded blood tests
  - Fewer blood samples taken
  - Reducing wasted dead space blood volumes
  - Using closed arterial blood sampling systems, when appropriate
  - Consulting blood conservation specialists early for patients with worsening health or complications
- Set protocols for transfusions:
  - Advocate for more restrictive transfusion practices
  - Check for and maintain normal blood volume (normovolemia) before restricting transfusion
  - Set a protocol for RBC transfusion decision-making
  - Set a single unit transfusion policy
  - Use the Mercuriali algorithm to calculate RBC deficit
  - Consider alternative therapies to RBC transfusions such as intravenous iron and erythropoietin stimulating agents (ESAs)
  - Set a stricter limit on the hemoglobin level needed for a transfusion
  - Consider both the change in a patient’s hemoglobin level from their baseline, as well as their current level, as indicators for transfusion
  - Use hemoglobin monitoring and NIRS tissue oxygen monitoring technologies to augment lab tests
  - Make transfusion decisions based on signs and symptoms, in addition to hemoglobin level and NIRS tissue oxygen values
- Set protocols for surgery patients:
  - Test and treat all patients for anemia surgery, allowing enough lead time for treatment
  - Promptly assess anemia during and after surgery
  - Before surgery, test for problems with blood coagulation and manage platelet inhibitors and other anticoagulants
  - Use minimally invasive surgical techniques
  - Use surgical techniques to minimize bleeding including use of electrocoagulation, bipolar, and argon beam
  - Consider acute normovolemic hemodilution (minimize blood loss by removing blood before surgery and replacing it afterward)
  - Many blood sparing techniques exist for cardiac surgery, such as minimized extracorporeal circuits, retrograde autologous priming, modified ultrafiltration, blood cardioplegia, and meticulous hemostasis in saphenous vein graft removal
- Consider other techniques to minimize blood loss such as:
  - Vasoconstrictors, topical coagulation agents, and tourniquets
- Controlled hypotension
- Blood salvage technologies
- Basic conditions for hemostasis
- Reversal of anticoagulants
- Point-of-care diagnostics in coagulopathic patients
- Optimized coagulation management with the use of clotting factor concentrates
- Antifibrinolytic agents or desmopressin
- Basic conditions for hemostasis, reversal of anticoagulants, point-of-care diagnostics in coagulopathic patients, optimized coagulation management with the use of clotting factor concentrates, and the use of antifibrinolytic agents or desmopressin are further important considerations

- Create protocols for hemorrhage identification and control:
  - Identify patients at risk for development of hemorrhage (OB)A massive and have a hemorrhage protocol in place
  - Where needed, massive hemorrhage protocols should be extended by specific algorithms for different subgroups of high-risk patients, such as postpartum and trauma (Figure 2)

**Figure 2:** Preoperative anemia management workup algorithm (Goodnough et al., 2011) to optimize coagulation and reduce bleeding
Technology plan
These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: [http://patient.sm/dgQogJ](http://patient.sm/dgQogJ)

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  - Drug-drug interaction check  
  - Drug-allergy interaction check  
  - Clinical Decision Support tools (CDS) | • For example, if a physician is planning on putting an order in for blood product, instead of filling the order immediately, the EHR can have it “ON RESERVE”. This prevents product being unused and wasted. |
| Leverage the electronic health record (EHR) to provide real-time decision support for all blood and blood product orders, based on evidence-based transfusion rationale | • Decision support iForms |
| Noninvasive and continuous hemoglobin monitoring | |
| Cell recovery technology in the operating room | |
| Point of care coagulation testing | |
| Smaller blood test tube volumes | |
| Reducing priming volume of extracorporeal circuits | |
| Closed blood sampling systems for arterial and central venous lines | |
| An IT structure for benchmarking | |
Measuring outcomes

Key performance indicators

Anemia and transfusion management:
For patients with untreated and treated preoperative anemia, find:
- Rate of transfusion (Number of preoperative patients with anemia who receive a transfusion per total number of preoperative patients with anemia)
- Adverse events (AE)
- Patient deaths
per 1,000 patients who undergo elective surgery

Outcome measure formula:
Establish Baseline Harm using:

Numerator: the number of patient deaths with untreated and treated preoperative anemia (you may keep these numbers separate or combine for this measure)

Denominator: Total number of anemic patients undergoing elective surgery

Metric recommendations

Direct Impact:
All patients undergoing elective surgery

Lives Spared Harm:
Lives Spared Harm = (Adverse Events baseline – Adverse Events measurement) X Elective Anemic Surgery Patients measurement

Lives Saved:
Lives Saved = (Mortality Rate baseline – Mortality Rate measurement) X Elective Anemic Surgery Patients measurement

Notes
The table below contains the levels WHO uses to define anemia (WHO, 2011):

Table 1
Haemoglobin levels to diagnose anaemia at sea level (g/l)*

<table>
<thead>
<tr>
<th>Population</th>
<th>Non-Anaemia*</th>
<th>Anaemia*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mild*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe</td>
</tr>
<tr>
<td>Children 6 - 59 months of age</td>
<td>110 or higher</td>
<td>100-109</td>
</tr>
<tr>
<td></td>
<td></td>
<td>70-99</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lower than 70</td>
</tr>
<tr>
<td>Children 5 - 11 years of age</td>
<td>115 or higher</td>
<td>110-114</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80-109</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lower than 80</td>
</tr>
<tr>
<td>Children 12 - 14 years of age</td>
<td>120 or higher</td>
<td>110-119</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80-109</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lower than 80</td>
</tr>
<tr>
<td>Non-pregnant women (15 years of age and above)</td>
<td>120 or higher</td>
<td>110-119</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80-109</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lower than 80</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>110 or higher</td>
<td>100-109</td>
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<tr>
<td></td>
<td></td>
<td>70-99</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lower than 70</td>
</tr>
<tr>
<td>Men (15 years of age and above)</td>
<td>130 or higher</td>
<td>110-129</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80-109</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lower than 80</td>
</tr>
</tbody>
</table>

*Adapted from references 5 and 6
*Haemoglobin in grams per litre
a “Mild” is a misnomer; iron deficiency is already advanced by the time anaemia is detected. The deficiency has consequences even when no anaemia is clinically apparent.
Data collection
Data sources may include electronic billing data, data through manual chart review, or a hybrid method of chart review and electronic billing data.

Settings:
All in-patients (≥ 18 years) undergoing a surgical procedure and with at least one overnight stay

Mortality:
This will be calculated by the Patient Safety Movement Foundation

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs
*Aryeh Shander  Englewood Hospital and Medical Center
Kai Zacharowski  University Hospital Frankfurt
Riyad Albard  Thalassaemia International Federation

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

*Steven J. Barker  Patient Safety Movement Foundation; Masimo
Michel Bennett  Patient Safety Movement Foundation (formerly)
William Floyd  iPASS, Inc.
Debbie Garbade  Houston Methodist
Mike Hoffman  MedStar
Ariana Longley  Patient Safety Movement Foundation
Jacob Lopez  Patient Safety Movement Foundation (formerly)
Olivia Lounsbury  Patient Safety Movement Foundation
*Stacey Orsat  Masimo
Donna Prosser  Patient Safety Movement Foundation
Rachael Raynes  Patient Safety Movement Foundation
Tomas Sanabria  Fundacion Proyecto Maniapure
Rachael Sarnowski  Patient Advocate
Nat Sims  Massachusetts General Hospital
*Kerry Tomlin  
Medtronic  
Jonathan Walter  
University of Pittsburgh Medical Center  
Mary Kay Wisniewski  
University of Pittsburgh Medical Center  
Thomas Zeltner  
World Health Organization (WHO)

**Metrics integrity**

Robin Betts  
Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

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How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for hand-off communications. In it, you’ll find:

Executive summary checklist ........................................ 226
What is known about hand-off communications (HOCs) .................................................. 227
Leadership plan .......................................................... 230
Action plan ................................................................. 231
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Appendix A: Hand-off communications (HOC) checklists .................................................. 237
Executive summary checklist

Hand-off communications (HOCs) must happen whenever care of a patient is transferred from one individual or care team to another. Accurate, effective, and complete HOCs are vital for patient safety. Serious patient harm can occur when HOC information is absent, incomplete, erroneous, or delayed.

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

☐ Educate all hospital staff on these principles and requirements for effective HOC:
  ☐ Recognize that each HOC involves a “sender” and “receiver”
  ☐ HOC failures occur when:
    1. The sender omits vital patient information from their report
    2. The receiver fails to understand or properly record vital information given by the sender
    3. The sender and/or receiver fails to understand or manage the subject information in a complete, accurate, and timely manner

☐ Establish an HOC core team that includes:
  ☐ A strong sponsor (senior clinical and administrative leadership is strongly encouraged), physician champion, nursing champion, and project leader
  ☐ Other members include practicing physicians, nurses, pharmacists, therapists, technicians, and information technology experts

☐ Measure the effectiveness of current HOC processes and create performance goals from this baseline

☐ Define the exact roles of the sender and receiver for each type of HOC at your institution

☐ Develop and use checklists (both written and electronic) for effective HOCs that ensure accurate, complete, and timely communication among healthcare providers and caregivers

☐ See proposed checklists in Appendix A

☐ Consider an existing structure for HOCs such as:
  ☐ IPASS (Illness, Patient Summary, Action Item, Situation Awareness & Contingency Planning, Synthesis by Receiver)
  ☐ SBAR (Situation, Background, Assessment, Recommendation)

☐ Train all hospital staff on the principles and requirements for effective HOCs

We’ve identified 18 different HOCs that commonly happen in healthcare institutions and include 10 example checklists in Appendix A.
What we know about hand-off communications (HOCs)

The risks of HOC mistakes

HOCs introduce mistakes when clinicians don’t communicate patient-specific medical care and treatment information (e.g. patient’s condition, therapies and treatment plans, or any special considerations) in a complete, accurate, and timely manner. A study from AAMC shows that risk for communication error is high when there’s power and status differences or role conflict or role ambiguity (Communication Failures: An Insidious Contributor to Medical Mishaps).

The Agency for Healthcare Research and Quality (AHRQ) reports that nearly half of hospital staff believe patient information is lost during transfers across hospital units or during shift changes (Sorra and Nieva, 2004).

Breakdowns in communication were the leading cause of sentinel events (death or serious harm to a patient that requires further review) reported to The Joint Commission between 1995 and 2006 (The Joint Commission, 2013).

Preventing HOC mistakes

The most common mistakes with HOCs are that the sender omits vital data, or the receiver doesn’t understand or record it. The mode of message delivery, whether oral, written or digital, can determine the success of reception. These problems aren’t unique to medicine – these are also common in other industries, such as aviation. Their solution to these communication mistakes is a system of checklists for each major task, such as takeoff, landing, and emergency management. They identify 4 issues that make checklists mandatory: workload stress, distractors, concurrent activities and increasing levels of complexity.

While each checklist needs to be tailored to the sender and receiver of each HOC, they must all contain the vital information needed by the receiving caregiver/team to provide the best care of the patient. That information must include (but is not limited to) the following:

- The reason the patient is in the hospital
- All medical problems for the patient, even if not relevant to this admission
- Patient treatment and physical history, including relevant parts of review of systems
- Results from labs and other tests
- A patient’s medications and treatments – both current and planned
- I and O’s (patient Intake and Output, such as catheters or blood draws)
- Hospital course, progress, and/or complications
- The discharge plan for the patient or final hand-off
- Recommendations: “Here is what I [the caregiver] think and suggest”

While checklists are vital, there is no “one-size-fits-all” approach to addressing HOCs, and they should never take the place of creative problem solving when needed. HOCs require a data-driven approach to find the contributing factors unique to the specific transition of care and the proper targeted solutions.

The Joint Commission Center for Transforming Healthcare’s Targeted Solutions Tool (TST) gives healthcare institutions a comprehensive, step-by-step approach that improves HOCs and helps organizations:
• Accurately measure actual performance
• Identify barriers to excellent performance
• Direct them to proven solutions tailored to their particular barriers related to HOCs

The evidence for effective HOCs
The TST reports healthcare institutions that have used their approach have an increase in patient and family satisfaction, staff satisfaction, and successful transfers of patients. One healthcare organization reduced their readmissions by 50% and another reduced the time it takes to move a patient from the emergency department to an inpatient unit by 33%.

Healthcare institutions have been able to complete their HOC project in approximately 4 months, using minimal resources. By using targeted solutions for your organization’s specific root causes of poor HOCs, you can begin to see results within 16-21 weeks.

The Checklist Solution
The most common failures of HOCs are that the sender omits vital data from their presentation, or the receiver fails to understand or record it. This has been a very common source of errors in aviation, and their approach is to use a system of checklists for each major task, such as preflight, takeoff, emergency management, and landing.

The checklist is not a fixed recipe for flying the airplane - it is not intended to prevent creative problem solving. Its purpose is to prevent an overloaded and stressed flight crew from forgetting things. The same logic applies to the use of checklists in the field of medicine.

This has been recognized by Dr. Atul Gawande, among others, in his creation of a “Checklist Manifesto” for use by surgeons in the operating room (Gawande, 2014).

Three issues that make checklists mandatory in aviation are: (1) workload stress, (2) distractors, and (3) increased levels of complexity. These 3 problems are abundant in the clinical settings in which handoff communications must happen. For example:

• Workload stress
  o Patient is very ill and may even be an emergency situation
  o Fatigue is very common: “I was up all night on-call”
  o Multiple priorities: “This is not my only patient!”

• Distractors
  o Noise and hallway traffic during rounds
  o Pagers going off during hand-off communication
  o Emergency arises on a different patient

• Increased level of complexity
  o Electronic Medical Record (EMR) requirements
  o Compliance documentation
  o More complex monitors and other devices

All of these factors have increased significantly in recent years, making the use of checklists obligatory in clinical medicine today. HOC is a key application for medical checklists, because the most common errors in HOC are omissions of vital facts or data.

Items to include in every checklist
While each checklist will be different, there are a few elements that you should include in all HOC checklists to ensure best patient care. These elements include, but are not limited to:

- The reason the patient is in the hospital
- All medical problems for the patient, even if not relevant to this admission
- Patient treatment and physical history, including relevant parts of review of systems
- Results from labs and other tests
- A patient’s medications and treatments – both current and planned
- I and O’s (patient Intake and Output, such as catheters or blood draws)
- Hospital course, progress, and/or complications
- The discharge plan for the patient or final hand-off
- Recommendations: “Here is what I [the caregiver] think and suggest”

List of identified HOCs

We identified 18 different interactions that have some form of HOCs and listed them below. Each of these will require its own specific checklist. Your institution may have fewer or a greater number of HOCs. For each HOC, your institution should have a checklist that includes guidelines for both the sender and receiver.

Appendix A includes an example checklist for those marked with an asterisk (*) below.

From emergency department to:

1. Hospital ward team
   a. MedSurg*
2. Operating room*
3. Surgery team*
4. Critical care unit*
5. Testing unit (radiology, etc.)

From hospital unit (ward or ICU) to:

6. Operating room
7. Outpatient clinic*
8. Long-term care unit
9. Testing unit (radiology, etc.)
10. Home (discharge instructions)*
11. Within same unit:
   a. Shift changes*
   b. Medication management during transitions*

From operating room to:

12. Post-anesthesia care unit (PACU)
13. Hospital unit (ward or ICU)*
14. Home (ambulance or surgery)*

From paramedics to:

15. Emergency department*
Leadership plan
To prioritize effective HOCs, leaders must take these actions:

• Hospital governance and senior administrative leadership must commit to becoming aware of this major performance gap in their own organization

• Hospital governance, senior administrative leadership, and clinical/safety leadership must close this performance gap by implementing a comprehensive approach to HOCs

• Healthcare leadership must reinforce their commitment by taking an active role in championing process improvement, giving their time and attention, removing barriers, and providing necessary resources

• All leadership must show their commitment and support by shaping a vision of the future, clearly defining goals, supporting staff as they work through improvement initiatives, measuring results, and communicating progress towards goals:
  o As role models, leadership must ‘walk the walk’ when it comes to supporting process improvement across an organization
  o There are many types of leaders within a healthcare organization and in order for process improvement to be successful, leadership commitment and action are required at all levels
  o The Board, the C-Suite, senior leadership, physicians, directors, managers, and unit leaders all have important roles and must be engaged

• Use patient stories – in written and video form – to identify gaps and inspire change in your staff, such as the story of Jennifer Nibarger, wife of Brent Nibarger: https://youtu.be/ssWSoN00yyI

Managing change
Change management is a critical element that must be included to sustain improvements. 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 increases the opportunity for success and sustainability of improvements.

“Facilitating Change,” the change management model developed by The Joint Commission, contains 4 key elements to consider while working through a change initiative for hand-off communications:

• **Plan the project**
  o At the outset of the project, build a strong foundation for change by assessing the culture for change, defining the change, building a strategy, engaging the right people, and painting a vision of the future

• **Inspire people**
  o Solicit support and active involvement in the plan to improve HOCs, obtain buy-in and build accountability for the outcomes
  o Identify a leader for the HOC initiative, which is critical to the success of the project
  o Understand all possible sources of resistance
• 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 HOC initiative with a designated champion and a clearly communicated vision by leadership

**Support the change**

- All leaders within the organization must be a visible part of the hand-off communication initiative
- Communicate frequently regarding all aspects of the hand-off communication initiative in order to enhance the initiative
- Celebrate success as it relates to hand-off communication
- Identify resistance to the hand-off communication initiative as soon as it happens

The standards that apply to patient safety are specified by the Commission and are listed in the current edition of the Commission’s hospital accreditation manual, in an appendix to the Patient Safety Systems chapter (Joint Commission. (2017). Comprehensive Accreditation Manual for Hospitals: Appendix K. Key Patient Safety Requirements.).

### Action plan

- Set effective HOCs as an organizational priority and performance expectation
- Establish an HOC core team with:
  - A strong sponsor (we strongly encouraged senior leadership for this role)
  - A nurse leader and a physician leader
  - A project leader/manager with a relevant background
  - Other team members, including practicing physicians, nurses, pharmacists, therapists, technicians, and information technology experts
- The team should include a strong sponsor (senior leadership is recommended for this role), physician champion, nursing champion, and project leader:
  - The project leader will facilitate meetings and help gain buy-in from stakeholders
  - We recommend that the project leader has operational understanding of the project’s areas
- Identify and consider the project stakeholders, such as with a stakeholder analysis, to help your HOC team identify roles or people who are key to the success of your project
- Define effective HOCs and the roles of the sender and receiver for every HOC
- Measure the effectiveness of current HOC processes:
  - Define failure condition for HOCs
  - Review the analysis of the collected data to identify the top contributing factors
  - Share the baseline data results within your institution, such as posting the data in staff areas and scheduling meetings with all staff to review the data, find ways to improve, and perform training as needed
- Implement solutions targeting the top contributing factors identified at your organization:
- Describe each solution with actions to implement
- Identify who will lead each action
- Examples of specific contributing factors and targeted solutions:
  - **Contributing factor:** Receiver unable to focus
    - **Solution:** Create environment for successful hand-off communications
  - **Contributing factor:** Unable to contact receiver
    - **Solution:** Formalize how to establish contact

- Measure progress and the effectiveness of change:
  - Measure progress and effectiveness by using the same data collection and analysis tools utilized to calculate baseline performance
  - Share the results of the project

- Implement a plan with the process owner to ensure that process and gains are sustainable. See applicable Joint Commission standards at [http://patient.sm/O2xCku](http://patient.sm/O2xCku)

### Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: [http://patient.sm/2sopQK](http://patient.sm/2sopQK)

The technologies you use should focus on ensuring that, at the point of hand-off, the sender communicates all data critical to the care of the patient and the receiver applies them in real-time. This ensures that the teams carry out the required care in an accurate and timely manner.

Consider implementing the following technologies:

<table>
<thead>
<tr>
<th>System or practice</th>
<th>Available technologies</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities:</td>
<td></td>
</tr>
<tr>
<td>Computerized Provider Order Entry (CPOE)</td>
<td></td>
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<tr>
<td>Drug-drug interaction check</td>
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<tr>
<td>Drug-allergy interaction check</td>
<td></td>
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<tr>
<td>Clinical Decision Support tools (CDS)</td>
<td></td>
</tr>
<tr>
<td>Workflow customization</td>
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<tr>
<td>Incorporation of hand-off checklists</td>
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<tr>
<td>Support the efficient utilization and data capture of the checklist methods</td>
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</tr>
<tr>
<td>Support clinician communication</td>
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</tr>
</tbody>
</table>
Support the ability for clinicians to detail specific information regarding emergent or new-onset conditions that may have happened during the previous shift or in the previous care environment

Use a reliable IT platform that minimizes dependence on staff expertise

Encourage patient and family engagement with communication

**Measuring Outcomes**

**Topic:** Hand off Communication

**Serious Safety Event (SSE) Rate:** Rate of Serious Safety Events attributed to hand off communication failure per 10,000 Serious Safety Events.

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 attributed to:

- Communication Failure
- Hand-off communication failure
- Critical Value communication
- (other similar attributes defined in your event management system)

**Denominator:** Total number of Serious Safety Events

Rate is typically displayed as: Serious Safety Events attributed to hand off communication failure per 10,000 Serious Safety Events

**Metric recommendations:**

**Direct Impact:** All patients

**Elimination of patient harm:** As measured by elimination of serious safety events, sentinel events, state reportable events, or hospital acquired conditions (HACs) attributed handoff communication.

**Lives spared harm:**

\[
\text{Lives spared harm} = (\text{handoff communication SSE rate baseline} - \text{handoff communication SSE rate measurement}) \times \text{Serious Safety Events measurement}
\]

**Lives saved:**

\[
\text{Lives saved} = (\text{handoff communication SSE mortality rate baseline} - \text{handoff communication SSE mortality rate measurement}) \times \text{handoff communication SSE measurement}
\]

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

Data Collection:
Manual chart review of events to determine if an event is a serious safety event and is attributed to handoff communication.

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 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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Chair
Steven J. Barker
Patient Safety Movement Foundation; Masimo
Brent Nibarger
BioVigil

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Nick Adams
Care Thread, Inc.
Misti B. Baskett
Victoria Baskett Patient Safety Foundation
Victoria Baskett
Victoria Baskett Patient Safety Foundation
Michael Becker
Masimo
Michel Bennett
Patient Safety Movement Foundation (formerly)
**References**


Schick, L. & Windle, P. (2016). Discharge Criteria, Education and Postprocedure Care. PeriAnes-


Appendix A: Hand-off communications (HOC) checklists

Emergency department to operating room (anesthesiology team) checklist

**SENDER:**  
**RECEIVER:**

**Chief complaints**  
- Why is patient coming to OR?  
- What made it an emergency?  
- If a chronic disease, what are its history, treatments, complications, prognosis?

**Surgical plan**  
- Exactly what surgery will happen?  
- Major known surgical risks?

**Special anesthesia needs**  
- Patient position, paralysis, or lack thereof, anticipated blood loss, etc.

**Cervical spine status**  
- "Cleared"? If so, how?  
- History of neck disease or injury?

**Other acute disease or injury**  
- Other known acute disease, other than the reason for emergency surgery?  
- If trauma, other injuries not related to surgery?

**Medical/surgical history**  
- To extent known, and as time allows. Review of systems if available.

**Physical exam findings: Positive findings only. Include ABC’s**  
- Airway: Patent? Assistance required?  
- Breathing: Status of ventilation and oxygenation  
- Circulation: Vital signs, including BP and other findings re circulation

**Blood loss & fluid status**  
- Estimated blood loss from current injury or disease  
- IV fluids given: type, amount route  
- Other I and O: recent oral intake, urine output, vomiting, drainage

**Patient lines & access**  
- All intravenous lines - size and location.  
- All other patient cannulas, including central line, chest tube, Foley catheter, arterial etc.

**Labs and studies**  
- Current lab results and relevant older lab results  
- Results of X-rays, CT, MRI, other studies

**Drugs**  
- Analgesia given by any route, past 24 h. Opiates?  
- All other meds usually taken by patient
☐ Any other meds given since current problem began. Dose, frequency, response?

Special instructions or findings
☐ Anything unusual or remarkable, not covered by above?
☐ Any special instructions or restrictions? (For example: patient refuses blood products for religious reasons)

Hospital unit to home (discharge) checklist (Bloink, 2013)

_SENDER:_ Nurse or physician discharging patient
_RECEIVER:_ Family member, loved one, whoever is taking the patient home

Initial transitional care contact
☐ Patient name
☐ Date of contact

Medication reconciliation
☐ Medication list updated
☐ New medication list given to patient

Sources of information
☐ Patient, family member, or caregiver
☐ Hospital discharge summary
☐ Hospital fax
☐ List of recent hospitalizations or ED visits
☐ Other
  ☐ Discharged from (location)
  ☐ Discharged on (date)
  ☐ Diagnosis/problem:
    ☐ Medication changes (yes/no)
☐ Medication list updated (yes/no)
☐ Needs referral (yes/no)
☐ Needs lab (yes/no)
☐ Needs follow-up appointment
☐ Within seven days (highly complex visit)
☐ Within 14 days of discharge (moderately complex visit)
☐ Appointment made for (date)
☐ Appointment with (physician name)
☐ Additional information needed and requested (yes/no)
☐ Face-to-Face transitional care visit documentation (for use in plan section of visit note)

Referrals
☐ None needed
☐ Referrals made

Community resources identified for patient/family
☐ None needed
☐ Home health agency
The following technique called the Situation, Background, Assessment and Recommendation (SBAR) is the industry’s best practice for standardized communication between caregivers (Schick and Windle, 2016). The SBAR technique was developed by the United States Navy for use on nuclear submarines. SBAR was introduced into healthcare in the late 1990’s. It is recognized as a simple and effective way to standardize communication between caregivers in hospitals across the world.

**S (Situation)**
- Reason for admission
- Contact information
- Allergies
- Current attending/resident

**B (Background)**
- Status of advanced directives/code status
- Pertinent medical history
- Labs: abnormals this shift and pending or to do next shift
- Tests/Procedures: current shift and expected for next shift
- Current Problems: medical and nursing

**A (Assessment)**
- VS/pain past 24 hours/shift
- Neuro
- CV
Respiratory
GI/GU (include I and O)
Skin
Mobility
Patient safety issues: current and anticipated
Medication concerns and updates

R (Recommendation)
Pending/anticipated tests and procedures
Other concerns
Current and anticipated family issues
Status of current shift goals/problems
Anticipated Goals/problems for next shift
Other TO Dos/Do you have any questions?
Patient/Nurse introduction
Joint review of lines/drips, neuro check, etc.

Operating Room anesthesiology team to Post-Operative Care Unit (PACU) checklist

**SENDER:** Anesthesiologist or anesthetist
**RECEIVER:** PACU Nurse

- Patient identification, age, gender.
- Present anesthesia status (awake, asleep, emerging from GA, regional & sedation, etc.)
- Respiratory status (controlled vent., spontaneous, assisted, airway requirements).
- Vital signs before/during transport.
- Surgery course:
  - Exact procedure planned and done.
  - Surgical complications, difficulties.
  - Lab results before/during surgery.
  - Surgical care plan; further surgeries?
  - Transfer plan after PACU (surgical ward, SICU, specialty unit, home).
- Anesthesia management:
  - Type of anesthesia (general, regional, local).
  - Names and amounts of anesthesia drugs.
  - Anesthesia recovery progress and plan.
- Fluid management.
  - Crystalloids: nature (LR, NS, etc.) and amounts.
  - Blood products.
    - Indications for transfusion.
    - Types and amounts of each product.
    - Any unexpected reactions?
☐ Other colloids?
☐ Fluid status during and at the end of surgery.
☐ Fluids plan during recovery.
☐ Patient medical and surgical history.
☐ History of Present Illness: disease that led to this surgery.
☐ Surgical history: related to HPI and other unrelated surgery.
☐ Medical history: All medical conditions, their present status and treatments, prognosis.
☐ Allergies: Specific drug, type of reaction, last exposure.
☐ General health status; activity level; mental functioning.
☐ Summary review of treatment plan.
☐ Any questions? I can be reached at ____.

**Operating room to hospital unit checklist**

**SENDER:** PACU nurse or anesthesia provider  
**RECEIVER:** Nurse who will be caring for the patient

**Team**
- ☐ Patient Name, sex & MRN
- ☐ Attending anesthesiologist
- ☐ Anesthesia resident/Fellow/CRNA
- ☐ Surgeon

**Pre-op**
- ☐ Age
- ☐ ASA
- ☐ Weight
- ☐ Height
- ☐ Guardianship
- ☐ Surrogate
- ☐ Advance directives
- ☐ DNR status
- ☐ Allergies

Pre-op vital signs:
- ☐ BP
- ☐ HR
- ☐ SpO2
- ☐ Temp
- ☐ RR
- ☐ Current medications
- ☐ Past medical history
- ☐ Past surgical history
- ☐ Past anesthesia history
- ☐ Pertinent pre-op labs and studies
Pre-op mental status and primary language
NPO status
Blood/bloodless status

Intra-op events
- Surgical procedure performed
- Anesthetic technique & airway management

IV sites:
- Fluid
- Location
- Difficult access

Fluid status:
- Intake
- Output
- EBL
- Blood products

Medications given (including antibiotics)
Complications / interventions

Post-op
- Surgical procedure performed
- Anesthetic technique & airway management

Post-op vital signs:
- BP
- HR
- SpO2
- Temp
- RR

Assessment:
- Respiratory
- CV
- Neuro
- GU
- Skin

Post-op pain management plan
Recent labs
Pending labs
Medications
Special instructions & concerns
Questions from receiving provider

Operating room to home checklist (Bloink, 2013)

sender: PACU nurse or anesthesia provider
RECEIVER: Nurse who will be caring for the patient
- Responsible adult to stay with patient for 24 hours
- Patient understands they may not drive or make major decisions for 24 hours
- Patient understands precautions after anesthesia:
  - Drowsiness, impaired judgment and slower reaction time, sore throat, muscle aches
  - Sensory block understanding:
    - May not be able to feel sharp pain, hot or cold at the involved site
    - Understanding to begin pain medication before block wears off
- Instruct patient on expected activity levels:
  - Rest the remainder of the day
  - Move slowly when changing positions (dizziness is normal)
  - Gradually do a little more each day
  - Follow the surgeon’s instructions for return to normal activities
- For best outcomes:
  - It is important to walk often, change positions and move legs if resting in a lying or sitting position
  - Take 10 deep breaths and cough every hour or two while awake
  - Remember to hold a small pillow or towel over your incision while doing your deep breathing and coughing exercises
- Review medications:
  - Medications will be reviewed and when to resume and take them
  - Follow directions on the label
  - Pain medication should be taken before the pain is severe during the first 2-3 days after surgery:
    - Medications like Percocet and Vicodin contain acetaminophen (Tylenol), so do not take plain Tylenol when using these medications
  - Pain medication can cause constipation and nausea:
    - Remember to follow instructions for taking a laxative, if needed
    - Use a post-op nausea information sheet with suggestions for treating these side effects
- Review diet and elimination:
  - Progress to regular diet as tolerated
  - Begin with comfort foods such as soup, crackers, jello, juices
  - Stay away from food that may increase the chance of nausea and vomiting, such as spicy or greasy foods
  - If you have trouble voiding (burning or urgency while peeing), call your surgeon
  - If you are unable to urinate when you get home, have someone bring you to the emergency room
  - No alcoholic beverages, marijuana, or other drugs for 24 hours or while taking pain medications
- Importance of handwashing to prevent infection:
  - Keep dressing dry and protect dressing, incisions, and casts
When you can take a shower or bath, depending on the procedure

Review special equipment (if applicable, based on the procedure):
- Incision care and when to remove dressing
- Drain instructions
- Foley care instruction
- Crutch walking
- Incentive spirometer

Instruct patient when it’s appropriate to call their surgeon:
- Pain is not relieved with the pain medication
- Bleeding
- Fever over 101ºF
- Continuous nausea and unable to keep fluids down
- Redness and swelling around the surgical wound or drainage that changes to yellow or green
- Intravenous site with signs of redness or drainage
- If unable to get physician come to the emergency department
- Instruct patient to call 911 if they have breathing problems or chest pain

**Hospital unit to outside care unit checklist**

**SENDER:** Nurse who is caring for the patient  
**RECEIVER:** Caretaker in outside unit

**Chief complaint**
- Why was patient admitted to hospital?  
- If the result of a chronic disease, what are its history, treatments, complications, prognosis?

**Hospital course**
- Duration of stay in each hospital unit  
- Therapeutic procedures done: indications and results  
- Medications while in hospital. Effectiveness? Complications?
- General condition at discharge

**Diet**
- Current diet as well as any restrictions and preferences

**Allergies**
- To medications as well as anything else. Include specific type of reaction (skin, pulmonary, anaphylaxis, etc.), severity, type of exposure for trigger (enteric, topical, inhaled).

**Activity**
- Amount, type, frequency of exercise
- Activity restrictions?
- Bathroom privileges

**Hygiene**
Mental status
☐ Ability to communicate and understand instructions, such as other language. Sleep habits.

Other known diseases or injuries
☐ All diseases requiring continuing treatment or precautions
☐ Current status of each: chronic, recurrent, cured?

Hospital/surgical history
☐ Hospitalizations: reasons, treatments, outcomes
☐ Surgeries: procedures, dates, indications, outcomes

Physical exam findings
☐ Positive findings only

I’s & O’s (Intakes and Outputs)
☐ Patient lines and access: intravenous lines - size and location. All other patient cannulas, including any drains, Foley catheter.
☐ Daily intake/output of each site, including oral, wound drainage, etc.

Labs and studies
☐ Current lab results, note all abnormal values
☐ Relevant older lab results
☐ Results of recent X-rays, CT, MRI, other studies

Drugs
☐ Daily analgesia required? Opiates?
   ☐ If so, how is respiration being monitored?
☐ All other meds taken by patient: dose, route (oral or other?), frequency
☐ Any other meds given since current problem began. Dose, frequency, response?

Social
☐ Family and/or friends contact information and visiting needs

Special instructions or findings
☐ Anything unusual or remarkable, not covered by above?
☐ Any special instructions or restrictions?

Emergency department to hospital ward (med/surg) checklist

SENDER: Emergency department physician or nurse
RECEIVER: Medsurg nurse in hospital unit

The following technique called the Situation, Background, Assessment and Recommendation (SBAR) is the industry’s best practice for standardized communication between caregivers (Schick and Windle, 2016). The SBAR technique was developed by the United States Navy for use on nuclear submarines. SBAR was introduced into healthcare in the late 1990’s. It is recognized as a simple and effective way to standardize communication between caregivers in hospitals across the world.

S (Situation)
☐ Introduction of person- name, age, and baseline physiology
Chief complaint on arrival
Advanced Directives
Allergies
Admitting diagnosis and provider

B (Background)
- Past medical history - chronic and relevant acute conditions, home medications
- Diagnostics - abnormal and relevant lab and imaging information
- Diagnostics awaiting results
- Current condition/problems: self-management goal, medical and nursing

A (Assessment)
- Current status - any change from presenting condition
- Neurological status
- Vital signs
- Assessment of condition related to admitting diagnosis
- Any abnormal findings (skin, wound)
- Health literacy initiation

R (Recommendation)
- Interventions needed within next 2 hours
- Current and anticipated person and family concerns and needs
- Review of problems and plan of care
- Review of self-management goal
- My-story®

Face-to-face
- Person, family, RN actively participate in transitions to Med/Surg location

1My Story is the property of Parrish Medical Center

Emergency department to critical care unit checklist

SENDER: Emergency department physician or nurse
RECEIVER: Critical care nurse or physician

Illness severity
- Unstable/Watch/Stable/Discharging (structured)

Findings
- Chief complaint
- Vitals:
  - HR (beats/min)
  - BP (sys/Dis; mL Mercury)
  - PulseOx (O2Sat)
  - Temperature (C/F)
  - Respiratory rate (breaths/min)
  - Current pain threshold (Universal Pain Scale, 1-10)
- Pertinent findings:
☐ Is systolic BP <110?
☐ RALES or evidence of CHF
☐ Any evidence ischemia on electrocardiogram (ECG/EKG)?
☐ Significant toxin of infectious agent exposure
☐ MDRO to consider
☐ What did you find?
☐ Key results?
☐ Pending results and timing?

**Action list**
- What diagnoses, confirmed or in the differential, need follow-up investigations in the next 12 hours?
- List out appropriate action items:
  - Has a radiologist reviewed all neuroimaging as correct?
  - Are there any services this patient may need in the next 48 hours that are both life-threatening and cannot be arranged quickly for inpatients?
  - What procedures need to be done in the next 48 hours to care for this patient?
- Additional action items (list out)

**Situational awareness/contingency planning**
- Has there been, or could there be, any hemodynamics instability (pulse <55 or >110, MAP<70, SBP>150)?
  - If so, what is the plan to manage this?
- What cardioactive substances were administered in the ED?
  - What is the continuation plan for each of them?
- In what way could this patient’s condition get worse in the next 48 hours? (not yet present)
  - What IV’s, central lines, other access ports and indwelling devices (foley, implants) has this patient had in the last 2 weeks?

**Synthesis (Teach-back)**
- Teach-back

**Paramedics to emergency department checklist**

**IZER: Paramedic**
**RECEIVER: Emergency department physician**
- Is patient awake and alert now?
  - Was there any loss of consciousness?
- Presumed diagnosis? (very short version – less than 50 words)
- Establish A-B-C-D (Airway - Breathing - Circulation - Drugs)
  - **A = Airway**
  - Is the airway open and patent, or obstructed?
  - **B = Breathing**
  - Is patient breathing?
  - Breath sounds heard in both lungs?
**C = Circulation**
- Blood pressure; Peripheral pulses; Skin color; Mental status
- End-tidal CO2 if intubated

**D = Drugs**
- What drugs given by paramedics?
- What recreational drugs has patient taken? What medications is patient taking?

**Patient history:**
- Chief complaint:
  - Why is the patient in an ambulance?
  - What led to a 911 call?
- What is the history of this illness?
  - Details of diagnosis
  - Differential diagnosis
- What other illnesses or medical problems in past?

**Physical exam:**
- Abnormal findings on general exam?
- Specific findings related to present illness

**Discuss treatment plan with patient (have a 2-way discussion!):**
- What treatments and interventions have been done? (include IV catheters)
- What immediate treatments are needed?
  - Risks/benefits?
- What additional diagnostics or studies needed?
- Family members or others who should be contacted for information and consent?
- Known patient preferences or restrictions (e.g., living will, DNR)?

**Medication management during transitions of care checklist**

This checklist was created to set up the process of medication management during transitions of care. Once your institution imbeds it in their workflow, it is not necessary to use as a traditional checklist. While this list focuses on aspects important for hospital discharge, your organization should apply the principles of medication reconciliation in this list during all hand-offs. Roles may vary by institution, but it is important to clearly define the roles for who takes ownership of these activities.

**Ensure medication reconciliation is completed in EHR by physician**
- Reconciliation of full medication list including prior to admission, as an inpatient, and at discharge
- Evaluate for appropriate indication, dosing, frequency, and route
- Identify and resolve errors of omission, duplication, drug interactions, and incorrect dosing
- Update medications based on changes to patient health status and appropriate labs
- Prescriptions ordered to preferred pharmacy

**Ensure collaboration between pharmacist, nursing, and care management**
- Screen for and identify high risk patients requiring medication review and education
- Plan for discharge:
Identify time and date of discharge
 Coordinate with co-learners if indicated
 Identify and address barriers to medication use

**Ensure patient can access medications**
- Identify financial barriers
- Resolve prior authorizations
- Switch to cheaper alternatives when available
- Coordinate social work and care management if patient doesn’t have insurance
- Identify and resolve barriers to medication access
- Ensure stock of medication
- Coordinate compounding when indicated
- Comply with prescribing requirements (REMS)
- Arrange transportation or medication delivery to bedside when indicated
- Order appropriate medical equipment
- Provide patient education about medications
- Address language barriers, such as using interpreter, patient educational resources
- Coordinate with caregiver and co-learner
- Reinforce teaching around high-risk medications and educational deficits
- Use “Teach-back” method

**Ensure follow-up and monitoring**
- Schedule appropriate follow up visits
- Schedule labs and monitoring
- Coordinate home health care when indicated

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**Appendix B: Examples of standardized checklists**

1. **I-PASS hand-off checklist and components**

<table>
<thead>
<tr>
<th>I</th>
<th>Illness severity</th>
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<tr>
<td></td>
<td>• Stable, “watcher,” unstable</td>
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<table>
<thead>
<tr>
<th>P</th>
<th>Patient summary</th>
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<tbody>
<tr>
<td></td>
<td>• Summary statement</td>
</tr>
<tr>
<td></td>
<td>• Events leading up to admission</td>
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<tr>
<td></td>
<td>• Hospital course</td>
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<td></td>
<td>• Ongoing assessment</td>
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<tr>
<td></td>
<td>• Plan</td>
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2. SBAR

The following technique called the Situation, Background, Assessment and Recommendation (SBAR) is the industry’s best practice for standardized communication between caregivers (Schick and Windle, 2016). The SBAR technique was developed by the United States Navy for use on nuclear submarines. SBAR was introduced into healthcare in the late 1990’s. It is recognized as a simple and effective way to standardize communication between caregivers in hospitals across the world.

S (Situation)
- Reason for admission
- Contact information
- Allergies
- Current attending/resident

B (Background)
- Status of advanced directives/code status
- Pertinent medical history
- Labs: abnormals this shift and pending to do next shift
- Tests/Procedures: Current shift and expected for next shift
- Current Problems: medical and nursing

A (Assessment)
- VS/pain past 24 hours/shift
- Neuro
- CV
- Respiratory
- GI/GU (include I and O)
- Skin
- Mobility
☐ Patient safety issues: current and anticipated
☐ Medication concerns and updates

R (Recommendation)
☐ Pending/anticipated tests and procedures
☐ Other concerns
☐ Current and anticipated family issues
☐ Status of current shift goals/problems
☐ Anticipated goals/problems for next shift
☐ Other TO Dos/Do you have any questions?
☐ Patient/Nurse introduction
☐ Joint review of lines/drips, neuro check, etc
How to use this guide
This guide gives actions and resources for creating and sustaining practices for optimal neonatal oxygen targeting. In it, you’ll find:

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What we know about neonatal oxygen targeting ... 256
Leadership plan ................................................................. 259
Action plan ........................................................................ 259
Technology plan ................................................................. 260
Measuring outcomes......................................................... 261
Conflicts of interest disclosure .......................................... 262
Workgroup ........................................................................ 262
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APSS #7A: Optimal neonatal oxygen targeting

Executive summary checklist

Hypoxia (low blood oxygen) in preterm infants can cause severe harm or death. Giving supplemental oxygen helps avoid hypoxia, but also raises the chance of hyperoxia (excessive blood oxygen). Hyperoxia can cause retinopathy of prematurity (ROP) and increase the risk for other conditions.

Implementing an optimal oxygen targeting guideline can improve neonatal outcomes. Use this checklist to help you prioritize your actions and measure your organization's progress in your neonatal oxygen targeting efforts:

- Assess your hospital's current methods of oxygen administration and monitoring to find opportunities for improvement
- Develop an action plan that includes a timeline with concrete goals and milestones for implementing an optimal oxygen guideline for neonates
- Choose and fund technologies that have been shown to improve neonatal outcomes, such as blenders, pulse oximetry, and heated humidifiers
- Use blenders in all circumstances when administering oxygen, including the delivery room
- Use heated humidifiers:
  - In the delivery room
  - In the NICU when using CPAP
  - In all circumstances where the infant is intubated, even for a few minutes
- For pulse oximetry, select equipment that:
  - Can measure through motion and low perfusion conditions to avoid inaccurate measurements/false alarms and identify true alarms, and
  - Has been proven effective for neonatal oxygen targeting
    - Example: Masimo Signal Extraction Technology (SET) pulse oximetry (until another technology is proven to be equivalent)
- Determine the oxygen targeting guideline that your clinical staff should use:
  - The SpO2 for a preterm baby breathing supplemental oxygen should not exceed 95
  - The SpO2 for other larger infants and neonatal patients breathing supplemental oxygen should stay in the range of 88-95% or 90-96%, depending on infant and condition
  - When SpO2 dips below the desired % or when the low alarm sounds, avoid responding in a way that results in high saturation (>95%)
- Always keep the monitor alarms on and active when an infant is breathing supplemental oxygen:
  - Neonates in an intensive care environment should always be monitored by a pulse oximeter capable of monitoring through motion and low perfusion with appropriate alarm limits
  - The high SpO2 alarm should be set to 95%, depending on the infant
  - The low SpO2 alarm should be set no lower than 85%
  - Alarms signaling should receive attention from the nurse, doctor, or respiratory therapist
☐ When a baby is not breathing supplemental oxygen or receiving any from respiratory support, but is being monitored for desaturations, set the low SpO2 alarm at 85% and turn off the high alarm

☐ Implement an action plan for including educational activities, workshops, and tools for all members of the neonatal healthcare team

☐ Develop a process for continuous improvement by communicating with staff and implementing measures to improve processes that will help you meet your oxygen targeting goals

☐ Use patient stories – in written and video formats – to identify gaps and inspire change in your staff
What we know about neonatal oxygen targeting

Problems of administering oxygen to newborn infants

It has been clear for many decades that preventing hypoxia in newborns increases survival and lowers the rates of cerebral palsy and other severe neurologic conditions. For this reason, staff should work to prevent hypoxia in newborns.

On the other hand, staff should also prevent hyperoxia. Supplemental oxygen in newborns has been over-used worldwide. This practice can cause various health problems, including:

- Prolonged hospitalizations
- Blindness for life due to retinopathy of prematurity (ROP)
- Cancer in childhood
- Chronic lung disease
- Developmental disabilities, periventricular leukomalacia (a type of brain injury), cerebral palsy, and other oxidant-stress related adverse effects including DNA damage, endocrine and renal damage, decreased myocardial contractility, alveolar collapse, infection, inflammation and fibrosis (Collins, Lorenz, Jetton and Paneth, 2001; Haynes et al., 2003; Sola, Rogido, and Deulofeut, 2007; Klinger, Beyene, Shah, and Perlman, 2005; Sola, 2008; Sola, Saldeño, and Favareto, 2008)
- At 5 years of age, motor impairment, cognitive impairment, and severe hearing loss that is 3-4 times more common in children with severe ROP than those without it

Most, if not all, of these complications result from care in the newborn period and cause lasting health issues. These health issues create significant healthcare costs, such as from lengthy hospital stays, and tremendous emotional costs for families.

The standard neonatal oxygen treatment

Hospital practices for oxygen monitoring are variable. Many delivery rooms and neonatal intensive care units worldwide adhere to outdated or otherwise inappropriate protocols. Evidence shows that excessive oxygen administration during the first few minutes of life is noxious. Yet, many delivery rooms worldwide:

- Still administer pure oxygen (100% O2) unnecessarily
- Do not measure FiO2
  Do not adequately monitor oxygen saturation (SpO2) levels (Baquero et al., 2011; Shah, Ragaswamy, Govindugari, and Estanol, 2012; Bizzarro et al., 2013; Chow, Wright, and Sola, 2003; Deulofeut, Critz, Adams-Chapman, and Sola, 2006; SUPPORT Study, 2010)

Evidence shows that stopping inappropriate oxygen administration and increasing the use of oxygen monitoring can significantly lower the rates of these preventable conditions (Sola et al., 2014; Sola, 2015). Hospitals that actively address the administration and monitoring of oxygen in newborn infants to prevent both hypoxia and hyperoxia can realize significant improvements in the quality and safety of healthcare as well as cost savings (Vaucher et al., 2012).

Evidence for change in neonatal oxygen treatment

You can prevent many adverse effects by educating neonatal staff on appropriate oxygen management. This includes measuring oxygen titration with a blender and monitoring an infant’s saturation level with pulse oximetry technology that can measure through motion and low perfusion (Chow, Wright, and Sola, 2003).
Research shows evidence for change in neonatal oxygen treatments:

**Evidence for delayed cord clamping**
It has been estimated that 300,000-700,000 lives could be saved worldwide if 1% of the 130,000,000 global live births who are born at less than 30 weeks receive delayed cord clamping (DCC) which increases arterial oxygen tension at birth and in the first minutes of life (AJOG, 2017).

**Evidence for SET**
In a 2-phased study of 2 centers that previously used conventional pulse oximetry, both centers changed their neonatal oxygen targeting guideline at the same time, however, only 1 of the centers switched to SET pulse oximetry (Castillo, Deulofeut, Critz, and Sola 2010):
- In the 1st phase of the study:
  - The center using non-SET had no decrease in retinopathy of prematurity
  - The center using SET had a 58% reduction in significant retinopathy of prematurity and a 40% reduction in the need for laser eye treatment
- In the 2nd phase of the study:
  - Both centers used SET and got similar results
- A follow-up study measured outcomes for very low birthweight infants treated with oxygen before and after (304 infants before and 396 infants after) the center switched to SET (Bizzarro et al., 2013). The center’s switch to SET resulted in a:
  - 59% reduction in incidence of severe ROP
  - 69% reduction in ROP requiring surgery

**Evidence for oxygen targeting guidelines**
Research on neonatal oxygen targeting shows how challenging it is to find optimal levels. For example, a study showed that narrow SpO\textsubscript{2} target ranges are difficult to maintain for more than 50-60% of the time (Fiore, 2014).

To date, the “perfect” SpO\textsubscript{2} target range is still not known for all newborns at all times (Saugstad, 2010). A summary of recent publications on extremely premature infants randomly assigned to a lower target SpO\textsubscript{2} intention to treat (85-89%) or higher target SpO\textsubscript{2} intention to treat (91-95%) shows there was neither increased mortality nor serious brain injuries as a result of avoiding hyperoxia in preterm infants (Stenson et al., 2011; Saugstad and Aune, 2011; Castillo, Deulofeut, Critz, and Sola, 2008; Askie et al., 2011).

A recent presentation by Askie and colleagues also shows no difference in the primary outcome of death or disability between a higher (91-95%) versus a lower (85-89%) arterial oxygen saturation. However, a higher rate of NEC occurred at 85-89% and a higher rate of severe ROP occurred at 91-95%. Recently the Committee on Fetus and Newborn of the AAP made clinical recommendations which are included in this document (Cummings and Polin, 2016).

Therefore, avoid an intention to treat with an SpO\textsubscript{2} of 85-89%. There are several issues that suggest extreme caution should be used in the interpretation of these randomized controlled trials (Manja, Lakshminrusimha, and Cook, 2015; Lakshminrusimha, Manja, Mathew, and Suresh, 2015; Schmidt et al., 2014).

In a recent meta-analysis (Askie, 2018), research suggests that:
- In infants born at less than 28 weeks gestation there was no significant difference in the primary outcome variable of death or major disability at 18-24 months of corrected age when comparing the low SpO\textsubscript{2} target range (85-89%) versus the high one (91-95%)
• In addressing secondary outcome variables, and in post-hoc analysis, an association was found with higher risk for mortality and necrotizing enterocolitis and a lower risk for ROP, when the intention to treat was 85-89%.

The accompanying editorial (Bizzarro, 2018) mentions that SpO2 of 91-95% may be better than 85-89%, but that, in clinical practice, SpO2 intention to treat can be different than the 2 intentions studied in the randomized controlled trials.

In summary, in extremely low birth weight infants:
• The ideal oxygen saturation range or intention to treat remains unknown and is often a compromise among negative outcomes associated with either hyperoxemia (such as ROP and BPD) or hypoxemia (such as NEC and death).
• The appropriate SpO2 range for each infant will depend on the type of SpO2 monitor used, gestational age, postnatal age, hemoglobin A concentration, hemoglobin level, oxygen content, cardiac output, clinical diagnosis, and illness severity (Castillo, Deulofeut, Critz, and Sola, 2010).

Despite this variability, it is clear that to improve clinical outcomes, some outdated clinical practices must be stopped and replaced with newer clinical care guidelines aimed at preventing both hyperoxia and hypoxia.

Evidence for SpO2 alarms
Using oxygen saturation alarms and guidelines for limits can help avoid harmful extremes of hyperoxemia or hypoxemia in newborns.

To be most effective:
• Alarms should always be operative - do not disconnect or deactivate alarms.
• Busy NICU nurses respond much better to SpO2 alarms rather than to “mental SpO2 target ranges or intention to treat”.
• Given the limitations of SpO2 and the uncertainty about the ideal SpO2 intention to treat for infants of extremely low birth weight, wider alarm limits are easier to target.
• The lower alarm limit:
  o Generally needs to extend somewhat below the lower SpO2 chosen as the intention to treat
  o Must take into account practical and clinical considerations, and the steepness of the oxygen saturation curve at lower saturations.
  o For extremely low birth weight infants, should be set no lower than 85%, although 86-87% may also be appropriate.
• The upper alarm limit:
  o Should not be higher than 95% for extremely low birth weight infants while the infant remains on supplemental oxygen or any form of ventilatory support.

These considerations highlight the need to introduce clinical guidelines at all institutions caring for newborn infants, and to close the gap between knowledge and practice. The lack of a systematic approach to prevent hypoxia and hyperoxia significantly affects patient safety, quality, and cost of care.

Hospitals, healthcare systems, and all members of the neonatal health care team (RNs, RTs, and MDs) must commit to creating specific and sustainable leadership, action, and technology plans that will help improve safety for newborn infants who require oxygen supplementation.
Leadership plan

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to optimize neonatal oxygen targeting.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions:

- Implement a plan that includes the fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action (National Quality Forum, 2010)

Show leadership’s commitment to safer oxygen administration:

- Make sure hospital governance and senior administrative leadership commit to learning about any performance gaps in oxygen management within their own healthcare system
- Make sure that hospital governance, senior administrative leadership, and clinical/safety leadership implement a comprehensive approach to addressing the performance gap, including any gaps of their own
- Allocate a budget for the action plan to be evaluated by governance boards and senior administrative leaders
- Get clinical/safety leadership to endorse the plan and drive implementation across all providers and systems

Create the infrastructure needed to make changes:

- Set a goal date to implement the action plan with measurable quality indicators. “Some is not a number. Soon is not a time.” (IHI, n.d.).
- Collect and analyze data on oxygen administration and monitoring to help you:
  - Identify areas for improvement
  - Implement changes
  - Assess outcomes
  - Track your progress toward safer oxygen administration
- Address and re-address these 2 questions for quality improvement: Are we doing the right things? Are we doing things right?
- Use patient stories -in written and video formats - to identify gaps and inspire change in your staff
  - http://patient.sm/8ddkyz

Action plan

Engage leadership and staff:

- Make an organization-wide commitment by administrative, clinical, and patient engagement leaders to address safety in neonatal oxygen targeting
- Create educational activities, workshops, and tools for all members of the neonatal healthcare team
- Develop a systematic process for creating continuous, sustained improvement in oxygen targeting. To do this, communicate with staff and implement measures to improve processes.
- Assess opportunities to improve oxygen administration and monitoring
Establish guidelines for oxygen administration and monitoring:

- Develop an action plan that includes a timeline with concrete milestones for implementing optimal neonatal oxygen targeting guidelines:
  
  o **Establish oxygen levels:**
    
    - \(\text{SpO}_2\) for a preterm baby breathing supplemental oxygen should not exceed 95%
    
    - \(\text{SpO}_2\) for other larger infants and neonatal patients should stay in the range of 88-95% or 90-96%, depending on the infant and their condition
    
    - When the saturation or \(\text{SpO}_2\) dips below 88%, avoid responding in a way that may cause hyperoxia or high saturation
  
  o **Use alarms to help monitor oxygen:**
    
    - Make sure the monitor alarms are always on and active when an infant is breathing supplemental oxygen or is in the neonatal intensive care unit
    
    - Set the high \(\text{SpO}_2\) alarm to 95%, depending on the infant
    
    - Set the low \(\text{SpO}_2\) alarm 85%
    
    - Alarm signaling should receive attention from a nurse, doctor, or respiratory therapist
    
    - When a baby is not breathing supplemental oxygen but is being monitored for desaturations, the low \(\text{SpO}_2\) alarm should be set at 85% and the high alarm can be turned off

**Technology plan**

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the Technology Vetting Workgroup to consider: [https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/](https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/)

Select technologies that have been shown to improve neonatal oxygen targeting include:

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Available technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use blenders in all circumstances when administering oxygen, including the delivery room</td>
<td></td>
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<tr>
<td>Use heated humidifiers when using CPAP and in all circumstances where the infant is intubated, even for a few minutes, and in the delivery room</td>
<td></td>
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<tr>
<td>For pulse oximetry, select equipment that:</td>
<td></td>
</tr>
<tr>
<td>- Can measure through motion and low perfusion conditions to avoid inaccurate measurements/ false alarms and identify true alarms</td>
<td></td>
</tr>
<tr>
<td>- Is proven effective for neonatal oxygen targeting</td>
<td></td>
</tr>
</tbody>
</table>
Measuring outcomes

**Topic:**
Neonatal Oxygen Targeting actively addresses the administration and monitoring of oxygen in newborn infants to prevent both hypoxia and hyperoxia.

**Outcome measure formula:**
Percent of pre-term babies (under 32 weeks) receiving supplemental oxygen who acquire ROP

**Numerator:**
Number of pre-term babies (under 32 weeks) receiving supplemental oxygen who acquire ROP

**Denominator:**
Number of pre-term babies (under 32 weeks) receiving supplemental oxygen who were examined by an ophthalmologist

- This measure is usually displayed as a percentage: Numerator/Denominator *100

**Data collection for outcome measure:**
Collect all data on pre-term babies (under 32 weeks) who were examined by an ophthalmologist. This will allow you to calculate the outcome measure using the formula above.

**Metric recommendations:**

**Indirect impact:**
All pre-term babies (under 32 weeks) who received supplemental oxygen

**Direct impact:**
The percent of time that pre-term babies (under 32 weeks) who received supplemental oxygen are kept within the accepted SpO2 range

**Lives spared harm:**
Lives spared harm = (ROP rate baseline - ROP rate measurement) X pre-term babies under 32 weeks receiving oxygen measurement

**Data collection for direct impact:**
The percent of time that pre-term babies (under 32 weeks) who received supplemental oxygen are kept within the accepted SpO2 range

- One approach could be: At minimum, take a random sampling of 3-4 babies on supplemental oxygen on different shifts during 1 week each month. Use different shifts because nursing shifts vary from 6-12 hours across the world and nurse-to-patient ratios also vary. For this reason, the data collection method should be tailored by hospital and by unit.
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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Chair:
Mitch Goldstein  Loma Linda University Children’s Hospital
Annamarie Saarinen  Newborn Foundation

Members:
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

*Steven Barker  Patient Safety Movement Foundation; Masimo
Michel Bennett  Patient Safety Movement Foundation (formerly)
Hector Cruz  Genomi-k
Balaji Govindaswami  Santa Clara Health and Hospital System
Anne Granelli  NU-sjukvården
Alex Kemper  Duke University School of Medicine
Herman Kettenhofen  Genomi-k
Deb Kilday  Advocate
Ariana Longley  Patient Safety Movement Foundation
Jacob Lopez  Patient Safety Movement Foundation (formerly)
Olivia Lounsbery  Patient Safety Movement Foundation
Una McFayden  Forth Valley Royal Hospital
Brendan Miney  Mindray
Donna Prosser  Patient Safety Movement Foundation
Jason Smith  Emerson Rose Heart Foundation
Fernando Yuste  Medtronic

Metrics integrity:
Robin Betts  Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.
References


How to use this guide
This guide gives actions and resources for creating and sustaining a plan to improve your organization’s detection of critical congenital heart disease (CCHD) in newborns. In it, you’ll find:

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Executive summary checklist

Congenital heart disease (CHD) is one of the most common types of birth defects. 40% of deaths from CHD are caused by critical congenital heart disease (CCHD), including ductal-dependent lesions. CCHD is life threatening, represents at least 25% of CHD and typically requires intervention in the first months or up to the first year of life. Use this checklist to help you prioritize your actions and measure your organization’s progress in detecting CCHD in newborns.

STEPS to creating a universal pulse oximetry screening program

☐ Choose a proven an FDA-approved technology cleared for use in newborns that can accurately monitor and read through during motion and low perfusion

☐ Establish the screening protocol. The current AAP-recommended screening protocol (2019) includes:

☐ Screen newborns more than 24 hours after delivery or before discharge. If discharged prior to 24 hours of age, screen as close to discharge as possible. If not screened in the hospital or born at home, make arrangements for screening as soon as possible.

☐ Get pulse oximetry measurements from preductal (right hand) and postductal (either foot) sites following the protocol below:

☐ SpO2 of less than 90% from any site, or SpO2 of less than 95% from the right hand or either foot OR if the difference between the hand and foot is >3%, REPEAT within one hour. Persisting saturations that are greater in the foot compared to the right hand require immediate evaluation by the primary care physician.

☐ If the 2nd measurement are greater than 95% OR the difference between the hand and foot is less than (<) 3%, the screening is negative

☐ If the 2nd measurements are less than 95%, OR the difference between the hand and foot is greater than (>) 3%, the screening is positive

☐ A greater-than 3% difference in SpO2 measurements between the right hand and either foot. For these results, take 2nd and 3rd measurements as described in the items above.

☐ If 2nd screen is positive, REPEAT the screening within on hour. If results are same as above, the screen is considered POSITIVE and primary care physician should be notified for further evaluation and/or testing:

☐ Take a perfusion measurement if it is available on your device. Consider the following guidance to help corroborate differences in perfusion. If oximetry values do not corroborate the presence of CCHD consider the following:

☐ For a PI measurement of less than 0.7, increase the frequency of assessment

☐ For a PI measurement of less than 0.4, assess the baby immediately (Kemper, et al., 2011).

☐ Provide regular pulse oximetry screening training for all care providers. This will help them:

☐ Engage with families

☐ Understand protocols for positive screenings
Understand the results reporting policy

Develop a process for continuous improvement:
- Educate and communicate with staff
- Implement measures to improve processes to meet the universal newborn screening objective
- In the United States, follow your state’s public health department guidelines for reporting. (Oster, et al., 2016).
- Use patient stories – in written and video forms – to find gaps and inspire change in your staff
What we know about failure to detect CCHD in newborns

Problems of detecting CCHD in newborns

CHD is the most common birth defect, affecting approximately 8 in 1,000 live-born infants (Reller et al., 2008; Bernier et al., 2010). Each year, nearly 40,000 infants are born with CHD in the U.S., and 1.35 million infants are born with CHD globally (Hoffman and Kaplan, 2002; Van et al., 2011).

One-quarter to one-third of these infants have CCHD, including ductal dependent lesions (Oster et al., 2013; Glidewell et al., 2015; Ailes, Gilboa, Honein, and Oster, 2015). CCHD causes (Hoffman and Kaplan, 2002):

- About 40% of the deaths from congenital anomalies
- Most of the deaths due to CHD that occur in the 1st year of life

Before newborn screening programs were introduced in the U.S. in 2012, it was estimated that between 70-100 infants died each year from late-diagnosed CCHD (Govindaswami, Jegatheesan and Song, 2012). Screenings show that the number of deaths from CCHD is closer to 120 each year (Grosse et al., 2017).

Many CCHD deaths are preventable

Antenatal ultrasound (during pregnancy) and physician examination after birth improve detection and perinatal outcomes for certain forms of CCHD (Tworetzky et al., 2001; Bonnet et al., 1999). Evidence shows that prenatal detection:

- Increased every year from 2006-2012
- Now occurs in 34% of patients (Quartermain et al., 2015)

A CCHD diagnosis before birth allows for parent counseling and coordination of delivery at an experienced cardiac center.

The gap in patient safety

- More than 30% of CCHD deaths have been attributed to late or missed diagnosis (Chang, Gurvitz and Rodriguez, 2008)
- Each year, an estimated 2,000 infants die or are undiagnosed in the U.S. and some 300,000 infants die or are undiagnosed globally (Salvi, 2016)
- In the developing world, fewer than 50% of CHD cases are diagnosed in the 1st week of life (Hoffman, 2013). The magnitude of the problem has been extensively documented (Singh, Rasiah, and Ewer, 2014; de-Wahl Granelli et al., 2014; Ewer, 2014; Ewer, 2013; Ewer, 2013; Granelli et al., 2007).

Evidence for change in diagnosing CCHD

Evidence for pulse oximetry

Pulse oximetry measures oxygen saturation (SpO2) and pulse rate in a non-invasive way:

- In 2009, de-Wahl Granelli and colleagues published a breakthrough cohort study in which 39,821 infants were screened for CCHD by identifying abnormal SpO2 measurements from Signal Extraction Technology (SET) pulse oximetry. SET’s ability to measure through motion and low-perfusion is essential for accurate CCHD screening
In a separate CCHD screening study of 20,055 asymptomatic newborns, Ewer et al, confirmed the importance of utilizing SET technology that can “produce accurate saturations that are stable in active neonates and in low perfusion states, making them suitable for use in the first few hours of a newborn baby’s life” (Ewer et al., 2012).

In 2014, Zhao and colleagues reported similar positive results from a prospective study using an additional pulse oximetry measurement in more than 100,000 newborns in China (Zhao et al., 2014).

Adding pulse oximetry screening to antenatal ultrasound and physical examination may increase detection rates for CCHD to over 90%. It also helps detect non-critical CHDs and significant non-cardiac neonatal conditions, such as respiratory problems or early-onset sepsis.

However, clinicians need to know that the problem will still be missed in some infants. The Journal of Pediatrics published a study estimating that universal pulse oximetry screening for CCHD can miss the problem in some infants (Frank et al., 2013). CDC researchers estimated that each year in the U.S.:

- About 1,755 infants with CCHDs would be diagnosed late (on or after the 3rd day after birth)
- Of these, pulse oximetry would detect about half (875 infants) with a CCHD, but an equal number (880 infants) might still be missed

Evidence for adding perfusion measurement to screening

Most studies report that the lesions most often missed are those causing obstruction to aortic outflow (such as coarctation and interrupted arch). They may not be detected in antenatal ultrasound, physical examination, or by abnormal SpO2 values from pulse oximetry.

However, an additional pulse oximetry measurement, perfusion measurement, may help detect CCHD with obstructions to aortic outflow. It is an assessment of strength of perfusion at the monitored site. The use of the perfusion measurement is crucial but it is equally important to understand that the pulse oximeter should be used only on the hand for accurate data. Attention to limb positioning is important in the interpretation of perfusion measurement.

In a 2007 study, Granelli and colleagues showed that adding abnormal perfusion measurement to pulse oximetry screening may increase sensitivity to identifying CCHD with an obstruction to the aortic outflow. The authors of this study also noted that adding perfusion measurement to the screening criteria may also result in an increase in false positives (Granelli et al., 2007).

In 2011, a federal CCHD workgroup developed a report, Strategies for Implementing Screening for Critical Congenital Heart Disease (Kemper et al., 2011). After a thorough review, the workgroup relied upon a thorough body of evidence and independent published studies to recommend:

Screening [should] be performed with motion tolerant pulse oximeters that report functional oxygen saturation, have been validated in low-perfusion conditions, have been cleared by the FDA for use in newborns, and have a 2% root mean-square accuracy (Kemper et al., 2011).

The workgroup included members selected by the U.S. Health and Human Services Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children, the American Academy of Pediatrics, the American College of Cardiology Foundation, the Newborn Foundation, the March of Dimes, and the American Heart Association.
Several domestic and international studies have shown that parents are predominantly satisfied with pulse oximetry screening:

- Parents whose babies had a false positive result were no more anxious than those with true negative tests (Ewer 2012)
- Parents generally perceived it as an important and valuable test to detect ill babies

Additionally, all staff groups (healthcare assistants, midwives, nurses, and doctors) were mostly positive about the testing procedure and perceived the test as important. In 2013, Peterson and colleagues found that screening for CCHD:

- Reduces pain and suffering of infants and families
- Reduces costs associated with severe cardiovascular and other organ or neurological compromise upon delayed admission to a cardiac unit
- Has been tied to:
  - Significantly reduced mortality
  - Fewer poor surgical outcomes
  - Lower incidence of prolonged ventilation and potential developmental issues

### Causes of newborn death

- In the developing world, the prevalence of certain neonatal conditions varies significantly on the global map, as does the burden of hypoxemia-related conditions such as neonatal pneumonia, sepsis, necrotizing enterocolitis (NEC), and PPHN (Hoffman 2013)
- Every year, nearly 41% of all under-age-5 child deaths are among babies in their 1st 28 days of life or the neonatal period (WHO, 2012)
- Three-quarters of all newborn deaths occur in the 1st week of life
- One-third of these deaths are from infection, such as pneumonia, tetanus, and sepsis

Each of these conditions are likely to manifest with below-normal oxygen saturation. Some are preventable deaths; when diagnosed in a timely fashion, clinical staff can save a life or improve an outcome by giving a course of antibiotics and/or supplemental oxygen therapy.

### Considerations when using algorithms for screening

A recent review describes CCHD screening in the U.S. and the efforts to optimize the algorithm for screening, educate all stakeholders, and perform screening using the proper equipment (Oster et al., 2016).

There are many factors to consider when you determine the optimal screening algorithm, including the balance of high altitude, timing of screening, sensitivity and specificity, resource utilization, and cost. For this reason, other screening protocols have been evaluated in the U.S. and in other countries (Ewer and Martin, 2016; Ewer, 2016).

### High altitude

Infants at high altitude may have a lower oxygen saturation than those at sea level with potential implications at elevations over 6,800 feet:

- To identify the optimal algorithm in particular settings, you may need to modify the screening protocol described in this document, including the saturation cutoff points and the timing of screening
- Although usually reserved for former premature infants going to a high altitude, any infant who fails high altitude stress testing (HAST) also merits special consideration and
may require an echocardiogram to confirm normal anatomy

**Timing of screening**
A certain degree of controversy still remains, and debate continues regarding the most appropriate time to screen, the most effective screening pathway, what saturations are acceptable, which conditions we are trying to identify, and screening outside the well-baby nursery.

**Sensitivity, specificity, and false-positive/false-negative rates**
When evaluating algorithms, it is important to consider sensitivity, specificity, and false-positive and false-negative rates. In addition:

- It is vital that screening leads to timely diagnosis, such as before an infant presents with acute collapse
- The screening should be pre- and post-ductal, because analysis of raw saturation data from infants who had both limb measurements showed that some infants with CCHD would be missed by post-ductal testing alone
- False-positive rates are significantly higher with earlier testing (less than 24 hours of age). This led to recommendations that screening be performed after 24 hours of age.
- However, analysis of recent studies shows that many false-positive tests (30%–80%) indicate alternative non-cardiac conditions (such as congenital pneumonia, early-onset sepsis, or pulmonary hypertension), which may be equally as life threatening as CCHD if diagnosed late
- In published studies that adopted earlier screening (less than 24 hours), the false-positive rate was higher, but more non-cardiac disease was identified
- In some countries, mothers and infants are discharged from the hospital within 24 hours after birth, and an increasing proportion is born at home. In these circumstances, screening in-hospital at less than 24 hours is not practical.

Be this as it may:

- If \( \text{SpO}_2 \) is less than 90% in either limb, the infant needs to be assessed immediately
- If \( \text{SpO}_2 \) is between 90-94% in one or both limbs and the infant does not look completely healthy, clinical assessment is mandatory without delays for repeated measurements
- If infant is completely healthy, measurements should be repeated as described

In summary, not having a systematic approach for detecting and treating CCHD significantly affects patient safety, quality, and cost of care. Universal newborn screening with pulse oximetry technology has been shown to increase the detection of CCHD by identifying potential abnormalities that are not apparent in prenatal or postnatal examinations.

Closing the performance gap with CCHD will require hospitals, healthcare systems, and all members of the neonatal healthcare team (RNs, RTs, and MDs) to commit to action in the form of specific leadership, practice, and technology plans for all newborn infants.

**Leadership plan**
Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce preventable events from unrecognized CCHD in newborns.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions:

- Implement a plan that includes fundamentals of change outlined in the National Quality

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Forum safe practices, including awareness, accountability, and action

- Hospital governance and senior administrative and medical and nursing leadership should commit to becoming aware of this major performance gap in their own healthcare system
- Hospital governance, senior administrative leadership, and clinical/safety leadership should close their own performance gap by implementing a comprehensive approach to addressing the performance gap across all providers and systems
- Commit to a goal date to implement the plan you create
- Allocate a budget for the plan to be evaluated by governance boards and senior administrative leaders
- Clinical/safety leadership should endorse the plan and drive implementation across all providers and systems
- Address the performance gap with measurable quality indicators
- Conduct data collection and analysis to help implement and assess outcomes
- Use patient stories - in written and video formats - to identify gaps and inspire change in your staff:
  - The story of Cora McCormick is an example of a newborn who died because of unrecognized CCHD. That can be viewed freely here: http://patient.sm/cCfcAA

**Action Plan**

This plan focuses on actions providers and hospitals can take to improve CCHD results:

- Evaluate guidelines and reviews
- Choose a screening strategy that models the recommendations below and in well-designed, large published studies
- Set concrete milestones in a timeline to implement these practices
- Select technology proven to be effective for newborn screening, including SET pulse oximetry screening strategies
- Determine the screening protocol:
  - Screen newborns more than 24 hours after delivery or before discharge
  - Get pulse oximetry measurements from preductal (right hand) and postductal (either foot) sites. The following results should be considered positive and require further testing:
    - **SpO2 of less than 90% from any site, or SpO2 of less than 95% from the right hand or either foot.** For these results, take 2nd and 3rd measurements, and:
      - If the 2nd and 3rd measurements are greater than 95%, the screening is **negative**
      - If the 2nd and 3rd measurements are less than 95%, the screening is **positive**
    - **A greater-than 3% difference in SpO2 measurements between the right hand and either foot.** For these results, take 2nd and 3rd measurements as described in the bullets above.
  - If available, take a perfusion measurement:
    - **For a perfusion measurement of less than 0.7**, increase the need for assessment
• **For a PI measurement of less than 0.4**, assess the baby immediately
• Implement interdisciplinary strategies and educational activities for all members of the neonatal healthcare team, including:
  o Proper screening methods
  o Strategies for family education and engagement
  o Follow-up investigation protocols for positive screens
  o Public health results reporting policy
• Implement optimization and workflow guidelines to ensure staff is adequately screening, such as:
  o As a quality indicator, each week randomly assess the number of babies that should have been screened but were not
  o Communicate with staff and, based on results, implement measures to improve processes in order to meet the goal of screening all newborns
  o Use clinical decision support tools and software whenever available to avoid misinterpretation of screening results or faulty data entry
• Report screening results per state and federal requirements

**Technology plan**

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: [https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/](https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/)

Select technologies that have been shown to improve neonatal oxygen targeting include:

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<tbody>
<tr>
<td>Pulse oximetry technologies that are effective in helping clinicians screen for CCHD</td>
<td></td>
</tr>
</tbody>
</table>
| Devices that reduce operator-induced variability and improve efficiency by:  
  • Automating the screening steps  
  • Selecting measurements  
  • Applying those measurements to the screening criteria chosen by the hospital  
  • Categorizing the test as a positive or negative screen | |
| • Public health reporting systems for newborn screening | |

*Company has signed some form of the Open Data Pledge. Find more information on the Patient Safety Movement Foundation website: [https://patientsafetymovement.org/partners/](https://patientsafetymovement.org/partners/)*
Measuring outcomes

**Topic:**
Critical Congenital Heart Defects (CCHD) is the number of patients identified with CCHD through technology-enabled pulse oximetry newborn screening. The rate is the reflection of the number of patients diagnosed with CCHD over the total number of infants screened.

**Outcome measure formula:**

**Numerator:**
Number of newborns identified with CCHD

**Denominator:**
Number of patients screened

- This measure is usually displayed as a percentage: Numerator/Denominator *100

**Metric recommendations:**

**Indirect impact:**
All newborns that received technology-enabled newborn screening of CCHD via pulse oximetry

**Direct impact:**
Number of asymptomatic infants identified with CCHD through pulse oximetry and received successful clinical intervention

**Lives spared harm:**
Number of asymptomatic infants identified with CCHD through pulse oximetry or echocardiogram and received successful clinical intervention

**Lives saved:**
Lives saved = Lives spared harm x 0.825

**Data collection for direct impact:**
- Both the numerator and denominator data could be collected from the medical record

**Conflicts of interest disclosure**

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References


Congenital Heart Disease. MMWR Morb Mortal Wkly Rep, 66, 888–890.


How to use this guide
This guide gives actions and resources for creating and sustaining safer airway management in patients. In it, you’ll find:

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APSS #8A: Safer airway management

Executive summary checklist

Major causes of patient morbidity and mortality include delays or failure to provide adequate oxygenation by means of a patent airway. Frequently, this is achieved with a secured breathing tube. Failure to recognize a malpositioned breathing tube, or to secure it in a fashion that prevents unplanned removal (“unplanned extubation”-see APSS #8B) or delays in recognizing its removal contribute to significant morbidity and mortality. These are all high priorities for airway safety efforts.

A specific APSS (#8C) addressing the pediatric and neonatal population has also been published.

Use this checklist to help you prioritize your actions and measure your organization’s progress in your airway safety management efforts.

Create a Safer Airway Team and toolkit

☐ Assemble a core multidisciplinary leadership team to advance airway safety, including:
  ☐ ED (emergency department), ICU (intensive care unit), hospitalist, and anesthesiology physician leaders
  ☐ ED, ICU nursing leaders
  ☐ Respiratory therapy leaders
  ☐ Quality assurance (QA)/Safety leadership (VP or higher level)
  ☐ Obstetric/neonatal/pediatric - their representation and expertise is crucial

☐ Under the leadership of an airway specialist physician develop a comprehensive airway toolkit method (such as the Safer Airway Bundle):
  ☐ Start in the Operating Room (OR) or Post-anesthesia Care Unit (PACU), then ED and ICUs, and then move to pre-hospital settings, operating and recovery rooms, floor units, and other departments
  ☐ Include these key components: Failed Airway Algorithm, Airway Cart, Airway Checklist/Time out/cognitive aids, Quality Assurance, intra-hospital and inter-hospital transport, and Team Training and dissemination of information of difficult airway management
  ☐ Implement Safer Airway Essential Components, as described in “Actions for hospitals” in the Action Plan section

Track and analyze clinical data to find areas for improvement

☐ Require tracking and reporting of “near-misses” and complications of airway management

☐ Identify adverse outcomes that are iatrogenic (caused by medical examination or treatment) and preventable, including multiple intubation attempts, esophageal intubation, \( \text{SpO}_2 \) less than 90% or a decline of greater than 10%, and dental or soft tissue injury, front of neck (airway) access (FONA), brain injury or death resulting from resulting from airway management.

☐ Use these case data in medical staff training sessions to prevent recurrences, as a part of Continuous Quality Improvement (CQI)

☐ Provide regular airway management training for all care providers. This will help them:
Identify potential airway problems
Select and use the correct course of action
Understand when and how to call for expert help
Analyze delays in care related to airway management problems, including any delays in surgery, in applying invasive (or non-invasive) mechanical ventilation, and in diagnostic studies
Use patient stories – in written and video formats – to identify gaps and inspire change in your staff
What we know about airway management

This set of Actionable Patient Safety Solutions (APSS) promotes airway safety and gives broad recommendations for urgent and emergent airway management in settings both inside and outside of the OR, including: pre-hospital emergency medical services (EMS), EDs, ICUs, general medical/surgical units, procedural areas, and outpatient settings.

The Centers for Medicare and Medicaid Services (CMS) has identified airway safety as a priority area for Round 2 of the Hospital Engagement Networks (HENs) due to the high risk and significant impact of airway-related injuries and deaths.

Several U.S. and European organizations have provided focused evidence-based clinical recommendations to their specialty membership and general audiences. However, there have been few calls for specific standards outside of the OR. We strongly promote that this needs to change.

This Airway Safety APSS serves to:

- Highlight key need areas for best practice development and implementation
- Promote evolving programs that introduce a new level of practice and comprehensive airway safety engagement
- Launch the call for a multi-disciplinary airway safety collaborative – the collaborative will support further development, assessment, implementation, and promotion of clear actionable solutions to strengthen airway safety awareness, education, management, research, and policy

The problems with airway management

Delay or failure to secure a patient’s airway or to have an unrecognized airway malposition (such as intubation of the esophagus) can result in preventable death or catastrophic injuries. Time delays are especially critical in pregnant women, infants, and children because the time to desaturation is markedly decreased due to various anatomical and physiological factors.

Using direct laryngoscopy for endotracheal intubation requires skill and training. It is a physically challenging, single-operator technique which has an unacceptable rate of failure, especially in the hands of non-airway specialists. Harm and death from any of these events can be preventable:

- Unrecognized esophageal intubation
- Many failed (repeated) attempts to secure the airway
- Failure to correctly secure the endotracheal tube (with tape or an alternative securing method), which delays recognition of airway malpositioning
- Patient aspiration of gastric contents, airway injury, trauma to teeth, hypoxemia (low blood oxygen), and brain injury

The incidence of failed airways can be as high as 1 in 50-100 in ED and ICU settings and the occurrence of death or brain damage have been reported to be 38-fold (ED) to 58-fold (ICU) higher compared to the operating room setting (Cook and MacDougall-Davis, 2012). Even when airway management is ultimately successful, delays and multiple unsuccessful attempts may cause serious harm and death (Mort, 2004; Sakles et al., 2013; Natt et al., 2016).

Causes of preventable patient harm and death include:

- The wide variation of airway management techniques and technology
  The goals of airway management are essentially uniform, but clinical best practices
are not standardized and depend heavily on provider specialty and physical locale in healthcare settings.

In the most recent meta-analysis looking at prehospital intubation success rates (Crewdson, Lockey, Roislien, Lossius, & Rehn, 2017), the overall intubation success rate was 0.969 (0.616-1.000). The median overall intubation success rate for physicians was 0.988 (0.781-1.000) compared to the median overall intubation success rate of non-physicians being 0.917 (0.616-1.000). Thus failed intubations occur in as high as 38% of patients in non-physician intubator field cases and as high as 22% of patients in physician intubator field cases.

- Lack of video laryngoscopy (VL) equipment availability in all areas

A wealth of scientific evidence shows VL’s advantage over direct laryngoscopy in a variety of clinical settings, but the high cost of VL equipment has kept it from being widely adopted.

VL allows the approach to airway management in the EMS setting to undergo a dramatic transformation (Chemsian, Chananker, and Ramaiah, 2014). VL:

- Improves the laryngeal view and results in higher success rates of endotracheal intubation (ETI), both during first pass attempts and after difficult or failed direct laryngoscopy in the hospital setting (Silverberg, Li, Acquah, and Kory, 2015; Aziz et al., 2011)
- May also enable remote viewing and coaching, while recording may facilitate documentation and quality improvement

- Unrecognized esophageal intubation (intubation of the esophagus instead of the trachea)

Studies show that unrecognized esophageal intubation in prehospital settings is as high as 25% (Katz and Falk, 2001) and leads to a high likelihood of death.

Waveform capnography can identify an endotracheal tube that has not been placed correctly in the trachea and incorrectly placed in the esophagus and therefore should be readily available to avoid preventable deaths. Yet some EMS agencies and some emergency departments have not yet adopted waveform capnography. The use of waveform capnography in the intubated patient is considered standard of care by the American Society of Anesthesiologists (ASA). It should be adopted as standard of care by all organizations whose providers are responsible for airway management.

- Unplanned extubation (See APSS 8B)

Unplanned extubation, both in the field and in the hospital, is generally avoidable and potentially very costly. It happens in over 7% of patients who undergo mechanical ventilation in the ICU and complications of unplanned extubations result in over $4 billion in healthcare costs (da Silva and Fonseca, 2012).

Although unplanned extubations are more likely in EMS settings due to the difficulties of transporting critically ill patients in a chaotic environment, incidents are not tracked in most EMS data systems. Similarly, most hospitals do not track unplanned extubations and therefore the 7% incidence may be an underestimate.

Inconsistent outcome definitions lead to underreporting and the true frequency of airway management-related injuries is unknown. It is clear, however, that the healthcare industry must transition away from viewing airway management-related injuries as the inevitable “cost of doing business”, and redefine these complications as preventable iatrogenic harm.
Leadership plan

Show leadership’s commitment to safe airway management

Hospital governance and senior administrative leadership must:

- Commit to reducing the incidence of preventable airway safety events, especially failed intubations, unrecognized malpositioned esophageal intubations, and unplanned extubations
- Promote correct documentation to minimize the risk of recurrent adverse airway events
- Strive to achieve a goal of zero preventable deaths
- Drive awareness regarding the seriousness of preventable airway-related safety events
- Determine the facility’s rates of preventable airway safety events through reporting and tracking within a formal QI program
- Engage your QI/Patient safety leaders to implement the Institute for Healthcare Improvement’s (IHI) Model for Improvement to reduce the incidence of preventable airway safety events
- Once you know your incidence rates, develop an organizational story and use the skill set of storytelling to drive organizational awareness, action, and focus on why there is a need for change
- Create a core multidisciplinary Safer Airway Team that includes:
  - VP of Quality/Safety
  - Physician, nursing, and respiratory care team leaders from Anesthesiology, ED, OR/PACU, and ICU
  - Clinical expertise from obstetrics, neonatal, and pediatrics

Hospital governance, senior administrative leadership, clinical leadership and safety/risk management leadership must:

- Commit to taking inventory and defining the performance gaps that exist within their own hospital/healthcare system
- Commit the financial support needed to implement this Actionable Airway Safety Solution (APSS)
- Work collaboratively and champion efforts that raise awareness about the seriousness of preventable deaths from complications of airway management
- Shape a vision of the future, clearly define safety goals, and support staff as they work through improvement initiatives, measure results, and communicate progress towards these goals
- Commit to defining performance gaps within the organization (system-wide, hospital-wide, and by department)

Create the infrastructure needed to make changes:

- Support a comprehensive approach to standardized data tracking, quality management, and process improvement efforts
- Support the implementation of practice and technology plans necessary to stop preventable deaths from complications of airway management
- Support the IHI Model for Improvement
• Set clear aims
• Identify changes that are likely to lead to improvement
• Establish measures that will clearly define if changes are leading to improvement
• Conduct small-scale tests of change using the Plan-Do-Study-Act (PDSA) cycle
• Hospital governance, senior administrative leadership, clinical leadership and safety/risk management leadership must commit to sharing airway safety best practices and lessons learned throughout your hospital and your hospital’s healthcare system, and with other organizations outside your hospital’s healthcare system
• Use patient stories – in written and video formats – to identify gaps and inspire change in your staff.
  • The story of Dave Bunoski, told by his wife Mimi Toomey, is an example of an unrecognized esophageal placement that can be viewed freely here: https://patient.sm/6oOTDZ
  • The story of Drew Hughes, told by his father David Hughes, is an example of an unplanned extubation, followed by a failed reintubation and unrecognized esophageal intubation, that led to the preventable death of Drew. You can view the story for free here: https://patient.sm/9nYJaK

Action plan

This plan focuses on actions EMS and hospitals can take to improve airway safety. Actions for other stakeholder groups (such as outpatient procedure centers using moderate or deep sedation, professional healthcare stakeholder groups, industry, accrediting agencies, government, safety organizations, risk management and insurance companies, and consumer groups), are listed in Appendix A: Recommended actions for stakeholders.

Actions for EMS Basic Life Support (BLS) Units
• Use a Supraglottic Airway (SGA) device for cardiac arrests
• Schedule regular training courses and competency assessments for specific airway safety scenarios
• Enroll in regional and national systems for reporting adverse events and near-miss events, such as the EMS-based Emergency Medical Error Reduction Group at http://patient.sm/msvt13

Actions for EMS Advanced Cardiac Life Support (ACLS) Units
• Ensure adequate training and promote the use of a SGA device for initial treatment of cardiac arrest and as a rescue device for failed or difficult intubation
• Ensure adequate training and promote the use of VL as your main device for endotracheal intubation
• Encourage the routine recording of VL attempts and where possible, time-stamped events such as heart rate and SpO2
• Use continuous waveform capnography on:
  o All SGA or intubated patients
  o Certain conditions known for creating problems with airway safety or adequate ventilation, such as overdose, respiratory distress, severe congestive heart failure,
morbid obesity, and obstructive sleep apnea

• Schedule regular training courses and competency assessments for specific airway safety scenarios
• Enroll in regional and national systems for reporting adverse events and near-miss events, such as the EMS-based Emergency Medical Error Reduction Group at www.emerg.org

**Actions for hospitals**

- Establish high-reliability as the driving principle for airway safety, and as part of the overall culture of safety in all clinical areas
- Proactively embrace airway safety best practices before they are adopted by regulatory or accrediting organizations
- Form a standing leadership group for airway management safety including key stakeholders in C-suite Safety/Quality Administration, Emergency Medicine, Critical Care, Anesthesiology, Hospital Medicine, Respiratory Care, and Nursing
- Implement a system that quickly allows an anesthesiologist to assist with difficult airways in non-OR settings
- Develop standardized, site-specific systems for airway management in areas including ED, ICU, general units, and procedural areas.

The Safer Airway Program is a comprehensive, team-based system solution that hardwires evidence-based best practices in clinical settings and safety science. It provides broad recommendations and customizable tools for multiple healthcare settings including emergency departments, intensive care units, general medical/surgical units, and procedural areas. It calls for implementation of proven solutions such as Failed Airway Protocols (FAP), comprehensive equipment cart/systems, essential clinical practices, checklist utilization and team training. You can access more information here: [http://patient.sm/yCMA9I](http://patient.sm/yCMA9I)

The Safer Airway Program has been developed via a collaboration of Emergency Medicine Associates, (Germantown, MD), the Emergency Medicine Patient Safety Foundation (EMPSF), Society for Airway Management (SAM), and national advisors.

The American College of Emergency Physicians’ Quality Improvement and Patient Safety Section (QIPS), the Patient Safety Movement Foundation, and other medical specialty organizations are leading the advancement of the Safer Airway Program.

<table>
<thead>
<tr>
<th>Hospital-wide Failed Airway Protocol/Pathway (FAP)</th>
</tr>
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<tbody>
<tr>
<td><strong>Solution and key features</strong></td>
</tr>
<tr>
<td>Failed Airway Protocol/Pathway (FAP)</td>
</tr>
<tr>
<td>Alternative term is “Difficult Airway Pathway” (DAP)</td>
</tr>
</tbody>
</table>

| **Level of recommendation**                      |
| Mandate                                          |

| **Safety rationale**                             |
| FAP should be operational, standardized, and actionable. Creates a team approach. |

<p>| <strong>Reference source</strong>                             |
| American Society of Anesthesiologists (ASA) and Difficult Airway Society (DAS) |</p>
<table>
<thead>
<tr>
<th></th>
<th>Solution and key features</th>
<th>Level of recommendation</th>
<th>Safety rationale</th>
<th>Reference source</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Choose a <strong>consolidated Airway Cart</strong> (standardized) that includes equipment for basic and</td>
<td>Mandate</td>
<td>Avoids critical delays, assures equipment availability, and prompt access.</td>
<td>ASA</td>
</tr>
<tr>
<td></td>
<td>difficult airway management. Use for all intubations and airway emergencies in the ED, ICU,</td>
<td></td>
<td>Workspace with references.</td>
<td></td>
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<tr>
<td></td>
<td>OR, Post anesthesia Care Unit (PACU) and general unit settings.</td>
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<tr>
<td>B</td>
<td><strong>Cart components</strong></td>
<td>Highly Recommend</td>
<td>Reinforces FAP and increases reliability</td>
<td>Mark L et al</td>
</tr>
<tr>
<td></td>
<td>Organize the cart to support FAP progression of need.</td>
<td></td>
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<tr>
<td>1</td>
<td>Oral (mouth) and nasal (nose) airways</td>
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<tr>
<td>2</td>
<td>Full face masks</td>
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<tr>
<td>3</td>
<td>Nasal CPAP mask</td>
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<tr>
<td>4</td>
<td>VL - in room and ready for all intubations</td>
<td>Mandate</td>
<td>Gives higher 1st pass success and is an essential airway tool</td>
<td>ASA, NAP4, Cochran database</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Recommendation</td>
<td>Notes</td>
<td></td>
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<tr>
<td>5</td>
<td>Bougie type introducer catheters and stylets</td>
<td>Mandate</td>
<td>Critical adjunct</td>
<td>ASA, Emergency Medicine Australia, 2017</td>
</tr>
<tr>
<td>6</td>
<td>SGA devices - appropriately sized to meet the needs of the patient population</td>
<td>Mandate</td>
<td>ASA and Canadian Guidelines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. SGA device</td>
<td>Mandate</td>
<td>ASA</td>
<td></td>
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<tr>
<td></td>
<td>- SGA device with intubation capability</td>
<td>Highly recommend</td>
<td>ASA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- SGA devices with gastric access capability</td>
<td>Recommend</td>
<td>DAS; Piegelir et al., 2016 Hansel et al., 2016</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Highly recommend</td>
<td>Key rescue device option</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Cricothyrtomy kits (simple surgical)</td>
<td>Mandate</td>
<td>ASA</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Needle jet ventilation kits/sets - for pediatric patients under age 10, ONLY Use in ED/ICU after failure of VL, DL, SGA and BVM. for adults Front of neck Access (EFONA)</td>
<td>Mandate</td>
<td>NAP4, ASA</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Continuous Waveform Capnography - maintained on all intubated patients including ED/ICU/Transports and with central monitoring enabled</td>
<td>Mandate</td>
<td>ASA, AHA 2010 AARC (2003), ACEP, NAP4, AAGBI, ICS, EBA</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Endoscope (flexible fiberoptic scope or video scope) and/or optical stylets - in ED/ICU at all times</td>
<td>Mandate</td>
<td>ASA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Recommendation</td>
<td>Benefits</td>
<td>Category</td>
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<tr>
<td>11</td>
<td>LED blades(handles) for direct laryngoscopy - replace bulb models with single-use models, which may be better</td>
<td>Highly recommend</td>
<td>10x brighter, higher reliability, and better visibility</td>
<td>Anesthesi</td>
</tr>
<tr>
<td>Solution and key features</td>
<td>Level of recommendation</td>
<td>Safety rationale</td>
<td>Reference source</td>
<td></td>
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<tr>
<td><strong>Critical practices</strong></td>
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</tr>
<tr>
<td>Use these recommended clinical and safety practices for preparing, performing, and maintaining artificial airways</td>
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<td></td>
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</tr>
<tr>
<td><strong>A</strong> Use a Checklist Quality Assurance (QA) tool for hardwiring and assessing critical practices</td>
<td>Mandate</td>
<td>Tool for practical preparation and critical practice assurance and QA monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>B</strong> Use assessment, planning, and team communication for airway management - as appropriate in the various clinical settings</td>
<td>Mandate</td>
<td>Basic clinical and safety practices are known and accepted but often not utilized or hardwired into practice</td>
<td>ASA, NAP 4</td>
<td></td>
</tr>
<tr>
<td><strong>C</strong> Use optimized patient positioning - such as tragus to sternal notch, head elevated laryngoscopy position (HELP), and ramped position in obese patients (Levitan et al., 2003)</td>
<td>Mandate</td>
<td>Critical but commonly overlooked</td>
<td>ASA, DAS</td>
<td></td>
</tr>
<tr>
<td><strong>D</strong> Follow apneic oxygenation protocols - such as “no desat” or heated, humidified high-flow nasal oxygen or nasal CPAP</td>
<td>Mandate</td>
<td>Significant potential to prevent or delay desaturation in patients</td>
<td>Ann Emer Med, Wong, et al., (2017)</td>
<td></td>
</tr>
<tr>
<td><strong>E</strong> Use 1- and 2-person BVM techniques - appropriate seal, jaw thrust, and prn Nasopharyngeal/airway (NPA) and oropharyngeal airway (OPA)</td>
<td>Mandate</td>
<td>Key basic airway skill for all healthcare personnel in all settings. Often not effectively performed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>F</strong></td>
<td>Use BIPAP/CPAP/High Flow nasal oxygen (HFNO) pre-oxygenation in patients with persistent hypoxia</td>
<td>Highly recommend</td>
<td>Use useful with persistent hypoxia in obesity, CHF, other</td>
<td>Ann Emer Med, Wong, et al., 2017; Smith, 2015</td>
</tr>
<tr>
<td><strong>G</strong></td>
<td>Use delayed sequence intubation with ketamine – use for agitated patients with hypoxia</td>
<td>Recommend</td>
<td>Important for allowing pre-oxygenation</td>
<td>Ann Emer Med</td>
</tr>
<tr>
<td><strong>H</strong></td>
<td>Quickly use SGA if DL/VL failed</td>
<td>Highly recommend</td>
<td>Important airway rescue device when intubation fails</td>
<td>ASA,DAS</td>
</tr>
<tr>
<td><strong>I</strong></td>
<td>Place SGA and high flow nasal oxygen or nasal CPAP during codes (cardiac/respiratory arrest)</td>
<td>Highly recommend</td>
<td>Assures open airway, prompt easy placement, and avoids resuscitation delay</td>
<td>ASA,DAS</td>
</tr>
<tr>
<td><strong>J</strong></td>
<td>Quickly use surgical cricothyrotomy when VL/DL, SGA, and BVM ventilation have failed (a cannot intubate cannot oxygenate situation). Only qualified personnel should perform this procedure.</td>
<td></td>
<td></td>
<td>NAP4, ASA</td>
</tr>
<tr>
<td><strong>K</strong></td>
<td>Use flexible bronchoscope to convert SGA to ETT</td>
<td>Highly recommend</td>
<td>Blind techniques with only 65% 1st pass success rate</td>
<td>NAP4, DAS</td>
</tr>
<tr>
<td><strong>L</strong></td>
<td>Use AFOI or other non-paralyzed intubation techniques. Use for intubations that may be difficult or highly difficult.</td>
<td>Highly recommend</td>
<td>Essential practice that is not commonly performed in EM</td>
<td>ASA , DAS, NAP4</td>
</tr>
<tr>
<td><strong>M</strong></td>
<td>Immediately use and maintain Continuous Waveform Capnography - on all intubated patients</td>
<td>Mandate</td>
<td>See equipment above</td>
<td>See references above</td>
</tr>
<tr>
<td>N</td>
<td>Optimize sedation and restraint protocols to minimize UE</td>
<td>Highly recommend</td>
<td>Patients who are under sedation or agitated are at risk for airway loss (e.g. UE)</td>
<td>AJCC</td>
</tr>
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<tr>
<td>O</td>
<td>Formalize system for optimally securing ETT (Tube holders for adults, C- Collar infants in transport)</td>
<td>Highly recommend</td>
<td>UE causes high death rates - reportedly as high as 7%. High risk in pediatric patients</td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>Implement a system for flagging identified difficult airway patients in EHR system</td>
<td>Highly recommend</td>
<td>Many EHR systems are able to flag difficult airway patients, but flagging is not developed or used</td>
<td></td>
</tr>
<tr>
<td>Q</td>
<td>Use extubation guidelines</td>
<td>Highly recommend</td>
<td></td>
<td>ASA, NAP 4</td>
</tr>
<tr>
<td>R</td>
<td>Implement system for tracking and reviewing QA data from intubations or UEs - see Airway Registry</td>
<td>Highly recommend</td>
<td>Safety reporting systems have shown low yield for near-miss events from fear of punishment</td>
<td>DAS</td>
</tr>
<tr>
<td>S</td>
<td>Use strategies for avoiding peri-intubation hypotension by having medications ready prior to intubations</td>
<td>Highly recommend</td>
<td>Use IVF, positioning, and pressers in high-risk groups</td>
<td></td>
</tr>
<tr>
<td>T</td>
<td>Promote routine recording of airway management when video devices are utilized. Promote use of cognitive aids for routine and failed airway management, such as the Vortex Airway Approach (<a href="http://patient.sm/1R0dl3">http://patient.sm/1R0dl3</a>)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Solution and key features</td>
<td>Level of recommendation</td>
<td>Safety rationale</td>
<td>Reference source</td>
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<td></td>
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<tr>
<td>4 Team training</td>
<td>Mandate</td>
<td></td>
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<tr>
<td><strong>A</strong></td>
<td>Train all clinical staff on airway safety protocols, equipment, and critical practices - including basic and advanced practices for preparation, performance, and post-intubation management. Make sure all clinicians doing airway management are credentialed.</td>
<td>Mandate</td>
<td></td>
<td></td>
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<tr>
<td><strong>B</strong></td>
<td>Promote teamwork and clear communication - include a plan for sharing, open communication, and debriefing</td>
<td>Mandate</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>System for ensuring that practitioners are trained and credentialed in airway management</td>
<td>Mandate</td>
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</tbody>
</table>

**Technology Plan**

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: [patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/](http://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/)

Test and use airway management devices that improve safety and drive better patient outcomes, including:

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Available technology</th>
</tr>
</thead>
</table>
| **ONC Meaningful Use Certified Electronic Health Record (EHR) System** | An effective EHR System should include:  
  - Computerized Provider Order Entry (CPOE)  
  - Drug-drug interaction check  
  - Drug-allergy interaction check  
  - Clinical Decision Support tools (CDS) |
Laryngoscopes

A laryngoscope is a rigid airway visualization device that allows the user direct vision of the glottis (vocal cords), through which he/she will manually pass an endotracheal tube. It generally consists of a handle, held in the user’s left hand, and an attached blade, inserted through the mouth in such a way as to move the tongue and allow a direct visual path to the glottis. The use of this device requires considerable skill and training, and it may be unsuccessful in patients with difficult airway anatomy. The most commonly used laryngoscope blades include the straight blade (Miller Blade), traditional curved blade (Macintosh Blade) and acute angle blade.

Direct laryngoscopy (DL) has been used for decades to perform placement of endotracheal tubes. In 2001, video laryngoscopy (VL) was introduced. Although the literature has little to support that VL improves first pass success, some meta-analyses suggest that VL reduces the incidence of difficult or failed intubation.

Therefore, based on VLs ability to reduce failed intubations, it is highly recommended that:

- VL equipment be readily available for all intubations
- All airway providers responsible for intubation be trained and comfortable with these devices

Many providers and hospitals haven’t made the transition to VL, either because the cost of VL equipment or the change in technique required for successful VL. More recently, many video laryngoscopes have developed VL equipment that allows use of a traditional DL technique. This change may help with the transition.
**Video Laryngoscopes**
A video laryngoscope is a rigid device similar to an ordinary laryngoscope, with the addition of a fiber-optic light pathway for both illuminating and visualizing the glottis. Properly inserted into the mouth, the video laryngoscope can show the user an image of the glottis on a screen, without the requirement to establish a direct line of sight from the glottis to the user’s eye. The user can then insert the endotracheal tube through the glottis while monitoring the displayed image.

An effective VL system should:
- Be portable and easy to use
- Have clear and reliable airway visualization without fogging
- Permit ETT delivery with minimal operator fine motor skills
- Have a large video screen that allows multiple operators to act as a team. Devices with small video screens may be better when space is limited, such as in helicopters
- Have large image storage capability
- Have low risk for cross-contamination
- Have capabilities for recording events for clinical documentation, review and teaching
Fiberscopes
A “fiberscope” or fiber-optic bronchoscope is a highly flexible, guided tubular device that can be passed through the lumen of an endotracheal tube. The scope provides both light illumination and indirect visualization through its tip. The user can control the exact shape of the fiberscope tip to guide it through the patient’s glottis. Once the tip of the scope has passed through the glottis, the endotracheal tube is advanced over the scope and into the trachea.

Although video laryngoscopes have reduced the need for fiberoptic intubation, fiberscopes remain the device of choice in certain critical airway conditions, such as (angioedema, oropharyngeal neoplasm, head and neck radiation, and congenital deformity).

A combined use of fiberoberoptic and Video Laryngoscope would be recommended as placing ETT through cords over just fiberoptic is still a blind intubation

Low cost single-use fiberscopes with reusable video monitoring are now available asan alternative to high-priced reusable fiberscope systems. The availability of single-use flexible scopes requires little capital investment and may be particularly suited in areas where they will be infrequently used.
**Supraglottic Airways**

Supraglottic airway devices are inserted through the mouth and do not pass through the vocal cords. They displace the tongue using a variety of technologies, thus creating an open airway between the mouth or nares and the glottis.

Second-generation SGAs are now available and provide safety advantages over first-generation devices by allowing for easier placement, higher ventilation pressures, gastric decompression, and intubation through the device.

It is recommended not to do a blind intubation through an intubating LMA as success rates are low, thus use a fiberoptic bronchoscope.

These technological advances have furthered the importance of having the latest generation of SGA devices available when needed as rescue or primary airway devices.

**Waveform Capnography**

Capnography is the measurement of carbon dioxide tension (in mmHg) in the respired gas during both inspiration and expiration, and the display of that quantity versus time.

This important technology has become the standard of care for intubated patients in the UK and parts of Europe. North American Intensive Care Units, Emergency Departments, and Emergency Medical Services are beginning to adopt this technology, but significant gaps exist.

Continuous Waveform Capnography:
- Should become a mandated safety practice for all SGA or intubated patients
- Should have the capability to integrate into your facility’s monitoring systems
Endotracheal Tube Stabilizers
The current systems for stabilizing endotracheal tubes include adhesive tape, cotton twill ties, and multiple commercial devices. Although the current literature does not clearly identify any particular device or technique that is superior, numerous devices on the market are clearly inferior in their ability to restrain against extubation forces.

The most current cited unplanned extubation rate of 7.3% (with a range of studies showing rates as high as 35.8%) suggests that current stabilization techniques and devices are inadequate. Further research into developing a better stabilization system should be supported (da Silva and Fonseca, 2012).

Measuring outcomes
Tracking will help your organizations improve and helps hospitals evaluate their progress on how they are doing. At this time, this workgroup has not developed metrics to track failed intubations or unrecognized esophageal placements. Please refer to APSS #8B for metrics on unplanned extubations.

Topic 1
Rate:

Outcome Measure Formula:

Numerator:
Denominator:

Metric recommendations
Indirect Impact:
Direct Impact:
Lives Spared Harm:
Lives Saved:
Notes:

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

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 APSSs recommend technologies offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

**Workgroup**

**Co-Chairs**

Lorraine Foley  
Society for Airway Management

Arthur Kanowitz  
Airway Safety Movement,  
Society for Airway Management, Securisyn Medical

David Hughes  
Do It For Drew Foundation

**Members**

*This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Gillian Abir  
Stanford University

Sharon Armstead  
Ascension Health

Jim Augustine  
US Acute Care Solutions, LLC

Steven J. Barker  
Patient Safety Movement Foundation; Masimo

Michel Bennett  
Patient Safety Movement Foundation (formerly)

Lauren Berkow  
Society for Airway Management

Jestin Carlson  
Allegheny Health Network

Richard Cooper  
University of Toronto

Gina Farquharson  
Medtronic

Drew Fuller  
Emergency Medicine Associates

Kate Garrett  
Ciel Medical

Victor Grazette  
Virginia Hospital Center

Mitch Goldstein  
Loma Linda University

Hans Huitink  
VU University Medical Center

Thomas Kallstrom  
American Association for Respiratory Care

Sarah Kandil  
Yale New Haven Children’s Hospital

Ariana Longley  
Patient Safety Movement Foundation

Jacob Lopez  
Patient Safety Movement Foundation (formerly)

Olivia Lounsbury  
Patient Safety Movement Foundation

Ariel MacTavish  
Medtronic

Rhea May  
Medtronic

Kevin McQueen  
University of Colorado Health

Joaquim Pinheiro  
Albany Medical Center

Micheline Plantada  
Advocate

Donna Prosser  
Patient Safety Movement Foundation
References


Appendix A: Recommended actions for stakeholders

These are recommended actions for stakeholder groups, other than EMS and hospitals, to improve airway safety.

Actions for outpatient procedure centers using moderate or deep sedation

- Ensure staff who administer sedation are trained to monitor and manage airways appropriate to the setting
- Use proper monitoring equipment and tools, including pulse oximetry and waveform capnography
- Equip your facility with needed airway management equipment and skills for use, including: oxygen therapy, bag-valve mask ventilation, BLS-level use of supraglottic airway devices

Actions for professional/healthcare/stakeholder organizations

Seek national collaboration with other professional, safety, and healthcare organizations in an Airway Safety Collaborative with the aim to help the industry:

- Learn more about airway management practices in a broad representation of hospitals and other clinical environments
- Develop and promote high impact best practices to be implemented in specified clinical units, such as pre-hospital, ED, ICU, medical/surgical floor, procedural areas, and outpatient settings
- Research system solutions to improve airway safety
- Develop education programs and materials for trainees and practicing clinicians

Actions for companies in the airway industry

- Collaborate with current and future safety initiatives to develop or modify products or solutions that best address airway safety threats. To do this:
  - Optimize human factors and device usability
  - Label products to be clearly and easily identified for size and use (considering human factors in high-stress events)
  - Seek out and respond to clinical and safety requests for modification
- Establish a mechanism for industry to collaborate on:
  - Rapidly identifying and responding to vulnerabilities
  - Seeking fast dissemination and adoption of high-reliability components to products or services
  - Package products for high reliability and easy access
  - Package essential supplies to work with portable airway cart systems
- Support:
  - Airway safety research
  - The development of a national airway safety policy
  - Unbiased educational forums for airway safety
- Participate in the Global Airway Safety (GAS) Collaborative
Actions for accrediting agencies

- Work with professional clinical/safety organizations to establish airway safety process, performance, and measurement standards
- Highlight and assess airway standards during site visits as a high priority focus
- Elevate airway safety as a national patient safety goal

Actions for government (funders/regulators/service providers)

- Work with professional clinical/safety organizations to establish airway safety process, performance, and measurement standards
- Fund, and encourage other to fund, research for improving airway management safety through the entire spectrum of hospital and healthcare settings
- Use financial incentives to help drive adoption of established highly reliable airway safety practices

Actions for safety organizations (global, national, regional, state levels)

- Assist, support, and participate in the development of a Global Airway Safety Collaborative
- Elevate airway safety as a national safety goal
- Support and promote the development and implementation of actionable airway safety solutions
- Network with potential funders to help empower development and research of airway safety solutions
- Support the development of airway safety training programs and tools

Actions for the risk management/insurance industry

- Elevate airway safety as a national safety goal
- Fund and support the development and implementation actionable airway safety solutions
- Establish financial incentives for groups that demonstrate implementation, tracking, assessments, and training in airway safety practices, tools, and procedures

Actions for consumer groups

- Support and help fund the development of a Global Airway Safety (GAS) Collaborative with the aim to elevate the airway safety standard of care
- Support and help fund safety organizations and programs that will help protect constituent members with regard to airway safety, including key focus areas in patient groups for older adults, children, and people with obesity
- Demand specific, demonstrable, and highly reliable airway safety programs from healthcare organizations and institutions.
- Help establish and promote public awareness campaigns for airway safety engagement, practices, and performance
How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for unplanned extubation (UE). In it, you’ll find:

- Executive summary checklist ........................................ 306
- What we know about UE .................................................. 309
- Leadership plan .................................................................. 309
- Action plan ........................................................................ 310
- Technology plan ................................................................. 312
- Measuring outcomes .......................................................... 314
- Conflicts of interest disclosure ............................................. 316
- Workgroup ......................................................................... 316
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Executive summary checklist

A planned extubation occurs as part of a normal process of weaning the patient from their breathing tube. It is typically intentional and occurs in a controlled manner. Unplanned extubation (UE) is typically the unintentional and uncontrolled dislodgement of a patient’s breathing tube that occurs outside of a strategic weaning process. The dislodgement may occur when the patient exerts a force to remove the tube (self-extubation) or by an external force applied to the tube (accidental extubation). Both self-extubation and accidental extubation may present with the tube completely removed from the patient’s oral cavity or the tube may remain internal and appear to be in the proper position, however, EtCO2 indicates it is no longer in the trachea (internal dislodgement). In neonates, the position of the tube may become mal positioned outside of the trachea and remains within the posterior pharynx (internal dislodgement) but may be difficult to confirm proper positioning due to lack of EtCO2 monitoring and occasionally unreliable colorimetric CO2 detection. In those cases, the practitioner may decide to extubate and reintubate the patient. This type of extubation, although intentional, is done outside of a normal weaning process and therefore is also classified as unplanned. Another intentional extubation that is done outside a normal weaning process occurs when there is a malfunction of the endotracheal tube (obstruction, deflation of balloon, etc.) and therefore the tube must be urgently or emergently removed and replaced and is considered an unplanned extubation.

UE, both in the field and in the hospital, is a common and costly problem and results in significant morbidity and mortality.

The information in this document relates to adult patients.

A specific APSS (#8D) addressing unplanned extubation in the pediatric and neonatal population has also been published.

Use this checklist to help prioritize your actions and measure your organization’s progress in your UE prevention.
Create an action plan to prevent UE

- Form a core multidisciplinary airway safety leadership team, including:
  - Quality/Safety Leadership (Preferably Director / VP level or higher)
  - Physician, nursing, and respiratory care team leaders across all hospital units to ensure recognition of the problem and support the development of systems that will eliminate UE and its associated complications, especially preventable deaths
  - Create a leadership plan where top level leadership regularly review a dashboard of occurrences of UEs, the complications that occur due to UE, and the cost of these occurrences in morbidity, mortality and healthcare dollars

Engage staff and ensure best patient care

- Provide periodic education for all airway management providers:
  - Educate providers regarding the importance of prevention of UE and the need for accurate data tracking
  - Include UE as part of every presentation about management of the intubated patient, especially in patients with difficult airways

- Implement Clinical Best Practices for Preventing UE:
  - Standardize tracheal tube restraint devices, using the most proven methods and devices
  - Utilize strategies for high-risk situations
  - Formalize systems for appropriate sedation and patient restraint to decrease the risk of unplanned self-extubation
  - Create systems for alerting clinicians to patients with a known difficult airway
  - Use patient stories, in written and video format, to identify gaps and inspire change in your staff

Track UE and use data to find areas for improvement

- Determine baseline rate of UE (see Measuring Outcomes section)
- Determine baseline rate of complications (oral mucosa and facial skin pressure injuries, pneumonia, vocal cord injury, hypoxemia, brain injury, death) caused by UE
- Perform an event review for all incidences of UE
- Perform a root cause analysis (RCA) for all deaths associated with UE: Use a multidisciplinary team including physicians, nurses, and respiratory therapists to evaluate the root cause of every UE, determine a plan to eliminate the root cause, implement the plan, and track results
- Institutions should use the techniques described in Failure Modes and Effects Analysis or Safety II to create strategies that mitigate the risks of UE
- Use a multidisciplinary team including physicians, nurses, and respiratory therapists to evaluate the root cause of every UE, determine a plan to eliminate the root cause, implement the plan, and track results
- Institutions should use techniques described in Failure Modes and Effects Analysis or Safety II to create strategies that mitigate the risks of UE
- Implement the core UE dataset as defined in the Measuring Outcomes section of this APSS:
  - Every (endotracheally) intubated, mechanically ventilated patient should have the
entire PSMF core dataset for extubation recorded in the electronic medical record (EMR)

☐ Evaluate your hospital’s EMR to determine if the entire core dataset is included in the EMR

☐ If not included, contact the EMR company and request they add the dataset - develop a system for temporarily tracking the dataset until the EMR company institutes the dataset

☐ Develop a Quality Management Process to promote and ensure continuous improvement with an initial goal of eliminating preventable deaths from UE and ultimately eliminating all incidents of UE:

☐ Mandate tracking and reporting of all incidents of UE and complications of UE, including hypoxemia, pneumonia, vocal cord injury, brain injury and death

☐ Use patient stories- in written and video formats- to identify gaps and inspire change in your staff
What we know about UE

UE, both in the field and in the hospital, is a common and costly problem. An extensive review of 50 studies revealed:

- 7.3% (range 0.5% - 35.8%) of adult endotracheally intubated Intensive Care Unit (ICU) patients are affected by an unplanned extubation (daSilva et al., 2012; Anesthesia & Analgesia, 2012)
- 1.65 million patients are intubated and mechanically ventilated each year in U.S. adult ICUs according to The Society for Critical Care Medicine’s 2017 statistics
- Extrapolation of the average 7.3% UE rate to intubated patients in U.S. adult ICUs would suggest that there are over 120,000 UEs annually
- Based on morbidity and mortality data, those 120,000 UEs are associated with over 33,000 deaths (De Lassence et al., 2002)
- UE increases the incidence of pneumonia from 14% to 30% (De Lassence et al., 2002), resulting in over 36,000 pneumonias annually
- UE more than doubles the average ICU stay (De Lassence et al., 2002), increasing 9 days to 18 days (De Lassence et al., 2002)
- Complications of UEs in US adult ICUs result in over $4.9 billion in unnecessary healthcare costs (Dasta, McLaughlin, Mody, and Piech, 2005; Needham and Pronovost, 2005).

The need to accurately track UE

Although the incidence of UE is likely higher in emergency medical services (EMS) settings due to difficulties of transporting critically ill patients in a chaotic environment, UE is not tracked in most EMS systems. Similarly, many hospitals do not track UE. Currently, none of the major electronic health records include the UE core dataset. To obtain an accurate measure of frequency and cost of prehospital and in-hospital UE, we must develop widespread systems to accurately track all incidences.

Closing the performance gap will require hospitals and healthcare systems to commit to actions in the form of specific leadership, practice, and technology plans. This APSS gives examples to help hospitals prioritize their efforts at designing and implementing evidence-based bundles for reducing UE.

Leadership plan

Hospital governance, senior administrative leadership, quality and safety leadership, risk management leadership, and clinical leadership must work collaboratively to reduce UE.

Show leadership’s commitment to reduce UE

- Hospital governance and senior administrative leadership must commit to and take action reducing the incidence of UE with a goal of zero preventable deaths
- Raise awareness regarding the frequency, cost and consequences of UE
- Determine the facility’s rate of UE through reporting and tracking within a formal Quality Improvement (QI) program, and engage QI/Patient Safety to implement steps to reduce the incidence of UE and eliminate preventable deaths:
  - After you know your facility’s incidence rate, develop an organizational story and use the skill set of storytelling to raise organizational awareness and actions to stay
focused on why there is a need for change

• Demonstrate commitment and support by shaping a vision of the future, clearly defining goals, and supporting staff as they work through improvement initiatives, measuring results, and communicating progress towards those goals

Create a team to reduce UE

The core multidisciplinary team should consist of the following:

• Quality/Safety Leadership (Director / VP or higher)
• Physician, nursing, and respiratory care team leaders from ED, OR/PACU, and ICU
• Neonatal/Pediatric representation (expertise) is crucial – please see APSS (#8C, #8D)

Engage staff and make policy changes to reduce UE

• Commit to defining performance gaps within the organization (system-wide, hospital-wide, and by department)
• Support a comprehensive approach to standardized data tracking, quality management, and process improvement efforts, and implementation of practice and technology plans necessary to eliminate UE
• Use patient stories – in written and video formats – to identify gaps and inspire change in your staff:
  o The story of Drew Hughes, told by his father David Hughes, is an example of an UE that led to the preventable death of Drew. You can view Drew’s story here: https://patient.sm/DQgH75

Action plan

Create protocols to reduce UE

• Use current evidence-based guidelines and known best practices during airway management of the intubated patient to eliminate incidents of UE
• Implement systems for alerting clinicians to patients with a known difficult airway
• Position the endotracheal tube with the tip of the tube within the optimal tip position range (for adults this is half-way between the glottis and the carina (about 2-6 cm above the carina), and the majority of endotracheal tubes have a suggested vocal cord marker on the side) - correct initial positioning of the endotracheal tube decreases the risk of UE if the tube moves
• Once appropriately positioned, maintain that position with a tube stabilizer that eliminates clinically significant movement of the tube
• Utilize proven strategies for high-risk situations (Kandil, 2018):
  o Require 2 caregivers to participate in the identification and tracking of ETT positioning before and after any bedside manipulation, adjustment of the ETT or movement of any patient with an ETT (Movement includes any bedside procedure, radiographs, patient transport and simple patient repositioning of the head and upper body).
  o One caregiver should have the sole responsibility for protecting the ETT, often called an “airway guardian”
  o Before any movement of the patient, the caregiver who is responsible for the security of the ETT should perform a verbal call-out of the depth of the ETT. After movement
of the patient is completed, a second verbal call-out of the ETT depth is performed, along with confirmation that the position of the ETT has not changed.

- All healthcare providers are responsible to ensure that the high-risk strategies are utilized at all times.

- Restrain the patient using a combination of physical restraint and chemical restraint (sedation):
  - Institute a continuous sedation protocol with daily interruption of sedatives
  - Avoid intermittent or no sedation protocols (Chao et al., 2017)
  - Communication about sedation interruption/vacation should be an integral part of daily rounds/huddles for all intubated patients and should include all members of the team, including the respiratory therapy team.
  - The risks and benefits of sedation and restraint should be carefully considered, especially in the patient with a known difficult airway.

- Use Continuous Waveform Capnography in ALL intubated patients to ensure rapid recognition of a malpositioned tube:
  - The initial clinical evaluation of any cardiopulmonary arrest in an intubated patient should include determination, via continuous waveform capnography, that the endotracheal tube is correctly positioned and the patient is being adequately ventilated. Waveform capnography along with clinical evaluation must be used to make this determination. Assume that the lack of a capnography waveform is due to a malpositioned endotracheal tube until proven otherwise - “Flat trace, wrong place.”
  - If the evaluation suggests the tracheal tube might be mal-positioned, outside the trachea (unplanned extubation), the patient must be immediately reintubated. UE should be considered as the cause of the arrest and a root cause analysis of the unplanned extubation performed

- Communication about sedation interruption/vacation should be an integral part of daily rounds/huddles for all intubated patients and should include all members of the team, including the respiratory therapy team

**Track and analyze your progress**

- Develop a Quality Management Process to promote and ensure continuous improvement with an initial goal of eliminating preventable deaths from UE and ultimately eliminating all incidences of UE. To do this:
  - Every extubation should be classified according to the Extubation Classification Schema to ensure that all incidents of UE are identified and not overlooked
  - Review all incidents of UE
  - Determine root causes, which may include:
    - Inadequate stabilization of the endotracheal tube
    - Inappropriate sedation (chemical restraint)
    - Inadequate physical restraint
    - Inadequate monitoring
    - Inadequate patient supervision
  - Plan and implement changes to the system based upon findings from reviews
  - Track UE to determine if the implemented processes cause improvement
• Require tracking and reporting of all incidents of UE and complications of UE (e.g., hypoxemia, pneumonia, vocal cord injury, brain injury, and death)

Create best practices for out-of-hospital management of UE
• Airway management in the field (EMS/military) should incorporate the same prevention, tracking, and quality management concepts as described above for medical facilities
• All patients that are transported with an endotracheal tube in place must receive continuous waveform capnography to ensure early recognition of displacement of the tube. Failure to rapidly recognize and correct a displaced tube has a very high probability of hypoxemia that can result in severe brain injury and death.
• All incidents of UE in the field must be reported to the receiving facility during hand-off communications
• EMS airway providers must communicate the incident of UE to the receiving facility and the receiving providers should consider antibiotic therapy to reduce the likelihood of pneumonia – the incidence of pneumonia doubles in patients who experience a UE

Technology plan
These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

Test and use airway management devices that improve safety and drive better patient outcomes, including:

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Considerations</th>
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<tbody>
<tr>
<td>ONC Meaningful Use Certified Electronic Medical Record (EMR) System</td>
<td>• EMR equipped with the following capabilities:</td>
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<tr>
<td></td>
<td>• Computerized Provider Order Entry (CPOE)</td>
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<td>• Drug-drug interaction check</td>
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<td></td>
<td>• Drug-allergy interaction check</td>
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<td>• Clinical Decision Support tools (CDS)</td>
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<td>• Endotracheal tube (ETT) depth alerts for documentation of placement that is outside the normal range</td>
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<td></td>
<td>• An alert if &gt;6 hours since patient completed and passed a spontaneous breathing trial</td>
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</table>
**Standardize tracheal tube restraint devices**

The current methods and devices for stabilizing endotracheal tubes include:

- Adhesive tape
- Cotton twill ties
- Multiple commercial devices

The literature does not clearly identify any device or technique currently on the market that is superior at preventing movement against externally applied forces. However, numerous devices on the market are clearly inferior in their ability to restrain the tube against extubation forces.

Therefore, when choosing an endotracheal tube stabilizer, the device’s ability to restrain against applied force should be the primary consideration.

Secondary considerations include: ease of use, facilitation of oral / dental care, and prevention of skin breakdown / medical device related pressure injuries.

A review article, published in 2012 in Anesthesia and Analgesia (da Silva, et al., 2012), which evaluated more than 50 studies published worldwide, demonstrated an average rate of UE of 7.3% (range 0.5% - 35.8%). This high rate of UE suggests that current stabilization techniques and devices are inadequate and therefore further research into developing better stabilization systems should be supported to achieve zero preventable deaths.

Optimal endotracheal tube stabilizers should:

- Be secure
- Be fast and easy to apply
- Provide easy access to the mouth for routine oral care
- Be repositionable and not exert any major pressure points to the skin or oral mucosa that would cause ischemic tissue injury

In adults, the stabilizer should, at a minimum, prevent clinically significant movement that could result in an UE. Optimally, it should prevent any movement of the endotracheal tube relative to the stabilizer. Even small incremental movements can result in UE.

<table>
<thead>
<tr>
<th>Waveform Capnography</th>
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<tr>
<td>Mandate the use of continuous waveform capnography in ALL intubated patients to ensure rapid recognition of a mal-positioned tracheal tube.</td>
</tr>
<tr>
<td>This important technology has become the standard of care for intubated patients in the UK and parts of Europe. United States’ ICUs, EDs and EMS are beginning to adopt this technology, but significant gaps exist. Continuous waveform capnography should become a mandated safety practice for all intubated patients.</td>
</tr>
</tbody>
</table>
**Measuring outcomes**

**Key performance indicators**
- UE in intubated patients
- Rate of UE for patients intubated via endotracheal tube

**Outcome measure formula**

**Numerator:** Number of incidents of UE in patients intubated via an endotracheal tube

**Denominator:** Total number of days intubated

*Rate of unplanned extubation is expressed in terms of: number of incidents unplanned extubation per 100 intubation days

**Metric recommendations**

**Direct impact:** All patients intubated via endotracheal tube

**Lives spared harm:**

\[
\text{Lives Spared Harm = Unplanned Extubation Rate}_{\text{baseline}} - \text{Unplanned Extubation}_{\text{measurement}} \times \text{Days Intubated}_{\text{baseline}}
\]

* Days Intubated is the Outcome Measure Formula Denominator: (Total Number of Intubated Days)

**Data collection**

Use a tracking sheet for UEs. Data is best collected through electronic capture of data fields from electronic patient care reports. This requires having an EMR system that includes the following PSMF Core Data Set for UE:

- Does the patient have a history of a difficult airway (and/or failed intubation)?
- What method was used to identify the difficult airway patient?
- Was a pre-intubation assessment predictive of a difficult airway?
- Route of intubation (e.g., oral, nasal, or tracheostomy)
- What was the method of tube restraint? (e.g., tape, twill, commercial tube holder); if a commercial tube holder, specify the type
- Date and time of extubation
- Extubation type (planned or unplanned)
- UE cause (self-extubation or accidental extubation)
- Location where the UE occurred (e.g., GI suite)
- Did UE occur while the patient was being transported or moved?
- Was the patient adequately restrained at the time of extubation?
- Was the patient adequately sedated at the time of extubation?
  - Facility sedation policy type (continuous with daily interruptions, intermittent, no sedation)
- Was reintubation required?
- Was reintubation attempted (successful or unsuccessful)?
- Outcome/complications of UE (e.g., pneumonia, vocal cord injury, hypoxemia, brain injury, death)
• Did the UE occur during a sedation interruption or “sedation vacation”?
  o Was the respiratory therapist made aware of the sedation vacation?
  o Did appropriate communication to all members of the team (i.e. between nurse and respiratory therapist) occur related to the initiation of the sedation interruption or “sedation vacation”?

• Was the patient on spontaneous breathing trials?
  o If so, was there a delay in extubation due to a delay in the physician ordering the extubation?

• What team members were present when the UE occurred?

• Encourage the addition of an “other” field in the EMR to collect information to learn about new or specific trends identified by staff

This standardized core dataset should be incorporated (by legislative mandate if necessary) by all major EMR companies to facilitate hospitals’ ability to track UE:

• Many hospitals’ Electronic Medical Records currently do not have the PSMF Core Data Set for UE and any information on UE is difficult to retrieve from narratives and notes. Any hospital whose EMR does include the PSMF Core Dataset should contact their EMR company and request adoption of the PSMF Core Dataset for UE.

• Risk factors for UE should be measured including patient sedation and patient restraint

• Rate of complications and mortality related to incidents of UE are important to determine the extent of adverse effects of UE:
  o Rate of pneumonia in intubated patients with an incident of UE compared to rate of pneumonia in intubated patients without an incident of UE
  o Rate of severe brain injury in intubated patients with an incident of UE compared to the rate of brain injury in intubated patients without an incident of UE
  o Mortality rate in intubated patients with an incident of UE compared to the rate of mortality in intubated patients without an incident of UE

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 Patients’ (PfP) grant funded Hospital Improvement

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Innovation Networks (HIIN). The program targeted 10 hospital-acquired conditions to reduce medical harm and costs of care. “At the outset of the Partnership for Patients 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 (Agency for Healthcare Research and Quality, 2015). Adverse events related to UE were not included in the AHRQ National Scorecard document. 61% of patients experiencing UE do not require reintubation and those patients have a low mortality rate (5%) (Gao, et al., 2016). 39% of patients experiencing UE require reintubation and those patients have a high mortality rate (37%) (Gao, et al., 2016). The overall mortality rate for all incidents of UE is 28% (de Lassence et al., 2002) and accounts for over 33,000 deaths annually, in the U.S.

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 APSSs recommend technologies offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Chairs
Lorraine Foley  
Society for Airway Management
David Hughes  
Do It For Drew Foundation
*Arthur Kanowitz  
Airway Safety Movement, Society for Airway Management, Securisyn Medical

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Gillian Abir  
Stanford University
Sharon Armstead  
Ascension Health
Jim Augustine  
US Acute Care Solutions, LLC
Steven Barker  
Patient Safety Movement Foundation; Masimo
Michel Bennett  
Patient Safety Movement Foundation (formerly)
Lauren Berkow  
Society for Airway Management
Jestin Carlson  
Allegheny Health Network
Richard Cooper  
University of Toronto
Gina Farquharson  Medtronic
Drew Fuller  Emergency Medicine Associates
Kate Garrett  Ciel Medical
Mitch Goldstein  Loma Linda University
Victor Grazette  Virginia Hospital Center
Hans Huitink  VU University Medical Center
Thomas Kallstrom  American Association for Respiratory Care
Sarah Kandil  Yale New Haven Children's Hospital
Ariana Longley  Patient Safety Movement Foundation
Jacob Lopez  Patient Safety Movement Foundation (formerly)
Olivia Lounsbury  Patient Safety Movement Foundation
Ariel MacTavish  Medtronic
Rhea May  Medtronic
Kevin McQueen  University of Colorado Health, Memorial Hospital Colorado Springs
Joaquim Pinheiro  Albany Medical Center
Micheline Plantada  Advocate
Donna Prosser  Patient Safety Movement Foundation
Kellie Quinn  Advocate
Patricia Roth  UCSF Medical Center
Claire Roy  Patient Safety Movement Foundation
Kenneth Rothfield  Medical City Dallas
Stacey Schoenenberger  St. Vincent's HealthCare
Rahel Selassie  Advocate
Michael Taylor  Fairview Hospital
Dianne Vass  Museum of Pop Culture
Donna Wood  Airway Safety Movement

Metrics integrity
Robin Betts  Kaiser Permanente, Northern California Region
References


Actionable Patient Safety Solutions (APSS) #8C: Safer airway management in neonates and children

How to use this guide
This guide gives actions and resources for creating and sustaining safer airway management in neonates and pediatric patients. In it, you’ll find:

Executive summary checklist........................................ 320
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Action plan ........................................................................ 325
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Measuring outcomes ......................................................... 341
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for stakeholders ................................................................. 346
Executive summary checklist

Major causes of patient morbidity and mortality include delays or failure to secure a patient’s airway, recognize a malpositioned airway device, and maintain an airway device (Unplanned extubation See APSS 8D). These are all high priorities for airway safety efforts.

This checklist is to be used to help prioritize actions and measure an organization’s progress in your airway safety management efforts.

Create a Safer Airway Team and toolkit

☐ Assemble a core multidisciplinary leadership team (Steering Committee) to advance airway safety, including:
  ☐ Emergency, critical care, and anesthesia physician leadership
  ☐ ED and ICU nursing leadership
  ☐ Respiratory therapy leadership
  ☐ Quality assurance (QA)/Safety leadership (VP or higher level)
  ☐ Obstetric/neonatal/pediatric – representation and expertise are crucial for this population

☐ Develop a comprehensive airway toolkit (such as the Safer Airway Bundle) under the leadership of a physician airway expert,
  ☐ Include these key components: Failed Airway Algorithm, Airway Cart, Airway Checklist/Time out, Quality Assurance, intra-hospital and inter-hospital transport, and Team Training and dissemination of information on difficult airway management
  ☐ Implement Safer Airway Essential Components, as described in “Actions for hospitals” in the Action Plan section

Track and analyze clinical data to find areas for improvement

☐ Require tracking and reporting of “near-misses” and complications of airway management

☐ Identify adverse outcomes, including multiple intubation attempts, unrecognized esophageal intubation, endobronchial intubation, SpO2 below target levels or a decline of > 20%, need for CPR during the procedure, and dental or soft tissue injury

☐ Utilize these case data in medical staff training sessions to prevent recurrences, as a part of Continuous Quality Improvement (CQI)

☐ Provide regular airway management training for all care providers. This will help them:
  ☐ Identify airway problems
  ☐ Select and use the correct course of action
  ☐ Understand when and how to call for expert help

☐ Analyze delays in care related to airway management problems, including any delays in surgery, in applying invasive mechanical ventilation, and in diagnostic studies

☐ Use patient stories – in written and video formats – to identify gaps and inspire change in your staff
What we know about airway management

This set of Actionable Patient Safety Solutions (APSS) promotes airway safety and gives broad recommendations for urgent and emergent airway management in settings both inside and outside of the hospital, including: pre-hospital emergency medical services (EMS), emergency departments (EDs), delivery rooms (DRs), intensive care units (ICUs), general medical/surgical units, procedural areas, and operating rooms.

The Centers for Medicare and Medicaid Services (CMS) has identified airway safety as a priority area for Round 2 of the Hospital Engagement Networks (HENs) due to the high risk and significant impact of airway-related injuries and deaths.

Several U.S. and European organizations have provided focused evidence-based clinical recommendations to their specialty membership and general audiences. However, there have been few calls for specific standards outside of the operating room (OR). We strongly promote that this needs to change.

This Airway Safety APSS serves to:

• Highlight key need areas for best practice development and implementation
• Promote evolving programs that introduce a new level of practice and comprehensive airway safety engagement
• Launch the call and provide the platform for a multi-disciplinary Global Airway Safety (GAS) Collaborative. The collaborative will support further development, assessment, implementation, and promotion of clear actionable solutions to strengthen airway safety awareness, education, management, research, and policy

The problems with airway management

Delay or failure to secure a patient’s airway or to recognize a malpositioned airway (such as intubation of the esophagus) can result in preventable death or catastrophic injuries. Similarly, failure to prevent an unplanned dislodgement of an endotracheal tube can also result in catastrophic injuries or death. Time delays are especially critical in pregnant women, infants, and children because the time to desaturation is markedly faster due to various anatomical and physiological factors.

Using direct laryngoscopy for endotracheal intubation requires skill and training. It is a physically challenging, single-operator technique which has an unacceptable rate of failure, especially in the hands of non-airway specialists. Harm and death from any of these events can be preventable:

• Unrecognized esophageal intubation
• Multiple failed attempts to secure the airway
• Failure to correctly position and secure the endotracheal tube leading to unplanned extubation
• Patient aspiration of gastric contents, airway injury, trauma to teeth, skin, and mucosal pressure injuries, hypoxemia (low blood oxygen), and brain injury

Failed Intubations in Children

The incidence of failed intubations in children in out-of-hospital settings, defined by 3 or more unsuccessful attempts, is as high as 58%, and these or other major intubation difficulties are associated with higher odds of cardiac arrest (Hansen et al., 2016). Even for intubations
performed by hospital-based transport teams, 70% of neonates required multiple attempts, compared to 30% of the pediatric population (Smith et al., 2015).

In the hospital setting, first attempt intubation success in neonates is <50% (Sauer et al., 2016; Leone, Rich, and Finer, 2005; Foglia et al., 2019). Furthermore, endobronchial intubations occur up to 25% of intubated children (Hansen et al., 2016), and 7% to 58% of neonates (Pinheiro and Munshi, 2015) (Mainie, Carmichael, McCullough, and Kempley, 2006); they further contribute to ventilatory failure and other complications of tracheal intubation.

Thus, even for ultimately successful intubations, the combination of delays, multiple failed attempts, and ineffective ventilation due to ETT malposition may cause serious harm or death. Although no prospective studies provide data on the direct impact of difficult intubation on mortality rates in newborns (Sawyer et al., 2019), repeated intubation attempts in the highest risk newborns (those of extremely low birthweight) are associated with an increased risk of intraventricular hemorrhage (Sauer et al., 2016), as well as neurodevelopmental impairment or death (Wallenstein et al., 2016). Meanwhile, intubation success rates have shown a decreasing trend, possibly related to decreased experience during training (Hubble et al., 2010; Leone, Rich, & Finer, 2005).

Causes of preventable patient harm and death include:

1. The wide variation of airway management techniques and technology

   The goals of airway management are essentially uniform, but clinical best practices are not standardized and depend heavily on provider specialty and physical locale in healthcare settings.

   For example, the incidence of failed intubations in children in out-of-hospital settings, defined by 3 or more unsuccessful attempts, is as high as 58%, and these or other major intubation difficulties are associated with higher odds of cardiac arrest (Hansen et al., 2016). Even for intubations performed by hospital-based transport teams, 70% of neonates required multiple attempts, compared to 30% of the pediatric population (Smith et al., 2015). For both pre-hospital and in-hospital locations including the delivery suite, neonatal and pediatric intubation success rates have shown a decreasing trend, possibly related to decreased experience during training (Hubble et al., 2010; Leone, Rich, and Finer, 2005).

2. Lack of video laryngoscopy (VL) equipment in all areas

   A wealth of scientific evidence shows VL’s advantage over direct laryngoscopy in a variety of clinical settings, but the high cost of VL equipment has kept it from being widely adopted. Also, videolaryngoscope blades for the smallest neonates (size 00) are not yet available, and the design of existing blades may be suboptimal for ETT insertion in preterm newborns (Pouppirt, Foglia, and Ades, 2018). VL accelerates acquisition of intubation skills by trainees and it is useful for difficult airway management, although its advantages are less clear for expert intubators and outcomes were not improved by VL in a randomized trial in adult ICU patients (Lascarrou et al., 2017; Pouppirt et al., 2018). VL allows the approach to airway management in the EMS setting to undergo a dramatic transformation (Chemsian, Bhananker, and Ramaiah, 2014).

   VL also:
   - Improves the laryngeal view and results in higher success rates of endotracheal
intubation (ETI), both during first pass attempts and after difficult or failed direct laryngoscopy in the hospital setting (Silverberg, Li, Acquah and Kory, 2015; Aziz et al., 2011)

- May also enable remote viewing and coaching, while recording may facilitate documentation and quality improvement

3. Unrecognized esophageal intubation (intubation of the esophagus instead of the trachea)

Studies show that even in adults, unrecognized esophageal intubation in prehospital settings is as high as 25% (Katz and Falk, 2001). It leads to a high likelihood of death. In newly born infants, who normally start with oxygen saturations in the 60% range from birth, rapid detection of esophageal intubation is crucial, and this may occur in more than 50% of intubation attempts. (Repetto et al., 2001)

Waveform capnography can rapidly help identify an endotracheal tube that has not been placed correctly in the trachea (Repetto et al., 2001) and should be readily available to avoid preventable deaths. Yet some EMS agencies have not yet adopted waveform capnography and technical limitations have delayed their routine use in newborns. However, colorimetric CO2 detection is widely available, inexpensive and easy to use, and it has been recommended by the internationally used Neonatal Resuscitation Program (NRP) to verify tracheal tube placement in newborns (Textbook of Neonatal Resuscitation, 2016)

4. Endobronchial Intubation

Successful insertion of a breathing tube in the trachea is not sufficient to provide a functional airway since a tube that is placed too deep and lies in a mainstem bronchus may restrict ventilation to one lung, resulting in severe hypoventilation, particularly in patients with pre-existing lung dysfunction. Endobronchial intubations were noted in 25% of children successfully intubated by EMS staff (Hansen et al., 2016), and also reported in 7% to 58% of neonates intubated in the hospital (Pinheiro and Munshi, 2015; Mainie, Carmichael, McCullough, and Kempley, 2006), thereby contributing to ventilatory failure and other complications of tracheal intubation. Thus, even for ultimately successful intubations, the combination of delays, multiple failed attempts, and ineffective ventilation due to ETT malposition may cause serious harm or death. Other complications of endobronchial intubation include physical trauma to the airway by the tube tip, and accidental dislodgement of the tube during subsequent attempts to correct the tube position.

5. Unplanned Extubation

Unplanned extubation, both in the field and in the hospital, is a common and costly problem. On average, it happens in 8% (0.8 - 18.5%) of patients who undergo mechanical ventilation in the PICU (Lucas da Silva and de Carvalho, 2010) and 18.2% (1.0% - 80.8%) of patients who undergo mechanical ventilation in the NICU (Lucas da Silva, Reis, Aqui bar, and Fonseca, 2013). Although the literature does not address the rate of UE in EMS, it is expected that it is likely as high or higher than in the hospital, due to the uncontrolled environment and need for emergent transport of these patients. The complications of unplanned extubations result in the PICU and NICU result in over $500 million in healthcare costs (Roddy et al., 2015; Dominguez and Thiruchelvam, 2015).

The true frequency of airway management-related injuries is unknown. Recently, the National Emergency Airway Registry for Children (NEAR4KIDS) (Li et al., 2016) reported a 20% rate of
adverse tracheal intubation-associated events, whereas the National Emergency Airway Registry for Neonates (NEAR4NEOS; Foglia et al., 2019) reported similar adverse event rates, in addition to severe desaturation rates up to 69%. These data are from selected Children’s Hospitals, and are underreported elsewhere. It is clear, however, that the healthcare industry must transition away from viewing airway management-related injuries as the inevitable “cost of doing business,” and redefine these complications as preventable iatrogenic harm.

**Leadership plan**

Show leadership's commitment to safe airway management

Hospital governance and senior administrative leadership must:

- Develop a culture of safety
- Commit to reducing the incidence of preventable airway safety events, especially failed intubations, unrecognized esophageal intubations, endobronchial intubations and unplanned extubations
- Strive to achieve a goal of zero preventable deaths
- Drive awareness regarding the seriousness of preventable airway-related safety events
- Determine the facility’s rates of preventable airway safety events through reporting and tracking within a formal QI program
- Engage your QI/Patient safety leaders to implement Quality Improvement Methodologies such as the Institute for Healthcare Improvement’s (IHI) Model for Improvement to reduce the incidence of preventable airway safety events
- Once you know your incidence rates, develop an organizational story and use the skill set of storytelling to drive organizational awareness, action, and focus on why there is a need for change
- Create a core multidisciplinary Safer Airway Team that includes:
  - VP of Quality/Safety
  - Physician, nursing, and respiratory care team leaders from Anesthesia, ED, OR/PACU, and ICU
  - Clinical expertise from obstetrics, neonatal, and pediatrics

Hospital governance, senior administrative leadership, clinical leadership and safety/risk management leadership must:

- Commit to taking inventory and defining the performance gaps that exist within their own hospital/healthcare system
- Commit the financial support needed to implement this Airway Safety APSS
- Work collaboratively and champion efforts that raise awareness about the seriousness of preventable deaths from complications of airway management
- Shape a vision of the future, clearly define safety goals, and support staff as they work through improvement initiatives, measure results, and communicate progress towards those goals
- Commit to defining performance gaps within the organization (system-wide, hospital-wide, and by department)
Create the infrastructure needed to make changes:

- Support a comprehensive approach to standardized data tracking, quality management, and process improvement efforts
- Support the implementation of practice and technology plans necessary to stop preventable deaths from complications of airway management
- Support the IHI Model for Improvement, or other formalized QI approach.
- Set clear aims, including timelines
- Identify changes that are likely to lead to improvement
- Establish measures that will clearly define if changes are leading to improvement
- Conduct small-scale tests of change using the Plan-Do-Study-Act (PDSA) cycle
- Hospital governance, senior administrative leadership, clinical leadership and safety/risk management leadership must commit to sharing airway safety best practices and lessons learned throughout your hospital and your hospital’s healthcare system, and with other organizations outside your hospital’s healthcare system
- Use patient stories - in written and video formats - to identify gaps and inspire change in your staff.
  - The story of Drew Hughes, told by his father David Hughes, is an example of an unplanned extubation, followed by a failed reintubation and unrecognized esophageal intubation that led to the preventable death of Drew. You can view the story for free here: [http://patient.sm/lvF1Hz](http://patient.sm/lvF1Hz)
  - The story of how St. Louis Children’s Hospital has championed efforts to reduce preventable harm and death is told in this video: [https://patient.sm/5RMN0W](https://patient.sm/5RMN0W)

Action plan

This plan focuses on actions EMS and hospitals can take to improve airway safety. Actions for other stakeholder groups (such as outpatient procedure centers using moderate or deep sedation, professional healthcare stakeholder groups, industry, accrediting agencies, government, safety organizations, risk management and insurance companies, and consumer groups), are listed in Appendix A: Recommended actions for stakeholders.

Actions for EMS Basic Life Support (BLS) Units

- Use a Supraglottic Airway (SGA) device for cardiac arrests
- Schedule regular training courses and competency assessments for specific airway safety scenarios
- Enroll in regional and national systems for reporting adverse events and near-miss events, such as the EMS-based Emergency Medical Error Reduction Group at [www.emerg.org](http://www.emerg.org)

Actions for EMS Advanced Cardiac Life Support (ACLS) Units

- Ensure adequate training and promote the use of a supraglottic airway device (SGA) device for initial treatment of cardiac arrest and as a rescue device for failed or difficult intubation
- Ensure adequate training and promote the use of Video Laryngoscopy (VL) as your main device for endotracheal intubation
- Encourage the routine recording of VL attempts and where possible time-stamped
events such as heart rate and SpO2

- Use Continuous Waveform Capnography on:
  - All SGA or intubated patients
  - Certain conditions known for creating problems with airway safety or adequate ventilation, such as overdose, respiratory distress, severe congestive heart failure, morbid obesity, and obstructive sleep apnea

- Schedule regular training courses and competency assessments for specific airway safety scenarios

- Enroll in regional and national systems for reporting adverse events and near-miss events, such as the EMS-based Emergency Medical Error Reduction Group at [http://patient.sm/4a516C](http://patient.sm/4a516C)

### Actions for hospitals

- Establish high-reliability as the driving principle for airway safety and as part of the overall culture of safety in all clinical areas

- Proactively embrace airway safety best practices before they are adopted by regulatory or accrediting organizations

- Form a standing leadership group for airway management safety including key stakeholders in C-suite Safety/Quality Administration, Emergency Medicine, Critical Care subspecialties, Anesthesiology, Hospital Medicine, Respiratory Care, and Nursing

- Implement a system that quickly allows an anesthesiologist to assist with difficult airways in non-OR settings

- Develop standardized, site-specific systems for airway management in areas including ED, delivery suite, ICUs, general units, and procedural areas.

The Safer Airway Program is a comprehensive, team-based system solution that hardwires evidence-based best practices in clinical settings and safety science. It provides broad recommendations and customizable tools for multiple healthcare settings including emergency departments, intensive care units, general medical/surgical units, and procedural areas. It calls for implementation of proven solutions such as Failed Airway Protocols (FAP), comprehensive equipment cart/systems, essential clinical practices, checklist utilization and team training.

The Safer Airway Program is being developed via a collaboration of Emergency Medicine Associates, (Germantown, MD), the Emergency Medicine Patient Safety Foundation (EMPSF), Society for Airway Management (SAM), and national advisors. The American College of Emergency Physicians’ Quality Improvement and Patient Safety Section (QIPS), the Patient Safety Movement Foundation, and other medical specialty organizations are leading the advancement of the Safer Airway Program.
## Hospital-wide Failed Airway Protocol/Pathway (FAP)

<table>
<thead>
<tr>
<th>Solution and key features</th>
<th>Level of recommendation</th>
<th>Safety rationale</th>
<th>Reference source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Failed Airway Protocol/Pathway (FAP) <strong>Alternative term is “Difficult Airway Pathway” (DAP)</strong></td>
<td>Mandate</td>
<td>FAP should be operational, standardized, and actionable. Creates a team approach.</td>
<td></td>
</tr>
<tr>
<td>A Choose a simple format (3-4 key steps) that can be known &amp; used by all team members</td>
<td>Mandate</td>
<td>Aligns teams to focus on major vulnerabilities and key actions</td>
<td>NAP4</td>
</tr>
<tr>
<td>B Integrate “awake” non-paralyzed intubation into difficult airway pathway for ED/ICU</td>
<td>Highly recommend</td>
<td>Essential practice not commonly performed in EM</td>
<td>ASA DAS</td>
</tr>
<tr>
<td>C Include Video Laryngoscopic (VL) intubation for ED/ICU</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D Standardize throughout hospital</td>
<td>Highly recommend</td>
<td>Validated safety practice</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Solution and key features</th>
<th>Level of recommendation</th>
<th>Safety rationale</th>
<th>Reference source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2</strong> Airway Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A Choose a consolidated Airway Cart (standardized for the appropriate age range) that includes equipment for basic and difficult airway management. Use for all intubations and airway emergencies in the ED, ICU, OR, Post Anesthesia Care Unit (PACU), DR and general unit settings.</td>
<td>Mandate</td>
<td>Avoids critical delays, assures equipment availability, and prompt access. Workspace with references.</td>
<td>ASA NRP</td>
</tr>
<tr>
<td>B</td>
<td>Cart components</td>
<td>Highly Recommend</td>
<td>Reinforces FAP and increases reliability</td>
</tr>
<tr>
<td>---</td>
<td>-----------------</td>
<td>------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>1</td>
<td>Oral (mouth) and nasal (nose) airways</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Full face masks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Nasal CPAP mask</td>
<td>Smith, 2015</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Video laryngoscope (VL) - in room and ready for all intubations</td>
<td>Mandate</td>
<td>Gives higher 1st pass success and is an essential airway tool ASA, NAP4</td>
</tr>
<tr>
<td>5</td>
<td>Bougie type introducer catheters and stylets</td>
<td>Mandate</td>
<td>Critical adjunct ASA</td>
</tr>
<tr>
<td>6</td>
<td>Supraglottic airway devices (SGAs) - appropriately sized to meet the needs of this patient population</td>
<td>Mandate</td>
<td>Essential Rescue Device ASA</td>
</tr>
<tr>
<td>a. Laryngeal mask airways (LMAs)</td>
<td>Mandate</td>
<td>Essential Rescue Device ASA, NRP</td>
<td></td>
</tr>
<tr>
<td>- LMAs with intubation capability</td>
<td>Highly recommend</td>
<td>Allows conversion to ETT ASA</td>
<td></td>
</tr>
<tr>
<td>- LMAs with gastric access capability</td>
<td>Recommend</td>
<td>Lowers aspiration risk</td>
<td></td>
</tr>
<tr>
<td>b. King airway/combitube - alternative to LMA or rescue for LMA</td>
<td>Highly Recommend</td>
<td>Key rescue device option</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Cricothyrtomy kits (simple surgical)</td>
<td>Mandate</td>
<td>High reliability kits ASA</td>
</tr>
<tr>
<td>8</td>
<td>Needle jet ventilation kits/sets - for pediatric patients under age 10 and adults, Use in ED/ICU after failure of VL, DL, SGA and BVM.</td>
<td>Mandate</td>
<td>NAP4, ASA</td>
</tr>
<tr>
<td></td>
<td>Continuous Waveform Capnography - maintained on all intubated patients including ED/ICU/Transports and with central monitoring enabled; at a minimum, colorimetric capnometry for neonatal intubations</td>
<td>Mandate</td>
<td>Monitoring ventilation effectiveness and continued placement with ETT and SGA. Standard of care in UK/Europe and U.S. EMS but have significant gaps in U.S. EDs and ICUs.</td>
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<tr>
<td></td>
<td>Endoscope (flexible fiberoptic scope or video scope) and/or optical stylets - in ED/ICU at all times</td>
<td>Mandate</td>
<td>Essential for awake intubation, SGA conversion. Video scope preferred.</td>
</tr>
<tr>
<td></td>
<td>LED blades/handles for direct laryngoscopy - replace bulb models with single-use models, which may be better</td>
<td>Highly recommend</td>
<td>10x brighter, higher reliability, and better visibility</td>
</tr>
<tr>
<td></td>
<td>Devices or systems for securing airway in patient - to avoid unplanned extubation</td>
<td>Highly recommend</td>
<td>High rates of unplanned extubation (UE) in ED, ICU, and Transport settings</td>
</tr>
<tr>
<td>Level of recommendation</td>
<td>Safety rationale</td>
<td>Reference source</td>
<td></td>
</tr>
<tr>
<td>-------------------------</td>
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</tr>
</tbody>
</table>

**3** Critical practices

Use these recommended clinical and safety practices for preparing, performing, and maintaining artificial airways

A  Use a Checklist Quality Assurance (QA) tool for hardwiring and assessing critical practices

Mandate

Tool for practical preparation and critical practice assurance and QA monitoring

B  Use assessment, planning, and team communication for airway management – as appropriate in the various clinical settings

Mandate

Basic clinical and safety practices are known and accepted but often not utilized or hardwired into practice

C  Use optimized patient positioning – such as tragus to sternal notch, head elevated laryngoscopy position (HELP), and ramped position in obese patients (Levitan et al., 2003)

Mandate

Critical but commonly overlooked

ASA, DAS

D  Follow apneic oxygenation protocols – such as “no desat” or heated, humidified high-flow nasal oxygen or nasal CPAP

Mandate

Significant potential to prevent or delay desaturation in patients; however, hyperoxia should be avoided in newborns

Ann Emer Med, NRP

E  Use 1- and 2-person bag-mask ventilation (BVM) techniques – appropriate seal, jaw thrust, and prn bilateral NPA and OPA

Mandate

Key basic airway skill for all healthcare personnel in all settings. Often not effectively performed.
<table>
<thead>
<tr>
<th></th>
<th>Use BIPAP/CPAP/High Flow nasal oxygen (HFNO) pre-oxygenation in patients with persistent hypoxia</th>
<th>Highly recommend</th>
<th>Useful with persistent hypoxia in obesity, CHF, other</th>
<th>Ann Emer Med</th>
</tr>
</thead>
<tbody>
<tr>
<td>G</td>
<td>Use delayed sequence intubation with ketamine – use for agitated patients with hypoxia</td>
<td>Recommend</td>
<td>Important for allowing pre-oxygenation</td>
<td>Ann Emer Med</td>
</tr>
<tr>
<td>H</td>
<td>Quickly use SGA if DL/ VL failed; In neonatal resuscitation, LMA is functionally equivalent to ETT</td>
<td></td>
<td></td>
<td>NRP</td>
</tr>
<tr>
<td>I</td>
<td>Place SGA during codes (cardiac/ respiratory arrest)</td>
<td>Highly recommend</td>
<td>Assures open airway, prompt easy placement, and avoids resuscitation delay</td>
<td></td>
</tr>
<tr>
<td>J</td>
<td>Quickly use surgical cricothyrotomy when VL/DL, SGA, and BVM ventilation have failed (a cannot intubate cannot oxygenate situation). Only qualified personnel should perform this procedure.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>K</td>
<td>Use flexible bronchoscope to convert SGA to ETT</td>
<td>Highly recommend</td>
<td>Blind techniques with only 65% 1st pass success rate</td>
<td>NAP4</td>
</tr>
<tr>
<td>L</td>
<td>Use awake fiberoptic intubation (AFOI) or other non-paralyzed intubation techniques. Use for intubations that may be difficult or highly difficult.</td>
<td>Highly recommend</td>
<td>Essential practice that is not commonly performed in EM</td>
<td>ASA, DAS, NAP4</td>
</tr>
<tr>
<td>Column</td>
<td>Text</td>
<td>Recommendation</td>
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<tr>
<td>M</td>
<td>Immediately use and maintain Continuous Waveform Capnography - on all intubated patients</td>
<td>Mandate</td>
<td>See equipment above</td>
<td>See references above</td>
</tr>
<tr>
<td>N</td>
<td>Optimize sedation and restraint protocols to minimize unplanned extubations (UEs); in newborns, use developmental positioning, selective sedation</td>
<td>Highly recommend</td>
<td>Patients who are under sedation or agitated are at risk for airway loss (UE)</td>
<td>AJCC</td>
</tr>
<tr>
<td>O</td>
<td>Formalize system for optimally securing ETT (Tube holders for adults, C- Collar infants in transport)</td>
<td>Highly recommend</td>
<td>UE causes high death rates - reportedly as high as 7%. High risk in pediatric patients</td>
<td></td>
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<tr>
<td>P</td>
<td>Implement a System for flagging identified difficult airway patients in electronic health records (EHR) system</td>
<td>Highly recommend</td>
<td>Many EHR systems are able to flag difficult airway patients, but flagging is not developed or used</td>
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<tr>
<td>Q</td>
<td>Use extubation guidelines</td>
<td>Highly recommend</td>
<td></td>
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<tr>
<td>R</td>
<td>Implement system for tracking and reviewing QA data from intubations or UEs - see Airway Registry</td>
<td>Highly recommend</td>
<td>Safety reporting systems have shown low yield for near-miss events from fear of punishment</td>
<td>DAS</td>
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<tr>
<td>S</td>
<td>Use strategies for avoiding peri-intubation hypotension by having medications ready prior to intubations</td>
<td>Highly recommend</td>
<td>Use IVF, positioning, and pressers in high-risk groups</td>
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</tbody>
</table>
Promote routine recording of airway management when video devices are utilized. Promote use of cognitive aids for routine and failed airway management, such as the Vortex Airway Approach (vortexapproach.org).

<table>
<thead>
<tr>
<th>Solution and key features</th>
<th>Level of recommendation</th>
<th>Safety rationale</th>
<th>Reference source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4</strong> Team training</td>
<td>Mandate</td>
<td></td>
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<tr>
<td>A</td>
<td>Train all clinical staff on airway safety protocols, equipment, and critical practices - including basic and advanced practices for preparation, performance, and post-intubation management. Make sure all clinicians doing airway management are credentialed.</td>
<td>Mandate</td>
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<tr>
<td>B</td>
<td>Promote teamwork and clear communication - include a plan for sharing, open communication, and debriefing</td>
<td>Mandate</td>
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<tr>
<td>C</td>
<td>System for ensuring that practitioners are trained and credentialed in airway management</td>
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</table>
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

Test and use airway management devices that improve safety and drive better patient outcomes, including:

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Considerations</th>
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<tr>
<td><strong>ONC Meaningful Use Certified Electronic Health Record (EHR) System</strong></td>
<td>An effective EHR System should include:</td>
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<tr>
<td></td>
<td>• Computerized Provider Order Entry (CPOE)</td>
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<td></td>
<td>• Drug-drug interaction check</td>
</tr>
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<tr>
<td></td>
<td>• Clinical Decision Support tools (CDS)</td>
</tr>
<tr>
<td><strong>Laryngoscopes</strong></td>
<td>A laryngoscope is a rigid airway visualization device that allows the user direct vision of the glottis (vocal cords), through which he/she will manually pass an endotracheal tube. It generally consists of a handle, held in the user’s left hand, and an attached blade, inserted through the mouth in such a way as to move the tongue and allow a direct visual path to the glottis. The use of this device requires considerable skill and training, and it may be unsuccessful in patients with difficult airway anatomy. Direct laryngoscopy (DL) has been used for decades to perform placement of endotracheal tubes. In 2001, video laryngoscopy (VL) was introduced. Although the literature has little to support that VL improves first pass success, some meta-analyses suggest that VL reduces the incidence of difficult or failed intubation. Therefore, based on VLs ability to reduce failed intubations, it is highly recommended that:</td>
</tr>
<tr>
<td></td>
<td>• VL equipment be readily available for all intubations</td>
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<tr>
<td></td>
<td>• All airway providers responsible for intubation be trained and comfortable with these devices</td>
</tr>
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<td></td>
<td>Many providers and hospitals haven’t made the transition to VL, either because the cost of VL equipment or the change in technique required for successful VL. More recently, many video laryngoscopes have developed VL equipment that allows use of a traditional DL technique. This change may help with the transition.</td>
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### Video Laryngoscopes

A video laryngoscope is a rigid device similar to an ordinary laryngoscope, with the addition of a fiber-optic light pathway for both illuminating and visualizing the glottis. Properly inserted into the mouth, the video laryngoscope can show the user an image of the glottis on a screen, without the requirement to establish a direct light pathway from the glottis to the user’s eye. The user can then insert the endotracheal tube through the glottis while monitoring the displayed image.

An effective VL system should:

- Be portable and easy to use
- Have clear and reliable airway visualization without fogging
- Permit ETT delivery with minimal operator fine motor skills
- Have a large video screen that allows multiple operators to act as a team. Devices with small video screens may be better when space is limited, such as in helicopters.
- Have large image storage capability
- Have low risk for cross-contamination

### Fiberscopes

A “fiberscope” or fiber-optic bronchoscope is a highly flexible, guided tubular device that can be passed through the lumen of an endotracheal tube. The scope provides both light illumination and indirect visualization through its tip. The user can control the exact shape of the fiberscope tip to guide it through the patient’s glottis. Once the tip of the scope has passed through the glottis, the endotracheal tube is advanced over the scope and into the trachea.

Although video laryngoscopes have reduced the need for fiberoptic intubation, fiberscopes remain the device of choice in certain critical airway conditions, such as (angioedema, oropharyngeal neoplasm, head and neck radiation, and congenital deformity).

Low cost single-use fiberscopes with reusable video monitoring, such as the Ambu aScope, are now available as an alternative to high-priced reusable fiberscope systems.
**Supraglottic Airways**

Supraglottic airways devices are inserted through the mouth or the nares, but do not pass through the vocal cords. They displace the tongue using a variety of technologies, thus creating an open airway between the mouth or nares and the glottis.

Second-generation supraglottic airway (SGA) devices are now available and provide safety advantages over first generation devices by allowing for easier placement, higher ventilation pressures, gastric decompression, and intubation through the device.

These technological advances have furthered the importance of having the latest generation of SGA devices (and their advanced technology) available when needed as rescue or primary airway devices.

**Waveform Capnography**

Capnography is the measurement of carbon dioxide tension (in mmHg) in the respired gas during both inspiration and expiration, and the display of that quantity versus time.

This important technology has become the standard of care for intubated patients in the UK and parts of Europe. North American Intensive Care Units, Emergency Departments, and Emergency Medical Services are beginning to adopt this technology, but significant gaps exist.

Continuous Waveform Capnography:

- Should become a mandated safety practice for all SGA or intubated patients
- Should have the capability to integrate into your facility’s monitoring systems

**Endotracheal Tube Stabilizers**

The current systems for stabilizing endotracheal tubes include adhesive tape, cotton twill ties, and multiple commercial devices. Although the current literature does not clearly identify any particular device or technique that is superior, devices may differ in their ability to resist extubation forces. Standardization of the use of endotracheal tube stabilization systems by care teams has decreased unplanned extubation rates.

The most current cited unplanned extubation rate of 7.3% (with a range of studies showing rates as high as 35.8%) suggests that current stabilization techniques and devices are inadequate. Further research into developing a better stabilization system should be supported (da Silva et al., 2012).

*Company has signed some form of the Open Data Pledge. Find more information on the Patient Safety Movement Foundation website: patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/

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- Have a large video screen that allows multiple operators to act as a team. Devices with small video screens may be better when space is limited, such as in helicopters
- Have large image storage capability
- Have low risk for cross-contamination
- Have capabilities for recording events for clinical documentation, review and teaching
A “fiberscope” or fiber-optic bronchoscope is a highly flexible, guided tubular device that can be passed through the lumen of an endotracheal tube. The scope provides both light illumination and indirect visualization through its tip. The user can control the exact shape of the fiberscope tip to guide it through the patient’s glottis. Once the tip of the scope has passed through the glottis, the endotracheal tube is advanced over the scope and into the trachea.

Although video laryngoscopes have reduced the need for fiberoptic intubation, fiberscopes remain the device of choice in certain critical airway conditions, such as (angioedema, oropharyngeal neoplasm, head and neck radiation, and congenital deformity).

A combined use of fiberoberoptic and Video Laryngoscope would be recommended as placing ETT through cords over just fiberoptic is still a blind intubation

Low cost single-use fiberscopes with reusable video monitoring are now available as an alternative to high-priced reusable fiberscope systems. The availability of single-use flexible scopes requires little capital investment and may be particularly suited in areas where they will be infrequently used.
**Supraglottic Airways**

Supraglottic airway devices are inserted through the mouth and do not pass through the vocal cords. They displace the tongue using a variety of technologies, thus creating an open airway between the mouth or nares and the glottis.

Second-generation SGAs are now available and provide safety advantages over first-generation devices by allowing for easier placement, higher ventilation pressures, gastric decompression, and intubation through the device.

It is recommended not to do a blind intubation through an intubating LMA as success rates are low, thus use a fiberoptic bronchoscope.

These technological advances have furthered the importance of having the latest generation of SGA devices available when needed as rescue or primary airway devices.

**Waveform Capnography**

Capnography is the measurement of carbon dioxide tension (in mmHg) in the respired gas during both inspiration and expiration, and the display of that quantity versus time.

This important technology has become the standard of care for intubated patients in the UK and parts of Europe. North American Intensive Care Units, Emergency Departments, and Emergency Medical Services are beginning to adopt this technology, but significant gaps exist.

Continuous Waveform Capnography:
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The current systems for stabilizing endotracheal tubes include adhesive tape, cotton twill ties, and multiple commercial devices. Although the current literature does not clearly identify any particular device or technique that is superior, numerous devices on the market are clearly inferior in their ability to restrain against extubation forces.

The most current cited unplanned extubation rate of 7.3% (with a range of studies showing rates as high as 35.8%) suggests that current stabilization techniques and devices are inadequate. Further research into developing a better stabilization system should be supported (da Silva and Fonseca, 2012).

---

**Measuring outcomes**

Tracking will help your organizations improve and help hospitals and evaluate your progress. At this time, this workgroup has not developed metrics to track failed intubations or unrecognized esophageal placements. Please refer to APSS #8B for metrics on unplanned extubations.

---

**Quality and safety metrics for intubations**

Refer to NEAR4NEOS (Foglia et al., 2019) and NEAR4KIDS (Li et al., 2016) for detailed definitions on airway management encounters.

A tracheal intubation “Attempt” begins with the insertion of a laryngoscope or other airway insertion accessory device into a patient’s mouth or nose, and ends with the removal of the device. A “Course” of advanced airway management denotes one method for securing an airway, which may involve one or more attempts. An “Encounter” for advanced airway placement may include one or more methods (courses), each involving one or more attempts.

Key performance indicators:

- Attempts per tracheal intubation encounter (mean)
- Failed tracheal intubation courses (%)
- Esophageal intubation with delayed recognition (%)
- Endobronchial intubation (%)
- (Severe adverse tracheal intubation-associated event - composite [%])

---

**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 APSSs recommend technologies offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence,
that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

**Workgroup**

**Chairs**
- **Arthur Kanowitz**  
  Airway Safety Movement,  
  Society for Airway Management, Securisyn Medical
- **David Hughes**  
  Do It For Drew Foundation
- **Joaquim Pinheiro**  
  Albany Medical Center

**Members**

This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

- **Gillian Abir**  
  Stanford University
- **Paul Baker**  
  University of Auckland, New Zealand; AirwaySkills
- **Kris Bysani**  
  Medical City Children’s Hospital
- **Anna Cleobone Ruskin**  
  University of Chicago
- **Rhashedah Ekeoduru**  
  McGovern Medical School, University of Texas Health
- **Mitchell Goldstein**  
  Loma Linda University Children’s Hospital
- **Narasimhan Jagannathan**  
  Northwestern University
- **Sarah Kandil**  
  Yale New Haven Children’s Hospital
- **Ariana Longley**  
  Patient Safety Movement Foundation
- **Olivia Lounsbury**  
  Patient Safety Movement Foundation
- **Lalainya O’Connell**  
  Albany Medical Center
- **Chad Pezzano**  
  Albany Medical Center
- **Donna Prosser**  
  Patient Safety Movement Foundation
- **Kellie Quinn**  
  Advocate
- **Patricia Roth**  
  UCSF Medical Center
- **Larry Roy**  
  Advocate Children’s Hospital, Chicago
- **Lamia Soghier**  
  Children’s National

**References**


Appendix A: Recommended actions for stakeholders

These are recommended actions for stakeholder groups, other than EMS and hospitals, to improve airway safety.

Actions for outpatient procedure centers using moderate or deep sedation

- Ensure staff who administers sedation are trained to monitor and manage airways appropriate to the setting
- Use proper monitoring equipment and tools, including pulse oximetry and waveform capnography
- Equip your facility with needed airway management equipment and skills for use, including: oxygen therapy, bag-valve mask ventilation, BLS-level use of supraglottic airway devices

Actions for professional/healthcare/stakeholder organizations

Seek national collaboration with other professional, safety, and healthcare organizations in an Airway Safety Collaborative with the aim to help the industry:

- Learn more about airway management practices in a broad representation of hospitals and other clinical environments
- Develop and promote high impact best practices to be implemented in specified clinical units, such as pre-hospital, ED, delivery suite, ICU, medical/surgical floor, procedural areas, and outpatient settings
- Research system solutions to improve airway safety
  - Adapt tools and use data from NEAR4KIDS and NEAR4NEOS registries
- Develop education programs and materials for trainees and practicing clinicians

Actions for companies in the airway industry

- Collaborate with current and future safety initiatives to develop or modify products or solutions that best address airway safety threats. To do this:
  - Optimize human factors and device usability
  - Label products to be clearly and easily identified for size and use (considering human factors in high-stress events)
  - Seek out and respond to clinical and safety requests for modification
- Establish a mechanism for industry to collaborate on:
  - Rapidly identifying and responding to vulnerabilities
  - Seeking fast dissemination and adoption of high-reliability components to products or services
  - Package products for high reliability and easy access
  - Package essential supplies to work with portable airway cart systems
- Support:
  - Airway safety research
  - The development of a national airway safety policy
  - Unbiased educational forums for airway safety
- Participate in the Global Airway Safety (GAS) Collaborative
Actions for accrediting agencies
• Work with professional clinical/safety organizations to establish airway safety process, performance, and measurement standards
• Highlight and assess airway standards during site visits as a high priority focus
• Elevate airway safety as a national patient safety goal

Actions for government (funders/regulators/service providers)
• Work with professional clinical/safety organizations to establish airway safety process, performance, and measurement standards
• Fund, and encourage other to fund, research for improving airway management safety through the entire spectrum of hospital and healthcare settings
• Use financial incentives to help drive adoption of established highly reliable airway safety practices

Actions for safety organizations (global, national, regional, state levels)
• Assist, support, and participate in the development of a Global Airway Safety Collaborative
• Elevate airway safety as a national safety goal
• Support and promote the development and implementation of actionable airway safety solutions
• Network with potential funders to help empower development and research of airway safety solutions
• Support the development of airway safety training programs and tools

Actions for the risk management/insurance industry
• Elevate airway safety as a national safety goal
• Fund and support the development and implementation of actionable airway safety solutions
• Establish financial incentives for groups that demonstrate implementation, tracking, assessments, and training in airway safety practices, tools, and procedures

Actions for consumer groups
• Support and help fund the development of a Global Airway Safety (GAS) Collaborative with the aim to elevate the airway safety standard of care
• Support and help fund safety organizations and programs that will help protect constituent members with regard to airway safety, including key focus areas in patient groups for older adults, children, and people with obesity
• Demand specific, demonstrable, and highly reliable airway safety programs from healthcare organizations and institutions.
• Help establish and promote public awareness campaigns for airway safety engagement, practices, and performance
How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for unplanned extubation (UE). In it, you’ll find:

Executive summary checklist............................................ 350
What we know about UE.................................................. 353
Leadership plan ............................................................. 354
Action plan ...................................................................... 355
Technology plan .............................................................. 358
Measuring outcomes......................................................... 360
Conflicts of interest disclosure........................................... 362
Workgroup ...................................................................... 363
References ........................................................................ 364
EXECUTIVE SUMMARY CHECKLIST

A planned extubation occurs as part of a normal process of weaning the patient from their breathing tube. It is typically intentional and occurs in a controlled manner. Unplanned extubation (UE) is typically the unintentional and uncontrolled dislodgement of a patient’s breathing tube that occurs outside of a strategic weaning process. The dislodgement may occur when the patient exerts a force to remove the tube (self-extubation) or when an external force is applied to the tube that dislodges it (accidental extubation). Both self-extubation and accidental extubation may present with the tube completely removed from the patient’s oral cavity or the tube may remain internal and appear to be in the proper position, however, EtCO2 indicates it is no longer in the trachea (internal dislodgement). In neonates, the position of the tube may become mal positioned outside of the trachea and remains within the hypopharynx or esophagus (internal dislodgement) but may be difficult to confirm proper positioning due to lack of EtCO2 monitoring and occasionally unreliable colorimetric CO2 detection. In those cases, the practitioner may decide to extubate and reintubate the patient. This type of extubation, although intentional, is done outside of a normal weaning process and therefore is also classified as unplanned. Another intentional extubation that is done outside a normal weaning process occurs when there is a malfunction of the endotracheal tube (obstruction, deflation of balloon, etc.) and therefore the tube must be urgently or emergently removed and often replaced; this is also considered a UE.

UE, both in the field and in the hospital, is a common and costly problem. It results in significant morbidity and mortality. This document was adapted from APSS #8B which relates to adult patients; it aims to address the specific needs of the pediatric and neonatal population.

Use this checklist to help prioritize your actions and measure your organization’s progress in your UE prevention.

CREATE AN ACTION PLAN TO PREVENT UE

☐ Develop a hospital-wide Culture of Safety

☐ A Culture of Safety within a healthcare organization refers to a safe and reliable environment where the foundation of transparency, safety, trust, and accountability
is established and maintained between the workers of the facility and the patients it serves. (https://psnet.ahrq.gov/primer/culture-safety)

- Should be driven from the top-down and from the bottom-up.
- Consider joining the Children’s Hospital’s Solutions for Patient Safety Collaborative. Work closely with this safety collaborative, share ideas related to processes that improve safety including tube securement methods and processes for high-risk situations.

- Form a core multidisciplinary airway safety leadership team (Steering Committee) including:
  - VP (Director) of Quality
  - VP (Director) of Safety
  - Physician, nursing, and respiratory care team leaders across all hospital units (ED, ICU, Anesthesia) to ensure recognition of the problem and support development of systems that will eliminate UE and its associated complications, especially preventable harm or death.
  - Neonatal and Pediatric representation (expertise) is vital

- Create a leadership plan where top-level leadership regularly review a dashboard of UE occurrences, the complications that are associated with UE, and the cost of these occurrences in morbidity, mortality and healthcare dollars.

**Engage staff and ensure best patient care**

- Provide periodic education for all airway management providers:
  - Educate providers that unplanned extubation is a common and costly complication of airway management
  - Educate providers regarding the importance of prevention of UE and the need for accurate data tracking (if you don’t track it you can’t improve it).
  - Include UE as part of every presentation of management of the difficult airway patient

- Implement Clinical Best Practices for Preventing UE:
  - Standardize tracheal tube restraint devices and techniques, using the most proven methods and devices
  - Strategies for High-Risk Situations (Kandil et al., 2018).
  - Emergency extubations by staff due to concern for tube obstruction may be minimized by standardized assessment of acute decompensation events and team training (Ferraz et al., 2019)
  - Create systems for alerting clinicians to patients with a known difficult airway

- Use patient stories, in written and video format, to identify gaps and inspire change in your staff.

**Track UE and use data to find areas for improvement**

- Determine baseline rate of UE (see Measuring Outcomes section)
- Determine baseline rate of complications (oral mucosa and facial skin pressure injuries, pneumonia, vocal cord injury, hypoxemia, brain injury, death) caused by UE
- Perform an event review for all incidences of UE
- Perform a root cause analysis (RCA) for all deaths associated with UE: Use a multidisciplinary team including physicians, nurses, and respiratory therapists to evaluate the root cause of every UE, determine a plan to eliminate the root cause, implement the plan, and track results.
Institutions should use the techniques described in Failure Modes and Effects Analysis or Safety II to create strategies that mitigate the risks of UE.

Use a multidisciplinary team including physicians, nurses, and respiratory therapists to evaluate the root cause of every UE, determine a plan to eliminate the root cause, implement the plan, and track results.

Institutions should use techniques described in Failure Modes and Effects Analysis or Safety II to create strategies that mitigate the risks of UE.

Implement the core UE dataset as defined in the Measuring Outcomes section of this APSS:
- Every (endotracheally) intubated, mechanically ventilated patient should have the entire PSMF core dataset for extubation recorded in the patient’s medical chart.
- Evaluate your hospital’s Electronic Health Record (EHR) to determine if the entire core dataset is included in the EHR:
  - If included, educate all providers of airway management how to properly track UE.
  - If not included, contact the EHR company and request they add the dataset - Develop a system for temporarily tracking the dataset until the EHR Company institutes the dataset.

Develop a Quality Management Process to promote and ensure continuous improvement with an initial SMART aim of achieving a realistic benchmark UE rate, and ultimately eliminating all incidents of UE:
- Require tracking and reporting of all incidents of UE and complications of UE, including hypoxemia, CPR, pneumonia, vocal cord injury, brain injury and death. Perform a formal RCA for deaths in which a UE occurred as part of the terminal events.
What we know about unplanned extubation

Unplanned extubation, both in the field and in the hospital, is a common and costly problem. Although formal studies of UE in children and neonates have been less extensive than those in adults, they reveal:

- 8% (range: 0.8% - 18.5%) of endotracheally intubated children in Pediatric Intensive Care Unit (PICU) have a UE, with rates averaging 1.0 per 100 ventilation days (Lucas da Silva and de Carvalho, 2010)
- In NICU, 18% (range 1% to 81%) of intubated neonates have a UE, at a rate of 2.0 per 100 ventilator days (range 0.15 to 5.3 per 100 ventilator days) (Lucas da Silva, Reis, Aguiar, and Fonseca, 2013)
- At least 80,000 neonates are mechanically ventilated each year in U.S. NICUs (Angus et al., 2001), in addition to about 24,000 ICU patients in the pediatric age range. (Wunsch et al., 2010)
- Estimates based on these statistics would suggest that there are over 14,000 UEs yearly, in U.S. NICUs, plus nearly 2,000 UEs in pediatric age patients
- There are no data that would permit estimating pediatric or neonatal mortality attributable to UEs.
- Adverse events were noted in 71% of UE incidents in a NICU study. (Hatch et al., 2017) UE can induce cardiovascular collapse in neonates and children, (da Silva & Fonseca, 2017; Klugman et al., 2013), and as many as 13% of patients may require CPR (Kambestad et al., 2019). Risks associated with reintubation include airway trauma, subglottic stenosis and ventilator-associated pneumonia (Thomas et al., 2017; Panagos and Pearlman, 2017). In addition, the need for reintubation has been associated with the risk of intraventricular hemorrhage in preterm neonates, an important morbidity in this particularly vulnerable population (Guardia et al., 2011)
- UEs are associated with a doubling of the median ICU stay in infants and children, and it increases hospital length of stay from 10 days to 16.5 days (Roddy et al., 2015)
- Hospital costs are nearly $37,000 higher in pediatric patients with UEs, indicating potentially avoidable healthcare costs (Roddy et al., 2015; Dominguez and Thiruchelvam, 2015). Costs associated with UEs have not been estimated in newborns, the most vulnerable population.

The need to accurately track UE

The incidence of UE events is uncertain in most settings. UEs in children occur not only in ICUs but also in delivery rooms, during inter-hospital transports or in emergency medical services (EMS) settings, in the ED, OR and imaging suites, and during in-hospital transfers between units. EHR documentation is typically not uniform among all those systems. Consequently, UE is not tracked in most EMS or hospital systems; even when UEs are systematically tracked, those occurring in the delivery room or during transport may not be counted. (Mbi Ndakor, Nelson, & Pinheiro, 2017) In addition, there is wide variation in which unscheduled extubation events are counted as UEs, especially when endotracheal tubes are removed emergently by staff (Meyers, Pinheiro, & Nelson, 2015); this may result in substantial undercounting of UEs, particularly in neonates. (Mbi Ndakor, Nelson, and Pinheiro, 2017). Some authors would count all unscheduled extubations as UEs, (Murphy et al., 2016), others require additional evidence for tracheal tube dislodgement, (Lucas da Silva and de Carvalho, 2010) and yet others use nomenclature such as “unintentional”, or “unintentional and premature” to define UEs, which implicitly might exclude
emergency intentional tube removals by staff (Kambestad et al., 2019; Galiote et al., 2019; Kudela et al., 2018). If we are going to get an accurate measure of the frequency and costliness of UE, both in the hospital and in the field, we must develop widespread systems to accurately track all UE incidents, using clear nomenclature and uniform operational definitions.

Closing the performance gap will require hospitals and healthcare systems to commit to action in the form of specific leadership, practice, and technology plans. This APSS gives examples to help hospitals prioritize their efforts at designing and implementing evidence-based bundles for reducing UE.

**Leadership plan**

Hospital governance, senior administrative leadership, quality and safety leadership, risk management leadership, and clinical leadership must work collaboratively to reduce UE.

**Develop a hospital-wide culture of safety**

- A Culture of Safety within a healthcare organization refers to a safe and reliable environment where the foundation of transparency, safety, trust, and accountability is established and maintained between the workers of the facility and the patients it serves. ([https://psnet.ahrq.gov/primer/culture-safety](https://psnet.ahrq.gov/primer/culture-safety))
- Should be driven from the top-down and from the bottom-up.
- Join the Children’s Hospitals’ Solutions for Patient Safety Collaborative or similar collaborative. Work closely with safety collaboratives, share ideas related to processes that improve safety including tube securement methods and processes for high-risk situations.

**Show leadership’s commitment to reduce UE**

- Hospital governance and senior administrative leadership must commit to reducing the incidence of UE with a goal of zero preventable deaths and harm
- Raise awareness and champion efforts to raise awareness regarding the seriousness (frequency and costliness) of UE
- Determine the organization’s rate of UE through reporting and tracking within a formal Quality Improvement (QI) program, and engage QI/Patient safety to implement steps to reduce the incidence of UE and eliminate preventable harm or death
  - After you know your organization’s incidence rate, develop an organizational story and use the skill set of storytelling to raise awareness and action to stay focused on why there is a need for change
- Demonstrate commitment and support by shaping a vision of the future, clearly defining goals, and supporting staff as they work through improvement initiatives, measuring results, and communicating progress towards those goals

**Create a team to reduce UE**

The core multidisciplinary team (steering committee) should consist of the following:

- VP (Director) of Quality and VP (Director) of Safety
- Physician, nursing, and respiratory care team leaders from ED, OR/PACU, and ICU
- Neonatal and Pediatric representation in the institutional team is crucial, since mechanisms and prevention of UEs differ from those in adult populations, and distinct APSSs address the needs of pediatric and neonatal patients
Engage staff and make policy changes to reduce UE

- Commit to defining performance gaps within the organization (system-wide, hospital-wide, and by department)
- Support a comprehensive approach to standardized data tracking, quality management, and process improvement efforts, and implementation of practice and technology plans necessary to eliminate UE
- Use patient stories – in written and video formats – to identify gaps and inspire change in your staff:
  - The story of Drew Hughes, told by his father David Hughes, is an example of an unplanned extubation that led to the preventable death of Drew. You can view the story for free here: https://patient.sm/IanY0O

**Action plan**

Create protocols to reduce UE

- Use current evidence-based guidelines and available potentially better practices during airway management of the intubated patient to eliminate incidents of UE
- Implement systems for alerting clinicians to patients with a known difficult airway
- Position the endotracheal tube with the tip of the tube within the optimal tip position range (mid-trachea or T1-T2 level, in pediatric populations). Proper initial positioning of the endotracheal tube decreases the need for tube repositioning and the risk of UE if the tube moves.
- Once appropriately positioned, maintain that position with a tube stabilizer that eliminates clinically significant total movement of the tube, which may be 1 cm in the smallest neonates
  - If tape is the chosen method for restraint, standardize the type of tape and application method. Consider documenting directly on the tape the date applied, depth of the ETT and provider initials.
  - One caregiver should have the sole responsibility for protecting the ETT, often called an “airway guardian”
- Monitor and document ETT position with routine cares (Hu et al., 2017).
- Use strategies for High-Risk Situations (Kandil et al., 2018).
  - Require 2 caregivers to participate in the identification and tracking of ETT positioning before and after any bedside manipulation, adjustment of the ETT or movement of any patient with an ETT (Movement includes any bedside procedure, radiographs, patient transport and simple patient repositioning of the head and upper body).
  - One caregiver should have the sole responsibility for protecting the ETT, often called an “airway guardian”.
  - Before any movement of the patient, the caregiver who is responsible for the security of the ETT should perform a verbal call-out of the depth of the ETT. After movement of the patient is completed, a second verbal call-out of the ETT depth is performed, along with confirmation that the position of the ETT has not changed.
  - All healthcare providers are responsible to ensure that the high-risk strategies are utilized at all times.
• UE risk is minimized, during times when staff or family are present, when a dedicated airway “guardian” is utilized for repositioning, procedures, transfers out of bed including kangaroo care (Galiote et al., 2019).

• Formalize systems for appropriate sedation and patient restraint to decrease the risk of self-extubation. Note: In intubated neonates, sedation may not be routinely used due to a perception of limited evidence of benefit and risk of significant adverse effects in certain diagnoses. (Bellu, de Waal, and Zanini, 2010; Anand et al., 2004); immobilizing restraints are not appropriate, so developmentally appropriate positioning is used, along with accessories such as mittens that minimize reflex grasping of tubes. (Merkel et al., 2014)

• Restrain the patient using a combination of age-appropriate physical restraint and chemical restraint (sedation) if indicated:
  o Institute a continuous sedation protocol with daily interruption of sedatives
  o In children, a standardized policy for sedation and weaning has decreased UE rates (Tripathi, Nunez, Katyal, and Ushay, 2015)

• In neonates receiving mechanical ventilation, routine sedation is not recommended due to unfavorable benefit-risk balance. If selective sedation is required, morphine is safer than midazolam. (Bellu, de Waal, & Zanini, 2010; Anand et al., 2004)

• Avoid intermittent or no sedation protocols (Chao et al., 2017)

• In neonates, rather than immobilizing restraints, developmentally appropriate positioning is used, along with accessories such as mittens that minimize reflex grasping of tubes. (Merkel et al., 2014)

• Using continuous Waveform Capnography can facilitate rapid recognition of a malpositioned tube; however, its accuracy is limited in small neonates and cannot be used with high frequency ventilation. (Hochwald et al., 2019) Transcutaneous CO2 monitoring is an important adjunct to care in the NICU and can indicate an increase in CO2 associated with UE.

• The initial clinical evaluation of any acute cardiopulmonary deterioration event in an intubated patient should include determination that the endotracheal tube is correctly positioned and the patient is being adequately ventilated via waveform capnography or, if this is not available, colorimetric CO2 detection. Capnography or capnometry along with clinical evaluation must be used to make this determination. Assume that lack of exhaled CO2 is due to a malpositioned endotracheal tube until proven otherwise. “Flat trace, wrong place.” In the context of colorimetric analysis, if there is no color change, the tube position should be assumed to be inappropriate. If CPR is ongoing, colorimetric change may not occur despite appropriate position. In neonates, a rapid improvement in bradycardia along with exhaled CO2 are the most reliable indicators of effective ventilation, although this may require higher than baseline inflation pressures. Some infants with bronchopulmonary dysplasia have recurrent “BPD spells” which mimic tube displacement or obstruction (Ambalavanan and Carlo, 2006); these may resolve with brief substantial increase in pressures to effect gas exchange, without requiring emergency extubation and reintubation.

• If the evaluation suggests the tracheal tube might be mal-positioned, the tube should be immediately repositioned to the appropriate depth or replaced if necessary; in the latter case, UE should be considered as the cause of the cardiorespiratory event.

• Communication about extubation risk, its prevention, contingency management, should
be an integral part of daily rounds/huddles for all intubated patients and should include all members of the team, including the respiratory therapy team and families.

- Determine appropriate criteria for NICU patients transitioning to the PICU. This may be institution dependent but is important as cares should be age appropriate.

**Track and analyze your progress**

- UE should be considered through an event review as the cause of any acute cardiorespiratory deterioration and if determined to be the cause of death a formal root cause analysis should be performed.
- Develop a Quality Management Process to promote and ensure continuous improvement with an initial aim of decreasing UE rates to a benchmark, and ultimate goals of eliminating all incidents of UE and preventable UE-related deaths. To do this:
  - Review all UE incidents
  - Determine contributing causes, which may include:
    - Inadequate stabilization of the endotracheal tube (Veldman et al., 2006; Hatch et al., 2019)
    - Inadequate monitoring of endotracheal tube status (Hu et al., 2017)
    - Inadequate staff at the bedside for moving the patient or manipulating the airway
    - Inadequate sedation (chemical restraint)
    - Inadequate physical restraint or comfortable positioning
  - Plan and implement changes to the system based upon findings from reviews
  - Track UE to determine if the implemented processes cause improvement
  - Require tracking and reporting of all incidents of UE and complications of UE (e.g., hypoxemia, pneumonia, vocal cord injury, brain injury, and death)

**Create best practices for out-of-hospital management of UE**

- Airway management in the field (EMS/transports) should incorporate the same prevention, tracking, and quality management concepts as described above for medical facilities.
- Patients that are transported with an endotracheal tube in place should receive continuous oximetry and waveform capnography when technically possible, to ensure early recognition of displacement of the tube; otherwise, colorimetric capnometry may be used intermittently to assess tube location. Transcutaneous CO2 monitoring is an important adjunct to care. Failure to rapidly recognize and remediate a displaced tube has a very high probability of hypoxemia that can result in severe brain injury and death.
- All incidents of UE in the field must be reported to the receiving facility during hand-off communications.
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

Test and use airway management devices that improve safety and drive better patient outcomes, including:

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Considerations</th>
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<tbody>
<tr>
<td><strong>ONC Meaningful Use Certified Electronic Health Record (EHR) System</strong></td>
<td>EHR equipped with the following capabilities:</td>
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<tr>
<td></td>
<td>• Computerized Provider Order Entry (CPOE)</td>
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<td></td>
<td>• Drug-drug interaction check</td>
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<td></td>
<td>• Drug-allergy interaction check</td>
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<td></td>
<td>• Clinical Decision Support tools (CDS)</td>
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<td></td>
<td>• ETT depth alerts for documentation of placement that is outside the expected range for each patient</td>
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<td></td>
<td>• An alert if &gt; 6 hours since patient completed and passed a spontaneous breathing trial (this is not applicable in pediatrics or neonates)</td>
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<tr>
<td>Standardize tracheal tube restraint devices</td>
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The current methods and devices for stabilizing endotracheal tubes include:

- Adhesive tape
- Cotton twill ties
- Multiple commercial devices
- Locally adapted devices

Early reports on ETT holding devices showed that holders locally adapted from umbilical clamps reduced UE rates when compared to traditional taping methods (DeJonge and White, 1998; Loughead et al., 2008), but a Cochrane review found that the available evidence on securing ETTs in newborns is so scant and of poor methodological quality that it cannot be collated or subject to a meta-analysis (Lai et al., 2014). While parents of neonates may prefer devices that facilitate visibility of the face and interaction, compared to tape (James and Spence, 2011) QI work has shown inconsistent impact of holding devices on ETT stability or UE rates (Brinsmead and Davies, 2010; Loganathan et al., 2017; Drumm & Packard, 2016). The current literature does not clearly identify any device or technique on the market that is superior at preventing movement against externally applied forces. Therefore, when choosing an endotracheal tube stabilizer, the device’s ability to restrain against applied force should be the primary consideration.

Other considerations, such as ease of use or ability to prevent skin breakdown should be secondary considerations, although the latter is important in extremely preterm newborns.

A review article which evaluated more than 50 studies published worldwide, demonstrated an average rate of UE of 7.3% (range = 0.5% - 35.8%). (da Silva, et al, 2012) This high rate of unplanned extubation suggests that current stabilization techniques and devices are inadequate and therefore further research into developing better stabilization systems should be supported to achieve zero preventable deaths by 2020.

Optimal endotracheal tube stabilizers should:

- Be secure
- Be fast and easy to apply
- Provide easy access to the mouth for routine oral care
- Be repositionable and not exert any major pressure points to the skin or oral mucosa that would cause ischemic tissue injury

The stabilizer should prevent clinically significant movement (>1-2 cm) that could result in a UE. At a minimum, it should prevent any movement of the endotracheal tube relative to the stabilizer.

Standardizing taping methods or stabilizer use within an ICU has been associated with decreased UE rates (Galiote et al., 2019).
Use Waveform Capnography in ALL intubated patients to ensure rapid recognition of a mal-positioned tracheal tube.

This important technology has become the standard of care for intubated adults in the UK and parts of Europe. United States’ Intensive Care Units, Emergency Departments and Emergency Medical Services are beginning to adopt this technology, but significant gaps exist. Evolving technology is decreasing the limitations of its use in neonates (Hochwald et al., 2019) Continuous Waveform Capnography should become a safety practice for intubated patients where its use is practical and not encumbered by technological limitations. In its absence, colorimetric CO2 detection and continuous transcutaneous CO2 monitoring should be used for rapid assessment of ETT location in acute respiratory decompensation of intubated patients.

### Measuring outcomes

**Key performance indicators**
- UE in intubated patients
- Rate of UE for patients intubated via endotracheal tube

**Outcome measure formula**

**Numerator:** Number of incidents of UE in patients intubated via an endotracheal tube

**Denominator:** Number of intubated patient-days at the organization

*Rate of unplanned extubation is expressed in terms of: Number of unplanned extubation incidents per 100 intubation days (1 intubation day = any fraction of a calendar day during which a patient has been tracheally intubated)*

**Metric recommendations**

**Direct impact:** All patients intubated via endotracheal tube

**Lives spared harm:**

*Lives Spared Harm = Unplanned Extubation Rate\_baseline - Unplanned Extubation\_measurement\) X Days Intubated*\_baseline

* Days Intubated is the Outcome Measure Formula Denominator: (Total Number of Intubated Days)

**Data collection**

Use a tracking sheet for UEs. Data is best collected through electronic capture of data fields from electronic patient care reports. This requires having an EMR system that includes the following PSMF Core Data Set for UE:

- Does the patient have a history of a difficult airway?
- What method was used to identify the difficult airway patient?
- Was a pre-intubation assessment predictive of a difficult airway?
- Route of intubation (e.g., oral, nasal, or tracheostomy)
- What was the method of tube restraint? (e.g., tape, twill, commercial tube holder); if a
commercial tube holder, specify the type

- Date of extubation
- Time of extubation
- Extubation type and Reason for Extubation

<table>
<thead>
<tr>
<th>Extubation Classification Schema</th>
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<tbody>
<tr>
<td><strong>Reason for Extubation</strong></td>
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<tr>
<td>Normal Extubation; Part of normal weaning process:</td>
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<tr>
<td>Self Extubation:</td>
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<tr>
<td>Accidental Extubation:</td>
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<tr>
<td>Device Malfunction; Obstructed ETT or Deflated Balloon:</td>
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<tr>
<td>Possible Internal Dislodgement (unable to confirm due to No ETCO21):</td>
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</tbody>
</table>

- Location where the UE occurred (e.g., delivery suite, OR)
- Activities preceding extubation (e.g., agitation, ETT repositioning, turning, procedure, surfactant administration)
- Did UE occur while the patient was being transported or moved?
- Was the patient adequately restrained at the time of extubation?
- Was the patient adequately sedated at the time of extubation?
- Unit sedation policy type (continuous with daily interruptions, intermittent, no sedation)
- Was reintubation required?
- Was reintubation attempted (successful or unsuccessful)?
- Outcome/complications of UE (e.g., pneumonia, vocal cord injury, hypoxemia, CPR, brain injury, death)
- Did the UE occur during a sedation interruption or “sedation vacation”?
  - Was the respiratory therapist made aware of the sedation vacation?
  - Did appropriate communication to all members of the team (i.e. between nurse and respiratory therapist) occur related to the initiation of the sedation interruption or “sedation vacation”?
- Was the patient on spontaneous breathing trials?
  - If so, was there a delay in extubation due to a delay in the physician ordering the extubation?
- What team members were present when the UE occurred?
- Encourage the addition of an “other” field in the EMR to collect information to learn about new or specific trends identified by staff

This standardized core dataset should be incorporated (by legislative mandate if necessary) by
all major EHR companies to facilitate hospitals’ ability to track unplanned extubation:

• Many hospitals’ Electronic Health Records currently do not have the PSMF Core Data Set for UE and any information on incidents of UE is difficult to retrieve from narratives and notes. Any hospital whose EHR does include the PSMF Core Dataset should contact their EHR company and request adoption of the PSMF Core Dataset for UE.

• Rate of complications and mortality related to incidents of UE are important to determine the extent of adverse effects of UE:
  
  o Rate of pneumonia in intubated patients with an incident of UE compared to rate of pneumonia in intubated patients without an incident of unplanned extubation
  
  o Rate of severe brain injury in intubated patients with an incident of unplanned extubation compared to the rate of brain injury in intubated patients without an incident of UE
  
  o Mortality rate in intubated patients with an incident of UE compared to the rate of mortality in intubated patients without an incident of UE

_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 Patients’ (PfP) grant funded Hospital Improvement Innovation Networks (HIIN). The program targeted 10 hospital-acquired conditions to reduce medical harm and costs of care. “At the outset of the Partnership for Patients 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 (Agency for Healthcare Research and Quality, 2015). Adverse events related to UE was not included in the AHRQ National Scorecard document. 61% of patients experiencing UE do not require reintubation and those patients have a low mortality rate (5%) (Gao, et al., 2016). 39% of patients experiencing UE require reintubation and those patients have a high mortality rate (37%) (Gao, et al., 2016). The overall mortality rate for adult patients experiencing UE incidents is 28% (De Lassence et al., 2002) and accounts for over 33,000[PJ1] deaths annually, in the U.S. There are presently no estimates of mortality associated with UE in children and neonates, despite the existence of case reports.(Halle-Richards, 2018).

**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 APSSs recommend technologies offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on the available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.
Workgroup

Chairs
Arthur Kanowitz  
Airway Safety Movement,  
Society for Airway Management, Securisyn Medical
David Hughes  
Do It For Drew Foundation
Joaquim Pinheiro  
Albany Medical Center

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Paul Baker  
University of Auckland, New Zealand; AirwaySkills
Kris Bysani  
Medical City Children’s Hospital
Anna Cleobone Ruskin  
University of Chicago
Rhashedah Ekeoduru  
McGovern Medical School, University of Texas Health
John Fiadjoe  
Children’s Hospital of Philadelphia
Mitchell Goldstein  
Loma Linda University Children’s Hospital
Narasimhan Jagannathan  
Northwestern University
Sarah Kandil  
Yale New Haven Children’s Hospital
Ariana Longley  
Patient Safety Movement Foundation
Olivia Lounsbury  
Patient Safety Movement Foundation
Lalainya O’Connell  
Albany Medical Center
Chad Pezzano  
Albany Medical Center
Donna Prosse  
Patient Safety Movement Foundation
Patricia Roth  
UCSF Medical Center
Larry Roy  
Advocate Children’s Hospital, Chicago
Lamia Soghier  
Children’s National


Tripathi, S., Nunez, D. J., Katyal, C., & Ushay, H. M. (2015). Plan to Have No Unplanned: A Collaborative, Hospital-Based Quality-Improvement Project to Reduce the Rate of Unplanned Extubations in the Pediatric ICU. *Respir Care, 60*(8), 1105-1112. doi:respcare.03984 [pii];10.4187/respcare.03984 [doi]


Actionable Patient Safety Solutions (APSS) #9A:
Early detection & treatment of sepsis for high-income countries

How to use this guide
This guide gives actions and resources for creating and sustaining safer sepsis management in patients. In it, you’ll find:

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Executive summary checklist

Sepsis is a growing threat worldwide. At least 10-15% of sepsis deaths could be prevented through vaccination and hygienic measures, early detection and prompt treatment (World Sepsis Day Head Office, 2014)

Use this checklist to help you prioritize your actions and measure your organization’s progress in detecting and treating sepsis in high-income countries:

Create an action plan

- Create a team approach to implement a protocol for early sepsis identification and treatment, including representation from patients, family members, advocates, administrators, nurses, providers, pharmacists, healthcare informaticists, physical and rehabilitation therapists, respiratory therapists, emergency responders, and laboratory staff.
- Create a sepsis dashboard with process and outcome measures.

Put systems in place

- Implement a Sepsis Rapid Response Team or incorporate early detection of sepsis into your existing medical emergency teams (e.g. rapid response team) (Nguyen, et al., 2016)
- Formalize processes to screen and rescreen patients for signs of sepsis throughout the entire institution
  - On presentation, take a detailed past medical history of sepsis or other severe infectious processes
  - Know if patient was ever previously diagnosed or treated for sepsis.
- Use automated electronic screening and documentation of process of care, based on existing data (SIRS criteria, MEWS or any other warning system being used)
- Design a workflow specific to level of alert:
  - Screening: SIRS/Sepsis/severe sepsis/Septic shock workflow
  - Mortality prediction: qSOFA (or “Level of Risk”)
- Create a protocol for rapid assessment and intervention at the bedside and use sepsis bundles (3-hour elements) For a higher level of care, use septic shock bundle (6-hour elements)
- Create a standard approach for review of process/protocol adherence trends and issues

Engage staff and track data on your progress

- Use patient stories – in written and video formats – to identify gaps and inspire change in your team
- Implement onboarding and continuing education for staff and providers.
- Create a process to report sepsis performance of the organization to their team (awareness of sepsis dashboard results).
- Implement an effective monitoring and screening system to accomplish continuous monitoring and early detection, based on existing data (SIRS criteria, MEWS, or any other warning system being used)
- Utilize your EHR as a data collection tool and source for predicting risk of sepsis for patients – a system that provides a data collection tool and allows for continuous analysis
and surveillance will be most beneficial

☐ Create a process for continuous monitoring of electronic systems and protocols, including compliance, efficacy, and outcome measures
What we know about sepsis

According to The International Consensus Definitions for Sepsis and Septic Shock:

- **Sepsis** is a “life-threatening organ dysfunction due to a dysregulated host response to infection”

- **Septic shock** is a “subset of sepsis where underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality”

Clinical criteria for identifying this condition include:

- The need for vasopressors to maintain a MAP ≥ 65 mmHg
  
  *Source: An increase in lactate concentration > 2 mmol/L, despite adequate fluid resuscitation (Singer, Deutschman, & Seymour, 2016; Review of the Sepsis-3 Articles, 2016)*

Sepsis is a growing threat worldwide, and the most common cause of death in U.S. hospitals:

- CDC estimates that 1.7 million adults in the U.S. develop sepsis every year (Data & Reports, 2016)

- At least 10-15% of sepsis deaths could be prevented through vaccination and hygienic measures

- Severe sepsis is estimated to affect 27 to 30 million people worldwide and has a 28.6% mortality rate - it kills more people than stroke and pneumonia (GSA, 2019).

- As many as 87% of sepsis cases originate in the community (Rhee, 2017)

- Nationally, mortality rates for sepsis cases entering the hospital through the emergency department range from 20% to more than 50%

### The problems with delayed sepsis detection

Mortality from sepsis increases by as much as 8% for every hour that treatment is delayed. As many as 80% of sepsis deaths could be prevented with rapid diagnosis and treatment (Kumar, et al., 2006). A more recent study estimates a 4 percent increase in the odds of in-hospital mortality odds with each hour of antibiotic delay. (Seymour CW, Gesten F, Prescott HC, et al. N Engl J Med. 2017;376(23):2235-2244.)

### Preventing morbidity and mortality through early detection of sepsis

It has become increasingly apparent that there is a long delay in both the recognition of sepsis and the initiation of appropriate therapy in many patients. This translates into an increased incidence of progressive organ failure and a higher mortality. Healthcare providers, therefore, need to have a high index of suspicion for the presence of sepsis and must begin appropriate interventions quickly.

Early detection of sepsis, with the timely labs, blood cultures, administration of appropriate fluids and antibiotics, appear to be the most important factors in reducing morbidity and mortality from sepsis.

Hospitals and healthcare institutions need to do all that is practicable to eliminate hospital-acquired infections.

### The evidence for early detection of sepsis

Multiple instruments have been developed to screen for sepsis (Kumar et al., 2006; Ferrer et al.,...
The Evaluation for Severe Sepsis Screening Tool, developed by the Surviving Sepsis Campaign and the Institute for Healthcare Improvement, consists of several components (Surviving Sepsis Campaign, 2012):

- A suspected or confirmed infection: checklist of common sites of infection
- Signs/symptoms of SIRS: temperature >38.3°C or <36°C, heart rate >90 beats/min, respiratory rate >20 breaths/min, acutely altered mental status, white blood cell count >12,000 μL (or 12 K/μL) or <4000 μL (or 4 K/μL)
- Signs of organ dysfunction/tissue hypoperfusion: systolic blood pressure <90 mmHg or decrease >40 mmHg from baseline, mean arterial pressure <70 mmHg, pulmonary infiltrates with increasing oxygen requirements to maintain SpO2 >90%, creatinine >2.0 mg/dL, bilirubin >2 mg/dL, platelet count <100,000/μL (or 100 K/μL), coagulopathy, or lactate >2 mmol/L
- Decrease in urine output and skin changes (mottling) or prolonged capillary-refill time

A team approach is essential to develop a protocol for sepsis identification and treatment in the patient care unit/department/hospital. Early detection of sepsis predicates early care interventions that impact patient outcomes. Compliance with early goal directed bundle of care elements is associated with lower mortality rates in patients with sepsis (Rhodes, et al., 2015). Three more recent large trials evaluating the early goal directed bundle of care elements all reported low mortality rates (Nguyen, et al., 2016). Successful quality improvement implementation requires participation by frontline clinicians, leadership and the interdisciplinary team’s key stakeholders.

**Important considerations**

A patient may present to the health care provider or emergency room with vital signs in a normal range, it is still important to fully assess the patient. Vital signs may be in normal range, but may not be normal for that patient if they are on other medications that can artificially lower BP, HR, etc that can look like normal values. The provider should be looking for a possible source of infection: cough, painful urination, reddened, warm to touch rash or skin irritation. A medication history along with asking the patient how they are feeling can open the door to the provider to begin to make a differential diagnosis. An important juncture for patient family teaching is at any transition of care point: transfer to inpatient setting or discharge home. The patient and family need to know that any change in clinical symptoms including but not limited to: fever (hypothermia and hyperthermia), chills, confusion, weak and general malaise they should be instructed to contact their healthcare provider immediately or return to the emergency room. In a matter of hours a patient’s condition can decline or become critical even after screening negative for sepsis and being discharged.

All surgical patients and departments regardless of the type of surgery need to know the signs and symptoms of infection and sepsis. Patients who have had urinary catheters, intra-venous line, endotracheal tube (breathing tube) are also at risk for sepsis.

**Leadership plan**

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce sepsis. To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions:
Show leadership’s commitment to a plan for early sepsis detection

- Evaluate their current performance regarding early sepsis detection and appropriate management in their healthcare system - use a questionnaire to gauge their level of readiness for a Sepsis Early Detection & Treatment Program (Appendix A)
- Create a plan based on the fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action (NQF, 2010)
- Hospital governance, senior administrative leadership, and clinical/safety leadership must create a comprehensive approach to address their performance gap (from strategy to evaluation), including:
  - Collect baseline process and outcome data
  - Create measurable quality indicators and a timeline - “Some is not a number. Soon is not a time.”
- Clinical/safety leadership should endorse the plan and drive implementation across all providers and systems

Create the infrastructure needed to make changes

- Governance boards and senior administrative leaders should approve specific budget allocations for the plan
- Train a Sepsis Coordinator to implement and evaluate the sepsis program for the multidisciplinary team throughout the facility
- Train prehospital and hospital personnel - use and evaluate prehospital and hospital care protocols
- Use patient stories - in written and video form - to identify gaps and inspire change in your board and staff. Stories from your own organization are particularly powerful. Other examples of free stories that can be used are listed below:
  - Gabby Galbo: http://patient.sm/XXlliC/
  - Kate Hallisy: http://patient.sm/aRat0K
  - Nile Moss: http://patient.sm/o6rlNW
  - Joshua Nahum’s story: http://patient.sm/wF5I1W
  - Rory Staunton: http://patient.sm/Tbqo5S
  - Sepsis Alliance Faces of Sepsis Video: http://patient.sm/vn5Zkk

Action plan

Create an automated surveillance system

- Use an effective electronic surveillance system to improve early recognition of septic patients based on monitoring of the following data:
  - SIRS criteria
    - Temperature > 38.3 C or < 36 C
    - HR > 90/min or greater than 2 SD above normal for age
    - RR > 20 breaths/min
    - WBC ( < 4,000 or > 12,000 or > 10% bands)
    - Glucose > 140 mg/dL or 7.7 mmol/L in the absence of diabetes
  - Markers of organ dysfunction
• Tissue perfusion: lactate > 2 mmol/L
• Cardiovascular: SBP < 90 mmHg or MAP < 70 mmHg or decrease in SBP > 40 mmHg
• Hepatic: Tbili > 2 mg/dL, INR > 1.5
• Renal: Cr increase > 0.5 mg/dL or 44.2 umol/dL from baseline or urine output < 0.5 mL/kg/hr for at least 2 hours despite adequate fluid resuscitation
• Pulmonary: PaO2 < 60 mmHg or SpO2 < 90 % or PF ratio < 200
• Coagulation: Platelets < 100,000 uL-1 or aPTT > 60 sec
  o Other
  • Plasma C reactive protein > 2 SD above normal
  • Plasma procalcitonin > 2 SD above normal

**Create protocol for screening**

- Formally assess opportunities to identify sepsis and to improve outcomes for those patients that acquire and are at risk for sepsis *(Figure 1)*
  - Implement strategies that will identify an early sepsis warning
  - Implement systematic protocols for early identification and time-sensitive evidence-based treatment of sepsis *(Rhodes et al., 2015)*
- Formalize a process to screen patients for signs of sepsis throughout the entire institution
- Implement a sepsis response team or incorporate early detection of sepsis into existing medical emergency teams (e.g. rapid response teams)
  - Identify the opportunities for implementation of a sepsis response team and protocol for initiating a sepsis response call for patients who have been identified as potentially septic
- Screen the workflow specific to the type and level of alert:
  - 2 SIRS criteria met:
    - Temperature >38.3°C or <36°C
    - Heart rate >90 beats/min
    - Respiratory rate >20 breaths/min
    - White blood cell count >12,000 μL (or 12 K/μL) or <4000 μL (or 4 K/μL)
  - OR
    - Clinically assess organ dysfunction: altered mental status, respiratory failure (dyspnea, elevated respiratory rate, desaturation), hypotension (systolic blood pressure <90 mmHg or decrease >40 mmHg from baseline, mean arterial pressure <70 mmHg)
    - Assess for infection, if patient has a source of infection
- Start sepsis protocol and assess if patient has other organ dysfunctions (laboratory dependent):
  - Lactate >2 mmol/L
  - Decrease in urine output or acutely increased creatinine
  - Bilirubin >2 mg/dL
  - Platelet count <100,000/μL (or 100 K/μL) or coagulopathy
• If organ dysfunction is present (i.e. severe sepsis), start sepsis bundle (or septic shock bundle) as per the Treatment Section below
• If qSOFA is positive (2 of the following - altered mental status (Glasgow coma scale < 15), respiratory rate ≥ 22/min, systolic blood pressure ≤ 100 mmHg) then increase monitoring and assess for ICU admission (qSOFA, n.d.)

Create protocols for communication
• Use standardized protocols for patient/family engagement/communication, including:
  o Coordinate with family or caregiver to reduce sepsis risk factors and identify clinical indicators at first sign
  o Disclose all sepsis related events
  o Provide an explanation as to why and how the sepsis occurred
  o Explain how the effects of sepsis will be minimized
  o Discuss/state steps that the caregiver or organization will take to prevent recurrences of sepsis

Use treatment and intervention best practices
• Adhere to the Surviving Sepsis Campaign practices
• Formalize workflows for clinicians to adhere to after a patient sepsis alert has been noted:
  o For sepsis, implement workflow for rapid assessment and intervention at the bedside and initiate sepsis bundle (3 hour elements). Even though CMS calls this the 3 hour bundle it is important to get these items completed as quickly as possible.
  o Obtain blood cultures prior to administration of antibiotics
  o Administer broad spectrum antibiotics
  o Administer 30 mL/kg crystalloid for hypotension or lactate ≥4 mmol/L
  o Remeasure lactate if initial lactate was elevated
• For septic shock, implement workflow for rapid assessment, intervention, and need for higher level of care and initiate septic shock bundle (6 hour elements):
  o Apply vasopressors (for hypotension that does not respond to initial fluid
resuscitation to maintain a mean arterial pressure (MAP) ≥65 mmHg)

- In the event of persistent hypotension despite volume resuscitation (septic shock) or initial lactate ≥4 mmol/L (36 mg/dL), re-assess volume status and tissue perfusion and document findings:
  - Either:
    - Repeat focused exam (after initial fluid resuscitation) by licensed independent practitioner can including vital signs, cardiopulmonary, capillary refill, pulse and skin findings. Or document sepsis reassessment completed.
  - Or 1 of the following:
    - Measure CVP
    - Measure ScvO2
    - Bedside cardiovascular ultrasound
    - Dynamic assessment of fluid responsiveness with passive leg raise or fluid challenge
  - Consider remeasuring lactate level regardless of initial lactate level

**Monitor for Post Sepsis Syndrome**

Post Sepsis Syndrome (PSS) affects up to 50% of sepsis survivors, leaving them with physical and/or long terms effects after a sepsis hospitalization (Prescott & Angus, 2018). These effects include insomnia, nightmares, vivid hallucinations and panic attacks, disabling muscle and joint pains, extreme fatigue, poor concentration, decreased cognitive functioning, and loss of self-esteem.

Almost 60% of sepsis survivors experience worsened cognitive and/or physical function. Older sepsis patients experience on average 1 to 2 new limitations on activities of daily living, such as bathing, dressing, or managing money, after hospitalization. In addition, one-sixth of sepsis survivors experience difficulties with memory, concentration, and decision making. Many sepsis survivors also report symptoms of post-traumatic stress disorder.

Sepsis survivors are also at increased risk for rehospitalization. About one-third of all patients have another hospitalization within three months of the initial sepsis, most commonly due to a repeat episode of sepsis or another infection. The higher risk of infection following sepsis results from suppression of the immune system in the first few weeks and months following the initial bout of sepsis. In addition to infection, other common causes of rehospitalization after sepsis are heart failure, kidney failure, and pulmonary aspiration.

Informing sepsis survivors of their increased risk of hospital readmission and the potential for post-sepsis effects can improve outcomes. Patients can be alerted to the be watchful of the onset of new infection and recurrent sepsis. They can also take steps towards rehabilitative treatments in the form of physical and occupational therapies that may improve recovery from sepsis.

**Offer sepsis resources to the public**

Innovative ways to engage patients and families as safety partners are critical to improve sepsis awareness and ultimately improve outcomes. Health care advocates have long supported patient education and engagement as a means to reduce the incidence of all medical events, including sepsis. A significant struggle is the public’s lack of awareness of the existence and the prevalence and seriousness of sepsis, which hinders their ability to recognize and report early signs of the disease. Thirty-five percent (35%) of U.S. adults have NEVER heard of sepsis (Sepsis Alliance, 2019).
Information, resources and support need to be provided to the community to help know the symptoms of sepsis and that it is a medical emergency. Helping the public develop basic skills and confidence and providing them with appropriate support both during and after a sepsis diagnosis is the key to reducing injuries and deaths from sepsis. Sepsis survivors and their loved ones need assistance to cope during the immediate recovery period and to know what to expect during the often times protracted post-sepsis healing process. Resources to share with the public include:

- **Sepsis Alliance** resources:
  - Sepsis 911 Education Toolkit to raise sepsis awareness in your community: [http://patient.sm/TzrdPp](http://patient.sm/TzrdPp)
  - Resources for those diagnosed with sepsis: [http://patient.sm/f153Mg](http://patient.sm/f153Mg)
  - If a loved one has sepsis: [http://patient.sm/1qrNZu](http://patient.sm/1qrNZu)
  - Life after sepsis: [http://patient.sm/1qrNZu](http://patient.sm/1qrNZu)
  - Sepsis Information Guides: [http://patient.sm/QOs9fh](http://patient.sm/QOs9fh)
  - Share your story on Faces of Sepsis: [http://patient.sm/MORel9](http://patient.sm/MORel9)


- Sepsis resources from the **Centers for Disease Control and Prevention (CDC)**: [http://www.cdc.gov/sepsis/basic](http://www.cdc.gov/sepsis/basic)


**Other useful resources for your organization**

- **Sepsis Alliance** resources
  - Video for Emergency Medical Service (EMS) personnel to learn to rapidly identify and treat sepsis in the field as well as how to effectively coordinate with the emergency department and in-hospital team: [http://patient.sm/yvmbvU](http://patient.sm/yvmbvU)
  - Sepsis Coordinator Network: [http://patient.sm/AviFPK](http://patient.sm/AviFPK)
  - Sepsis: Across the Continuum of Care webinars for healthcare professionals: [http://patient.sm/For2zb](http://patient.sm/For2zb)
  - Sepsis 911 Education Toolkit to raise sepsis awareness in your community: [http://patient.sm/1arOcY](http://patient.sm/1arOcY)
  - Life after sepsis: [http://patient.sm/dXDFGC](http://patient.sm/dXDFGC)
  - Posters and infographics: [http://patient.sm/WBKkrO](http://patient.sm/WBKkrO)
  - The Sepsis Institute - continuing education on sepsis for healthcare providers: [http://patient.sm/UrfHcY](http://patient.sm/UrfHcY)

- Sepsis resources from the CDC: [http://patient.sm/KGTfcS](http://patient.sm/KGTfcS)

- **Center for Medicare and Medicaid Services (CMS)** Webinar: SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.3a Measure Updates [http://patient.sm/oclDrQ](http://patient.sm/oclDrQ)

- **Surviving Sepsis Campaign**: [http://patient.sm/nzBJdH](http://patient.sm/nzBJdH)
## Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: [http://patient.sm/zW1G7p](http://patient.sm/zW1G7p)

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Available technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic Health Record (EHR)</td>
<td>• An algorithm-driven biomarker using basic patient chart information routinely available in the EHR. This algorithm allows adaptation to site-specific data by training the model with baseline data from the proposed implementation center. Across two recent studies, the algorithm score had a sensitivity and a specificity of 0.83 and 0.96, respectively, for sepsis. These results show promise for the early detection of sepsis in adult and pediatric patients (Mao et al., 2017).</td>
</tr>
<tr>
<td>Continuous pulse oximetry</td>
<td>• Adhesive pulse oximetry sensor connected with pulse oximetry technology proven to accurately measure through motion and low perfusion to avoid false alarms and detect true physiologic events, with added importance in care areas without minimal direct surveillance of patients</td>
</tr>
<tr>
<td>Real-time PCR (polymerase chain reaction)</td>
<td>• Multiplex target-specific real-time PCR/in situ hybridization/melt analysis to identify 25 of the most sepsis relevant pathogens using a 1.5-ml whole-blood sample within 6 h. Reported sensitivity of between 3 and 100 CFU per ml. Reported summary sensitivity and specificity of 68% and 86% (Sinha et al., 2018).</td>
</tr>
</tbody>
</table>
### Integrated digital PCR/HRM (high-resolution melt) technology

- A rapid, broad-based microbial identification technology requiring blood samples of less than 1 ml. It can currently detect 37 bacterial pathogens with single-organism and single-genome sensitivity as well as resolve polymicrobial infections in <4 h. U-dHRM integrates universal digital PCR (dPCR) with high-resolution melt (HRM) analysis on a microfluidic chip to enable probe-free differentiation and quantification of bacteria within a sample. The speed and simplicity of U-dHRM along with its integrated technology platform suggest a promising first-pass screening method for neonatal sepsis. This technology also shows the potential to deliver at- or near-point-of-care diagnosis.

### Artificial Intelligence Methods

- The use of Artificial Intelligence (AI) to provide early identification of patients at high risk has shown great promise. The AI system continuously examines all data in the EMR to find combinations and trends indicating early signs or increased risk. Systems are in clinical use in both the US and Australia, with promising early results.

## Measuring outcomes

### Key performance indicators:
Life threatening organ dysfunction caused by a dysregulated host response to infection.

### Sepsis Mortality Rate
Rate of mortality for severe sepsis and/or septic shock patients per 1000 patients with severe sepsis and/or septic shock.

### Outcome measure formula:

**Numerator:**
Number of inpatient mortalities for patients with severe sepsis and/or septic shock

**Denominator:**
Total number of patients with severe sepsis and/or septic shock diagnosis codes that are admitted to the intensive care unit from the emergency department or from an acute floor setting

- *Rate is usually displayed as: Mortalities/1,000 Patients
Metric recommendations:

Direct impact:
All patients with severe sepsis and/or septic shock

Lives spared harm:
Lives Spared Harm = Mortality Rate\textsubscript{baseline} – Mortality Rate\textsubscript{measurement}) X Patients\textsubscript{baseline}

*Patients\textsubscript{baseline}: the total number of patients that are counted with the diagnosis of severe sepsis and/or septic shock

Notes
Patients with severe sepsis or septic shock are determined by the following diagnosis codes:
- ICD-9
  - 995.92 (Severe Sepsis)
  - 785.52 (Septic Shock)
- ICD-10
  - R65.20 (Severe sepsis without septic shock)
  - R65.21 (Severe sepsis with septic shock)

Additionally, patients must be admitted to the intensive care unit from the emergency department or from an acute floor setting. If feasible, manual review of diagnosis codes is desirable due to the complex nature of sepsis.

If manual review is feasible, consideration may be given to include an ICD-9/ICD-10 diagnosis code: 995.91 (Sepsis)/A41.9 (Sepsis, unspecified organism) with an additional diagnosis for acute organ failure.

Data collection
Data may be pulled from electronic billing data with the above diagnosis codes. Additionally, data may be collected exclusively through manual chart review, or a hybrid method of chart review and electronic billing data.

Limitations
Sepsis mortality rates are derived by healthcare organizations differently. We recommend risk adjusting the outcome measure, in this case mortality, and consider exclusion criteria such as: DNR status, comfort care as goal of care established.

Settings
Intensive care units, emergency department, and acute floor 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 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” (AHRQ, 2015).

**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 APSSs recommend technologies offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

**Workgroup**

**Co-Chairs**

Tony Galbo  
Patient Advocate  
Charles Murphy  
Inova Health System

**Members**

This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Lisa Anderson  
Sepsis Alliance  
Mark Ansermino  
BC Children’s Hospital  
Ryan Arnold  
Christiana Care Health System  
Steven J. Barker  
Masimo; Patient Safety Movement Foundation  
Michel Bennett  
Patient Safety Movement Foundation (formerly)  
Jean-Daniel Chiche  
Assistance Publique – Hôpitaux de Paris  
Trish Cruz  
Advocate  
Janet Diaz  
World Health Organization  
Jeff Dunn  
Redivus Health  
Christopher Fee  
University of California, San Francisco Medical Center  
Julia Hallisy  
Empowered Patient Coalition  
Cindy Hou  
Jefferson Health New Jersey  
Kori Jew  
Medtronic  
Tex Kissoon  
BC Children’s Hospital  
Sarah Knowles  
University Hospitals Geauga Medical Center  
Marianne Kraemer  
Jefferson Health  
Ariana Longley  
Patient Safety Movement Foundation  
Jacob Lopez  
Patient Safety Movement Foundation (formerly)  
Olivia Lounsbury  
Patient Safety Movement Foundation
Flavia Machado  
Federal University of São Paulo

Imrana Malik  
MD Anderson Cancer Center

Sayane Marlla  
Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo

Sara McMannus  
Clinical Consultant, Advisory Board member Sepsis Alliance

Carole Moss  
MSN

Joshua Muthuiru  
Machakos Hospital

Armando Nahum  
Safe Care Campaign

Emmanuel Nsutebu  
Royal Liverpool and Broadgreen University Hospitals NHS Trust

Donna Prosser  
Patient Safety Movement Foundation

Claire Roy  
Patient Safety Movement Foundation

Sharon Ruiz  
LCMC Health

Sundary Sankaran  
Kaiser Permanente

Hildy Schell-Chaple  
University of California, San Francisco

Robin Shannon  
T-Systems

Ciaran Staunton  
Rory Staunton Foundation

Jennifer Tatro  
UC Health

Brian White  
Advocate

Metrics Integrity: Robin Betts  
Kaiser Permanente, Northern California Region

References


Appendix A: Sepsis early detection and treatment program questionnaire

Organization query
1. Demographics: hospital bed count; type: community, academic; Electronic Health Record vendor
2. Are there dedicated resources for a Sepsis Program/Sepsis as quality measure?
   a. Does your hospital have a defined sepsis program? Y/N
   b. Is there dedicated staff to lead the sepsis program? Y/N
   c. What department is the program housed within? Quality, Nursing, Central hospital administration, others?
3. Is there ongoing formal sepsis education offered for
   a. Nurses
   b. Physicians, NPs/PAs
   c. Allied health team members (Pharmacists, Rehab Therapists, Respiratory Therapists, et al.)

Sepsis screening and surveillance
1. Does your hospital have a standardized surveillance or routine screening process for early detection of sepsis, severe sepsis, and/or septic shock? Y/N/NA If yes, see below:
   a. Locations that have standardized surveillance: ED, urgent care, acute care, transitional care, ICU, other
   b. Is there an automated continuous surveillance of data in electronic health record? Y/N
      i. Who receives alerts? -RN, MD, Pharmacy, Rapid response clinicians others, all
      ii. What action does the alert prompt/activate? -Notification instructions, bringing clinicians to see patient, orders for care diagnostics or interventions, other
   c. Is there intermittent routine screening by clinicians/nurses using a standardized process e.g. sepsis checklist, section of assessment flow-sheet, etc.? 
      i. What is the frequency of intermittent screening? Every 8 hrs, 12 hrs, 24 hrs, and/or PRN change in patient condition
      ii. What action does the intermittent screening result prompt/activate? Notification instructions, bringing clinicians to see patient, orders for care diagnostics or interventions, other
2. Does your Emergency Department have an active surveillance or routine screening process for early detection of sepsis, severe sepsis, septic shock? Y/N/NA
   a. If yes, is it electronic-based? Y/N
3. Does your Urgent Care Department have an active surveillance or routine screening process for early detection of sepsis, severe sepsis, septic shock? Y/N/NA
   a. If yes, is it electronic-based? Y/N

Sepsis management
1. Does your hospital have a standardized sepsis care bundle as part of a protocol, policy, order set? Yes/No/NA
a. If Yes, see below:

i. Which of the following are included in your sepsis care bundle?

1. Obtain lactate level
2. Obtain blood cultures/other cultures (urine, CSF, wound, etc.) before antimicrobial agent administration
3. Administer broad-spectrum antimicrobial agents within 1 hour of time of presentation (for inpatients) or within 3 hours of time of presentation (for ED patients)
4. Administer IV fluid challenge for hypotension or lactate ≥ 4 mmol/L
5. Administer vasopressor medications to maintain MAP ≥ 65 mmHg after IV fluid challenge and within 6 hours of time of presentation
6. Obtain a follow up lactate level if initial lactate was elevated (>2), to evaluate resuscitation interventions (Target is normalization of lactate level)
7. If persistent hypotension, after 1-hour from completion of the 30 mL/kg IV fluid challenge resuscitation or lactate ≥ 4 mmol/L, measure CVP and/or Scv02 levels (Target is CVP 8-12 mmHg, Scv02 of ≥70% -these targets are being debated based on recent trial results -ARISE, PROCESS, PROMISE)

Measurement

What are the metrics used? What are the measurement procedures (manual, automated reports, etc.)? Where are measurement data reported to?

1. Screening compliance, screening tool accuracy (sensitivity/specificity)
2. Sepsis care/management bundle compliance
   a. CMS National Hospital Inpatient Quality Measure
   b. Reporting based on hospital discharges October 2015
3. Outcomes
   a. Sepsis-associated mortality (hospital)

Person and family engagement

1. Are materials or resources (website, classes, pamphlets, videos, etc.) available for patients and families regarding:
   a. Sepsis – what it is, risks, prevention, early detection, management, possible trajectory (ICU, post-ICU), outcomes -post-hospital resources
      i. How you, as the patient or family member, can participate in prevention and early detection
   b. The hospital’s sepsis program -what, when, who, etc.? e.g. screening, code sepsis, etc.
   c. For hospitals without a sepsis program – Do you have a rapid response team or a Condition H program?
   d. Is your rapid response or Condition H also patient-activated?
   e. How are patients and families alerted and oriented to the rapid response system?
   f. Which provider or department is the contact point if the patient or family suspects infection or sepsis after discharge?
Post sepsis syndrome resources
Sepsis Alliance Post-Sepsis Syndrome Page - information about post sepsis syndrome for patients and families, including a downloadable letter to healthcare professionals and others (teachers, coaches) to explain the syndrome. https://www.sepsis.org/sepsis-basics/post-sepsis-syndrome/
The UK Sepsis Trust https://sepsistrust.org/get-support/support-for-survivors/post-sepsis-syndrome/
JAMA Patient Page on Postsepsis Morbidity https://jamanetwork.com/journals/jama/fullarticle/2667724
Actionable Patient Safety Solutions (APSS) #9B:
Early detection & treatment of sepsis for low- to middle-income countries (LMICs)

How to use this guide
This guide gives actions and resources for creating and sustaining safer sepsis management in patients. In it, you’ll find:

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APSS #9B: Early detection & treatment of sepsis

Executive summary checklist

Sepsis is a growing threat worldwide. At least 10-15% of sepsis deaths could be prevented through vaccination, hygienic measures, early detection, and prompt treatment measures.

Use this checklist to help you prioritize your actions and measure your organization’s progress in detecting and treating sepsis in low- and middle-income countries (LMICs):

Choose a team and strategy

☐ Create a team of key stakeholders, including nursing, physician, and administration leadership, and choose a team leader
☐ Create a clear vision of your goals and when you intend to achieve them
☐ Be systematic in your approach to quality improvement (QI) - for example, consider using the Plan-Do-Study-Act (PDSA) cycle of change described later in this APSS

Put systems in place and track data on your progress

☐ Create systems to help detect sepsis early:
  ☐ Improve recording of vital signs such as blood pressure, heart rate, respiratory rate, and temperature
  ☐ Use early warning scores to identify severely ill patients, including patients with sepsis
  ☐ Detect sepsis early through measures such as screening and response throughout the hospital or in specific areas
☐ Adapt existing sepsis bundles and systems to fit your needs:
  ☐ The Society of Critical Care Medicine’s Surviving Sepsis Campaign (SSC) has bundles for recognizing and treating sepsis, which you can customize for your various clinical settings
  ☐ For sepsis, implement processes for rapid assessment and care at the bedside and use the sepsis bundle (SSC 3-hour element)
  ☐ For a higher level of care, such as for septic shock (dangerously low blood pressure caused by sepsis), use the septic shock bundle (SSC 6-hour elements)
☐ If you can acquire electronic systems, implement an automated system for electronic screening and documentation of the process of care based on existing data. This may involve using SIRS criteria, MEWS, qSOFA, or any other warning system being used.
☐ Implement a process for continuous monitoring of electronic systems and protocols:
  ☐ Track of compliance, efficacy, and outcome measures on a monthly or quarterly basis
  ☐ Design a workflow specific to level of alert
  ☐ For screening, use SIRS/Sepsis/Septic shock workflow
  ☐ For mortality prediction, use Early Warning Score, such as Universal Vital Assessment, MEWS, or qSOFA (or “Level of Risk”)
☐ Implement case reviews when cases are not managed well or when outcomes are poor, such as patient death, intensive care admission, or longer stay in the hospital, and learn from them
☐ Use patient stories – in written and video formats – to identify gaps and inspire change in your staff
What we know about sepsis detection and treatment for LMICs

In May 2017, the World Health Assembly passed a resolution to improve sepsis care. Sepsis is now recognized as a global priority with a significant public health impact. However, huge variation exists between high-income countries (HICs) and low- and middle-income countries (LMICs) and their programmatic approaches to improving sepsis care.

What is sepsis?
In simple terms, patients with sepsis are patients who are seriously ill with infection and likely to die or be admitted to the intensive care setting as a result. Sepsis:
- Can result from severe infections with bacteria, viruses, fungi, or parasites. It arises when the body's response to infection injures its own tissues and organs.
- Can lead to septic shock, multiple organ failure, and death, if not recognized early and managed promptly
- Is a major cause of morbidity and mortality in all populations living in LMICs. Pregnant women, neonates (newborns), and young children are among the most vulnerable.

A person can develop sepsis:
- In the community, such as from community-acquired pneumonia and from dangerous, emerging infectious diseases, such as viral hemorrhagic fevers
- In the hospital, such as from nosocomial infection

What is the burden of sepsis?
The burden of sepsis is considerable. An estimated 30 million cases of sepsis happen around the globe every year.

Sepsis is the leading cause of preventable death worldwide, with at least 1 million preventable deaths happening yearly. It is also the:
- 2nd leading cause of death overall: 6-8 million deaths yearly
- 3rd leading cause of maternal mortality: 11% of maternal deaths yearly
- Leading cause of infant mortality, including pneumonia, malaria, and diarrheal illnesses: 90% of infant deaths yearly

Worldwide, 1 in 10 patients gets a healthcare associated infection during their hospital stay. And current data, though limited, suggests the problem is worse in LMICs than in HICs. People in LMICs are estimated to have:
- A higher rate of sepsis due to higher rates of infectious diseases
- Higher rates of morbidity and mortality due to limitations in structural, organizational, and human resources

Knowledge about sepsis management is largely based on clinical trials, research, and improvement efforts from resource-rich countries. There are many ongoing efforts to adapt international guidance (such as the Surviving Sepsis Campaign 2016) to settings with limited resources, and to study management interventions in LMICs.

Is sepsis a medical emergency?
Yes, sepsis is a medical emergency. Once medical staff recognize that a patient has sepsis, the clock starts to tick. It is well proven that early detection and appropriate treatment saves lives.
In general, high quality sepsis care includes:
- Early recognition and triage
- Fast action to prevent and control infection
- Early administration of appropriate antimicrobial therapy
- Early start of safe, live-saving supportive care, including monitoring
- Systematic monitoring and reporting of performance indicators to ensure staff is delivering quality care

Why is sepsis care important to your organization?
Improving sepsis care is an integral part of strengthening healthcare systems. A programmatic approach to sepsis improvement will help to:
- Reduce patient deaths in your hospital
- Strengthen your health care system, services, and reputation
- Improve management and outcomes for severely ill patients in your hospital
- Save money and provide cost-efficient care
- Improve staff skills and satisfaction
- Improve infection prevention/control and reduce healthcare associated infections
- Reach and sustain safer sepsis care

Leadership plan
Use a quality improvement (QI) approach to improve sepsis care in your hospital. Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce preventable sepsis events.

To achieve a goal of zero preventable deaths, leaders need to take these key actions:

Show leadership’s commitment by creating a Sepsis Care Team:
- Choose a team leader who is well respected, a content expert, a good listener, and an enthusiastic champion of the cause
- Create a team that will lead a formal organization-wide QI program. The team should consist of key stakeholders, meaning people who represent the various involved groups or people whose support is needed to make sustained improvements.
- Team members may include:
  - Clinicians, such as doctors (emergency physicians, intensivists, surgeons, infectious disease specialists, obstetricians, pediatricians, primary care providers)
  - Nursing Leadership
  - Other health care workers such as nurses, mid-level providers (physician assistants, nurse practitioners), infection prevention specialists, laboratory specialists, microbiologists, pharmacists, physical therapists, and dieticians
  - Non-clinicians, such as audit clerks, information technicians, waste management workers, security officers, and database managers
  - Administrators and managers, including those responsible for budgets and purchasing of equipment and supplies for the hospital
  - Lay people, such as family members and former patients (sepsis survivors)
**Action plan**

**Assess your organization’s current sepsis care**

**Get help and feedback from frontline clinical staff**
Consult clinical staff, especially senior clinicians who are at the frontline of care, to help understand the current processes for sepsis care. They can help the Sepsis Care Team identify challenges and contributing factors for inadequate sepsis care.

For example:
- Staff may not understand what sepsis is and how to recognize and treat sepsis
- Staff may not be supported to identify patients with sepsis because of their workload, or by a lack of medicine, equipment, or senior clinician supervision
- Staff may not know that early interventions could save their patient’s life
- Patient families may need education on sepsis basics and contact precautions

**Use tools to evaluate the current workflow**
Use standardized tools such as process mapping, fishbone diagrams, and driver diagrams to dissect the sepsis care work flow in a systematic way (Figure 1).

---

**Figure 1:** Driver diagram for sepsis (courtesy of The Royal Liverpool and Broadgreen University Hospitals NHS Trust (RLBUHTs))
There are many opportunities for improvement in the daily workflow of the primary health center, emergency departments, hospital wards, and ICU.

For example:

- At the pre-hospital setting (primary health center, ambulance services), a patient with sepsis must be recognized early, treated promptly if they have emergency signs, and then transported safely to a hospital.
- At the hospital setting, patients with sepsis may present to the emergency department or may develop sepsis during their hospital stay.

The Sepsis Care Team should determine where to begin the improvement efforts, and how and when to continue them in other areas.

**Create and share your vision of quality sepsis care**

Once the Sepsis Care Team understands the current workflow and has identified areas for improvement, they must decide where to focus their initial efforts. To do this, the team:

- Must have a clear vision about what to improve first - it should be simple, easily understood, and inspiring to all staff (Figure 2).
  
  For example: If you want to focus in the Emergency Department (ED) first, then the vision could be “Improve the recognition of patients with sepsis and initial treatment in the ED”.

- Should ensure that all stakeholders, especially clinicians, are excited about the vision and are involved at this stage so they will support improvement efforts.

![Figure 2: Sepsis Strategy (courtesy of The Royal Liverpool and Broadgreen University Hospitals NHS Trust (RLBUHTs))](image-url)
Be systematic in your QI approach
Use QI methods to make sustained changes that improve care. Changes in healthcare do not happen overnight. Making changes that are significant and sustainable requires more than just educating staff; you must also change the culture and systems of care.

Hospital leadership and the Sepsis Care Team should:
- Set expectations at the start about the process of change and how it will be monitored
- Let staff know that real change will take time and encourage their support and efforts - because small tests of change over time can have great, sustained impact

Example of a proven, systematic QI method
The Plan-Do-Study-Act (PDSA) cycle of change is a well-established method to create sustainable change in healthcare settings. There are 4 phases:

1. Planning phase - develop a plan to test a change
2. Doing phase - carry out the test
3. Study phase - observe and learn from the consequences
4. Acting phase - determine what modifications you should make to the test

Phase 1: Planning
Sample questions for the Planning phase:

What intervention or change do we want to test first?
The team will have many ideas about improvements but must decide what to do first:
- Select an intervention that is most likely to have an impact
- Usually, implement 1 change at a time and keep it simple, practical, and focused
  For example: Develop a screening protocol for sepsis, or implement a sepsis treatment bundle/pathway (see Appendix A)
- Use international guidelines and learn from experiences of others when choosing an intervention

Most interventions do not require many extra resources. However, leadership must be ready to provide resources if needed, such as extra staffing or funding to make broad-spectrum antibiotics or intravenous fluids readily available in the ED.

How will we know we are improving?
Before you make a change, consider how you will measure and study the results of the change. This step is often forgotten and is arguably the most important, because without measuring you will not know if you have made an impact.

- Make a plan for collecting data:
  - If your clinicians use an electronic health record (EHR), use it to collect data
  - If they don’t use an EHR, use clinical data already collected in patient information systems - however, try not to give extra work to staff if they are already overextended
- Set improvement goals that are specific, measurable, achievable, reliable, and time-bound (SMART)
  For example:
  - Over the next 2 weeks, increase the percentage of patients arriving to the ED who are screened for sepsis from 20% to 60%
  - Over the next month, increase the percentage of patients with sepsis who receive intravenous antibiotics in the ED within 1 hour from 20% to 60%
• If possible, measure patient outcomes - however, it may be difficult to collect some of this data

For example: Measure the percentage of patients with sepsis who die within 30 days of admission to hospital. You may have to use proxies for sepsis such as pneumonia if sepsis is not routinely coded because pneumonia is often the most common cause of sepsis (Figures 3 and 4).

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
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<tr>
<td>Screening for sepsis</td>
<td>0.52</td>
<td>0.85</td>
</tr>
<tr>
<td>Antibiotics within 1 hour</td>
<td>0.49</td>
<td>0.62</td>
</tr>
<tr>
<td>Lives saved</td>
<td></td>
<td>548 estimated</td>
</tr>
</tbody>
</table>

**Figure 3**: Example of data

**Figure 4**: Example of use of data
Phases 2-4: Do-Study-Act
Making programmatic changes in your health system is no small feat. You may feel overwhelmed if you have limited access to structural and human resources.

- The WHO 6 building blocks of systems may help you decide what resources you need. You may need to improve:
  - Financing or funding for certain areas of care such as the emergency department
  - Health workforce such as recruiting more nurses or doctors
  - Use of health information systems to improve data about sepsis management
  - Service delivery such as improving triage in the emergency department or response to deteriorating patients
  - Leadership and governance in your hospital or specific departments
  - Access to essential medicines such as antibiotics and intravenous fluids
- Run your improvement project like a campaign, with senior managers and clinicians committed to winning hearts and minds, and removing barriers to change when they happen
- Implement 1 change at a time, start simple, and then build on successes:
  - Start with a pilot test on just a few patients over a limited time (hours-days)
  - Get feedback from bedside staff
  - Define interventions based on feedback and then conduct larger-scale interventions
  - Measure the changes
- Learn from your failures and your successes. Examples of both good and inadequate care incidents are necessary to bring about change.
- Use the initial “quick wins” to help motivate your staff - make sure you communicate and celebrate successes
- Use patient stories to describe the impact of improvements in care or inadequate care. Staff often relate to patient stories more than to quantitative data.

Engage patients and families
Educating and involving patients and families is crucial to improving your sepsis care. Major improvements in sepsis care have been made in other parts of the world by involving patients and relatives in improvement activities and advocacy. Clinical staff are also more likely to change behaviors when they listen to real-life patient stories.

To improve sepsis care in LMICs, doctors and hospitals must overcome these barriers:
- Low levels of public awareness about sepsis, which hinders early recognition and care management
- A desperate need for funds to provide information and support to:
  - Improve screening, prevention, recognition, diagnosis, and treatment of sepsis
  - Help sepsis patients and their loved ones cope during the immediate recovery period and know what to expect during the post-sepsis healing process, which is often lengthy

Offer sepsis resources to the public
You will need information to give to patients and families, as well as information for public awareness campaigns. You may use some of the resources on this list, but you should also
develop your own local resources.

- GSA and WSD material: [http://patient.sm/what-is-sepsis](http://patient.sm/what-is-sepsis)
- Resources for those diagnosed with sepsis: [http://patient.sm/kWQfrg](http://patient.sm/kWQfrg)
- If a loved one has sepsis: [http://patient.sm/Vn9d8T](http://patient.sm/Vn9d8T)
- Life after sepsis: [http://patient.sm/5zL7pT](http://patient.sm/5zL7pT)
- Faces of Sepsis video from Sepsis Alliance: [http://patient.sm/JXjeVz](http://patient.sm/JXjeVz)
- Kate Hallisy’s story, as told by her mother, Julia: [http://patient.sm/bMthVt](http://patient.sm/bMthVt)
- Sepsis resources from the CDC: [http://patient.sm/BaEdEH](http://patient.sm/BaEdEH)
- NIH Sepsis Fact Sheet: [http://patient.sm/lBcsgo](http://patient.sm/lBcsgo)

Other useful information for your organization

- Surviving Sepsis Campaign guidelines - Recommendations for Sepsis Management in resource limited settings (Reference): [http://patient.sm/yT2ggF](http://patient.sm/yT2ggF)
- New definition of sepsis and implications for quality improvement from the Quality Improvement Committee of the Global Sepsis Alliance
- WHO guidelines:
  - IMAI and IMCI guidelines
  - Emergency Triage Assessment and Treatment (ETAT) guidelines for RLS
- Examples of successful projects in low and middle income countries
- ESICM Global Health working group adapted guidelines for RLS

Examples of a sepsis screening and management tool for LMICs

**Screening:**

- Assess opportunities to identify sepsis in care settings (emergency department, wards, ICU) and to improve outcomes for patients who acquire and are at risk for sepsis
- Formalize a process/workflow to screen patients for signs of sepsis throughout your entire institution
- Choose a screening tool and decide:
  - Who does the screen?
  - When is the screen done?
  - What is done once the screen is positive?
  - Who responds to a positive screen?
  - How is the sepsis 3-hour bundle activated?
- Implement a sepsis response team or incorporate early detection of sepsis into existing medical emergency teams such as rapid response teams, if available
**Treatment/Intervention:**

- Use the Surviving Sepsis Campaign 2016 and other international guidelines for LMICs such as the WHO Emergency Triage Assessment and Treatment (ETAT) guidelines
- Formalize processes and workflows for clinicians to follow after a sepsis screen is positive - include activating sepsis bundles

**The 3-hour sepsis bundle** includes these actions:
- Get IV access and obtain blood cultures, if possible
- Give oxygen if:
  - SpO\textsubscript{2} is greater than 90% on room air, or
  - SpO\textsubscript{2} is greater than 94% if patient is in shock
- If pulse oximeter is not available, use clinical indicators to initiate oxygen therapy
- Administer appropriate broad spectrum antibiotics according to clinical suspicion and local antibiograms (when available) - preferably within 1 hour
- If patient is hypotensive or has other signs of hypoperfusion, give initial fluid bolus of 30 ml/kg over 30 minutes in adults
- Monitor clinical signs of perfusion after bolus:
  - Blood pressure (BP)
  - Skin exam
  - Capillary refill (CR)
  - Urine output
  - Alert, voice, pain, unresponsive (AVPU)
  - And vital signs
- If hypotension is resolved, then resume maintenance fluid and monitoring every 1-2 hours
- If hypotension persists, then activate 6-hour sepsis bundle shown below

**The 6-hour sepsis bundle for patients with septic shock** includes these actions:
- Give 2nd bolus of crystalloid fluid and monitor markers of perfusion. Repeat as clinically indicated as long as volume is responsive.
- Start vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) greater than or equal to 65 mm Hg.
- If vasopressors are needed, insert central venous catheter (CVC) under sterile conditions (when possible), though vasopressors can be delivered via peripheral IV with caution
- Monitor in the ICU, preferably continuous monitoring of HR, SpO\textsubscript{2} BP check at least every 30 minutes

**Measuring outcomes**

Please refer to APSS #9A for metrics to track lives spared harm and lives saved.
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 APSSs recommend technologies offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs
Tony Galbo Patient Advocate
Charles Murphy Inova Health System

Members:
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Lisa Anderson Sepsis Alliance
Mark Ansermino BC Children’s Hospital
Ryan Arnold Christiana Care Health System
Steven J. Barker Patient Safety Movement Foundation; Masimo
Michel Bennet Patient Safety Movement Foundation (formerly)
Jean-Daniel Chiche Assistance Publique – Hôpitaux de Paris
Trish Cruz Advocate
Janet Diaz World Health Organization
Jeff Dunn Redivus Health
Christopher Fee University of California, San Francisco Medical Center
Julia Hallisy Patient Safety Movement Foundation
Cindy Hou Jefferson Health New Jersey
Kori Jew Medtronic
Tex Kissoon BC Children’s Hospital
Sarah Knowles University Hospitals Geauga Medical Center
Marianne Kraemer Jefferson Health
Ariana Longley Patient Safety Movement Foundation
Jacob Lopez Patient Safety Movement Foundation (formerly)
Olivia Lounsbury Patient Safety Movement Foundation
Flavia Machado Federal University of São Paulo
Imrana Malik MD Anderson Cancer Center
Sayane Marlla Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo
Sara McMannus  Clinical Consultant, Advisory Board member  Sepsis Alliance
Carole Moss  MSN
Joshua Muthuiru  Machakos Hospital
Armando Nahum  Safe Care Campaign
Emmanuel Nsutebu  Royal Liverpool and Broadgreen University Hospitals  NHS Trust
Donna Prosser  Patient Safety Movement Foundation
Claire Roy  Patient Safety Movement Foundation
Sharon Ruiz  LCMC Health
Sundary Sankaran  Kaiser Permanente
Hildy Schell-Chaple  University of California, San Francisco
Robin Shannon  T-Systems
Ciaran Staunton  Rory Staunton Foundation
Jennifer Tatro  UC Health
Brian White  Advocate

Metrics Integrity:
Robin Betts  Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

References
Appendix A: A modified sepsis screening tool for LMICs with 3 entry points

Scenario A - for a patient with suspected or confirmed infection
Does the patient have:
- Acute, life-threatening organ dysfunction
- The look of being sick, in your clinical judgment, such as being unable to stand
- Alteration of mental status (ACVPU)
- SpO2 greater than 90% on room air
- Tachypnea RR greater than 22 breaths/minute
- Systolic blood pressure less than 90 mmHg or decrease greater than 40 mmHg from baseline, mean arterial pressure less than 65-70 mmHg
- Skin mottling delayed capillary refill
- Decrease in urine output (less than 0.5 ml/kg per hour) or has not passed urine for more than 12 hours
  These laboratory values (if available):
  - Creatinine greater than 2.0 mg/dL
  - Bilirubin greater than 2 mg/dL
  - Platelet count less than 100,000/µL (or 100 K/µL)
  - Coagulopathy (INR greater than 1.5, aPTT greater than 60), or
  - Lactate greater than 2 mmol/L

If YES to any of these, activate the 3-hour sepsis bundle.

Scenario B - for a patient with 1 or more SIRS
Does the patient have:
- Suspected or confirmed infection
- Acute, life-threatening organ dysfunction

If YES to both of these, activate 3-hour sepsis bundle.

Scenario C - for a patient with acute life-threatening organ dysfunction
- Does the patient have suspected or confirmed infection

If YES, activate 3-hour sepsis bundle.
Actionable Patient Safety Solutions (APSS) #10:
Systematic prevention of & resuscitation of in-hospital cardiac arrest

How to use this guide
This guide gives actions and resources for creating and sustaining systematic prevention and resuscitation of in-hospital cardiac arrest. In it, you’ll find:

Executive summary checklist................................. 404
What we know about in-hospital cardiac arrest....... 406
Leadership plan .......................................................... 409
Action plan ................................................................. 410
Technology plan .......................................................... 411
Measuring outcomes................................................... 412
Conflicts of interest disclosure .................................... 413
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Executive summary checklist

One-third of inpatient deaths may be preventable by improving systems for earlier detection and resuscitation for patients who suffer deterioration. Several of those systems are highlighted in this APSS.

Checklist for a comprehensive system for prevention and response to in-hospital cardiac arrest

☐ Convene an institutional multi-disciplinary steering taskforce consisting of physicians, nurses, respiratory therapists, and administrators, whose goal is to develop and optimize strategies for managing clinical deterioration and cardiac arrest prevention.

☐ Use selected internal and external data and guidelines to assess and develop a plan to reduce your institution’s in-hospital cardiac arrest rate.

☐ Create a formal mechanism for the use of performance improvement data to influence output actions.

☐ Data should include evidence-based guidelines and scientific literature, as well as internal (institutional) data.

☐ The taskforce should have input as to how data are used to improve clinical outcomes.

☐ Data should be presented on a regular basis (monthly, quarterly) to hospital leadership.

☐ Potential hospital specific data to be collected may include:

☐ Frequency, location and time of day of cardiac arrest and rapid response events trended in a run or control chart

☐ Hospital mortality rate trended in a run chart

☐ Types of interventions performed during rapid response events

☐ Cardiac arrest events preceded by severe vital sign abnormality

☐ Target the most prevalent causes of arrest for prevention and resuscitation efforts.

☐ Consider available evidence, technology, and performance improvement data when developing resuscitation protocols.

☐ Foster an institutional culture of safety that promotes teamwork and transparency.

Checklist for establishing a rapid response system

☐ The rapid response system (RRS) should have oversight by the appropriate dedicated committee. This can be the same committee that oversees the code blue response.

☐ Criteria for RRS activation should be clearly defined and publicized to all hospital staff. Training on the significance of the criteria to patient deterioration is recommended. Activation criteria or triggers may include:

☐ Vital sign patterns or thresholds

☐ Early warning scoring systems

☐ Software applications running predictive algorithms

☐ Laboratory assessments

☐ Novel technologies that assess perfusion, oxygenation, ventilation, neurologic
function, or other critical physiological processes
☐ Clinical judgment of providers
☐ Concern from patient and/or family
☐ A dedicated rapid response team (RRT) that is capable of addressing the needs of a patient who has suffered clinical deterioration. Potential participants include a critical care physician, or critical care nurse with access to a critical care physician, along with a respiratory therapist. Many hospitals also require that the primary team be contacted at the same time as the RRT.
☐ Specific protocols and equipment for use by the RRT should be considered.
☐ Training in early recognition and prevention of deterioration should be considered for all providers.
☑ Family members are valuable allies who can and should be enlisted by instructing them in signs of deterioration and encouraging them to raise concerns. A hospital policy supporting the ability of a family member to initiate a rapid response (or similar) team may promote event finding, and promote earlier detection of deterioration.
☐ Data collection and CQI should be performed to assess RRS effectiveness and identify opportunities for improvement.

Checklist setting up a resuscitation performance system
☐ Optimal CPR performance by all providers must be ensured. Training should address:
  ☐ Indications to initiate compressions
  ☐ Proper compression rate, depth, and recoil
  ☐ Integration of compressions and ventilations per institutional standards
☐ Additional CPR technology should be considered:
  ☐ Real-time compression feedback
  ☐ End-tidal CO2 as a guide to optimizing CPR
  ☐ Mechanical compression devices
☐ Provider training should be implemented to ensure optimal resuscitation performance that is specific to provider role, clinical unit, and available technology.
☐ Target post-resuscitative care for arrest victims with return of spontaneous circulation.
  ☐ Deliver optimal supportive critical care.
  ☐ Consider targeted temperature management.
  ☐ Consider early coronary revascularization.
What we know about prevention and resuscitation of in-hospital cardiac arrest

Cardiac arrest involves the unexpected loss of cardiac function, breathing, and consciousness. The majority of patients demonstrate signs and symptoms of instability and deterioration long before arrest occurs. In-hospital cardiac arrest is a major preventable cause of patient morbidity and mortality. However, survival rates reported by large databases have remained relatively stagnant at 10-20 percent for several decades. This is in sharp contrast to individual institutions that have taken a non-traditional approach to resuscitation training, practice, and oversight, with survival-to-discharge rates that approach 50 percent.

Systematic prevention of in-hospital cardiac arrest – and effective resuscitation when it does occur – includes staff training and leadership support to:

- Identify patients at high risk of cardiac arrest
- Recognize and reverse physiological deterioration
- Provide optimal CPR for arrest victims

This APSS gives recommendations to:

- Improve resuscitation systems of care
- Establish a rapid response system (RRS) to identify and respond to patients displaying signs/symptoms of deterioration
- Improve resuscitation performance, with emphasis on high quality CPR
- Provide optimal post-resuscitative care
- Integrate technology into clinical resuscitation practice
- Use data to inform and modify the resuscitation system

Rapid response systems (RRS) can prevent a substantial percentage of in-hospital cardiac arrest.

- Most in-hospital cardiac arrest victims demonstrate signs/symptoms of deterioration some time prior to arrest so as to allow intervention and arrest prevention.
  - This is particularly true in the non-ICU areas.
- Barriers to early recognition and prevention of arrest include:
  - Absence of an organized system that identifies and responds to deteriorating patients
  - Lack of knowledge on the part of the bedside staff
  - Social and cultural barriers that impair communication of nurse and other front level providers concerns to physicians and other team members
  - Overconfidence that cardiac arrests are rare and easily prevented
  - Inadequate/inappropriate monitoring
  - Institutional barriers, including unclear criteria, for summoning additional help
  - Improper training and expertise of rapid response team members
  - Poor engagement of patient and family members
- Effective RRS programs include the following four elements:
  - Administrative oversight of all aspects of the program, with a goal of reducing non-ICU morbidity and mortality.
  - Means for detecting deterioration and calling for critical care-trained help. This includes a combination of the following:
• Mechanisms for patient- and family-activated rapid response.
• Dedicated training of bedside nurses in the early recognition and response to deteriorating patients.
• Designation and training of a specialized response team that includes a critical care nurse and respiratory therapist as well as access to a critical care physician.
• Development of monitoring practices and protocols and establishment of calling criteria. These may include vital sign thresholds or patterns, scoring systems (e.g., NEWS), predictive algorithms and computer models, and provider/patient/family concerns.
• Creation of a safety culture that supports any and all calls for additional help.
  o A specific, designated team capable of rapid patient evaluation and escalation of care where appropriate. Traditionally, critical care-based physicians and nurses lead these teams and administer care.
  o Appropriate data collection and analysis efforts that seeks to understand local epidemiology of deterioration, follows patterns and trends, adjusts detection and response efforts to meet patient needs, and establishes appropriate training programs.

**Staff CPR skills are inadequate**

The foundation for successful arrest resuscitation is the performance of high-quality CPR. The published literature documents suboptimal performance of CPR by hospital providers.

- First responders are often reluctant to initiate chest compressions, resulting in prolonged ischemic periods and poor outcomes. This may reflect uncertainty regarding arrest status or an underappreciation for the importance of early CPR.
- There are often frequent and prolonged interruptions in chest compressions, reducing cardiac output and lowering the likelihood of a return of spontaneous circulation. This often reflects the misperception that other tasks (rhythm analysis, defibrillation, airway management, vascular access) are more important than chest compressions.
- Chest compressions are generally too fast and shallow, with poor chest wall recoil, limiting cardiac output during CPR.
- Ventilations are generally too fast, increasing intrathoracic pressure and limiting cardiac output during CPR.
- Suboptimal CPR performance may reflect inadequate training.
  o The primary mechanism for maintaining resuscitation competency for most institutions is limited to biennial completion of the American Heart Association life support training courses. This approach as the sole mechanism to maintain competency has several limitations, particularly for in-hospital providers (Morrison et al., 2013; Davis, 2010):
    - Biennial training is not frequent enough to maintain CPR skills, which appear to decay within 3-4 months.
    - ACLS/BLS curricula are not contextual and may not reflect the unique capabilities and technologies of a particular institution and its providers.
    - ACLS/BLS curricula cannot be modified to address institutional CQI needs.
    - Treatment algorithms upon which the ACLS/BLS courses are based cannot incorporate the variety of new technologies that offer potential to improve outcomes.
    - The ACLS/BLS curriculum does not include arrest prevention.
Advanced Resuscitation Training (ART): A model for reducing preventable deaths

The ART program was developed in 2007 at the University of California at San Diego (UCSD) and represents a comprehensive system of care that targets the reduction of preventable deaths in both the out-of-hospital and in-hospital environments. The ART model links scientific evidence, CQI data, technology, institutional treatment algorithms, and training. Ownership and accountability are transferred to the institution, enhancing both relevance and engagement.

ART training can be described as “adaptive” in that educational content is delivered to individual provider groups, defined by provider type (nurse, physician, respiratory therapist, technician) and clinical unit, based on patient mix and level of care provided. In addition, performance improvement data is used to address institutional and unit-specific issues. Annual training is conducted in 4-hour blocks, with content dedicated equally to prevention and response to cardiac arrest. Training format includes traditional didactics, dedicated skills sessions, and simulation. In addition to the scheduled training, ad hoc sessions are conducted based on performance improvement data trends or sentinel events.

ART clinical guidelines reflect the core elements of the International Liaison Committee on Resuscitation. Specific treatment recommendations as part of the institutional algorithm reflect available technologies as well as the collective interpretation and preferences of institutional clinical leadership. Training sessions are structured around the unique algorithms and the application of technology as part of a contextual learning philosophy.

ART employs a novel taxonomy for categorizing arrests based on physiological pattern and clinical condition. This allows anticipation of arrest based on static and dynamic risk factors and identification of deterioration patterns that allow for RRS team activation and intervention prior to arrest. A stepwise approach to early detection is employed to maximize both sensitivity and specificity and integrate clinical data, technology, and hospital processes. This same taxonomy forms the basis for ART CQI efforts to guide program refinement. Strategy to categorize arrest etiology for each at-risk patient. This facilitates a systematic approach to reducing preventable deaths within each category by targeting prevention as well as effective resuscitation. In addition, this taxonomy aligns with multiple hospital-based patient safety initiatives: Sepsis, perioperative respiratory depression and sleep apnea, occult hemorrhage, dysrhythmias, deep venous thrombosis/pulmonary embolus detection and treatment, respiratory distress, neurological emergencies, and general critical care.

The ART program has been successfully implemented at UCSD as well as multiple pilot sites across the U.S. As a direct result of ART program implementation:

- Arrest incidence has been reduced by more than 50%.
- Survival following arrest has doubled and good neurological outcomes have tripled.
- Life support expenditures have been reduced by 25%.
- A 10-fold return on investment has been realized, with potential savings in reduced cost-of-care, medicolegal payouts, and improved reimbursement for pay-for-performance/value-based purchasing.
Leadership plan

Demonstrate leadership’s commitment to comprehensive system of prevention and resuscitation of cardiac arrest

- Hospital administration and clinical leadership must commit to supporting the development and maintenance of an institutional program of cardiac arrest prevention and resuscitation, including support for program leadership and a commitment to provider training.

- Establish an Outcomes Steering Committee (OSC), which represents a multi-disciplinary institutional group with primary responsibility for the program. This group should have both ownership and accountability for outcomes and should have access to local data with the goal of using it to better understand the institution’s patients’ needs and optimizing the response to deterioration. Reporting from the institutional OSC should be upward to institutional leaders; horizontal to other committees, hospital units, and service lines; and downstream to providers.

- The resuscitation system of care should reduce preventable deaths by decreasing arrest incidence through an organized RRS program and improving arrest survival.

- Engaging individual providers and enhancing their personal sense of ownership and accountability will help create a culture of patient safety. This can be accomplished by:
  - Engagement and public support of the institutional OSC by hospital leaders and broad representation of various hospital groups on the OSC.
  - Effectively modifying training content to address provider and workplace-specific needs and issues, and giving routine feedback of institutional data on patient deterioration and resuscitation data.
  - Ultimately, the cardiac arrest prevention and resuscitation program should become the primary vehicle to reduce preventable deaths and ensure an institutional culture of safety.

Support rapid response system (RRS) development with funding and infrastructure

- Administration should provide financial support for the Rapid Response System including the establishment and training of the RRT.

- Oversight of the RRS program may occur through the OSC or another dedicated, multi-disciplinary committee with strong OSC linkage. Representation from the following hospital entities should be ensured:
  - Administration
  - Cardiac arrest resuscitation team
  - Critical Care
  - Education
  - Risk Management
  - Performance Improvement
  - Data/Analytics
  - Palliative Care/Hospice

- Support to designate RRS team members should be anticipated. Several models may be considered, depending upon coverage area, staffing models and presence of trainees.
Considerations include:
- Critical Care RN, RT, access to critical care MD
- ICU-based versus “patrolling” RRS team
- Integration with cardiac arrest team members
- Specialized protocols & equipment
- Regular training

- Data collection and documentation should include:
  - Documentation in the patient care record
  - Data collection to assess RRS program effectiveness
  - CQI efforts to guide program development and education
  - Core data from each encounter should include at a minimum: location and time, reason for calling, prior vital signs, diagnostic and therapeutic interventions performed, other key consultations or decisions, and post call disposition of the patient. Patient identifiers linkable to other databases such as ICU admissions and arrests should be used as well.
  - Feedback from patient or family regarding patient/family perceptions of the reason for the RRS call, events leading up to the call, outcome and effectiveness of the call.

Support resuscitation performance with funding and infrastructure
- Administration should provide financial support to adequately staff and train resuscitation teams. This may require shifting of work responsibilities, and likely additional expenses for training and equipment purchases.
  - Focus should be on ensuring optimal CPR performance.
  - Resuscitation team leadership training should include team management and integration of technology.
- Additional infrastructure support may be required for CQI activities related to resuscitation.
- Specific attention should be placed on optimal post-resuscitative care

Action plan
Implement training, technology, and data analysis to improve outcomes
- Establish a steering committee to provide ownership and accountability for preventing arrest and optimizing resuscitation performance.
- Implement a rapid response system (RRS) to target early recognition of deterioration and arrest prevention.
- Implement training, technology, and data analysis to improve resuscitation outcomes. Training should be adaptive to provider type, unit, and available technology and address role expectations in resuscitation events.
- Develop a treatment algorithm based on institutional capabilities, technology, CQI needs, and institutional interpretation of scientific evidence.
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

One of the core ART philosophies is to integrate technology into clinical practice, CQI, and training. The ART program has proven itself in facilitating this integration and documenting clinical effectiveness.

An institutional resuscitation program allows modification to clinical algorithms based on available technology and training to optimize clinical application. These are critically important in resuscitation, where staff needs to quickly interpret and respond to vital sign and sensor data. This underscores the importance of user interfaces that help clinicians interpret data, recognize patterns, and respond to therapy.

Integrating physiological data with the institutional operational response is also important to assure optimal and timely allocation of clinical resources and prevention of morbidity and mortality. This is another critical element of an ART program.

Available technologies support the 3 physiological processes identified by the ART Model of Physiology - perfusion, oxygenation, and ventilation - as well as data collection and monitoring:

<table>
<thead>
<tr>
<th>System or practice</th>
<th>Available technology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ONC Meaningful Use Certified Electronic Health Record (EHR) System</strong> with the following capabilities:</td>
<td>Adhesive pulse oximetry sensor connected with pulse oximetry technology proven to accurately measure through motion and low perfusion to avoid false alarms and detect true physiologic events, with added importance in care areas without minimal direct surveillance of patients (in a standalone bedside device or integrated in one of over 100 multi-parameter bedside monitors) (Taenzer et al., 2010; Shah et al., 2012)</td>
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<td>• Clinical Decision Support tools (CDS)</td>
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<tr>
<td><strong>Perfusion:</strong></td>
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<tr>
<td>• Vital signs</td>
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<td>• Sphygmomanometry</td>
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<td>• ECG</td>
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<td>• Capnometry</td>
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<tr>
<td>• Clinical assessment (mental status, capillary refill, pulse quality, extremity temperature)</td>
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<tr>
<td>• Pulse oximetry including related perfusion indices</td>
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<tr>
<td>• Laboratory measures of acidosis (pH, base deficit, lactate, anion gap)</td>
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<tr>
<td>• Newer modalities (near-infrared spectroscopy, orthogonal polarization, heart-rate variability)</td>
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</tbody>
</table>
## Measuring outcomes

### Rapid response outcome metrics

The goal of rapid response teams is to identify deteriorating patients and pair their clinical conditions to needs which may include:

- Escalation of observation and surveillance
- Escalation of care (typically ICU)
- Initiation of palliative therapies

Desirable outcomes of the RRS are the reversal physiologic deterioration and prevention of organ dysfunction and the alleviation of suffering if applicable. A recent consensus conference on quality metrics to assess efficacy of Rapid Response Systems recommended that hospitals should at least measure the following:

| Oxygenation: | • Vital signs pulse oximetry  
|• Blood gas analysis  
|• Near-infrared spectroscopy | • Implement noninvasive and continuous hemoglobin monitoring (Ehrenfeld; WFN)  
| | o SpHb adhesive sensors, or a multi-parameter patient monitor with SpHb, including but not limited to:  

| Ventilation: | • Vital signs  
|• Respiratory volumetrics (tidal volume, respiratory rate)  
|• Blood gas analysis  
|• Capnometry  
|• Capnography  
|• Apnea monitoring | • Capnography  
| | • Apnea Monitoring  
| | o Ability to accurately measure changes in respiratory rate and cessation of breathing with optimal patient tolerance and staff ease of use in order to avoid false alarms, with added importance in care areas without minimal direct surveillance of patients  
| | o Acoustic Monitoring  
| | o Sidestream end tidal carbon dioxide monitoring  

| Remote monitoring with direct clinician alert capability compatible with recommended pulse oximetry technology | • Multi-parameter monitoring system  

| Direct clinician alert through dedicated paging systems or hospital notification system |
1. Incidence of Cardiac Arrests on the wards (number/ # bed days) and the incidence of cardiac arrest responses. If palliative care increases, the cardiac arrest rate may not change, but the response rate would go down. This is an important metric because some patients will always die in the hospital: one goal would be for all those deaths to be following palliative interventions and none after the cardiac arrest response to prevent the death failed.

2. Predictability of cardiac arrests (# of ward arrests from above meeting RRS warning criteria / all ward arrests)

3. Timeliness of their response to ward deterioration (number of patients meeting warning criteria seen within the institutions time frame / total number of patients meeting warning criteria)

4. Timeliness of critical interventions (# patients receiving critical care interventions/ total # of patients receiving RRT calls)

5. Whether the hospital allows the patient, family, other staff to activate the RRS?

Specific numberators, denominators, exclusions, and additional guidance on the use of these metrics are provided in the paper by Subbe, et al.

Cardiac arrests

Key performance indicators

Arrest Related Death: An Arrest Related Death (ARD) is defined as a patient receiving arrest resuscitative efforts (either CPR or defibrillation) at any time during admission who does not survive to hospital discharge.

Outcome measure formula

**Numerator:** Total number of arrest related deaths

**Denominator:** Total number of admissions

Rate is typically displayed as ARDs per thousand admissions (ARDs * 1,000/admissions)

Metric recommendations

**Direct Impact:**

Any patient receiving resuscitative efforts

**Lives Spared Harm:**

$Lives \text{ Spared Harm} = (ARD \text{ Rate }_{\text{baseline}} - ARD \text{ Rate }_{\text{measured}} \times Admissions_{\text{measured}}$

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.
Workgroup

Chair
Daniel Davis  Air Methods Corporation
Helen Haskell  Mothers Against Medical Error, International Society of Rapid Response Systems
Jacinda Bunch  University of Iowa

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Hania Alim  Patient Safety Movement Foundation
*Steven J. Barker  Patient Safety Movement Foundation; Masimo
Michel Bennett  Patient Safety Movement Foundation (formerly)
Chantelle Dron  Windsor Severance Fire Rescue
Jeff Dunn  Redivus Health
Dana Edelson  University of Chicago
Russell Griffin  Heart Organization
Bill Honigman  Hoag Health
Douglas Kupas  Geisinger Health System
Brenna Lawrence  University of California, San Diego
Ariana Longley  Patient Safety Movement Foundation
Jacob Lopez  Patient Safety Movement Foundation (formerly)
Olivia Lounsbury  Patient Safety Movement Foundation
Mandy Odell  Advocate
Donna Prosser  Patient Safety Movement Foundation
Christine Raup  Geisinger Health System
Melanie Roberts  University of Colorado
Ed Salazar  Patient Advocate
Frank Sebat  Kritikus Foundation
Rebecca Sell  University of California, San Diego
Fiona Stan  Ochsner Medical Center
Eugene Tuyishime  University of Rwanda
Tyler Vadeboncoeur  Mayo Clinic
Praveen Venkatagiri  Ovum Hospitals
Sheri Villanueva  University of California, San Diego
Fiona Winterbottom  Ochsner

Metrics integrity
Robin Betts  Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.
References


How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for postpartum hemorrhage (PPH). In it, you’ll find:

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Leadership plan ...................................................................... 422
Action plan ............................................................................ 422
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APSS #11A: Postpartum hemorrhage (PPH)

Executive summary checklist

PPH is the most common complication of pregnancy, and is the leading cause of severe maternal morbidity and (sometimes) preventable mortality.

Prevent PPH-related maternal mortality

☐ Hospital governance and senior administrative leadership should commit to support of maternal safety initiatives such as for PPH in their healthcare system

Establish readiness for PPH in every unit

☐ Create a hemorrhage cart with supplies, checklists, and instruction cards for intrauterine balloon placement and compression sutures based on the recommendations referenced

☐ Ensure teams have immediate access to hemorrhage medications such as in a uterotonic medication kit (drugs that induce contraction of the uterus as a treatment for uterine atony) or equivalent

☐ Establish a response team who can be called when help is needed (blood bank, advanced gynecologic surgery, other support, and tertiary services)

☐ Establish massive and emergency release transfusion protocols (type-O negative/uncrossmatched blood for emergency transfusion use in patients whose blood group is not known)

☐ Educate all units on protocols, establish unit-based drills (with post-drill debriefs)

Recognize ‘at-risk’ patients and attempt to reduce the incidence of PPH

☐ Assess hemorrhage risk (prenatal, on admission, and at other appropriate times)

☐ Assess all PPH risk factors:
  ☐ Retained placenta
  ☐ Failure to progress during the 2nd stage of labor
  ☐ Lacerations
  ☐ Morbidly adherent placenta
  ☐ Instrumental delivery
  ☐ Large for gestational age newborn (>4000 gm)
  ☐ Hypertensive disorders
  ☐ Induction of labor
  ☐ Prolonged 1st or 2nd stage of labor

☐ Measure cumulative blood loss (formula, as quantitative as possible)
  ☐ Weigh the pads for quantitative measurement

☐ Manage the 3rd stage of labor actively (department-wide protocol)
Respond

☐ Establish a unit-standard, stage-based, obstetric hemorrhage emergency management plan with checklists
  ☐ Obstetric rapid response teams, AHRQ TeamStepps clinical communication framework
  ☐ Establish a support program for patients, families, and staff for all significant hemorrhages

Report & Learn

☐ Establish a culture of huddles for high-risk patients and post-event debriefs to identify successful strategies and opportunities for improvement
☐ Conduct a multidisciplinary review of serious hemorrhages for systems issues
☐ Monitor outcomes and process metrics in perinatal quality improvement (QI) committee

Create a culture of safety

☐ Use patient stories, in written and video form, to identify gaps and inspire change in your staff
What we know about PPH

PPH is excessive bleeding by the mother following the birth of a baby. It is among the leading global etiologies of maternal morbidity and mortality (Callaghan, Kuklina, and Berg 2010; Calvert et al., 2012; Ross and Mullin, 2012). In developing countries with high rates of maternal mortality, nearly one-fourth of deaths are attributable to PPH (AbouZahr, 1998).

According to the most recent mortality data reported to the CDC in 2011-2012, PPH caused 11% of pregnancy-related deaths in the U.S. (Berg, Atrash, Koonin, and Tucker, 1996). Between 1994 and 2006, the number of PPH cases increased by more than 25%.

Lack of a timely and medically appropriate response to PPH is associated with poor outcomes. Early recognition of PPH and timely, coordinated interventions are essential to reduce associated morbidity and mortality.

Causes and risk factors for PPH

The most common etiology of PPH is uterine atony (the inability of the uterus to contract and retract following childbirth). A 50% increase in the incidence of uterine atony may explain the increased incidence of PPH in the U.S.

Population-based studies have identified some significant risk factors that may result in PPH:
- PPH in a previous pregnancy
- Retained placenta
- Failure to progress during the 2nd stage of labor
- Placenta accreta, increta, or percreta (when the placenta attaches itself too deeply into the wall of the uterus)
- Lacerations
- Operative vaginal delivery
- Large gestational age newborns
- Hypertensive disorders
- Induced labor
- Augmentation of labor with oxytocin (Scheiner et al., 2005)
- Multiple gestation pregnancy
- Intraamniotic infection

Barriers to prioritizing PPH

There is a consistent global recognition that the lack of communication, patient engagement, and clinical intervention strategies for managing acute hemorrhage in the postpartum period lead to an increase in maternal morbidity and mortality. Despite this, attention to the implementation of coordinated approaches remains limited (Lewis et al., 2007; CAPH, 2011) for a variety of reasons:
- PPH is a “low-volume, high-risk” event for birth facilities (i.e. it may happen infrequently, however it can lead to significant morbidity and mortality). This has led to the down-prioritization for the development of standardized intervention protocols (Lyndon et al., 2015).
- There is no precise definition for the condition. The medical literature commonly defines PPH as blood loss of more than 500 mL following a vaginal delivery or more than 1,000 mL following a cesarean section delivery (Baskett, 1999). PPH is also classified by time
frame, with primary PPH occurring in the first 24 hours and secondary or late-term PPH occurring in the subsequent period.

- Blood loss during delivery can be difficult to measure, which is attributable to lack of standardization on how to manage blood collected during childbirth as well as improvements in medical products that can absorb a deceivingly high volume of fluid
- Bleeding may be concealed due to conditions such as abruption (premature separation of the placenta from the wall of the uterus, with blood trapped inside the uterus) or retroperitoneal hemorrhage (blood trapped in the abdominal cavity)
- The physiological changes of pregnancy can mask the underlying decrease in blood volume as a result of the hemorrhage. On average, mothers of singleton pregnancies have 30% higher blood volume than non-pregnant women (70 mL/kg vs. 100 mL/kg).
- Within the pregnant population, other blood-related physiological traits such as anemia, underlying cardiac conditions, or preeclampsia will also impact a mother’s ability to tolerate blood loss
- Lack of clear guidelines for measuring blood loss during childbirth often leads to underestimation and a clinician may not diagnose primary PPH

Maternal Morbidity and Mortality in the US and Globally

Global maternal mortality
Global maternal deaths have fallen 44% since 1990, but there are still more than 303,000 women who die each year from complications related to pregnancy, delivery, or within the first 6 weeks after delivery (WHO, 2015). The majority of deaths (64%) occur from the day of delivery through 41 days postpartum (Creanga et al., 2015). This equates to approximately 830 women dying every day, with 550 occurring in sub-Saharan Africa, 180 in Southern Asia, and 5 in developed countries (WHO, 2015). In some developing countries, the maternal mortality rate is as high as 1% of live births (AbouZahr, 1998).

Maternal mortality in the U.S.
Within the U.S., it is estimated that approximately 600 women die each year; 14 per 100,000 live births (CDC, 2015; WHO and UNICEF, 2015). While that number seems to pale in comparison to the global scale, the U.S. ranks 46th in the world for maternal mortality (Agrawal, 2015). Of all industrialized countries, the U.S. lags behind Kazakhstan, Libya, and Qatar, and is 1 of only 13 countries whose maternal mortality rates have continued to increase instead of improve (by declining) over the last 25 years (Kempner, 2015).

The reasons for the overall increase in maternal mortality within the U.S. are unclear. Delaying childbearing and assisted reproductive technology (e.g., in-vitro fertilization) have given rise to older mothers with an increased risk of complications than younger women (Joy et al., 2000; Bewley et al., 2005). Additionally, the obesity epidemic gives rise to chronic conditions such as hypertension, diabetes, and chronic heart disease which increase the risk of complications during pregnancy (CDC, 2015; Kuklina et al., 2009; Albrecht et al., 2010; Kuklina et al., 2012).

More than one-third of maternal deaths in the U.S. are preventable; 40% could be avoided if women had access to quality care (Berg et al., 2005). Most notably, black women have a 3- to 4-fold increased risk of death due to pregnancy compared to any other race or ethnicity (Creanga, Bateman, kuklina, and Callaghan, 2014; Callaghan et al., 2008). The reasons are extremely complex and are not well-documented.

Moreover, severe maternal morbidity is much more prevalent and preventable, affecting tens of thousands of women each year (Callaghan et al., 2012; Callaghan et al., 2008).
Leadership plan

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce PPH.

- Individual practices, hospitals, and hospital systems should develop systems of care that deliver risk-appropriate care to women pre- and post-delivery
- Medical and administrative leaders should commit to comprehensive and interdisciplinary PPH management
- Engage expectant mothers and the people who support them in holistic improvement of obstetric safety, including PPH
- Identify and counsel women with risk factors for PPH as appropriate for their level of risk and gestational age
- Ensure availability of resources such as personnel, equipment, blood products, and trained personnel
- Establish PPH protocols, create PPH kits, and conduct appropriate training and simulation drills to reduce the incidence of morbidity and mortality from PPH
- Participate actively in regional and state perinatal collaboratives
- Use patient stories, in written and video form, to identify gaps and inspire change in your staff

Action plan

The Council on Patient Safety in Women’s Health Care at the American College of Obstetricians and Gynecologists (ACOG) has developed comprehensive bundles and lists of resources that apply to the prevention of harm from PPH and other maternal safety issues. The bundles are a roadmap for hospitals to use in the prevention of harm from pregnancy-related conditions: https://patient.sm/WrtpKe

The approach to PPH management depends on the etiology in a patient who has had a vaginal delivery or a cesarean section. For example:

- Surgical treatment of atony depends on the route of delivery
- Coagulopathies (impaired ability of the blood to coagulate) are managed medically, while trauma-related PPH is managed surgically
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

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<td>• Clinical Decision Support tools (CDS)</td>
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<tr>
<td>Close monitoring of hemodynamics such as heart rate and blood pressure</td>
</tr>
<tr>
<td>Ultrasound technology for assessment of retained products, retained placenta, or abruption</td>
</tr>
<tr>
<td>Colorimetric Blood Loss Measurement Technology</td>
</tr>
</tbody>
</table>

Measuring outcomes

Topic: Severe Maternal Morbidity (SMM) among hemorrhage cases

Outcome measure formula

Numerator: Among the denominator, all cases with any SMM code

Denominator: All mothers during their birth admission, excluding ectopics and miscarriages, meeting 1 of the following criteria:
  • Presence of an abruption, previa, or antepartum hemorrhage diagnosis code
  • Presence of transfusion procedure code without a sickle cell crisis diagnosis code
  • Presence of a postpartum hemorrhage diagnosis code

The rate is typically displayed as:
All cases with any SMM code / All mothers meeting denominator criteria

Metric recommendations

Direct Impact: All pregnant patients

Lives Spared Harm:
Live Spared Harm = (SMM Rate baseline - SMM Rate measurement) X Denominator Procedures measurement

Note: Since this is a morbidity measure, the lives saved calculation is not applicable.

Data Collection
HDD File (ICD9/ICD10)
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 APSSs recommend technologies offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs
David Lagrew
Providence St. Joseph Health
Jill Arnold
Maternal Safety Foundation

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Gillian Abir
Stanford University School of Medicine
Hania Alim
Patient Safety Movement Foundation
Ari Babaknia
Chapman University
Steve Barker
Patient Safety Movement Foundation, Masimo
Michel Bennett
Patient Safety Movement Foundation (formerly)
Lilly Filler
Patient Safety Movement Foundation
Afshan Hameed
University of Irvine
Ariana Longley
Patient Safety Movement Foundation
Jacob Lopez
Patient Safety Movement Foundation (formerly)
Olivia Lounsbury
Patient Safety Movement Foundation
Jeanne Mahoney
The American College of Obstetricians and Gynecologists
Elliot Main
California Maternal Quality Care Collaborative
Claire Manneh
California Hospital Association
Ross McQuivey
Clinical Innovations, LLC
Charles Micheli
The University of Vermont Health Network
Donna Prosser
Patient Safety Movement Foundation
Rachael Raynes
University of Vermont
Claire Roy
Patient Safety Movement Foundation
Brittany Sanford
George Washington University Hospital
Sundary Sankaran
Kaiser Permanente
Kisha Semenuk
Maternal Safety Foundation
Abbas Shobeiri
Virginia Commonwealth University School of Medicine Inova Fairfax Medical Campus
References


Actionable Patient Safety Solutions (APSS) #11B:

**Severe hypertension in pregnancy and postpartum**

**How to use this guide**
This guide gives actions and resources for creating and sustaining safe practices for severe hypertension in pregnancy and postpartum. In it, you’ll find:

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APSS #11B: Severe hypertension in pregnancy and postpartum

Executive summary checklist
Complications that arise from hypertensive disorders are among the leading causes of severe maternal morbidity and preventable maternal mortality.

Establish readiness across every unit
- Adopt standards for early warning signs, diagnostic criteria, monitoring, and treatment of severe preeclampsia/eclampsia (include order sets and algorithms)
- Provide unit education on protocols and unit-based drills (with post-drill debriefs)
- Process for timely triage and evaluation of pregnant and postpartum women with hypertension, including in the ED and outpatient areas
- Ensure rapid access to medications used for severe hypertension/eclampsia; medications should be stocked and immediately available on Labor & Delivery and in other areas where patients may be treated. Include a brief guide for administration and dosage.
- Develop a system plan for escalation, obtaining appropriate consultation, and maternal transport, as needed

Recognize and prevent in every patient
- Adopt a standard protocol for measurement and assessment of blood pressure (BP) and urine protein for all pregnant and postpartum women
- Implement a standard response to maternal early warning signs, including listening to and investigating patient’s symptoms and signs, and assessing labs (e.g., CBC with platelets, AST, and ALT)
- Implement facility-wide standards for educating prenatal and postpartum women on symptoms and signs of hypertension and preeclampsia (Preeclampsia Foundation, 2018)
- Recognize that women with severe hypertension are at high risk for cardiovascular disease
- Use patient stories, in written and video form, to identify gaps and inspire change in your staff

Respond
- Develop facility-wide standard protocols with checklists and escalation policies for management and treatment of:
  - Severe hypertension, eclampsia, seizure prophylaxis, and magnesium overdose
  - Postpartum presentation of severe hypertension/preeclampsia
- Establish minimum requirements for protocol:
  - Notify physician or primary care provider if systolic BP ≥160 mm Hg or diastolic BP ≥110 mm Hg for 2 measurements (persistent for 15 minutes)
  - After the 2nd elevated reading, initiate treatment right away (within 60 minutes of verification)
  - Include onset and duration of magnesium sulfate therapy
  - Include escalation measures for those unresponsive to standard treatment
  - Describe manner and verification of follow-up within 7-14 days postpartum
  - Describe postpartum patient education for women with preeclampsia
- Refer patients with persistent symptoms to cardiac specialist
- Develop a support plan for patients, families, and staff for ICU admissions and serious complications of severe hypertension
- Reduce the likelihood of harm related to maternal severe hypertension/preeclampsia

**Report and learn**
- Establish a culture of huddles for high-risk patients and post-event debriefs to identify successes and opportunities
- Conduct a multidisciplinary review of all severe hypertension/eclampsia cases admitted to ICU for systems issues
- Monitor outcomes and process metrics (CPSWHC, 2016):
  - Adherence to protocols for acute management and appropriate response to early warning criteria
  - Documentation of your education of pregnant and postpartum women about symptoms and signs of preeclampsia for women at risk
  - Occurrence of severe maternal morbidity (SMM) event debrief and outcomes
  - Timeliness of medication administration, triage, and evaluation

**Create a culture of safety**
- Use patient stories, in written and video form, to identify gaps and inspire change in your staff
What we know about severe hypertension in pregnancy and postpartum
A leading preventable cause of maternal and neonatal morbidity and mortality

Hypertensive disorders occur in 12-22% of all pregnancies and are one of the leading conditions that impact women during pregnancy. Hypertension may be pre-existing, may be induced by pregnancy, or both may occur (Singh, Ahmed, Egondu, and Ikechukwu, 2014). Approximately 15-17% of all maternal mortality is caused by hypertensive disorders which include: chronic (pre-existing/essential) hypertension, gestational hypertension, preeclampsia with or without severe features, eclampsia, and HELLP (Hemolysis, Elevated Liver Enzymes, Low Platelets) (Walker, 2000). Studies show that between 50-70% of deaths due to severe preeclampsia are preventable (WHO, 2011; Aukes et al., 2007).

During pregnancy, hypertensive disorders not only affect the mother but also may contribute to significant neonatal morbidity and mortality (Backes et al., 2011).

The spectrum of hypertensive disorders of pregnancy
There are 4 main categories within the spectrum of hypertensive disorders of pregnancy:

- **Chronic hypertension during pregnancy:** Defined as blood pressure (BP) ≥140/90 mm Hg prior to the 20th week of pregnancy, and leads to complications in 5% of all pregnancies (Seely and Maxwell, 2007; Druzin, Shields, Peterson, and Cape, 2013; Yanit, Snowden, Cheng, and Caughey, 2012)

- **Gestational hypertension:** Defined as new-onset hypertension associated with a systolic BP of ≥140 mm Hg or diastolic BP ≥90 mm Hg, or both, presenting at or after 20-weeks gestation without proteinuria or other severe features of preeclampsia

- **Preeclampsia:** Defined as systolic BP ≥140 mm Hg or diastolic BP ≥90 mm Hg (on 2 occasions, at least 4 hours apart) or systolic BP ≥160 mm Hg or diastolic BP ≥110 mm Hg (within a short interval (minutes)) and associated with proteinuria ≥300 mg per day. In the absence of proteinuria, diagnosis can be confirmed with the inclusion of at least 1 severe feature:
  - Thrombocytopenia (platelet count ≤100,000/uL)
  - Renal insufficiency
  - Impaired liver function
  - Pulmonary edema
  - Cerebral or visual symptoms (preeclampsia is a multi-organ disease)

- **Preeclampsia superimposed on chronic hypertension:** preeclampsia that complicates hypertension of another cause

Causes and risk factors for severe hypertension in pregnancy and postpartum
The causes of pregnancy-induced hypertension and the risk factors are still being widely studied. However, hypertension among pregnant women in the U.S. has increased significantly over the last 2 decades, due to increased rates of obesity and diabetes (Schulkin, Power, and Leddy, 2008).

The leading patient factors among maternal deaths due to preeclampsia were (Main et al., 2015):
• Delays in seeking care - 42%
• Presumed lack of knowledge regarding the severity of a symptom or condition - 39%
• Underlying medical condition - 39%

**The connection with cardiovascular disease**

Some of the complications of preeclampsia may overlap with those seen in cardiovascular disease in pregnancy. This may particularly be relevant in the following settings.

If a patient with preeclampsia develops **pulmonary edema** during pregnancy or in the postpartum period, we suggest cardiac evaluation such as an echocardiogram. The standard treatment of preeclampsia includes use of magnesium sulphate infusion to prevent seizures. One of the known complications is pulmonary edema due to vascular damage in the lungs. However, in women with underlying cardiac disease or in the event of new onset peripartum cardiomyopathy, pulmonary edema may be the first presentation.

There is **overlap** in the pathophysiology of preeclampsia and peripartum cardiomyopathy. Preeclampsia has been shown to cause diastolic dysfunction, which is considered a form of cardiac toxicity. Furthermore, prevalence of preeclampsia is 4-5 times higher in women with peripartum cardiomyopathy. Therefore, early diagnosis and treatment of cardiomyopathy may decrease morbidity and even mortality (Melchiorre K et. al. Hypertension. 2011;57:708-715).

Preeclampsia complicates 2-8% of all pregnancies. Several studies have demonstrated that patients with preeclampsia are at a much higher risk of **developing cardiovascular disease in later life**. This may be due to a combination of the persistent endothelial, vascular, and metabolic derangements inherently linked to preeclampsia. The 2011 AHA guidelines for the prevention of cardiovascular disease in women added preeclampsia as an additional cardiovascular risk factor. This may provide an opportunity for these women to address modifiable risk factors to improve their long-term health outcomes.

Pregnancy may be considered as a failed “stress test” in this setting and therefore these young women may benefit from interventions to prevent cardiovascular disease (Ahmed et. al. JACC;63,No. 18,2014).

**Preventing severe hypertension in pregnancy and postpartum**

No clear strategies have emerged to prevent the onset of preeclampsia, although low-dose aspirin taken daily starting at the end of the 1st trimester has been shown to reduce preeclampsia among high risk women (“Emergent therapy for acute-onset, severe hypertension during pregnancy and the postpartum period”, 2015).

In the past, the focus was placed on prevention of eclamptic seizures, which are associated with an increase in both neonatal and maternal morbidity and mortality. The incidence of eclamptic seizures can be reduced with administration of magnesium sulfate (Sibai, 2004; Martin et al., 2005).

Unlike the relatively straightforward prophylaxis of eclamptic seizures, there is a gap in knowledge and application of therapeutic interventions for stroke prevention through controlled BP. Typically, treatment of systolic BP ≥160 mm Hg, and/or diastolic BP ≥105 mm Hg has been recommended (Kayem et al., 2011). In practice, clinicians institute therapies at a lower level of systolic or diastolic blood pressures.

**Treatment for severe hypertension in pregnancy and postpartum**

Early recognition and timely treatment of preeclampsia is a critical factor in reducing maternal
and neonatal morbidity and mortality. Delay in treating hypertension is the primary cause of concern. When a patient is diagnosed with preeclampsia, it is important to recognize worsening signs and symptoms to try and prevent progression to eclampsia or stroke.

The most important intervention in the treatment for preeclampsia/eclampsia is delivery of the fetus and placenta. The phrase “delivery is the cure” is widely accepted, however in many cases preeclampsia/eclampsia may continue for a variable amount of time after delivery. Therefore prophylaxis with magnesium sulfate is recommended for 24 hours post-delivery. For this reason, new mothers with previous complications of preeclampsia should continue to be evaluated post-delivery. Serious clinical outcomes can continue postpartum for days and even weeks (Chescheir, 2015).

The majority of women who die of severe preeclampsia die from stroke (Bushnell and Chireau, 2011). Stroke can only be prevented with rapid administration of antihypertensive medications. The key to saving lives from complications of severe preeclampsia is administration of antihypertensive medication within 30-60 minutes (“Emergent therapy for acute-onset, severe hypertension during pregnancy and the postpartum period”, 2017).

Maternal morbidity and mortality in the U.S. and globally

Global maternal mortality
Global maternal deaths have fallen 44% since 1990, but there are still more than 303,000 women who die each year from complications related to pregnancy, delivery, or within the first 6 weeks after delivery (WHO, 2015). The majority of deaths (64%) occur from the day of delivery through 41 days postpartum (Creanga et al., 2015). This equates to approximately 830 women dying every day, with 550 occurring in sub-Saharan Africa, 180 in Southern Asia, and 5 in developed countries (WHO, 2015). In some developing countries, the maternal mortality rate is as high as 1% of live births (AbouZahr, 1998).

Maternal mortality in the U.S.
Within the U.S., it is estimated that approximately 600 women die each year, which is 14 per 100,000 live births (CDC, 2015; WHO and UNICEF, 2015). While that number seems to pale in comparison on the global scale, the U.S. ranks 46th in the world for maternal mortality (Agrawal, 2015). Of all industrialized countries, the U.S. lags behind Kazakhstan, Libya, and Qatar, and is one of only 13 countries whose maternal mortality rates have continued to increase instead of improve (by declining) over the last 25 years (Kempner, 2015).

The reasons for the overall increase in maternal mortality within the U.S. are unclear. Delaying childbearing and using assisted reproductive technology (e.g., in-vitro fertilization) have given rise to older mothers with an increased risk of complications than younger women (Bewley et al., 2005). Additionally, the obesity epidemic gives rise to chronic conditions such as hypertension, diabetes, and chronic heart disease which increase the risk of complications during pregnancy (CDC, 2015; Kuklina et al., 2009; Albrecht et al., 2010; Kuklina et al., 2012). More than one-third of maternal deaths in the U.S. are preventable, and 40% could be avoided if women had access to quality care (Berg et al., 2005). Most notably, black women have a 3- to 4-fold increased risk of death due to pregnancy compared to any other race or ethnicity (Creanga et al., 2014; Callaghan, Mackay and Berg, 2008). The reasons are extremely complex and not well documented.

Moreover, severe maternal morbidity is much more prevalent and preventable, affecting tens of thousands of women each year (Callaghan, Creanga, and Kuklina, 2012; Callaghan, Mackay and Berg, 2008).
Leadership plan
Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce severe hypertension in pregnancy and postpartum.

- Individual practices, hospitals, and hospital systems should develop systems of care that deliver risk-appropriate care to women pre- and post-delivery
- A multidisciplinary team should be built to give quality care to a woman with severe preeclampsia. The team should be comprised of an obstetric provider credentialed to perform cesarean sections, nursing, anesthesiology, NICU, laboratory, blood bank, social work, and other sub-specialties as needed (Aukes et al., 2007).
- Actively participate in regional and state perinatal collaboratives
- Use patient stories, in written and video form, to identify gaps and inspire change in your staff:
  - The story of Joan Donnelly, as told by her husband, Todd Heiden, is an example of a case of preventable death due to unrecognized postpartum eclampsia. You can view it for free here: http://patient.sm/gpZOObC

Action plan
The Council on Patient Safety in Women’s Health Care developed comprehensive bundles and lists of resources that apply to the prevention of harm from severe preeclampsia (CPSWHC, 2016). The bundles are a roadmap for hospitals to use in the prevention of harm.

Technology plan
These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/

<table>
<thead>
<tr>
<th>System or practice</th>
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<td><strong>ONC Meaningful Use Certified Electronic Health Record (EHR) System</strong> with the following capabilities:</td>
</tr>
<tr>
<td>- Computerized Provider Order Entry (CPOE)</td>
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<td>- Drug-drug interaction check</td>
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<td>- Clinical Decision Support tools (CDS)</td>
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<tr>
<td><strong>Blood pressure measurement devices</strong></td>
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<td>- Smart devices that track BP at home</td>
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Measuring outcomes

Topic 1: Severe maternal morbidity (SMM) among preeclampsia cases

Outcome measure formula

**Numerator:** Among the denominator, cases with any SMM code

**Denominator:** All mothers during their birth admission, excluding ectopics and miscarriages, with one of the following diagnosis codes:
- Preeclampsia (with or without severe features or with blood pressures in the severe range)
- Eclampsia
- Preeclampsia superimposed on chronic hypertension

Metric recommendations

**Direct Impact:** All pregnant patients

**Lives Spared Harm:**
\[ \text{Lives Spared Harm} = (\text{SMM Rate }_{\text{baseline}} - \text{SMM Rate }_{\text{measurement}}) \times \text{Denominator }_{\text{baseline}} \]

**Note**
Since this is a morbidity measure, the lives saved calculation is not applicable.

Data collection

HDD File (ICD9/ICD10)

Outcome measure formula

**Numerator:** Among the denominator, all cases with any non-transfusion SMM code

**Denominator:** All mothers during their birth admission, excluding ectopics and miscarriages, with one of the following diagnosis codes:
- Preeclampsia (with or without severe features or with blood pressures in the severe range)
- Eclampsia
- Preeclampsia superimposed on chronic hypertension

Metric recommendations

**Direct Impact:** All pregnant patients

**Lives Spared Harm:**
\[ \text{Lives Spared Harm} = (\text{SMM Rate }_{\text{baseline}} - \text{SMM Rate }_{\text{measurement}}) \times \text{Denominator }_{\text{baseline}} \]

**Note**
Since this is a morbidity measure, the lives saved calculation is not applicable.

Data Collection

HDD File (ICD9/ICD10)
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

Co-Chairs
David Lagrew  Providence St. Joseph Health
Jill Arnold  Maternal Safety Foundation

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Gillian Abir  Stanford University School of Medicine
Hania Alim  Patient Safety Movement Foundation
Ari Babaknia  Chapman University
Steve Barker  Patient Safety Movement Foundation, Masimo
Michel Bennett  Patient Safety Movement Foundation (formerly)
Lilly Filler  Patient Safety Movement Foundation
Afshan Hameed  University of Irvine
Ariana Longley  Patient Safety Movement Foundation
Jacob Lopez  Patient Safety Movement Foundation (formerly)
Olivia Lounsbury  Patient Safety Movement Foundation
Jeanne Mahoney  The American College of Obstetricians and Gynecologists
Elliot Main  California Maternal Quality Care Collaborative
Claire Manneh  California Hospital Association
Ross McQuivey  Clinical Innovations, LLC
Charles Micheli  The University of Vermont Health Network
Donna Prosser  Patient Safety Movement Foundation
Rachael Raynes  University of Vermont
Claire Roy  Patient Safety Movement Foundation
Brittany Sanford  George Washington University Hospital
Sundary Sankaran  Kaiser Permanente
Kisha Semenuk  Maternal Safety Foundation
Abbas Shobeiri  Virginia Commonwealth University School of Medicine Inova Fairfax Medical Campus
Seyed Shobeiri
Kristen Terlizzi
Josef Wichilewski

Metrics integrity
Robin Betts
Jan Orton

Inova Health System
National Accreta Foundation
Clalit

Kaiser Permanente, Northern California Region
Intermountain Healthcare
References


Actionable Patient Safety Solutions (APSS) #11C:
Reducing unnecessary cesarean sections (c-sections)

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for reducing unnecessary cesarean sections (c-sections). In it, you’ll find:

Executive summary checklist................................................................. 444
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**Executive summary checklist**

An unnecessary c-section is when the decision to deliver a baby via c-section is driven by factors other than medical necessity. Unnecessary c-sections lead to short- and long-term complications and increased maternal and neonatal morbidity and mortality (Bauserman, et al., 2015). Short-term complications include blood loss, infection, and venous thrombosis. Long-term complications include an increased risk of abnormal placentation and uterine rupture in subsequent pregnancies. A recent multi-facility study demonstrated that the rate of cesareans in low-risk patients can be quickly lowered at scale with no maternal or neonatal harm by following guidelines from American College of Obstetricians and Gynecologists and Society for Maternal Fetal Medicine and providing enhanced labor support (Main, 2019).

**Establish readiness in every unit**

- Build a healthcare provider and maternity unit culture that values vaginal birth and understands the risks of c-section birth for current and future pregnancies (Chaillet & Dumont, 2007)
- Optimize patient and family engagement. Actively involve patients and families in areas such as:
  - Education
  - Informed consent
  - Shared decision-making about normal healthy labor and birth
- Develop healthcare provider expertise in approaches to labor that maximize the likelihood of vaginal birth (Chaillet, 2007). These areas include:
  - Assessment of labor
  - Methods to promote labor progress
  - Labor support
  - Pharmacologic and nonpharmacologic pain management
  - Shared decision-making
- Use patient stories, in written and video form, to identify gaps and inspire change in your staff

**Recognize and prevent in every patient**

- Develop and implement standardized practices for every patient (Spong, 2012, American Congress of Obstetricians and Gynecologists (ACOG), 2019; Society for Maternal Fetal Medicine (SMFM), 2019). in areas that include:
  - Admission criteria
  - Triage management
  - Education
  - Support for women who present in spontaneous labor
- Offer standardized techniques for pain management and comfort measures that promote labor progress and decrease the incidence of dysfunctional labor (Hodnett, 2013)
- Use standardized methods to assess the fetal heart rate status (Macones, Hankins, Spong, Hauth, & Moore, 2008), including:
  - Interpretation
Methods that promote freedom of movement

Adopt protocols for timely identification of specific problems, such as herpes and breech presentation, for patients who can benefit from proactive intervention before labor to reduce the risk for c-section birth (Hollier & Wendel, 2008).

Respond

Have the capability and equipment to provide appropriate-level maternity care and a readiness at all times to initiate emergency procedures to meet the needs of women and newborns within the center. (Cite OCC#9 - [https://patient.sm/BhrQHy](https://patient.sm/BhrQHy))

Apply standardized induction scheduling to ensure correct selection and preparation of women undergoing induction of labor (ACOG, 2009)

Recognize and treat dystocia promptly by following standardized evidence-based labor algorithms, policies, and techniques (Spong, 2012)

Adopt policies that outline standard responses to abnormal fetal heart rate patterns and uterine activity (Clark, et al., 2013)

Make available specialized expertise and techniques to lessen the need for c-section birth (Hollier, 2008) such as:

- Breech version
- Operative vaginal birth
- Twin birth protocols

Use data to find areas for improvement

Track and report labor and c-section measures in sufficient detail (Challitt, 2007; CMQCC, 2016) so your institution can:

- Compare to similar institutions
- Conduct case review and system analysis to drive care improvement
- Assess individual healthcare provider performance
- Use relevant metrics and balancing measures to assess maternal and neonatal outcomes that may be the result of changes in labor management strategies
What we know about reducing unnecessary c-sections

C-section rates have increased in the U.S.
The c-section is the most commonly performed surgery in the U.S.:
- Approximately 1.2 million of the procedures are performed annually (CDC, 2019)
- Between 1970 and 2009, the total cesarean rate rose from 5.5% to a high of 32.9%
- Current data show that it remains plateaued at 31.9% (Placek and Taffel, 1981; Martin et al., 2011; Martin et al., 2019)

Among the population of first-time mothers with low-risk births (also called Nulliparous, Term, Singleton, Vertex (NTSV)), 25.9% give birth by cesarean, which is a 40% increase since 1997 (Martin et al., 2019). C-section rates have also increased globally (Betran, Ye, Moller, and Zhang, 2016), primarily in developed countries.

Evidence shows the rise in utilization of the cesarean has not been accompanied by a reduction in cases of perinatal morbidity and mortality (Gregory, Jackson, Korst, and Fridman, 2011), nor can it be explained solely by patient characteristics, demographics, or comorbidities (Li, 2003).

C-section rates vary by hospitals and providers
A 2013 study identified a 10-fold variation in cesarean rates across the U.S. (Kozhimannil, Law, and Virnig, 2013). The overall trend of rising cesarean rates is attributed to a complex, multifactorial set of issues including:
- Payment incentives or disincentives (Main et al., 2012)
- Real or perceived liability fears (Main et al., 2006)
- Cultural acceptance and resource management (Plough et al., 2017)

Nevertheless, evidence shows that unwarranted variation in rates between hospitals and providers is largely due to subjectivity in clinical decision-making. Over 60% of hospital variation in NTSV patients can be attributed to first birth labor induction rates and first birth early labor admission rates (Main et al., 2006).

The NTSV Cesarean Birth measure - endorsed by the National Quality Forum in 2008 - was designed to identify variations between hospitals, and is used for hospital data reporting by The Joint Commission and the Leapfrog Group. It shows that outcomes for NTSV patients are largely influenced by physician factors, rather than patient characteristics or obstetric diagnoses, and specifically identifies variations between birthing facilities (Joint Commission, 2017).

C-section in low-income countries
Women in lower-income regions of the world do not have appropriate access to obstetric care, including cesarean births. This leads to high rates of perinatal morbidity and mortality (Thomas, Meadows, and Mcqueen, 2016).

Increased incidence of cesarean births in countries that lack infrastructure to safely manage the downstream consequences of a primary cesarean has resulted in an increased incidence of complications (Beltman et al., 2011), including:
- Postpartum hemorrhage
- Abnormal placentation
- Infection
Risks of c-section compared to vaginal birth

The risk of severe maternal morbidity is higher as a result of a cesarean birth compared with vaginal birth. The risk of maternal death is 4 times higher in cesarean births, while amniotic fluid embolism is 2-3 times more likely.

Other serious complications occur in cesarean birth at an overall rate that is 3 times higher than vaginal birth (2.7% vs. 0.9%) (Liu, Joseph, Liston, and Heaman, 2007):

- Obstetric hemorrhage requiring hysterectomy
- Complications from anesthesia
- Venous thromboembolism (VTE)
- Maternal cardiac arrest
- Major infection

Compared to vaginal births, cesarean births are also associated with:

- More neonatal intensive care unit stays
- Delays in establishment of breastfeeding
- Longer average length-of-stay
- Longer recovery times

Vaginal births carry an increased risk of 3rd- and 4th-degree perineal lacerations (tear or laceration through the perineal muscles and the muscle layer that surrounds the anal canal) (Caughey et al., 2014).

Risks of repeat c-section

A repeat cesarean increases a patient’s risk of placental abnormalities, such as placenta accreta (a condition in which some or all of the placenta attaches abnormally to the wall of the uterus). The complications associated with placenta accreta include:

- Nearly 90% of patients require a blood transfusion
- Bladder and bowel damage
- Amniotic fluid embolism
- Venous thromboembolism
- Infection
- An estimated maternal mortality rate of 6-7%

The increase in incidence of placenta accreta parallels the rise in the cesarean rate, and the estimated ratio of deliveries affected by placenta accreta in the last decade is 1:272 (Cite: https://www.ncbi.nlm.nih.gov/pubmed/25897639)

Women who want vaginal birth after cesarean can’t obtain it

About 87% of the approximate 593,241 women with a history of a prior cesarean who gave birth in the U.S. in 2018 did so by c-section.

The rate of vaginal birth after cesarean (VBAC) increased from 3% following the 1981 National Institutes of Health Consensus Conference on Cesarean Childbirth to a high of 28.3% in 1996, and decreased to a low of 8.3% in 2007 (Gregory et al., 2010). The VBAC rate has since climbed to 13.3% in 2018.

The rapid decline between 1996 and 2007 is commonly attributed to fear of liability or a hospital’s inability to meet the previously published safety recommendations for VBAC, such as having a physician “immediately available.”
These limited options for patients result in an unknown proportion of patients in the U.S. who may prefer the option of VBAC, yet must consent to repeat cesarean birth or attempt an out-of-hospital trial of labor if they are unable or unwilling to travel to the nearest hospital that will offer a trial of labor after cesarean (TOLAC). A 2018 report from Listening to Mothers California found that almost half of individuals surveyed were interested in planning a VBAC. However, half reported not being given the option due to the restrictions of VBAC in hospitals. In an effort to increase access to VBAC, ACOG published updated recommendations in November 2017 which removed the “immediately available” language and now state that any Level I (Basic Care) facility per ACOG’s Levels of Maternal Care standards can offer TOLAC (Grobman et al., 2017).

In an effort to increase access to VBAC, ACOG published updated recommendations in November 2017 which removed the “immediately available” language and now state that any Level I (Basic Care) facility per ACOG’s Levels of Maternal Care standards can offer TOLAC (Grobman et al., 2017).

**Preventing unnecessary c-sections**

The World Health Organization (WHO) stated in 2015 that “Every effort should be made to provide caesarean sections to women in need, rather than striving to achieve a specific rate.” Regional optimization of c-section utilization saves lives and prevents maternal and perinatal morbidity (WHO, 2015).

In 2014, SMFM and ACOG published a consensus statement on the evidence behind safely reducing primary cesarean rates (Caughey, Cahil, Guise, and Rouse, 2014). Other women’s health and obstetric safety organizations, such as the California Maternal Quality Care Collaborative (CMQCC) and the Council of Patient Safety on Women’s Health (CPSWH) have since published comprehensive toolkits to implement recommendations (CMQCC, 2016; CPSWH, 2016).

Global attention has been focused on both the overuse and underuse of cesarean births, with increasing emphasis on optimizing the rate of cesarean births (WHO, 2017; CDC, 2017; WHO, n.d.; Haelle, 2017) through:

- Regionalization of risk-appropriate care
- Access to trained birth attendants
- Quality improvement projects
- Payment reform and public-facing awareness
- Educational campaigns

**The evidence for programs that seek to increase appropriate use of c-section**

A three-year, cross-sectional study of 56 hospitals with more than 119,000 annual births, and with nulliparous, term, singleton, vertex cesarean delivery rates greater than 23.9% was conducted by the California Maternal Quality Care Collaborative (CMQCC) statewide collaborative. Researchers found that cesarean rates can be safely lowered at scale with no evidence of worsened birth outcomes for mothers and neonates by following American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine guidelines and providing enhanced labor support. ([https://patient.sm/yZB5zh](https://patient.sm/yZB5zh))

Other recent success stories include quality improvement projects to reduce unnecessary c-sections at:

- Beth Israel Deaconess Medical Center in Boston, MA (Vadnais et al., 2017)
Leadership plan

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce unnecessary c-sections.

Create a culture that values vaginal birth and avoids unnecessary c-sections

- To achieve lower c-section rates, individual practices, clinics, hospitals, birth centers, and health systems should develop a culture that values vaginal birth by preparing their providers and working with women to redesign their care
- Senior executive leadership should commit to creating a culture that values vaginal birth and avoids unnecessary c-section
- Participate actively in regional and state perinatal collaboratives
- Use patient stories, in written and video form, to identify gaps and inspire change in your staff
  - The story of Kristen Terlizzi, who nearly died of placenta accreta, is an inspiring story about how informing patients about the downstream risk of c-sections is imperative. You can view a film created by the Patient Safety Movement Foundation for free here: youtu.be/RMnQZUqQhjU.

Create the infrastructure needed to reduce unnecessary c-sections

- Redesign facilities and restructure provider teams to support physiologic labor methods and ensure prompt intervention for abnormal labors
- Create an interdisciplinary team that is led by a physician and administrative champions who are well-respected and knowledgeable, including:
  - Obstetrician/maternal fetal medicine specialists
  - Nursing leaders
  - Obstetrical anesthesiologists
  - Physicians in training (residents/fellows)
  - Nurse midwives/nurse practitioners
  - Labor/OR nurses
  - Doulas
  - Childbirth educators
  - Quality Improvement (QI) staff
  - Data analytics/information technology/EMR design and maintenance team
  - Pharmacists
- Leadership should give staff appropriate support and educational time to focus on clinical changes and labor techniques which have been shown to reduce unnecessary cesarean birth - hold managers accountable for implementing such changes

Adopt clinical and administrative practices that support vaginal birth

- Develop and execute specialized protocols and precautions to address the high-risk problems associated with a prior c-section, especially in patients with suspected
abnormal placentation

- Administrative and financial leadership should prepare for reimbursement strategies that favor vaginal delivery and shared risk
- QI practices should incorporate c-section rates to follow, especially the NTSV cesarean rate
- Conduct hospital- and system-wide review and transparently share with providers and patients

**Action plan**

**Analyze**

- Complete an in-depth analysis of your facility’s current rate of c-section with detailed analysis of:
  - Indications for procedures
  - Specific rates of total, primary, repeat, NTSV c-sections for the institution and individual providers
  - Analysis of risk factors such as parity, maternal age, and concurrent medical diagnoses
  - Audit of c-sections with tools to evaluate possible interventions, including stage of labor, induction protocols, cervical ripening, and use of instrumented delivery. Example of audit tools can be found in referenced toolkits.
  - Rates of labor inductions and techniques used
  - Evaluation of anesthesia techniques and availability
  - Scheduling protocols
  - Consenting procedures for elective cesareans for declined trial of labor candidates, without medical indications
  - Compliance with standard labor support techniques
  - Compliance with standard intervention for failure to progress

**Identify gaps**

- Identify gaps in procedures, protocols, and care which can be used to promote vaginal birth

**Use guidelines and toolkits**

- Adhere to guidelines outlined by the ACOG/SMFM consensus statement on preventing the first c-section and other recommendations in toolkits such as the CMQCC Toolkit on Promoting Vaginal Birth
- Although the results of the ARRIVE Trial published in 2019 showed a lower NTSV cesarean rate among its participants, no changes have been made to the SMFM/ACOG guidelines for induction of labor. A statement issued by CMQCC stated that the results in this study “were obtained in university hospitals with strict labor guidelines and a strict definition of failed induction. If a hospital’s induction guidelines are to be changed to allow for elective inductions at 39 weeks, strict guidelines for defining failed induction and for management of active phase and fetal monitoring abnormalities need to be adopted simultaneously” (Main, 2018).
Implement interventions

- Ensure a culture that values vaginal delivery and avoids unnecessary c-section is present in the institution
- Promote a shared decision-making process where prenatal providers discuss and promote patient-centered labor support and management
- Develop staff expertise in labor support and management which maximizes the likelihood of successful safe vaginal delivery
- Standardize admission criteria to prevent latent phase labor patients being admitted and requiring aggressive management to progress into active labor
- Offer a multitude of pharmacologic choices and physiologic methods for pain management to ensure patient comfort and satisfaction
- Standardize intervention plans based upon defined fetal heart rate characteristics which lead to prompt appropriate intervention and minimize the risk of over interventions
- Adhere to evidence-based algorithms for failure-to-progress interventions that increase successful labors and have minimal side effects to the mother and fetus
- Make available standard protocols, expertise, and techniques for decreasing the cesarean rate in breech presentations, history of genital herpes, and twin gestation
- Conduct transparent reporting of cesarean section rates, risk factors, and other information by facility and providers

Educate

- Educate patients and families of long-term risks and benefits of c-section and benefits of vaginal birth
- Review and train all providers in various techniques and protocols which reduce the need for protracted and unsuccessful labors

Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/
ONC Meaningful Use Certified Electronic Health Record (EHR) System – should have these capabilities:

**Proper data elements:** Review the EHR to make sure proper data elements are present, and are formatted and defined into standard terminologies for incorporating your alerting, measure reporting, and documentation needs.
- For example: Use national or international standards for definitions and value sets that are available, such as fetal heart rate interpretations defined by NIHCD consensus.

This will allow for comparisons between institutions and help in defining normal practice and thresholds.

**Labor tools:** Use standard reporting tools, such as a labor curve, intervention curve, and trending visualizations for fetal heart rate interpretations. These enable providers to more accurately assess the overall labor status that should be incorporated into systems.

**Device integration:** The EHR should have robust device integration of fetal monitoring data, intravenous pumps, and vital sign devices, which can reduce mundane documentation for caregivers and allow them to devote more of their time to more value-added processes such as labor support. In addition, newer monitoring devices incorporate continuous decision support/artificial intelligence and analysis which should integrate into the EHR and ensure a single source of accurate data truth and improve provider interpretations.

**Decision support:** Standard practice alerts, used in a judicious manner to prevent alert fatigue, can incorporate best practice guidelines for labor interventions and responses to fetal heart rate patterns in a standard way. Incorporate:
- Other methods of decision support into documentation tools and order sets to improve documentation and reporting, and allow clinicians to follow standardized protocols more frequently.
- Best practice content sources into standard workflows allowing for easier review by clinicians.

**Embedded reporting data elements:** EHR should allow collection of clinical data as part of standardized documentation, and collection of ongoing data entered by nurses, physicians, and others. Specific data elements for labor support can help you review and train on these new techniques and enable you to evaluate compliance. Carefully review and maintain these so that robust data analytics can be routine.

**Fetal monitors**
Newer fetal monitors have strip analysis artificial intelligence algorithms incorporated into the systems. These will aid clinicians in their interpretation skills and allow for easier and more complete documentation. Wireless monitoring can also lead to greater ambulation and positioning options for patients in active labor.

Developing Technology: Transcutaneous fetal oximetry
Cervical ripening techniques
Device manufacturers and pharmaceutical companies should expand the list of options for safe and effective ripening of the cervix. Programs should target reduction and elimination of induction of labor with an unripe cervix. Nevertheless, induction with unripe cervix will be required in many labors, and better methods are needed. In addition, the goal for safe outpatient methods should be proposed to reduce cost.

System or practice

Web/mobile-based learning tools
All major guidelines call for better education for providers and patients. Unfortunately, traditional didactic teaching will not be possible on that scale, and newer online education techniques are required for cost-effective delivery. For patients, convenient methods on electronic hand-held devices can be developed for both learning and communication. Paired with group prenatal care, the patients can also work and learn together to understand risks, benefits, and techniques of modern labor.

Measuring outcomes
Although there is not a specific metric, U.S. hospitals need to monitor their overall c-section rates. These are several elements hospitals can look at to reduce the number of unnecessary c-sections:

- The overall induction rate
- The rate of active labor patients admitted prior to 4 centimeters
  - C-section deliveries with no labor trial for low risk (NTSV), uncomplicated births
  - Elective c-section rate for low risk, uncomplicated births
  - Maternal, clinical and demographic characteristics for low risk, uncomplicated births with C-section as the elected method of delivery
  - C-section rate among women who aimed to deliver vaginally
  - Avg/median labor trial period (by stage?) before C-section delivery among women who aimed to deliver vaginally
  - Rate of complications during labor as reason given for emergent C-section among women who aimed to deliver vaginally
  - Rate of complications during pregnancy as reason given for emergent C-section among women who aimed to deliver vaginally
  - Low risk birth = single, term, vertex, and the absence of any medical condition preventing safe vaginal delivery

Performance Measure Name: Cesarean Birth
Description: Nulliparous women with a term, singleton baby in a vertex position delivered by cesarean birth
Type Of Measure: Outcome
Improvement Noted As: Decrease in the rate

Metric recommendations
Include reason for C-Section for numerator patients

**Numerator Statement:** Patients with cesarean births

**Included Populations:**
ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for cesarean birth as defined in Appendix A, Table 11.06

- 10D00Z0 Extraction of Products of Conception, High, Open Approach
- 10D00Z1 Extraction of Products of Conception, Low, Open Approach
- 10D00Z2 Extraction of Products of Conception, Extraperitoneal, Open Approach

**Data Elements:** ICD-10-PCS Principal Procedure Code, ICD-10-PCS Other Procedure Codes

**Denominator Statement:** Nulliparous patients delivered of a live term singleton newborn in vertex presentation

**Included Populations:**
ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for delivery as defined in Appendix A, Table 11.01.1

- 10D00Z0 Extraction of Products of Conception, High, Open Approach
- 10D00Z1 Extraction of Products of Conception, Low, Open Approach
- 10D00Z2 Extraction of Products of Conception, Extraperitoneal, Open Approach
- 10D07Z3 Extraction of Products of Conception, Low Forceps, Via Natural or Artificial Opening
- 10D07Z4 Extraction of Products of Conception, Mid Forceps, Via Natural or Artificial Opening
- 10D07Z5 Extraction of Products of Conception, High Forceps, Via Natural or Artificial Opening
- 10D07Z6 Extraction of Products of Conception, Vacuum, Via Natural or Artificial Opening
- 10D07Z7 Extraction of Products of Conception, Internal Version, Via Natural or Artificial Opening
- 10D07Z8 Extraction of Products of Conception, Other, Via Natural or Artificial Opening
- 10E0XZZ Delivery of Products of Conception, External Approach

**Excluded Populations:**
ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for multiple gestations and other presentations as defined in Appendix A, Table 11.09

- Less than 8 years of age
- Greater than or equal to 65 years of age
- Length of Stay >120 days
- Gestational Age < 37 weeks or UTD

**Data Elements:**
- Admission Date
- Birthdate
- Discharge Date
- Gestational Age
- ICD-10-CM Principal Diagnosis Code
- ICD-10-CM Other Diagnosis Codes
- Previous Live Births
- Risk Adjustment: No.

**Data Collection Approach:** Retrospective data sources for required data elements include administrative data and medical records.

**Data Accuracy:** Variation may exist in the assignment of ICD-10 codes; therefore, coding practices may require evaluation to ensure consistency.

**Measure Analysis Suggestions:** In order to identify areas for improvement, hospitals may want to review results based on specific ICD-10 codes or patient populations. Data could then be analyzed further to determine specific patterns or trends to help reduce cesarean births.

**Topic: Severe Maternal Morbidity (SMM) among C-Section cases**

**Outcome measure formula**

Numerator: Among the denominator, all cases with any SMM code

Denominator: All mothers during their birth admission, excluding ectopics and miscarriages, meeting 1 of the following criteria:
- C-Section as method of delivery

**The rate is typically displayed as:**

All cases with any SMM code / All mothers meeting denominator criteria

**Metric recommendations**

Limit your denominator to C-Sections performed without indication (term, singleton baby in a vertex position) since this sub APSS is specific to unnecessary C-Sections

**Direct Impact:** All patients who deliver by C-Section

**Lives Spared Harm:** Live Spared Harm = (SMM Rate baseline - SMM Rate measurement) X Denominator Procedures measurement

**Note:** Since this is a morbidity measure, the lives saved calculation is not applicable.

**Measuring Outcomes**

**Topic: Unnecessary C-Sections**

**Serious Safety Event (SSE) Rate:** Rate of Unnecessary C-Sections per 10,000 qualifying births

**Outcome Measure Formula**

Numerator: Nulliparous women with a term, singleton baby in a vertex position delivered live by cesarean birth

Denominator: Total number of nulliparous women with a term, singleton baby in a vertex position delivered live by vaginal or cesarean birth

**Rate is typically displayed as:** Unnecessary cesarean deliveries per 10,000 qualifying births

**Metric recommendations**
Direct Impact: All qualifying patients who deliver by C-Section

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

Lives spared harm:
Lives spared harm =
(Rate of Unnecessary C-Sections baseline - Rate of Unnecessary C-Sections measurement) X qualifying births measurement

Lives saved:
Lives saved =
(Unnecessary C-Sections mortality rate baseline - Unnecessary C-Sections mortality rate measurement) X Unnecessary C-Sections 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 determine whether a birth qualifies for inclusion in the denominator, look in the patient’s chart for confirmation of nulliparity and a delivery of a newborn with 37 weeks or more of gestation completed, as well as an ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for outcome of delivery:
Z370 Single live birth
And the following ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for delivery:
10D00Z0 - 10D00Z2, 10D07Z3-10D07Z8, 10E0XZZ

To determine whether a birth qualifies for inclusion in the numerator, look in the patient’s chart for confirmation of nulliparity and a delivery of a newborn with 37 weeks or more of gestation completed, as well as an ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for outcome of delivery:
Z370 Single live birth
And the following ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for delivery:
10D00Z0 - 10D00Z2

Excluded Populations:
ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for multiple gestations and other presentations: O30001-O30003, O30011-O30013, O30031-O30033, O30041-O30043, O30091-O30093, O30101-O30103, O30111-O30113, O30121-O30123, O30131-O30133, O30191-O30193, O30201-O30203, O30211-O30213, O30221-O30223, O30231-O30233, O30291-O30293, O30801-O30803, O30811-O30813, O30821-O30823, O30831-O30833, O30891-O30893, O3091-O3093, O3111X0-O3111X5, O3111X9, O3112X0-O3112X5, O3112X9, O3113X0-O3113X5, O3113X9, O3121X0-O3121X5, O3121X9, O3122X0-O3122X5, O3122X9, O3123X0-O3123X5, O3123X9, O318X10-O318X15, O318X19, O318X20-O318X25, O318X29, O318X30-O318X35, O318X39, O321XX0-O321XX5, O321XX9, O322XX0-O322XX5, O322XX9, O323XX0-O323XX5, O323XX9, O328XX0-O328XX5, O328XX9, O329XX0-O329XX5, O329XX9, O34211-O34212, O34219, O364XX0-O364XX5,
O364XX9, O4403, O4413, O4423, O4433, O6012X0-O6012X5, O6013X0-O6013X5, O6014X0-O6014X5, O6014X0, O632, O641XX0-O641XX5, O641XX9, O642XX0-O642XX5, O642XX9, O643XX0-O643XX5, O643XX9, O661, O666, Z371-Z374, Z3750-Z3754, Z3759-Z3764, Z3769, Z377

• Less than 8 years of age
• Greater than or equal to 65 years of age
• Length of Stay >120 days
• Gestational Age < 37 weeks or UTD

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 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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

Workgroup

Co-Chairs
David Lagrew
Jill Arnold

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Gillian Abir                      Stanford University
Hania Alim                       Patient Safety Movement Foundation
Ari Babaknia                     Chapman University
Steve Barker                     Patient Safety Movement Foundation, Masimo
Michel Bennett                   Patient Safety Movement Foundation (formerly)
Lilly Filler                     Patient Safety Movement Foundation
Afshan Hameed                    University of Irvine
Ariana Longley                   Patient Safety Movement Foundation
Jacob Lopez                      Patient Safety Movement Foundation (formerly)
Olivia Lounsbury                 Patient Safety Movement Foundation
Jeanne Mahoney                   The American College of Obstetricians and Gynecologists
Elliot Main                      California Maternal Quality Care Collaborative
Claire Manneh                    California Hospital Association
Ross McQuivey                    Clinical Innovations, LLC
Charles Micheli                  The University of Vermont Health Network
Donna Prosser                    Patient Safety Movement Foundation
Rachael Raynes                   University of Vermont
Claire Roy                       Patient Safety Movement Foundation
Brittany Sanford                 George Washington University Hospital
Sundary Sankaran                 Kaiser Permanente
Kisha Semenuk                    Maternal Safety Foundation
Abbas Shobeiri                   Virginia Commonwealth University School of Medicine Inova Fairfax Medical Campus
Seyed Shobeiri                   Inova Health System
Kristen Terlizzi                 National Accreta Foundation
Josef Wichilewski                Clalit

Metrics integrity
Robin Betts                      Kaiser Permanente, Northern California Region
Jan Orton                        Intermountain Healthcare

References


How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for VTE. In it, you’ll find:

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Executive summary checklist

Venous thromboembolism (VTE) is associated with increased mortality, poor patient outcomes, increased length of stay, and decreased patient satisfaction. It is the most common preventable hospital complication as well as the most common cause of preventable mortality in hospitals. Use this checklist to help prioritize your actions and measure your organization's progress in each area.

Ensure best patient care

- Ensure that providers perform a VTE risk assessment that accurately stratifies risk
- Assess risk using a validated risk assessment model as the basis for VTE among patients hospitalized patients
  - Medically ill patients: PADUA and IMPROVE
  - Surgical patients: Caprini
- Trauma patients: Roger Score
- Educate patient and families on VTE risks, complications, and the importance of mechanical and medication prophylaxis
- Ensure staff comply with VTE prophylaxis modalities based on VTE risk assessment including:
  - Medication prophylaxis (such as anticoagulants)
  - Mechanical prophylaxis (such as compression therapy)

Use data to inform action

- Measure appropriate quality measures related to VTE to close performance gap
- Complete in-depth chart review for hospital-associated thrombosis events to identify opportunities for improvement and then act on lessons learned
- Use patient stories - in written and video form - to help teach and inspire change in your staff

Follow best practices

- Follow VTE best practices from national organizations such as the Agency for Healthcare Research and Quality’s VTE Safety Toolkit (AHRQ, 2016). The toolkit contains 10 components that are evidence-based guidelines for preventing, diagnosing, treating, and educating patients and providers about VTE. The components are as follows:
  - VTE prophylaxis guidelines, VTE risk assessment tool, DVT diagnostic algorithm, PE diagnostic algorithm, HIT (heparin-induced thrombocytopenia) assessment, VTE treatment pathway, DVT outpatient treatment order set, Vascular laboratory requisition, Neural-axial anesthesia guidelines, Patient education (prevention and treatment) pamphlets
- Ensure healthcare professionals receive at least annual training on new VTE policies and processes
- Select technologies that show early evidence to reduce VTEs and positively impact both patient and provider outcomes in the clinical settings such as:
An EHR (electronic health records) system with prompt decision making support to ensure every hospitalized patient has a valid VTE prevention plan in place at all times
What we know about VTEs

VTEs are one of the three major cardiac events and a contributing cause to the global disease burden. In the United States, the prevalence increased from 2002 to 2004 from 3.2 per 1000 to 4.2 per 1000 persons (Raskob et al., 2014). For those aged 65 years and older the prevalence of VTE increases to 13.8 per 1000 persons and the highest rate of VTE is seen in Black men followed by White men (Raskob et al., 2014). However, VTE can still affect those under the age of 65 and all ethnicities.

While incidence rates of VTE vary by world region with a range of 0.138-2.69 per 1000 persons per year, VTE affects individuals in high-income countries and low- and middle-income countries (Raskob et al., 2014). The incidence of VTE per 100 hospitalizations is 3.0 in low- and middle-income countries as compared to 3.3 in high-income countries (Raskob et al., 2014). The estimated number of annual VTE cases is 3.9 million in high-income countries and 6.0 million in low- and middle-income countries (Raskob et al., 2014).

VTE has been identified as the leading cause of DALYs lost in hospitalizations accounting for one-third of total DALYs (Raskob et al., 2014). Additionally, “VTE is the leading cause of DALYs lost in low- and middle-income countries and ranked second in high income countries ... with premature death as the source of 64% of the DALYs lost in high-income countries and for 66% of the DALYs lost in low- and middle-income countries” (Raskob et al., 2014, p. 2368).

Although the classic symptoms of a deep vein thrombosis (DVT) can often be seen, such as redness and/or painful swelling of a limb, the clinical examination for DVT is known for being neither sensitive nor specific. In some studies of hospitalized patients, only a minority of those found to have DVT have classical clinical findings to suggest the diagnosis (Cook et al., 2005). Because of this, clinical decision rules have been developed to help guide the diagnostic evaluation (Wells et al., 1997).

Patients who develop a VTE have a higher in-hospital mortality rate, and have around a 33% chance of developing another clot within 10 years (CDC, 2014).

Although patients with an acute PE usually have shortened breaths, tachypnea and/or tachycardia, sudden cardiac arrest is the first symptom in 25% of PE patients (“Department of Health and Human Services”, 2014). A healthcare institution must maintain a high level of clinical suspicion to diagnose VTE.

The importance of VTE risk assessment

From a patient safety and a cost-aware point of view, primary prevention addresses VTEs before they begin. An institution should evaluate all patients admitted to the acute care setting for their risk of VTE, and then utilize guideline-appropriate VTE prophylaxis. This strategy results in far fewer hospital-acquired VTEs.

Diagnosis and treatment

Once clinically suspected, an institution should use clinical prediction rules to guide their diagnosis of a patient. Diagnostic imaging for confirmation includes venous doppler, V/Q scans or the highly sensitive computerized tomography angiography (CTA) of the chest. With the latter, small subsegmental, possibly non-clinical, pulmonary emboli can now be detected thus increasing a hospital’s reported VTE rate.

Patients with an acute VTE require a secondary prophylaxis program (ongoing treatment). For
most patients, this means extended use of anticoagulation and a close follow-up to carefully manage the risk and benefits of the secondary prophylaxis.

**Leadership plan**

- Identify senior executive leadership that is committed to reducing VTEs
- Assign a team that takes ownership over VTE from administrative, physician, and nursing champions, such as a chief nursing officer
- Gather staff that have in-depth knowledge of disease process and prevention of VTE such as:
  - Physicians
  - Nursing leaders
  - Advanced practice providers (nurse practitioners and physician assistants), such as
  - Physical and occupational therapists
  - Physicians in training
  - Residents
  - Bedside nurses
  - Quality Improvement staff
  - Safety/risk
  - Pharmacy
  - Information technology team with EMR
- Senior executive leadership and clinical/safety leaders should agree on the best ways to close their performance gap including measuring appropriate quality metrics
  - Senior executive leadership should set a timeline and budget for their goal
  - Clinical and safety leaders should act as agents of change and drive the execution of the goal
- Utilize patient stories – in written and video form – to identify gaps and inspire change in your staff.
  - The story of Charles Yogiraj Bates II, husband of Vonda Vaden Bates, is an excellent example of a story of a HA-VTE that could have been prevented. It can be viewed freely here: [http://patient.sm/xqtGld](http://patient.sm/xqtGld)

**Action plan**

**Find areas for improvement**

- Complete in-depth chart review of hospital-associated thrombosis events and identify trends in these events, such as:
  - Service line
  - Physician
  - Diagnosis
  - Risk score (See Appendix A for examples such as: Caprini Score, Padua Prediction Score, IMPROVE score, or “3-bucket” model)
  - Hospital units
o Pharmacological prophylaxis ordered
  • Pharmacological prophylaxis missed doses
  • Patient refusal of pharmacological prophylaxis
o Mechanical prophylaxis ordered
  • Mechanical prophylaxis missed therapy
  • Patient refusal of mechanical prophylaxis

• Identify gaps in care that promote VTE development
• Review HospitalCompare.com to see what is publicly posted about your hospital’s VTE rates

Create protocols and provide staff training
• Ensure the use of patient-centered interventions
• Follow the Agency for Healthcare Research and Quality’s Venous Thromboembolism Safety Toolkit: A System’s Approach to Patient Safety
• Incorporate VTE risk assessment into EHR for all new patient admissions
  o Reassess risk periodically when there is a change in the level of care, clinicians, and prior to discharge
• Ensure staff ordering appropriate VTE prophylaxis according to risk assessment
  o Consider adopting VTE power plans/order sets
  o Continue VTE prophylaxis past discharge if recommended
• Ensure timely and reliable delivery of pharmacological and/or mechanical prophylaxis as indicated
  o Track and find trends in missed doses and patient refusals
  o Educate patients that resist or refuse prophylaxis on their purpose and risks if not administered
• Develop specific and reliable protocols, endorsed by local surgical champions, for applying reliable mechanical or pharmacologic prophylaxis before anesthesia
• Consider nursing protocols for using mechanical prophylaxis in pre-op areas
• Understand your staff’s perception of the importance of VTE prophylaxis
  o Educate staff without the information needed on VTE prophylaxis
  o Consider yearly competence in VTE
  o Ensure that all team members - physicians, nurses, patient care assistants, trainees, pharmacists, transport personnel, physical therapists, patients, and family members are aware of their role in VTE-P (prophylaxis)
  o Assess patient mobility, such as through mobility trackers
• Set a plan for when pharmacological prophylaxis isn’t possible or recommended, such as using proactive monitoring
• Educate patients and families about the risks, complications, and importance of VTE prophylaxis, and the symptoms of DVT and PE

Misconceptions about Ambulation
“although we encourage early and frequent ambulation that is not sufficient enough to reduce the risk of VTE.” Brandyn - There is no evidence that ambulation is effective alone for VTE treatment.
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patient. sm/dgQogJ

With regard to VTE, there are a few novel technology platforms that offer a low entry cost that work alongside the Electronic Health Record (EHR). These technology platforms are secure with multimedia functions and can host checklists, education and much more to improve best practices and engagement across the care continuum. There is also technology that is important in the prevention of blood clots, like compression devices. Examples of those devices and technology solutions are detailed below and may be helpful in VTE prevention.

Electronic Health Record (EHR) system

Use an ONC Meaningful Use-certified EHR system with the following capabilities:

- Computerized Provider Order Entry (CPOE)
- Drug-drug interaction check
- Drug-allergy interaction check
- Clinical Decision Support (CDS) tools
  - Use to ensure every patient has a valid VTE prevention plan at all times (Morrison and England, 2015; Doyle and Hospital, n.d.)
- Vital signs (BP, Temp, HR, RR, and SpO2)
- Lab results
- Nurses notes and event reports

Compression devices

Graduated Compression Stockings (GCS)
Examples include:

- Anti-embolism stockings
- anti-thrombosis stockings
- elastic support hose
- graduated compression elastic stockings
- surgical hose
- TED hose
- white hose
- thrombosis stockings.

Note: When using GCS, proper fitting is essential to ensure safety from injury and effectiveness. Notably, 15-20% of patients cannot effectively wear AES because of unusual limb size or shape (Geerts et al., 2001).

Intermittent Pneumatic Compression (IPC) devices and anti-embolic (AE) pumps:
Examples include:

- Alternating Leg Pressure (ALP)
- athrombic pumps-calf/thigh
- Continuous Enhanced Circulation Therapy (CECT)
DVT boots-calf/thigh
EPC cuffs/stockings-External pneumatic compression-calf/thigh
Intermittent pneumatic compression stockings
Intermittent compression device (ICD)
Leg pumpers
PAS (Pulsatile anti-embolic stockings)
Rapid inflation asymmetrical compression (RIAC) devices
Sequential compression device
Sequential pneumatic hose
Thrombus pumps-calf/thigh
PAS (Pulsatile anti-embolic stockings)
Rapid inflation asymmetrical compression (RIAC) devices

**Note:** when using IPC AE, appropriate fitting is essential to ensure safety from injury and effectiveness.

### Measuring outcomes

#### Key performance indicator 1

**Hospital acquired potentially preventable venous thromboembolism rate (VTE-6)**

VTE-6 assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present at admission) who did not receive VTE prophylaxis between hospital admission and the day before date of the first positive VTE diagnostic test.

#### Outcome measure formula

**Numerator:** Patients who received no VTE/PE prophylaxis prior to the day before the date of the first positive VTE diagnostic test.

**Denominator:** Patients who developed confirmed VTE/PE during hospitalization. Rate is typically displayed: Numerator/Denominator*1000

#### Metric recommendations

**Indirect impact:**
All admitted patients

**Direct impact:**
All admitted patients

**Lives spared harm:**
Lives Spared Harm = (VTE or PE Ratebaseline - VTE or PE Ratemeasurement) X Total Patient Daysbaseline

**Lives saved:**
Lives Saved = Lives Spared Harm X 0.104

**Notes:**
Measure exclusions age < 18 years, LOS > 120 days, comfort measures only, clinical trials, principal diagnosis of VTE or VTE present on admission, provider reason for not administering mechanical and pharmacologic prophylaxis.
Data collection
Chart abstraction.

Mortality
(Will be calculated by the Patient Safety Movement Foundation)
Estimated mortality per VTE is 0.104

Reference:
Mortality and cost-per-case Information from AHRQ

<table>
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<tr>
<th>PIP Hospital Acquired Condition (HAC) for 2010-2014</th>
<th>Estimated Additional Cost per HAC (2010 dollars)</th>
<th>Estimated Additional Inpatient Mortality per HAC</th>
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<tr>
<td>Adverse Drug Events</td>
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<tr>
<td>Catheter-Associated Urinary Tract Infections</td>
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<tr>
<td>Postoperative Venous Thromboembolism</td>
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</tbody>
</table>

Key performance indicator 2
Hospital acquired **venous thromboembolism rate** Rate of patients having a hospital-acquired VTE/PE

Outcome measure formula
**Numerator:** Number of patients having a VTE/PE (note ICD codes below)

**Denominator:** Total patient days

Rate is typically displayed: Numerator/Denominator * 1,000

Use the following ICD diagnosis codes to identify hospital-acquired VTEs:

**ICD9:** 45111, 45119, 45181, 45340, 45341, 4151, 41511, 41513, 41519


**Note:** If a patient has a qualifying diagnosis at admission, exclude from the numerator.

Total patient days come from daily census counts for each inpatient nursing unit. Census counts are electronically derived at the same time of day each day. These counts may be collected manually if an electronic source is not available.
Metric recommendations

Indirect impact:
All admitted patients

Direct impact:
All admitted patients

Lives spared harm:
Lives Spared Harm = (VTE or PE Rate_{baseline} - VTE or PE Rate_{measurement}) \times \text{Total Patient Days}_{baseline}

Lives saved:
Lives Saved = Lives Spared Harm \times 0.104

Data collection:
Data collected from final diagnosis codes for encounter as determined by a professional health information coder.

Mortality (will be calculated by the Patient Safety Movement Foundation): Estimated mortality per VTE is 0.104, as listed under Topic 1.

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs
Michael Becker
Masimo
Brandyn Lau
Johns Hopkins Medicine
Vonda Vaden Bates
Patient Advocate; 10th Dot

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions

Jim Augustine
US Acute Care Solutions
Steven J. Barker
Patient Safety Movement Foundation; Masimo
Michel Bennett
Patient Safety Movement Foundation (formerly)
Ann Bilyew
ClearLine MD
Jestin Carlson
Allegheny Health Network
Richard Cooper
University of Toronto
Abbey Curran
Lorraine Foley
Drew Fuller
Kate Garrett
Victor Grazette
David Hughes
Hans Huitink
Thomas Kallstrom
Arthur Kanowitz
Ariana Longley
Jacob Lopez
Olivia Lounsbery
Amy Lukanski
Ariel MacTavish
Rhea May
Brendan Miney
Bill Nadeau
Donna Prosser
Kellie Quinn
Kenneth Rothfield
Claire Roy
Michael Taylor
Dianne Vass

Metrics Integrity:
Robin Betts

References
Doyle, C. and Hospital, K. C. (n.d.). VTE Prevention; Electronic Solutions.


## Calculation of the Caprini Risk Score

The table below shows the different scores for the factors represented in the Caprini score (Caprini, 1991). Calculate the Caprini score by adding the scores of all factors present in the patient. (Caprini, 2005)

<table>
<thead>
<tr>
<th>5 points</th>
<th>3 points</th>
<th>2 points</th>
<th>1 point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke (in the previous month)</td>
<td>Age ≥ 75 years</td>
<td>Age: 61-74 years</td>
<td>Age 41-60 years</td>
</tr>
<tr>
<td>Fracture of the hip, pelvis, or leg</td>
<td>Prior episodes of VTE</td>
<td>Arthroscopic surgery</td>
<td>BMI &gt; 25 Kg/m2</td>
</tr>
<tr>
<td>Elective arthroplasty</td>
<td>Positive family history for VTE</td>
<td>Laparoscopy lasting more than 45 minutes</td>
<td>Minor surgery</td>
</tr>
<tr>
<td>Acute spinal cord injury (in the previous month)</td>
<td>Prothrombin 20210 A</td>
<td>General surgery lasting more than 45 minutes</td>
<td>Edema in the lower extremities</td>
</tr>
<tr>
<td></td>
<td>Factor V Leiden</td>
<td>Cancer</td>
<td>Varicose veins</td>
</tr>
<tr>
<td></td>
<td>Lupus anticoagulants</td>
<td>Plaster cast</td>
<td>Pregnancy</td>
</tr>
<tr>
<td></td>
<td>Anticardiolipin antibodies</td>
<td>Bed bound for more than 72 hours</td>
<td>Post-partum</td>
</tr>
<tr>
<td></td>
<td>High homocysteine in the blood</td>
<td>Central venous access</td>
<td>Oral contraceptive</td>
</tr>
<tr>
<td></td>
<td>Heparin induced thrombocytopenia</td>
<td></td>
<td>Hormonal therapy</td>
</tr>
<tr>
<td></td>
<td>Other congenital or acquired thrombophilia</td>
<td></td>
<td>Unexplained or recurrent abortion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sepsis (in the previous month)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Serious lung disease such as pneumonia (in the previous month)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Abnormal pulmonary function test</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute myocardial infarction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Congestive heart failure (in the previous month)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bed rest</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inflammatory bowel disease</td>
</tr>
</tbody>
</table>
### Scoring and Recommended Prophylaxis (Gould et al., 2012)

<table>
<thead>
<tr>
<th>Caprini Score</th>
<th>Risk</th>
<th>VTE Incidence</th>
<th>Recommended Prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2</td>
<td>Very low-low</td>
<td>&lt;1.5%</td>
<td>Early ambulation, IPC</td>
</tr>
<tr>
<td>3-4</td>
<td>Moderate</td>
<td>3%</td>
<td>LMWH; UFH; or IPC If high bleeding risk, IPC until bleeding risk diminishes.</td>
</tr>
<tr>
<td>5-8</td>
<td>High</td>
<td>6%</td>
<td>LMWH + IPC; or UFH + IPC If high bleeding risk, IPC until bleeding risk diminishes.</td>
</tr>
<tr>
<td>&gt;8</td>
<td>Very high</td>
<td>6.5-18.3%</td>
<td>LMWH + IPC; or UFH + IPC If high bleeding risk, IPC until bleeding risk diminishes. Consider extended duration prophylaxis.</td>
</tr>
</tbody>
</table>

Abdominal or pelvic surgery for cancer should receive extended VTE prophylaxis with LMWH x 30 days (AHRQ, 2016).

IPC = intermittent pneumatic compression  
LMWH = low-molecular-weight heparin  
UFH = unfractionated heparin
Calculation of the Padua prediction score

The table below depicts the Padua Prediction score for VTE among hospitalized patients (Barbar et al., 2010). A score of:

- ≥4: high risk of VTE
- ≤4: low risk for VTE.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active cancer</td>
<td>3</td>
</tr>
<tr>
<td>Previous VTE</td>
<td>3</td>
</tr>
<tr>
<td>Decreased mobility</td>
<td>3</td>
</tr>
<tr>
<td>Thrombophilia</td>
<td>3</td>
</tr>
<tr>
<td>Previous trauma or surgery within that last month</td>
<td>2</td>
</tr>
<tr>
<td>Age≥ 70</td>
<td>1</td>
</tr>
<tr>
<td>Heart and/or respiratory failure</td>
<td>1</td>
</tr>
<tr>
<td>Ischemic stroke or acute myocardial infarction</td>
<td>1</td>
</tr>
<tr>
<td>Acute rheumatologic disorder and/or acute infection</td>
<td>1</td>
</tr>
<tr>
<td>Obesity</td>
<td>1</td>
</tr>
<tr>
<td>Hormonal therapy</td>
<td>1</td>
</tr>
</tbody>
</table>
Calculation of the IMPROVE Predictive Score
The IMPROVE score for VTE assesses the risk of VTE among hospitalized patients. The predictive score includes 4 independent risk factors for VTE, which are present at admission. The associative score includes 7 variables present either at admission or during hospitalization (Spyropoulos et al., 2011).

### IMPROVE Predictive Score

<table>
<thead>
<tr>
<th>Variable</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior episode of VTE</td>
<td>3</td>
</tr>
<tr>
<td>Thrombophilia</td>
<td>3</td>
</tr>
<tr>
<td>Malignancy</td>
<td>1</td>
</tr>
<tr>
<td>Age more than 60 years</td>
<td>1</td>
</tr>
</tbody>
</table>

### Interpretation of the IMPROVE Predictive Score

<table>
<thead>
<tr>
<th>Score</th>
<th>Predicted VTE risk through 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.5%</td>
</tr>
<tr>
<td>1</td>
<td>1.0%</td>
</tr>
<tr>
<td>2</td>
<td>1.7%</td>
</tr>
<tr>
<td>3</td>
<td>3.1%</td>
</tr>
<tr>
<td>4</td>
<td>5.4%</td>
</tr>
<tr>
<td>5-8</td>
<td>11%</td>
</tr>
</tbody>
</table>

### IMPROVE Associative Score

<table>
<thead>
<tr>
<th>Variable</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior episode of VTE</td>
<td>3</td>
</tr>
<tr>
<td>Thrombophilia</td>
<td>2</td>
</tr>
<tr>
<td>Paralysis of the lower extremity during the hospitalization</td>
<td>2</td>
</tr>
<tr>
<td>Current malignancy</td>
<td>2</td>
</tr>
<tr>
<td>Immobilization for at least 7 days</td>
<td>1</td>
</tr>
<tr>
<td>ICU or CCU admission</td>
<td>1</td>
</tr>
<tr>
<td>Age more than 60 years</td>
<td>1</td>
</tr>
</tbody>
</table>

### Interpretation of the IMPROVE Associative Score

<table>
<thead>
<tr>
<th>Score</th>
<th>Predicted VTE risk through 3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.4%</td>
</tr>
<tr>
<td>1</td>
<td>0.6%</td>
</tr>
<tr>
<td>2</td>
<td>1.0%</td>
</tr>
<tr>
<td>3</td>
<td>1.7%</td>
</tr>
<tr>
<td>4</td>
<td>2.9%</td>
</tr>
<tr>
<td>5-10</td>
<td>7.2%</td>
</tr>
</tbody>
</table>
How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for air embolism. In it, you’ll find:

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What we know about air embolism.................................. 481
Leadership plan.............................................................. 482
Action plan ................................................................. 483
Technology plan............................................................ 485
Conflicts of interest disclosure........................................ 486
Workgroup ................................................................. 486
References ................................................................. 487
APSS #12B: Air embolism

Executive summary checklist

Air embolism (AE) is the presence of gas (usually air) in the circulatory system. In the hospital setting, AE is usually the result of inadvertent injection of air into the venous system. Inadvertent AE causes serious mortality and morbidity in hospitalized patients.

Use this checklist to help you prioritize your actions and measure your organization’s progress in your efforts to prevent AE:

Create an action plan

☐ Healthcare leadership should support the design and use of standards and provider training programs for reducing AE risk:
  ☐ Ensure all providers perform an AE risk assessment to accurately stratify risk
  ☐ Measure quality indicators related to AE to determine the best way to close your institution’s performance gap
  ☐ Complete an in-depth chart review for in-hospital AE events to find areas for improvement and address these areas
  ☐ Adhere to AE best practices from national organizations
  ☐ Ensure that healthcare professionals receive annual training on AE policies and processes

Ensure best patient care

☐ Clinicians should assess and act on AE risk for higher risk groups including:
  ☐ Patients with right-to-left shunt anatomy, including patent foramen ovale (PFO), patent ductus arteriosus (PDA), atrial septal defect (ASD), etc.
  ☐ Patients who need large volumes of intravenous fluids, or rapid infusions using pressurized systems (such as major trauma surgery)
  ☐ Patients who have or need central venous access of any type
  ☐ Patients who will undergo a high-risk surgical procedure or surgery in a high-risk position (such as a surgery site above the heart)
  ☐ Educate patients and families on AE risks, complications, signs, and symptoms
  ☐ Educate clinicians on technologies that reduce the number of AE by prevent, detect, and actively remove air in intravenous access lines
  ☐ Implement an electronic health records (EHR) system with decision making support to ensure that every patient has an AE prevention and detection plan in place at all times during hospitalization
  ☐ Utilize patient stories – in written and video form – to identify gaps and inspire change in your staff
What we know about air embolism

Causes and symptoms of AE
While AE is often the result of inadvertent injection of air, it can also result from traumatic injuries, surgical procedures, or exposure of venous access systems (such as central venous lines) to the open air. AE can also occur outside of the hospital, such as during SCUBA diving or with blast injuries.

Inadvertent air injections can be sudden, as from an air-filled syringe or pumping system, or gradual, as through a continuous IV infusion. If gradual, it may not cause symptoms until serious damage to the pulmonary circulation has occurred. A patient's ability to tolerate and compensate for air embolism is variable, depending on general health status and presence of specific diseases (e.g., cerebrovascular).

Signs and symptoms of AE in patients can include:
(See also signs and symptoms of VTE, in APSS #12A)
- Chest pain
- Dyspnea
- Shortness of breath
- Unconsciousness or decreased level of consciousness
- Sudden cardiac arrest
- Neurological deficit from transient ischemic attack (TIA) or stroke

In adults with regular circulation, venous AE will enter the pulmonary circulation and become trapped in the lungs. The systems of healthy adults may be able to tolerate small amounts of pulmonary AE – even up to 50 ml or more in a healthy adult. However, at some point the air load in the lung capillaries will impede the pulmonary circulation, resulting in pulmonary hypertension and eventually right-heart failure (cor pulmonale). This can lead to circulatory collapse and death.

Right-left shunts increase AE risk
The risk of AE becomes more immediately serious in patients with any form of right-left shunt (an opening that allows blood to flow from the right side of the heart to the left), such as patent foramen ovale (PFO), atrial septal defect (ASD) or patent ductus arteriosus (PDA). 25-30% of healthy adults have PFO, and most of these are asymptomatic and undiagnosed (Hagen, Scholz and Edwards, 1984). The presence of one of these forms of right-left shunt allows venous AE to bypass the lungs and enter the arterial circulation as a “paradoxical embolism,” where even small amounts of air can block circulation to vital organs.

Because of the high incidence of undiagnosed PFO in adults, it’s difficult to know which patients are at risk. For any patient with a known diagnosis of potential right-left shunt, the increased risk of AE must be documented in the EMR, and clearly explained to all care-team members. Since newborns are far more likely to have right-left shunts, all infants should be treated as high risk for venous AE entering the arterial circulation.

Certain surgeries increase AE risk
The brain is particularly vulnerable to arterial AE, where even a few milliliters of air can cause a major stroke. A retrospective case study by Albin showed that AE occurred in 100 of 400
patients who underwent craniotomy in the sitting position – an incidence of 25% (Albin, 2011). Other surgical procedures that create high risk for air embolism include cardiopulmonary bypass, in which there are many reports of fatal cases (Van, Koene and Mariani, 2014; Robich et al., 2017), as well as intrathoracic surgery, major joint surgery, Cesarean section, eye surgery (Gayer et al., 2016), pacemaker placement (Xiao et al., 2016), and major trauma. An excellent review of venous AE during surgery is found in (Palmon, Moore, Lundberg and Toung, 1997).

Cannulation increases AE risk
AE can also occur when any type of intravascular cannula is used. This includes standard peripheral intravenous catheters, central venous catheters, pulmonary artery catheters, dialysis catheters, and arterial catheters – in other words, with any external cannulation of the circulation for any reason.

Pressurized intravenous infusion systems create a particularly serious risk of massive venous air embolism. One-liter plastic bags of intravenous crystalloid, such as Lactated Ringer’s Solution, contain up to 150 cc of air. If this air is not carefully removed before the fluid bag is placed in a pressurized device, it can be forcefully pumped into the patient’s vein. There have been a number of published case reports of fatal or near-fatal AE from this mechanism (Adhikary and Massey, 1998; Aldridge, 2005).

Central circulation catheters (CVP, PA, “triple lumen”, etc.) pose an even higher risk. If such a catheter becomes disconnected and exposed in a sitting patient who spontaneously breathes, the pressure from inhaling can rapidly suck massive amounts of air directly into the heart, with fatal results (Ploner, Saltuari, Marosi, Dolif and Salsa, 1991).

Preventing AE
The literature on the various types of venous or arterial AE seems to agree on one important point: most of these should be considered “never events” – potential disasters that should never occur if proper safeguards, precautions, and procedures are followed.

An excellent review and bibliography of the diagnosis and treatment of all of these types of air embolism can be found in (Mirski, Lele, Fitzsimmons and Young, 2007). Annual death rates from AE are difficult to document, because of the wide variety of causes and clinical settings of these cases. The serious nature of this problem is evidenced by the fact that there have been over 4,000 publications on the topic in the past 30 years (Mirski, Lele, Fitzsimmons and Young, 2007).

Almost all in-hospital AE events are preventable and should never occur. This is the goal of this APSS: to make AE a “never event.”

Leadership plan

Show leadership’s commitment to AE
- Identify senior executive leadership that is committed to a reduction in AE
- Identify team leads, ideally physician and administrative champions, such as the Chief Medical Officer or Chief Nursing Officer
- Gather staff that have an in-depth knowledge base of disease process and prevention of AE such as:
  - Physicians
  - Nursing leaders
Advanced Practice Providers, such as Physical and Occupational Therapists
- Physicians in training
- Residents
- Bedside nurses
- Quality improvement staff
- Safety/risk
- Pharmacy
- Information Technology team with EMR

Create the infrastructure needed to make changes
- Senior executive leadership and clinical/safety leaders should agree on the best measurable metrics and target actions to close the institution’s performance gap
- Senior executive leadership should select a goal and set a timeline and budget to achieve said goal
- Clinical and safety leaders should act as change agents and drive implementation
- Utilize patient stories - in written and video form - to identify gaps and inspire change in your staff

Action plan

Find areas for improvement
- Complete an in-depth chart review of hospital-related AE events and identify trends such as:
  - Service line
  - Physician
  - Diagnosis
  - Risk factors
  - Hospital units
  - Patient mobility
- Identify gaps in care that increase a patient’s risk for AE
- Understand your staff’s perception of the importance of AE precautions
- Educate care providers in all of the possible causes of AE
- Consider yearly competence in AE prevention, detection, treatment
- Reassess AE risk periodically upon change in level of care, clinicians, and prior to discharge
- Ensure that all team members - physicians, nurses, patient care assistants, trainees, pharmacists, transport personnel, physical therapists, patients and family members are aware of their roles in AE prevention
- Educate patients and families about the risks, complications, and symptoms of AE, as well as the importance of AE prophylaxis
Create protocols to prevent AE

- Ensure interventions are patient-centered
- Incorporate AE Risk Assessment into EHR for all new admissions
- For each potential AE cause, develop a checklist protocol for all caregivers to follow to avoid AE events
  - Example: Pressurized intravenous infusion systems
    - Eliminate all air from IV infusion bags before connecting to a patient
    - Use an air detection technology, such as ClearLine, to detect and eliminate air from infusion tubing
- When possible during surgery, avoid having surgical site well above level of the heart (e.g., “sitting craniotomy”)
- Use Positive End-Expiratory Pressure (PEEP) on ventilator during high-risk procedures on mechanically-ventilated patients

Create protocols to detect and diagnose AE

- Be aware of AE symptoms in a conscious patient:
  - Chest pain
  - Dyspnea
  - Shortness of breath
  - Unconsciousness or decreased level of consciousness
- Be aware of AE clinical signs:
  - Hypotension
  - Decreased end-tidal CO2
  - Rapid or irregular heartbeat
  - “Mill-wheel” murmur
  - Decreased SpO2 (late sign)
  - Peaked P-waves on ECG
- Use special monitors for AE:
  - Trans-esophageal echo (TEE)
  - Precordial Doppler
  - Transcranial Doppler
  - Pulmonary artery catheter
  - End-tidal nitrogen

Create protocols to treat AE

- First, prevent further air entrainment by removing the underlying cause, such as reposition patient, stop intravenous air infusion, flood surgical field, etc.
- Increase inspired oxygen fraction FiO2 to 100%
- Turn supine patient to 45-degree left-side down position - “Durant Maneuver”
- If a patient has no palpable pulse, promptly start CPR with chest-compression since compressions may help purge air from heart
- If a central venous (CVP) or pulmonary artery (PA) catheter is present, attempt to aspirate air from the right atrium
• Use pharmacological hemodynamic support as needed, including inotropes (dobutamine) and vasoconstrictors (phenylephrine, norepinephrine) to support systemic blood pressure
• Consider hyperbaric oxygen therapy – note this is unproven but supported by some clinical evidence

Technology plan
These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patient.sm/dgQogJ

Consider implementing the following technologies:

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Available Technology</th>
</tr>
</thead>
</table>
| ONC Meaningful Use-Certified Electronic Health Record (EHR) System with the following capabilities: | • Computerized Provider Order Entry (CPOE)  
• Drug-drug interaction check  
• Drug-allergy interaction check  
• Clinical Decision Support tools (CDS) |
| High AE Risk Cases (e.g. sitting craniotomy)  
• Use the following additional detection and treatment technologies when possible: | • Precordial Doppler Ultrasonography: Early detection  
• Trans-Esophageal Echocardiography (TEE): Early detection  
• Pulmonary Artery Catheter: Potential treatment by aspiration from right atrium and ventricle  
• End-tidal nitrogen (N2) monitoring: If there is no nitrogen in the inspired gas, then sudden appearance of end-tidal N2 implies AE until proven otherwise |
| Use air removal from infusion precautions with all intravenous cannulas, especially central venous (CVP) | • Consider technology for detecting and removing air from infusion fluids  
• Ensure that all central venous catheters (CVP, PA, “triple lumen”, etc.) use Luer-Lock or other secure locking technology to guard against inadvertent disconnection  
• **Note:** A disconnected CVP in a sitting, spontaneously breathing patient can be rapidly fatal |
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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

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Masimo  
Brandyn Lau  
Johns Hopkins Medicine  
Vonda Vaden Bates  
Patient Advocate; 10th Dot

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University of Toronto  
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ClearLine MD  
Lorraine Foley  
Society for Airway Management  
Drew Fuller  
Emergency Medicine Associates  
Kate Garrett  
Ciel Medical  
Victor Graayette  
Virginia Hospital Center  
David Hughes  
Do It For Drew Foundation  
Hans Huitink  
Vanderbilt University Medical Center  
Thomas Kallstrom  
American Association for Respiratory Care  
Arthur Kanowitz  
Securisyn  
Ariana Longley  
Patient Safety Movement Foundation  
Jacob Lopez  
Patient Safety Movement Foundation (formerly)  
Olivia Lounsbury  
Patient Safety Movement Foundation  
Amy Lukanski  
University of Pittsburgh Medical Center  
Ariel MacTavish  
Medtronic  
Rhea May  
Medtronic  
Brendan Miney  
Talis
**Metrics Integrity:**

**Robin Betts**
Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

## References


Actionable Patient Safety Solutions (APSS) #13B:
Collaborative care planning in mental health

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for collaborative care planning in mental health. In it, you’ll find:

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Leadership plan ............................................................. 492
Action plan ...................................................................... 493
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Measuring outcomes ......................................................... 502
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Workgroup ..................................................................... 505
References ...................................................................... 506
APSS #13B: Collaborative care planning in mental health

Executive summary checklist

Patient safety events in psychiatry are a serious concern. About 1,500 suicides take place at inpatient psychiatric units in the U.S. each year—over 70% by hanging (Mills, King, Watts, and Hemphill, 2013). Patients who are in acute psychiatric distress have a higher chance of harming themselves or others. Collaborative care planning is a tool designed and used to help patients and their family caregivers recognize when they are reaching levels of acute psychiatric distress.

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

☐ Create opportunities for staff and patients and family to collaborate on mental health care planning
☐ Encourage and teach patients to take an active role in and management of symptoms
☐ Promote family (as defined by the patient) involvement in support of established plan of care throughout the patient’s psychiatric care
☐ Determine which 2 pieces of information your facility should collect so you can better measure your facility’s progress in improving patient safety outcomes
☐ Increase patient safety by increasing awareness of and interventions for strong negative emotional states which may precede harm of self or others
☐ Track your outcomes with metrics, such as:
  ☐ Patient satisfaction surveys
  ☐ Patient lengths of stay
  ☐ Patient readmission rates
  ☐ Crisis incidents (i.e. “cCode white” frequency, acute psychiatric crisis, violence and aggression)
  ☐ Seclusion room use
☐ Utilize patient stories - in written and video form - to help teach and inspire change in your staff
What we know about mental health and patient safety

Collaborative care planning in mental health
Patient safety events in psychiatry are a serious concern. Patients who are in acute psychiatric distress have a higher chance of harming themselves or others. Collaborative care planning is a tool designed and used to help patients and their family caregivers recognize when they are reaching levels of acute psychiatric distress. The term “family” throughout this document refers broadly to lay caregivers that the patient considers family and consents to being identified by staff as family, even if not biologically or legally related.

This self-recognition translates into preventing patients from reaching a point of crisis where they are at a higher chance of harming themselves or others. Collaborative care planning refers to the combined efforts of staff, patients, and their family caregivers working together to set and achieve health goals, and involves greater patient involvement in the planning, delivery, and evaluation of care.

Ideally, collaborative care planning leads to better treatment by focusing on improving and maintaining health rather than just dealing with problems as they arise (Victoria State Government, 2012). Improved clinical outcomes are known to result from collaborative care planning (Craven and Bland, 2006).

Acute inpatient settings often do a good job of using the environment and medications to promote patient recovery. Patients are admitted to a relatively safe, calm environment removed from the complexities of life that may have triggered the acute psychiatric crisis. Patients receive medication trials under close medical supervision to determine the best pharmacological treatment plan.

The risks with the standard treatment
About 1,500 suicides take place at inpatient psychiatric units in the U.S. each year—over 70% by hanging (Mills, King, Watts, and Hemphill, 2013). Suicide is not the only metric for patient safety in behavioral health settings, which has other unique patient safety issues, such as:

- Violence and aggression
- Suicide and self-harm
- Seclusion and restraint
- Absconding and missing patients
- Access to hazardous materials
- Lack of supervision

Seclusion rates in an acute inpatient psychiatry unit can reach as high as 31%, with the most common indicator of seclusion being risk to others (74%) followed by risk to self (61%) and risk of absconding (55%) (Tunde-Ayinmode and Little, 2004). Up to 47% of mental health care providers have experienced violence at work (Nolan, 1999). As such, there is an urgent need to reduce and alleviate unsafe behaviors within the mental health care system.

However, a third arm of treatment, collaborative care planning, is often underutilized (Anthony and Crawford, 2000). Lack of collaborative care planning often manifests as:

- Patients being unaware of their treatment plan
- Patients feeling helpless
• Weak therapeutic relationships between patients and staff
• Ineffective communication of the mental health treatment plan through the healthcare system (between the supports for the patient)
• Lack of integration into more easily-accessible, preventative facilities, such as primary care
• Wider gap in unequal access to care based on socioeconomic factors
• Poor recognition of comorbidities

This, in turn, may result in poorer outcomes and increased number of patient safety events.

The purpose of this document is to increase patient safety by promoting collaborative care planning between staff, patients, and family in acute inpatient psychiatric settings. Collaborative care planning can be encouraged through a relatively simple framework utilizing:

• A Two-Step Comfort Toolkit:
  o This framework gives your staff the tools to work with patients and their support groups to build skills for both evaluation and management of emotional distress, which often happen before patient safety events

**Leadership plan**

Hospital and psychiatric governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work together to implement collaborative care in mental health care. Leaders need to commit to taking these key actions.

**Create the infrastructure needed to make changes**

• Use the Two-Step Comfort Toolkit to systematically build patient and support skills development in an effective and efficient way
• Collaborative care planning—providers, person (patient), and family—appears to have particularly strong effects in patients with more severe mental health disorders, and even low levels of collaboration can have positive outcomes (Craven and Bland, 2006)
• This is particularly important in acute inpatient psychiatry settings, where psychiatric severity tends to be high, and staff often are time and resource limited (Porter, 1992)

**Engage staff**

• Provide scope
  o Develop a guide for staff and physicians to determine appropriate family and supports to be involved in care planning
  o Prioritize information—if your team were to review the implementation of this program in 6 months, what are 2 pieces of information you wish you had so you could better gauge your facility’s progress?
• Create capacity
  o Protect time to engage in patient comfort planning
• Produce capability
  o Educate staff on:
    • How to leverage comfort planning
    • How to engage patients to identify their triggers
    • When to seek additional resources
  o Educate families on:
• How to support positive behaviors
• How to identify triggers
• When to ask for assistance

• Give motivation
  o Highlight the importance of patient involvement in patient outcomes
  o Empower staff to proactively assess and include patients in their treatment
  o Empower family involvement, if appropriate

• Track outcomes
  o Systematically track and improve patient engagement by collecting data about:
    • Outcomes
    • Success rates
    • Adverse events

• Use patient stories - in written and video format - to identify gaps and inspire change in your staff
  o The story of Glenn Saarinen is an inspiring story produced by the Patient Safety Movement Foundation
  • It can be viewed for free here: http://patient.sm/.dySMD2

**Action plan**

The Two-Step Comfort Toolkit can be completed in as little as two 30-minute sessions. It should ideally be completed as soon as a patient is settled enough to actively and collaboratively engage with your clinicians.

• Step 1 - Comfort Planning (Figure 2, Figure 3)
• Step 2 - Comfort Kits (Figure 4)
Figure 1: Comfort Plan: Collaborative Creation Guidelines and Process Measures

Process Measures
- Number of clients/family who self-refer
- Time between admission and review of appropriateness
- Frequency of client reviews
- % clients approved for Comfort Toolkit by clinicians
- Which discipline is assigned
- % follow-through by clinician
- % clients who agree to participate
- Time between admission and introduction of Comfort Kit/Plan
- Which Starter Kit items are rejected vs accepted
- Duration of introduction to Comfort Plan/Kit
- # times Comfort Toolkit used during stay (per documentation)
- # times Comfort Toolkit used immediately before/during/after incident
- # Comfort Plan revisions
- Trend of Comfort Toolkit use over time vs incidents
- # discharge summaries with Comfort Plan attached
- % clients who used Comfort Toolkit during their stay

Outcome Measures
- # incidents (AWOL, Code White, self-harm, seclusion)
- Length of Stay
- % readmissions
- pre-post self-report measures

Screening
- Client admitted to hospital
- Client appropriates for Comfort Toolkit?
  - N: Re-evaluate throughout stay
  - Y: Clinician assigned to introduce Comfort Toolkit

Comfort Toolkit Introduction
- Clinician obtains client permission?
  - N: Re-evaluate throughout stay
  - Y:
    - Client completes pre-measure
    - Clinician and client initiate Comfort Plan
    - Clinician and client review Starter Comfort Kit
    - Clinician documents encounter and attaches copy of Comfort Plan

Comfort Toolkit Utilization
- All staff:
  - Encourage client use of Comfort Plan when appropriate
  - Encourage client use and creation of personalized Comfort Kit based on the provided Starter Comfort Kit
  - Review/update Comfort Plan when client is having difficulties
  - Review/update Comfort Plan with client during team rounds
  - Review/update it with client after a crisis or code white as part of the debrief

Discharge
- Most recent Comfort Plan to be included in Discharge Summary
- Client completes post-measure
- Client and family encouraged to update and personalize Comfort Plan and Kit after discharge
Figure 2: Comfort Plan Template (Courtesy of: Vancouver Coastal Health)
## Comfort Plan Guide

**When a Challenge Happens... WHAT TO DO**

<table>
<thead>
<tr>
<th>People</th>
<th>Places</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Talk or sit quietly with a staff member</td>
<td>• Sit by the care team station</td>
</tr>
<tr>
<td>• Something others can say to help me calm down is: ___</td>
<td>• Go to my room</td>
</tr>
<tr>
<td>• Talk to another resident/friend</td>
<td>• Go outside</td>
</tr>
<tr>
<td>• Call a supportive friend/family member</td>
<td>• Be in soft/low light</td>
</tr>
<tr>
<td>• Be around other people</td>
<td>• Go to a quiet space</td>
</tr>
<tr>
<td></td>
<td>• Sit in the TV room</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Strategies</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Breathing techniques</td>
<td>• Listen to music/radio</td>
</tr>
<tr>
<td>• Grounding exercises</td>
<td>• Go for a walk</td>
</tr>
<tr>
<td>• Distraction activities</td>
<td>• Run/exercise</td>
</tr>
<tr>
<td>• Hope statements</td>
<td>• Spend time with a pet</td>
</tr>
<tr>
<td>• Naming my goals</td>
<td>• Spend time alone</td>
</tr>
<tr>
<td>• Mindfulness</td>
<td>• Write/journal/read/do art</td>
</tr>
<tr>
<td>• Progressive muscle relaxation</td>
<td>• Stretch/do yoga</td>
</tr>
<tr>
<td>• Guided imagery</td>
<td>• Clean my room</td>
</tr>
<tr>
<td>• Meditation</td>
<td>• Do something to stay busy</td>
</tr>
<tr>
<td>• Body scan</td>
<td>• Play music</td>
</tr>
<tr>
<td>• Positive affirmations</td>
<td>• Watch TV</td>
</tr>
<tr>
<td>• Yoga</td>
<td>• Do a word search/crossword/Sudoku</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Calming/comforting sensory ideas</th>
<th>Alerting/distracting sensory ideas</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Touch &amp; Temperature</strong></td>
<td><strong>Touch &amp; Temperature</strong></td>
</tr>
<tr>
<td>• Wrap myself in a warm or heavy blanket</td>
<td>• Lie down with a cold face cloth or ice</td>
</tr>
<tr>
<td>• Drink a cup of tea or warm milk</td>
<td>• Splash cold water on my face</td>
</tr>
<tr>
<td>• Have a cold drink</td>
<td>• Olfactory/Smelling</td>
</tr>
<tr>
<td><strong>Auditory/Listening</strong></td>
<td>• The smell of coffee</td>
</tr>
<tr>
<td>• Listen to soft/slow music</td>
<td>• Citrus smells</td>
</tr>
<tr>
<td>• Relaxation or meditation CDs</td>
<td>• Shower with good smelling soap</td>
</tr>
<tr>
<td><strong>Vision/Looking</strong></td>
<td><strong>Gustatory/Tasting/Chewing</strong></td>
</tr>
<tr>
<td>• Look at pictures that calm me</td>
<td>• Drinking something carbonated</td>
</tr>
<tr>
<td>• Watch things in nature (trees, clouds)</td>
<td>• Strong mints</td>
</tr>
<tr>
<td><strong>Olfactory/Smelling</strong></td>
<td>• Crunchy foods</td>
</tr>
<tr>
<td>• The smell of herbal tea or mint</td>
<td>• Sour candy or fruit</td>
</tr>
<tr>
<td>• The smell of chocolate</td>
<td></td>
</tr>
<tr>
<td>• The smell of baking or other food</td>
<td></td>
</tr>
<tr>
<td><strong>Gustatory/Tasting/Chewing</strong></td>
<td></td>
</tr>
<tr>
<td>• Drinking tea</td>
<td></td>
</tr>
<tr>
<td>• Chewy toffee or candy</td>
<td></td>
</tr>
<tr>
<td>• Chocolate</td>
<td></td>
</tr>
<tr>
<td>• Chewing gum</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 3:** Comfort Plan Guide (Courtesy of Vancouver Coastal Health)
DIY Comfort Kits

Grounding is a set of simple strategies to detach from emotional distress.

When you are overwhelmed with emotional distress, grounding can help you distract so that you can gain control over your feelings and stay safe.

Grounding can be useful part of your Comfort Plan.

What’s in a Comfort Kit?

Physical Grounding
- Breathing: inhale 4, pause 3, exhale 5
- Senses: 
  - Sight: photos, sparkle jar
  - Sound: favorite CD
  - Smell: fragrance, essential oils
  - Taste: chocolate, gum, tea
  - Touch: lotion, scarf

Mental Grounding
- Describe an item in detail
- Play a categories game
- Word finding
- Spell your name backwards

Figure 4: DIY Comfort Kits (Courtesy of Vancouver Coastal Health)
Detailed clinician guidelines: 
Comfort Toolkit

1. Introduce yourself to the patient:
   - “A Comfort Plan is a way of identifying strategies you can use to cope with intense emotions. This is a plan made by you to help you feel comfortable and safe
   - By filling out a Comfort Plan, both you and the staff will have better awareness of:
     - The main challenges you experience
     - What strong emotions look like and feel like when you experience them
     - How you can deal with those challenges and intense emotions
     - How staff can help”

2. Fill out the Comfort Plan:
   - Encourage the patient to contribute as many ideas as possible and to do the writing—if they are able—to better gain a sense that the Comfort Plan is their own
   - Ideas from community teams/families are welcome at patient’s consent
   - “When a challenge happens...what I/others notice”
     - Discuss how emotions are on a spectrum
     - A crisis happens when emotions are so strong that the emotion exceeds the window of tolerance and may feel unmanageable
     - The more we are aware of the “level” of our emotions, the more control we gain in making them more manageable
   - “When a challenge happens...what to do/how others can help”
     - Use the Comfort Plan Guide on page 8 for ideas
     - Discuss how there are things we and others can do to manage emotions and how these strategies may be different depending intensity of emotions
     - Strategies may change over time and the Comfort Plan can be revised

3. Introduce the Comfort Kit to strengthen the Comfort Plan
   - Use the Starter Comfort Kit to build a range of self-regulation resources for the patient
   - Display and discuss all items
   - Invite the patient to keep the items identified as useful, and make sure to reclaim the declined items
   - Explain to the patient that the Starter Comfort Kit is only a sample of sensory modulation and distraction techniques
   - Encourage the patient to build a personalized kit during the rest of their stay and after discharge
   - Encourage brainstorming of specific items the patient can use to personalize their own Comfort Kit
4. Document
   o The Comfort Plan is initiated by one clinician but should be used by all clinicians managing the patient’s care
   o It’s important to document the status of the Comfort toolkit for other staff
   o Comfort Plan copy is attached in patient chart
     • Update with revised versions
   o Clinical notes should be written about when and how the Toolkit was used

5. Promote ongoing use of the Comfort Plan and Kit:
   o Patient can hang their Comfort Plan on their wall or keep it in an accessible place to remind them of all the things they can do when a challenge arises
   o Staff can:
     • Keep Comfort Plan in Kardex next to care plan
     • Use it to help patients deal with challenging emotions
     • Review it during morning huddles if the patient is having difficulties
     • Review and update it during iCare with team, and with patient during rounds
     • Review and update it with patient after a crisis or code white as part of the debrief
     • Encourage use and creation of personalized Comfort Kit based on the Starter Kit provided

**Starter Comfort Kit**

Starter Comfort Kits (go to **Figure 5**) are given to patients to experiment with and brainstorm grounding skills. They consist of examples of both mental grounding and physical grounding. The Starter Comfort Kits are designed to be:

- Low cost (go to **Table 1**)
- Low risk:
  - Items in the Kit should not be more dangerous than other items that can be accessed in the unit
  - Patients should be able to use the Kit without staff supervision
- Given to patients to keep
  - The Kit does not need to be returned to staff
- Optional
  - Patients may choose to keep or decline various items in the Starter Kit
- Introductory
  - Patients should be informed that this Starter Kit contains only examples of different grounding strategies, and the patient should build their own personalized kit throughout the duration of their hospital stay and after discharge
  - Patients Can create larger Comfort Kits with more expensive items such as MP3 players, essential oils, etc.
    - Go to page 8 of Comfort Plan for more ideas
Table 1: Cost of Starter Comfort Kit

<table>
<thead>
<tr>
<th>Item</th>
<th>Price CAD (when purchased in bulk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIY Comfort Kit Instruction Sheet (photocopy)</td>
<td>$0.01</td>
</tr>
<tr>
<td>Crosswords, Word Searches, Mandalas (photocopy)</td>
<td>$0.04</td>
</tr>
<tr>
<td>Stress Ball</td>
<td>$0.90</td>
</tr>
<tr>
<td>Rubik’s cube</td>
<td>$0.40</td>
</tr>
<tr>
<td>Pom pom</td>
<td>$0.05</td>
</tr>
<tr>
<td>Velcro strip</td>
<td>$0.05</td>
</tr>
<tr>
<td>Bubble wrap</td>
<td>$0.05</td>
</tr>
<tr>
<td>Crayons</td>
<td>$0.40</td>
</tr>
<tr>
<td>Candy</td>
<td>$0.05</td>
</tr>
<tr>
<td>Cup (container)</td>
<td>$0.05</td>
</tr>
</tbody>
</table>

Figure 5: Example of $2 Starter Comfort Kit
Engage support persons and family
The inclusion of a patient’s family and/or support persons (friends, religious leaders, private mental health clinician, etc.) in a patient’s care planning while in hospital is vital to providing complete care for the patient. We have identified the involvement of family and other supports as a key factor in promoting optimal patient outcomes, and propose to:

- Create a conceptual model of family and support engagement in acute psychiatric settings
- Create tools to help clinicians better assess and map out a patient’s family and support system e.g. genograms
- Provide identified family and supports with psychoeducation about ways to best support a patient during an acute psychiatric crisis
- Develop metrics for quantifying the impact of family and support on patient outcomes to contribute to the existing body of research

Technology plan
Technology can be used to complement the Comfort Toolkit but is not a requirement. The technology outlined below may already be owned by users (e.g. smartphones, smartwatches), thus increasing the accessibility of comfort planning. An assessment is necessary to use technology to the full potential.

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: patient.sm/dgQogJ

<table>
<thead>
<tr>
<th>System or Practice</th>
<th>Available Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric settings vary widely, please adapt as necessary for your area</td>
<td></td>
</tr>
<tr>
<td>Tech tools for building patient awareness about mood state:</td>
<td></td>
</tr>
<tr>
<td>Physiological measures</td>
<td>• Mobile nursing medical cart</td>
</tr>
<tr>
<td>• Heart rate</td>
<td>• Smartwatch: Heart Rate Monitor</td>
</tr>
<tr>
<td>• Blood Pressure</td>
<td>• Smartphone App for measuring blood pressure or heart rate</td>
</tr>
<tr>
<td></td>
<td>• Traditional heart rate monitors and blood pressure cuffs</td>
</tr>
<tr>
<td>Symptom rating/mood diary</td>
<td>• Websites and smartphone apps for tracking mood and symptoms</td>
</tr>
<tr>
<td>Tech Tools for Grounding</td>
<td></td>
</tr>
<tr>
<td>Daily reminders to engage in self-care</td>
<td>• Smartphone App for tracking gratitude</td>
</tr>
</tbody>
</table>
### Measuring outcomes

The following surveys (pre- and post- surveys) have been implemented at Vancouver Coastal Health as part of their collaborative care planning pilot program. The surveys are being provided as examples that can be adapted within your facility.

#### VGH Segal Comfort Toolkit Pilot Program: Pre-measure

Patient initials:_________ Unit:______________Date:_________Clinician:____________________

1. How many times do you experience highly distressing emotions per day?
   
   _______ times per day

2. How confident are you in managing these periods of high distress?

   Low confidence  1  2  3  4  5  6  7  High confidence

3. How interested are you in learning how to better manage these periods of high distress?

   Low interest  1  2  3  4  5  6  7  High interest

4. How early on do you notice these periods of high distress?

   Early enough that I can manage them  1  2  3  4  5  6  7  Not until it is too late to manage them

5. How interested are you in non-pharmacological treatment? (e.g., grounding, therapy, counseling)

   Low interest  1  2  3  4  5  6  7  High interest
6. How interested are you in pharmacological treatment? (e.g., medications)
   Low interest  1  2  3  4  5  6  7  High interest

7. Would you be willing to give feedback and suggestions about this pilot project?
   During hospitalization:  yes  no
   After discharge:   yes  no

8. What skills would you like to build during your stay at the hospital?


VGH Segal Comfort Toolkit Pilot Program: Post-measure

Patient initials:_________ Unit:______________Date:_________Clinician:____________________

1. How many times do you experience highly distressing emotions per day?
   ________ times per day

2. How confident are you in managing these periods of high distress?
   Low confidence  1  2  3  4  5  6  7  High confidence

3. How interested are you in learning how to better manage these periods of high distress?
   Low interest  1  2  3  4  5  6  7  High interest

4. How early on do you notice these periods of high distress?
   Early enough that I can manage them  1  2  3  4  5  6  7  Not until it is too late to manage them

5. How interested are you in non-pharmacological treatment? (e.g., grounding, therapy, counseling)
   Low interest  1  2  3  4  5  6  7  High interest

6. How interested are you in pharmacological treatment? (e.g., medications)
   Low interest  1  2  3  4  5  6  7  High interest
7. How likely are you to keep using your Comfort Plan and Kit after discharge (including sharing Comfort Plan with others, adding to/making a new Comfort Kit)

Low likelihood 1  2  3  4  5  6  7  High likelihood

8. How effective was Comfort Planning in helping you manage distressing emotions during your stay?

Not effective 1  2  3  4  5  6  7  Very effective

9. What advice about Comfort Planning would you give to new patients?

Consider adding the selected measures under the facility's process improvement plan, refer to Figure 1 for a comprehensive list of process and outcome measures. A general process measure to track your adverse events specific to high-risk events is listed below.

**Topic: Adverse Events (e.g.: AWOL, Violence, Self-Harm, Suicide, Seclusion Use)**

Adverse Events (AE) in mental health include events deemed preventable that result in harm to patients.

**Outcome/Process Measure Formula**

**Numerator:** Number of reported adverse events with harm (as defined above)

**Denominator:** Patient days (The total number of days for all patients who were admitted for an episode of care and who separated during a specified reference period)

*Measure typically displayed as a percentage: Numerator/Denominator *100

*Fraction to be measured twice - at Baseline, and after Intervention

**Metric recommendations**

**Direct Impact:**
All patients

**Lives Spared Harm:**
Lives Spared Harm = (AE baseline - AE intervention) X patient days intervention
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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs
Monica McAlduff  
Vancouver Coastal Health
Janice Fyfe  
Vancouver Coastal Health
Lisa Ann Morrise  
Advocate

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions

Hania Alim  
Patient Safety Movement Foundation
Steven Barker  
Patient Safety Movement Foundation; Masimo
Michel Bennett  
Patient Safety Movement Foundation (formerly)
Isabelle Desjardins  
Wiser Systems
Vikas Duvvuri  
Fremont Hospital/ California Hospital Association
Leila Entezam  
Patient Valet
Anita Everett  
American Psychiatric Association
Dorris Fuller  
Treatment Advocacy Center
Mary Gutierrez  
Chapman University
Martin Hatlie  
Medstar
Carol Hessler  
Inova Health System
Elizabeth Holmes-Walker  
University of Pittsburgh Medical Center
Ron Honberg  
National Alliance on Mental Health
Heather Huszti  
Children’s Hospital of Orange County
Michael Mestek  
Medtronic
Sarah Miller  
Patient Safety Movement Foundation
Ariana Longley  
Patient Safety Movement Foundation
Edwin Loftin  
Parrish Medical Center
Jacob Lopez  
Patient Safety Movement Foundation (formerly)
Olivia Lounsbury  
Patient Safety Movement Foundation
Sheree Lowe  
California Hospital Association
Monica McAlduff  
Vancouver Coastal Health
References


How to use this guide
This guide gives actions and resources for creating and sustaining practices to help prevent patient falls. In it, you’ll find:

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Action plan .............................................................................. 515
Technology plan ........................................................................ 519
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APSS #14: Falls and fall prevention in adults

Executive summary checklist

Patient falls are a major cause of in-patient injury and even death. Healthcare administration must develop, revise, and support the plan through the following actionable steps (AHRQ, 2013; Boushon et al., 2008):

Use data to find areas for improvement

☐ Conduct a Gap Analysis to compare current best practices versus actual organizational practices.
☐ Evaluate if the organization has implemented the best practices.
☐ Include the patient and family voice in this process by involving your organization’s patient and family advisory body (such as a Patient and Family Advisory Council (PFAC)) or by including current or former patients or patient advocates.
☐ Identify opportunities for improvement and set aims (Goodwin et al., 2014; Mion et al., 2012; McCurley and Pittman, 2014; Waters et al., 2015).
☐ Collect fall and injury data to improve the performance of your fall prevention and protection from injury program:
  ☐ Consider tracking and collecting inpatient fall data and outcomes post-discharge to monitor the frequency and cost of morbidity and mortality.
  ☐ Sustain focus on fall prevention with system-wide visibility on metrics at multiple touch-points within the organization (ex: use a “days since last” fall or fall with injury).
  ☐ Share this data with patients and families.
☐ Consider bundling evidence-based recommendations to achieve greater outcomes.
☐ Consider new technologies to advance performance and reduce injuries.
☐ Provide role specific training for all staff to ensure knowledge of each person’s responsibility in falls prevention and fall injury prevention, appropriate use of screening tools and assessment frequency, and effective use of falls prevention and falls injury prevention strategies.
☐ Provide training for the patient and their family on preventing falls before, during, and after a patient’s hospital stay (see examples at CampaignZERO.org, especially the Fall Prevention Checklist for patients’ families).

Engage staff

☐ Develop a multidisciplinary team to create, implement, and sustain fall prevention and protection from injury initiatives. This team should include, but is not limited to:
  ☐ Executive sponsor, environmental manager, risk manager, physical therapist, occupational therapist, medical doctor, pharmacist, unit manager, frontline nursing staff, and/or certified nursing assistant.
  ☐ Current or former patients or patient advocates to represent the patient voice.
  ☐ Patients at high risk for falling and their family member care partners.
  ☐ Patient-centered principles to guide as many hospital representatives from all shifts and the entire team, best summarized as “Nothing about me without me”.
☐ Develop fall prevention champions throughout all departments who further drive organizational knowledge and action in the healthcare setting.
☐ Provide clear and concise communication on the champion’s role and responsibilities
☐ From the champion’s perspective, develop feedback mechanisms to learn what is working and what can be improved upon in the fall prevention and protection from injury plan
☐ Use patient stories – in written and video form – to identify gaps and inspire change in your staff
☐ For example, Bill Aydt’s story: https://patient.sm/bUfpUW
☐ Incorporate change management principles to promote maximum success and sustainment of the fall prevention and protection from injury initiatives
What we know about falls and fall prevention

Factors that increase fall risk
Fall prevention and protection from injury is an organizational issue and needs to be addressed by all employees who might encounter a person who is at risk for a fall. Consider ensuring that rotations of students, volunteers, and new employees understand the importance of your actions related to fall prevention and protection from injury. Establish processes to educate newly admitted patients and their families/advocates on admission and throughout their hospital stay as their condition changes. Education should include the risk-factors and how to avoid falls. Clearly define their role and expectations of their actions.

Guiding principles related to fall prevention and protection from injury are (RNAO, n.d.):
• Many falls are predictable and preventable
• Some falls cannot be prevented (i.e. unanticipated physiological events); in these cases, the focus should be on proactively preventing fall injuries and decreasing the frequency of falls
• Fall prevention is a shared responsibility within health care and throughout the institution
• Person and family-centered care is foundational to the care of patients at risk for a fall and fall injuries
• The risks and benefits should be considered in partnership with patients and their advocates when implementing interventions to fall prevention and protection from injury
• Evaluate for appropriateness of altering the content of their referenced points

The performance gap in preventing falls
Preventing falls and minimizing injuries is difficult and complex. Often, organizations have competing priorities which lead to placing management of fall prevention and protection from injury under just 1 discipline, such as nursing. Fall prevention and protection from injury must be organization-wide, with all employees understanding their role and the impact that they can have in creating a culture of safety (AHRQ, 2016).

The Joint Commission’s Sentinel Alert Event, Issue 55, released September 28, 2015, gives a review and synthesis of current research:
“A considerable body of literature exists on falls prevention and reduction. Successful strategies include the use of a standardized assessment tool to identify fall and injury risk factors, assessing an individual patient’s risks that may not have been captured through the tool, and implementing interventions tailored to an individual patient’s identified risks. In addition, systematic reporting and analysis of falls incidents are important components of a falls prevention program. Historically, hospitals have tried to reduce falls - and to some extent have succeeded - but significant, sustained reduction has proven elusive (Alert, 2015).”

Many successes in fall reduction are temporarily due to a “placebo” effect. Simply raising staff awareness will only work to reduce falls for a short period of time.

Use appropriate tools
Most organizations have instituted assessment tools as part of a fall prevention and protection from injury strategy. Organizations should be cautious about using tools that are internally designed without vetting through validation and interrater reliability processes. There needs to be clarification about the role that tools have within the practice setting:
• **Tools used to triage for a fall** are used to predict likelihood of an expected physiological fall and monitor fall risk (Degelau et al., 2012). The tools provide the probability of an anticipated physiological fall but does not inform caregivers what to do about it (Morse, Morse, and Tylko, 1989). A list of tools to consider are listed in Appendix B.

• **Assessment tools** provide an assessment of the patient, such as gait, medication, mental status, and other contributing factors. These tools are used to reduce the probability of an anticipated physiological fall by identifying risk factors with associated interventions. It is important that there is clarity about the tools being used and functionality to assure organizational performance (Degelau et al., 2012).

Analysis of falls with injury in the Sentinel Event database of The Joint Commission revealed the most common contributing factors are (Joint Commission 2015):

• Inadequate assessment
• Communication failures
• Lack of resources, including staffing
• Lack of adherence to protocols and safety practices
• Inadequate staff orientation, knowledge, supervision, or skill mix
• Deficiencies in the physical environment
• Lack of leadership

As part of The Joint Commission Center for Transforming Healthcare’s Preventing Falls with Injury Project, 7 U.S. hospitals entered into a pilot study using Robust Process Improvement© which incorporates tools from Lean Six Sigma to identify the root cause of falls and develop strategies to reduce them. The top contributing factors to a fall were (HRET, 2016):

• Fall risk assessment issues
• Handoff communication (HOC) issues
• Toileting issues
• Call light issues
• Education and organizational culture issues
• Medication issues

A lack of patient-centered practice, congruence, and organizational focus have caused - and continue to cause - preventable patient injury or death while increasing the costs of care. Closing the performance gap with an organizational focus will require leaders and their health systems to commit to specific actions by all disciplines throughout the organization in partnership with patients at risk, as well as their family-member care partners who support their safety before, during and after a hospital stay.

**A model to help you implement your safety plan**

A framework to consider is the “Knowledge-to-Action” model which provides the process steps required for putting knowledge inquiry and application into practice (Strauss, Tetroe & Graham, 2013.). Moving an organization forward to a precision performance requires an innovative approach with focused intent (Appendix A).

**Leadership plan**

Reducing fall injuries and deaths associated with falls is the ultimate outcome sought by leaders and their respective organizations. While all leaders strive to transform culture and advance
patient safety, reducing patient falls requires cutting the invisible rubber bands or biases of traditional actions and focus on the elevation of leadership and health systems’ performance.

**Create a culture of safety**

Leaders and their governing boards must:

- Find a balance among production efficiency, patient-centered responsibilities, reliability, and patient safety
- Understand trust violations among all stakeholders in care, including patients and families, and sustain a culture of trust among all such stakeholders
- Create a culture that removes the fear of reprisal among staff and, especially, fear among patients and families in expressing concerns to staff
  - In its place, leaders must foster and mentor open dialogue, curious inquiry, organizational learning, and solutions mindsets (Boushon et al., 2012)

**Define “falls” and “falls with injury” so you can track incidents**

- Clearly define what constitutes a patient fall and categorize falls with injury:
  - Leaders must also accept that with clearer definition of patient falls, there will most likely be a reportable increase in falls in the early days of a program
  - High reliability organizations understand that this is not a reflection of staff negligence, but of better data collection policies (HRET 2016)
- Categorize falls with injury. These National Database of Nursing Quality Indicators (NDNQI) definitions can help you standardize the compiling of the data for comparative analysis (National Report Card Metrics, 2012):
  - **None:** Patient had no injuries (no signs or symptoms) resulting from the fall, if an x-ray, CT scan, or other post fall evaluation results in a finding of no injury
  - **Minor injury:** in application of a dressing, ice, cleaning of a wound, limb elevation, topical medication, bruise, or abrasion
  - **Moderate injury:** Resulted in suturing, application of steri-strips/skin glue, splinting, or muscle/joint strain
  - **Major injury:** Resulted in surgery, casting, traction, required consultation for neurological (basilar skull fracture, small subdural hematoma) or internal injury (rib fracture, small liver laceration), or patients with coagulopathy who receive blood products as a result of the fall
  - **Death:** The patient died as a result of injuries sustained from the fall (not from physiologic events causing the fall)

**Use quality improvement (QI) processes**

- Actively manage the process of change and transformation. Leaders must be committed and stay committed to fall prevention and protection from injury by clearly communicating their commitment, strategies, and learnings (Boushon et al., 2012; Degelau et al., 2012; France et al., 2017; Miake-Lye, Hempel, Ganz, and Shekelle, 2013)
- Involve employees and representative patients and families through the QI process, including: debriefs, analysis of data, development of action plans, and the acquisition of resources that advance safety
- Use knowledge and management practices to facilitate learning and to promote
innovation within the organization. Leaders must apply evidence, innovation, and experimental knowledge to new and existing physical environments, workflow, practice challenges and changes, and decision making (Boushon et al., 2012)

- As you work to advance person and family engagement, there is a need for cultural transformation and heightened sensitivity to cultural indications and needs of the people you’re serving. Understanding how best to engage and empower patients and families will strengthen the partnership and communication that advances patient safety
- Use patient and family councils to redesign education, the physical environment, and patient/family partnerships that will reduce injuries (Ryu, Roche, and Brunton, 2009)
- Develop your organizational story and use storytelling to galvanize the organization into action and stay focused on why there is a need for change
- Use patient stories – in written and video form – to help identify gaps and inspire engagement and change in your staff
  - The story of Bill Aydt, as told by his daughter, Karen Curtiss, is an inspiring story about how cascading Never Events, initiated by a fall, led to Bill’s preventable death. You can freely view a video of the story here: http://patient.sm/8wV88O

**Action plan**

**Create the infrastructure needed to make changes**
(Miake-Lye, Hempel, Ganz and Shekelle, 2013)

- Assess the current state of your fall prevention and injury protection program:
  - Determine current processes within specific departments or units
  - Consider using tools, such as process mapping, to understand current practice and where actions could or should happen for fall prevention and protection from injury
  - Determine and understand the organizational context of the current program, such as lessons learned and barriers identified
- Review the assessment tools your program currently uses:
  - Include patient representatives in this assessment
  - Consider if the tools are used to triage or screen for the likelihood of a fall
  - Consider tools to evaluate patients for muscle strength, gait, and other contributing factors
  - Competency assessment of clinicians who utilize the tool should be done on an ongoing basis to ensure accuracy and knowledge application of the tools

**Engage staff, patients, and families**

- Review interventions for fall prevention and protection from injury:
  - Use visual cues to indicate high-risk fall patients for staff members, in addition to ambulation equipment:
    - Examples of visual cues: color coded gowns, wristbands, socks, and external magnets
  - Share this information with patients and families to raise their awareness of fall risks and your steps to prevent them
  - Solicit their agreement to help prevent falls as part of your care team (see CampaignZERO.org for an example fall prevention checklist you can share)
• Ensure those involved in medication regimes, including administration, understand their roles in fall prevention and protection from injury (Beasley and Patatanian, 2009)
• Preventing Patient Falls video: http://patient.sm/GgtWIq

Collect and communicate data about falls
• Decide how information about patient fall risk factors is communicated, documented, and shared, then communicate this information to patients at risk and their family member care partners
• Decide how to integrate practice changes in current workflows
• Determine staff knowledge and possible biases about fall assessment and prevention
• Use consistent data collection methods before and after changes are made to your fall prevention and injury protection plan:
  o Clearly define within your institution what constitutes a patient fall (see Measuring outcomes later in this APSS)
  o Note that defining falls may cause the measured number of falls to rise at first. High-reliability organizations understand that this is not a reflection of staff negligence, but of better data collection policies

Factors associated with patient falls
Factors associated with patient falls can be divided into 4 areas of influence. This table (Table 1) outlines the factors that can help you develop interventions and practice actions after assessing your current processes (Morgan, Mathison, Rice and Clemmer, 1985).

Table 1: Factors associated with patient falls

<table>
<thead>
<tr>
<th>Patient-specific</th>
<th>Environmental</th>
<th>Situational</th>
<th>Organizational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impaired gait</td>
<td>Furniture on wheels</td>
<td>Leaning forward</td>
<td>Staffing:</td>
</tr>
<tr>
<td>Impaired cognition</td>
<td>Cluttered pathways</td>
<td>Reaching up</td>
<td>Number</td>
</tr>
<tr>
<td>• Acute (e.g. delirium) and chronic (e.g. dementia)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forgetfulness</td>
<td>Poor lighting</td>
<td>Transferring on/off</td>
<td>Knowledge</td>
</tr>
<tr>
<td>Poor judgment</td>
<td>Slippery floors</td>
<td></td>
<td>Skill mix</td>
</tr>
<tr>
<td>Impulsiveness</td>
<td>Height of furniture</td>
<td></td>
<td>Attitudes</td>
</tr>
<tr>
<td>Sedation/recent surgery</td>
<td>Unit layout making it difficult to see patients from nurses’ station</td>
<td></td>
<td>Types of Policies:</td>
</tr>
<tr>
<td>Impaired vision</td>
<td>Medical devices (IV poles, indwelling urinary catheters)</td>
<td></td>
<td>Hourly rounding</td>
</tr>
<tr>
<td>Weakness, especially legs</td>
<td></td>
<td></td>
<td>Toileting schedules</td>
</tr>
<tr>
<td>Hypotension</td>
<td>Type of fall prevention program</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>---------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>Available Equipment purchases:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td>Bed/chair alarms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute event (e.g., MI, PE)</td>
<td>Transfer equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certain medications (sedatives, opioids, SSRIs)</td>
<td>Surveillance video monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of vertigo</td>
<td>Low/very low beds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low/drop in oxygen saturation rate</td>
<td>Seating</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normally uses a cane or walker to get around</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On a new med with potential side effects including dizziness or confusion</td>
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</table>

Clearly define what constitutes a patient fall

- Leaders must accept, that with clearer definitions of patient falls, there will most likely be an increase in falls in the early days of the program. **High-reliability organizations understand that this is not a reflection of staff negligence, but of better data collection policies.**
- Define the types of falls:
  - **Physiological (anticipated):** Most in-hospital falls belong to this category. These are falls that occur in patients who have risk factors for falls that can be identified in advance, such as altered mental status, abnormal gait, frequent toileting needs, or high-risk medications
  - **Physiological (unanticipated):** These are falls that occur in a patient who is otherwise at low fall risk, because of an event whose timing could not be anticipated, such as a seizure, stroke, or syncopal episode
  - **Accidental:** These falls occur in otherwise low-risk patients due to an environmental hazard. Improving environmental safety will help reduce fall risk in these patients but is helpful for all patients
- Categorize falls with injury:
  - **No apparent injury**
  - **Minor injury:** Bruises or abrasions as a result of the fall
  - **Moderate injury:** an injury that causes tube or line displacement, a fracture, or a laceration that requires repair
  - **Major injury:** injury that requires surgery or a move to intensive care unit for monitoring a life-threatening injury
  - **Death**
Build a safety team

- Develop a multidisciplinary team to create, implement, and sustain fall prevention and protection from injury initiatives. This team should include, but is not limited to:
  - Executive sponsor, environmental manager, risk manager, physical therapist, occupational therapist, medical doctor, unit manager, frontline nursing staff, or certified nursing assistant
  - Current or former patients or patient advocates to represent the patient voice
  - Patients who are at high risk for falling and family member Care Partners for loved ones at risk
  - Certified Nursing Assistant, Patients who are themselves at risk of falls, and family member Care Partners to loved ones who are fall risks. Efforts should be made to get as many representatives from all shifts.
- The multidisciplinary committee should meet on a predetermined basis to review fall prevention and protection from injury initiatives for areas of improvement

Create consistent data collection processes

- Without reliable data metrics, you can’t reliably compare validity before and after:
  - Falls per 1,000 patient days is the most reliable metric
  - Falls with injury per 1,000 patient days should also be noted

Review your current fall assessment tools

- Include representatives of fall-risk patients in this assessment:
  - You should be clear on the tool’s purpose and the outcomes you want from it. Is the tool being used to triage or screen for the likelihood of a fall? Do you have tools to evaluate patients for muscle strength, gait, and other contributing factors?
  - Assess the competency of clinicians who use the tool on an ongoing basis to ensure accuracy and knowledge application of the tools
- Other tools and resources can be found in Appendix B

Review your fall prevention and protection from injury interventions

- To indicate high-risk fall patients for staff, use ambulation equipment and also visual cues, such as color-coded gowns, wristbands, socks, external magnets, and other visual cueing. This notifies staff that a patient is at risk and requires greater monitoring.
  - Share this information with patients and families to heighten their awareness of fall risks and your proactive prevention cues
  - Solicit their agreement to help prevent falls as part of your care team. Share a simple checklist such as at CampaignZERO.org
- Tailor interventions to specific fall risk factors
  - Share this information with patients and families to heighten their awareness of fall risk factors and potential ways to collaborate with you to prevent falls

Review environmental risk factors

- Consider provisions for avoiding environmental risk factors:
  - Keep beds in the lowest position
  - Use glare reduction windows, such as with polarized coatings
Install window treatments that reduce or eliminate glare, such as tinted mylar shades, which can remove glare without loss of ambient light

Avoid gloss flooring - the glares it causes can reduce sight

Install highly-visible handrails in the room, walkways, and bathrooms

Inspect and service all ambulation and patient-transferring equipment

**Provide education and training**

- Educate staff on new fall prevention and protection from injury initiatives
  - These should be run by the fall champions and encourage feedback
  - Include representative patients and families

- Ensure that rotations of students, volunteers, and new employees understand the importance of the fall prevention and protection from injury actions

- Consistently educate newly-admitted patients and their advocates on the importance of their partnership in reducing and avoiding falls. Clearly define their role and actions.

- Patient and visitor education is vital to any fall prevention and protection from injury initiative. Get input from patients and families who, themselves, are managing conditions which put them or a loved one at risk for falls.

**Create a post-fall huddle protocol**

- Include guidelines on how to care for a patient that has fallen:
  - Once the immediate medical concerns of the fall have been addressed, perform a non-punitive root cause analysis, including the patient who fell, and any family member who may have witnessed the fall
  - There are 2 different types of root cause analyses: aggregate and individual
    - Organizations should consider having both processes in place to assure maximum learning and improvement. Highly reliable institutions create a safe environment for staff members, patients and their advocates to report any potential patient safety concerns.
  - Without this safe reporter environment, true root causes will never be found, thus creating negative patient safety outcomes indefinitely

**Technology plan**

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: [patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/](http://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/)

Leaders must plan for and incorporate a technology strategy to maximize the utilization of AI within their organization to create safer environments.

Technology in the field of fall prevention and protection from injury has advanced in the utilization of artificial intelligence (AI) with **predictive modeling**:

- Data and data analytic systems capture and utilize patient information through:
  - Wearables (Goodwin et al., 2014)
  - Sensors in garments and footwear
  - Smart technology embedded within beds, chairs, commodes and other durable
• Predictive modeling is being embedded into alert systems such as communication and nurse call, and into electronic healthcare records
• Data analytics will drive advances in fall prevention and protection from injury (Baus et al., 2016)

Technology is also advancing into the **physical environment** with systems designed to create safer environments. New advancements utilize high performance monitoring systems to reduce physical sitters needed for individual observation (Mccurley and Pittman, 2014).

In the field of fall prevention and protection from injury, there is a focused approach to **restore muscle strength and balance**:

• In the inpatient arena, technology has influenced advancements in rehabilitation equipment that is supporting earlier mobilization (Knutson, 2017)
• In the outpatient arena, exercising and classes such as Tai chi have provided methods to help individuals at high risk for a fall with an overall approach to strengthen muscles.

While these classes are good, they are problematic for many patients. Emerging is 3D technology and interactive games which have the potential to be customizable to the individual capabilities.

Approach technology use with the understanding that it is multifocal, evolutionary, and not static in both use and understanding. Investments of resources both capital and human are ongoing and need to be planned for as such (Hamm, Money, Atwal, and Paraskevopoulos, 2016).

Electronic Health Records can provide meaningful data that can inform predictive modeling, advances in patient safety and further application of evidence into practice. It is only through interoperability of clinical systems that this can be achieved.

<table>
<thead>
<tr>
<th>System or practice</th>
<th>Available technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONC Meaningful Use Certified EHR system</td>
<td>Bed Connection to Nurse Call with priority for fall alarm</td>
</tr>
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</table>


**Measuring outcomes**

**Key performance indicator**

**Falls with injury**
The definitions of a “fall” and a “fall with harm” from the state of Pennsylvania are:

• A fall is defined as any unplanned descent to the floor (or other horizontal surface such as a chair or table) with or without injury to the patient
• A fall with harm is defined as any fall that requires more than first-aid care. Treatment beyond first-aid care includes a laceration that requires physician intervention (e.g.,
sutures), more serious injury (e.g., fracture), or death.

Outcome measure formula
Numerator: Falls with injury
Denominator: Total number of adjusted patient days
• This measure is usually displayed as Total Falls with injury / Adjusted Patient Days *1,000

Metric recommendations
Direct Impact: All patients

Lives Spared Harm:
Lives Spared Harm =
(Falls Rate\_baseline – Falls Rate\_measurement) x Adjusted Patient Days\_measurement

Lives Saved:
Lives Saved = Lives Spared Harm *0.055

Notes
Adjusted Patient Days is defined as:
(Inpatient Revenue + Outpatient Revenue + (Miscellaneous Revenue) / (Inpatient Revenue))
x Total Patient Days

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup
Co-Chairs
Martie Moore Medline
Karen Curtiss CampaignZERO.org: Families for Patient Safety

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Hania Alim Patient Safety Movement Foundation
Faisal Almubarak Advocate
*Steven Barker Patient Safety Movement Foundation; Masimo
Michel Bennett Patient Safety Movement Foundation (formerly)
Haylie Coffey Blue Ridge Healthcare Hospitals, Inc.
Karen Curtiss                      CampaignZERO: Families for Patient Safety
Martin Hatlie                      Medstar
Sherry Henricks                    Henricks Coaching & Consulting, LLC
Mickie Kidd                        Advent Health
Wendy Knecht                       Advocate
Michelle Lindwall                  Advocate
Ariana Longley                     Patient Safety Movement Foundation
Jacob Lopez                        Patient Safety Movement Foundation (formerly)
Olivia Lounsbury                    Patient Safety Movement Foundation
Janice Morse                       Utah College of Nursing
Theresa O’Hollaren                  West-Com NCS
Patricia Palmietto                 Wachter
Rachael Raynes                     Patient Safety Movement Foundation
Jay Roque                          Medline
Allison Sandera                    Florida Hospital Association
Jennifer Tatro                     UC Health
Kathleen Trieb                     University of Vermont Health Network
Mary Waldo                         Providence Health
Lori Wiegand                       OSF Healthcare

Metrics integrity
Robin Betts                        Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

References


Appendix A: Revised knowledge-to-action framework
Appendix B: Toolkits and additional resources


- CampaignZERO: Families for Patient Safety, [www.CampaignZERO.org](http://www.CampaignZERO.org), Information and checklists for families to help them partner with care providers to prevent falls, infections and other hospital acquired conditions.

- ECRI Institute, Falls. ECRI. [www.ecri.org/components/HRC/Pages/SafSec2.aspx](http://www.ecri.org/components/HRC/Pages/SafSec2.aspx)

- Health Research & Educational Trust. Preventing patient falls: A systematic approach from the Joint Commission Center for Transforming Healthcare project. [www.hpoe.org/preventingfalls](http://www.hpoe.org/preventingfalls)


- Registered Nurses Association of Ontario. Preventing Falls and Reducing Injury from falls. [rnao.ca/sites/rnao-ca/files/bpg/Preventing_Falls_FINAL_WEB.pdf](http://rnao.ca/sites/rnao-ca/files/bpg/Preventing_Falls_FINAL_WEB.pdf)


How to use this guide
This guide gives actions and resources for creating and sustaining safe practices to help prevent patient falls. In it, you’ll find:

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APSS #14B: Mother/baby falls

Executive summary checklist

The Joint Commission cited the following in their March 2018 safety alert: “Inpatient falls have been well studied in the adult population, and there is a large body of research in fall prevention and cost reduction. Conversely, there is little attention to falls in the newborn population, although it has been estimated that 600 to 1,600 newborns in the United States experience an in-hospital fall every year.” Infant falls can have catastrophic impact to the infant from skull fractures to death.

Pregnant women are not typically identified as high risk for a fall. Yet, falls are the leading cause for Emergency Department visits for this population (Weiss, Sauber-Schatz & Cook, 2008). Additionally, traditional tools utilized for identifying high risk cohorts have not been applied to this specific population. The call for population-specific fall prevention solutions as a top safety goal for health delivery systems is becoming louder as the evidence demonstrates the need for differentiated actions by healthcare leaders and providers.

Use data to find areas for improvement

☐ Assess your existing fall prevention and protection from injury policies, procedures, protocols, and education in relation to this special population - do not limit review to Maternal-child department

☐ Include the patient and family voice in this process by involving your organization’s patient and family advisory body (such as Patient and Family Advisory Council (PFAC)) or by including current or former patients or patient advocates

☐ Develop data collection methodology isolating mother and newborn fall data - share data through state and national associations to promote benchmarking

☐ Sponsor research to advance understanding and knowledge of population specific fall prevention solutions and cultural changes required to elevate safety

Engage staff

☐ Develop a safety team to continually promote Mom-baby safety throughout the hospital stay and afterwards

☐ Consider creating a Newborn Safety Bundle to achieve greater outcomes

☐ Consider implementation of Maternal Safe Sleep protocols

☐ Debrief all falls, near misses and analyze the system of safety practice for points of failure and opportunities for improvement
What we know about falls and fall prevention

Fall prevention and protection requires a culture of vigilance and commitment to safety. Mother-Newborn safety requires a special focus on both mom and baby. For example one of the considerations is assessing moms ability to safely ambulate carrying her newborn.

The Agency for Healthcare Research and Quality (AHRQ) defines a fall as: An unplanned descent to the floor with or without injury to the patient. (AHRQ, 2013) This is the definition utilized for maternal falls. For newborn falls, there is the further expansion of definition. The National Database for Nursing Quality Indicators (NDNQI) defines newborn falls as the following:

“A newborn fall is a sudden unintentional descent, with or without injury to the patient that results in the patient coming to rest on the floor, on or against another surface, on another person or object.” A newborn drop is defined as “a fall in which a baby being held or carried by a healthcare professional, parent, family member, or visitor falls or slips from that person’s hand, arms, lap, etc. This can occur when a child is being transferred from one person to another. The fall is counted regardless of the surface on which the child lands and regardless of whether or not the fall results in injury” (NDNQI, 2012). The Joint Commission recommends that both a fall and/or a drop is a patient safety concern and should be investigated and treated with the same safety analysis process.

Factors that increase fall risk of the mother (Heafner, et al., 2013):

- Prior History: History of a fall, history of bedrest, visual impairment
- Cardiovascular: History of anemia or preeclampsia, orthostatic hypotension, dizziness
- Hemorrhage: Postpartum hemorrhage (>1500 ml), placental abruption or previa
- Neuro-function/anesthesia: Post-general, regional or neuraxial anesthesia, paresthesia in the thigh, epidural infusion discontinued <3 hours
- Motor/activity: Able to straight leg raise but unable to bridge, unable able to straight leg raise
- Medications: IV/IM narcotics, anti-hypertensive, tocolytics, sleep aids

Factors that increase fall risk of the newborn are associated with maternal risk factors and additionally (Hodges & Gibert, 2015):

- Second to third post-delivery night between 12 a.m. and 9 a.m
- Surgical delivery
- Maternal use of narcotics
- Mothers aged 18 - 23 years
- Breastfeeding

Additional risk factors for consideration:

- Mother (family) not aware of infant fall risk
- Falls occurred during feeding (bottle or breast)

The performance gap in preventing falls

Mother Fall Risk: Heafner and colleagues (2013), found in the absence of research on fall prevention tools for women hospitalized in obstetric units, most hospitals were utilizing one of the following in perinatal units: Morse Fall Score (MFS); Hendrich (1) Fall Risk Model; or Schmid. The MFS has undergone compelling reliability testing in adult medical-surgical patient
populations and long-term rehabilitation care areas. However, Morse identifies the exclusion of obstetric and pediatric populations. The Hendrich (1) Fall Risk Model was developed from a review of patients in an acute setting, mostly oncology and orthopedic patients. The Schmid tool was developed by comparing a group of “fallers” with age-matched “non-fallers” and tested on patients from four nursing units deemed high risk for falls.

The conclusion was these three instruments may not be appropriate tools to identify women in obstetric units at risk for falls.

**Newborn Fall Risk:** The literature supports maternal risk factors are more associated with newborn falls and drops than other risk factors usually associated with falls. The dichotomy facing healthcare providers is the very actions they take to promote infant health and well-being may in fact cause harm and hurt. There is strong evidence that supports skin to skin contact immediately after birth to facilitate infant physiological stabilization, however breast feeding to advance infant health and promotion of maternal-newborn interactions for attachment and bonding also contributes to infant falls or drops. Healthcare providers many times are singularly focused on activities, failing to expand their awareness of the possible risks.

**Use appropriate tools:**

**Consider the following:** Unless specifically developed for Maternal Fall Risk, most fall risk screening tools in electronic medical records have not been validated for this population.

**Given that the literature supports the following actions:**

1. Patients will temporarily be identified as high risk for falls for 6 hours after vaginal delivery or 6 hours after discontinuation of epidural anesthesia. For cesarean section delivery, patients will temporarily be identified as high for falls for 18 hours after delivery. This percan be extended depending upon assessment and condition.
2. Provide assistance with ambulation until motor blockade is absent and/or patient’s ability to maintain her balance is restored.
3. Explain to patient/family that patient is at risk for falls.

A possible resource: [http://patient.sm/YaiKQz](http://patient.sm/YaiKQz)

**Newborn Safety:**

To promote newborn safety in the acute care setting Simpson (2015) suggests the following strategies:

a. Assess the individual needs of each mother, considering the level of pain, fatigue, support, medication status, and the understanding of infant-safety by the mother and family.

b. Encourage mothers to room-in with their baby while avoiding maternal guilt if there is hesitation or resistance.

b. Appropriate Nurse to Mom/Baby assignments based on national standards of staffing recommendations.
## Infant Safety Bundle

### Maternal Risk Factors
- Epidural Analgesia/Anesthesia
- Cesarean Birth
- High Level of Trauma
- Second or Third Postpartum Night
- Recent opioid or Sedative Use

### Patient Safety Agreements
- Parental form with safety risks and education on keeping baby safe while in the hospital.
- Parents sign agreement after nurse reviews the agreement with the parents.

### Safety Interventions for Parents and Visitors
- Safety bulletin boards on Mother-Baby Units
- Crib cards for safe sleeping on every baby crib.
- Nurses role model safe sleep practices.
- Nurses round every 1-2 hours minimum.
- Patient doors are left unlatched at night for nurses to check on infant.
- Nurses instruct mothers (and family) to call the nurses when ready to feed their baby.

### Reporting and Debriefing Systems for Infant Falls
- Immediately assess the infant for injury. Assess for head injuries. Confirm attending neonatal provider has been notified and is aware of infant's status.
- Complete a post fall assessment and debriefing after each fall.
- Communicate fall incidence in handover communications to assure appropriate monitoring.

## Leadership plan
Reducing fall injuries and deaths associated with falls is the ultimate outcome sought by leaders and their respective organizations. While all leaders strive to transform culture and advance patient safety, reducing patient falls requires courageous leadership and action to address traditional actions and focus on the elevation of leadership and health systems' performance.

### Create a culture of safety
Leaders and their governing boards must (IOM, 2004):
- Find a balance among production efficiency, patient-centered responsibilities, reliability, and patient safety
- Understand trust violations among all stakeholders in care, including patients and families, and sustain a culture of trust among all such stakeholders
- Create a culture that removes the fear of reprisal among staff and, especially, fear among patients and families in expressing concerns to staff
In its place, leaders must foster and mentor open dialogue, curious inquiry, organizational learning, and solutions mindsets (Boushon, et al., 2012)

Clearly define what constitutes patient falls and infant drops.
- In the event of a fall or infant drop, providing emotional support to the family or caregiver who may suffer as second victim in the event.

Leaders must also accept that with clearer definition of patient falls and infant drops, there will most likely be a reportable increase in falls in the early days of a program.

High reliability organizations understand that this is not a reflection of staff negligence, but of better data collection policies.

Categorize falls with injury: These National Database of Nursing Quality Indicators (NDNQI) definitions can help you standardize the compiling of the data for comparative analysis:
- None: Patient had no injuries (no signs or symptoms) resulting from the fall, if an x-ray, CT scan, or other post fall evaluation results in a finding of no injury
- Minor injury: in application of a dressing, ice, cleaning of a wound, limb elevation, topical medication, bruise, or abrasion
- Moderate injury: Resulted in suturing, application of steri-strips/skin glue, splinting, or muscle/joint strain
- Major injury: Resulted in surgery, casting, traction, required consultation for neurological (basilar skull fracture, small subdural hematoma) or internal injury (rib fracture, small liver laceration), or patients with coagulopathy who receive blood products as a result of the fall
- Death: The patient died as a result of injuries sustained from the fall (not from physiologic events causing the fall)

Use quality improvement (QI) processes
- Actively manage the process of change and transformation. Leaders must be committed and stay committed to fall prevention and protection from injury by clearly communicating their commitment, strategies, and learnings (Boushon, et al, 2012; Degelau, et al., 2012; France, et al., 2017)
  - Involve employees and representative patients and families through the QI process, including: debriefs, analysis of data, development of action plans, and the acquisition of resources that advance safety
  - Use knowledge and management practices to facilitate learning and to promote innovation within the organization. Leaders must apply evidence, innovation, and experimental knowledge to new and existing physical environments, workflow, practice challenges and changes, and decision making (Boushon, et al., 2012).
  - As you work to advance person and family engagement, there is a need for cultural transformation and heightened sensitivity to cultural indications and needs of the people you’re serving. Understanding how best to engage and empower patients and families will strengthen the partnership and communication that advances patient safety.
  - Use patient and family councils to redesign education, the physical environment, and patient/family partnerships that will reduce injuries (Ryu, Roche and Brunton, 2009)
  - Develop your organizational story and use storytelling to galvanize the organization into action and stay focused on why there is a need for change
Use patient stories – in written and video form – to help identify gaps and inspire engagement and change in your staff

**Action plan**

**Create the infrastructure needed to make changes**
(Miake- Lye, Hempel, Ganz and Shekelle, 2013)

- Assess the current state of your fall prevention and injury protection program:
  - Consider the following:
    1. A welcome letter that includes safety interventions such as using a crib when up ambulating both in the room and beyond.
    2. An infant safety pledge form that is signed by the parents and family. The pledge should include avoiding co-sleeping and keeping the bed in the lower position.
    3. “Keep Me Safe” signs in the room as infant safety reminders.
    4. A “Days Since” sign on the unit visible for both Maternal and Infant safety days.
    5. Celebrate milestones.
- Determine current processes within specific departments or units and assure that all departments are aware of safety initiatives,
- Consider using tools, such as process mapping, to understand current practice and where actions could or should happen for fall prevention and protection from injury
- Determine and understand the organizational context of the current program, such as lessons learned and barriers identified

- Review the assessment tools your program currently uses:
  - Include representatives of fall-risk patients in this assessment
  - Consider if the tools are used to triage or screen for the likelihood of a fall
  - Consider tools to evaluate patients for muscle strength, gait, and other contributing factors
  - Competency assessment of clinicians who utilize the tool should be done on an ongoing basis to ensure accuracy and knowledge application of the tools

**Engage staff, patients, and families**

- Review interventions for fall prevention and protection from injury:
  - Use visual cues to indicate high-risk fall patients for staff members, in addition to ambulation equipment:
    - Examples of visual cues: color coded gowns, wristbands, socks, and external magnets
  - Share this information with patients and families to raise their awareness of fall risks and your steps to prevent them
  - Solicit their agreement to help prevent falls as part of your care team (see CampaignZERO.org for an example fall prevention checklist you can share)
- Ensure those involved in medication regimes, including administration, understand their roles in fall prevention and protection from injury (Beasley and Patatanian, 2009)
Collect and communicate data about falls

- Decide how information about patient fall risk factors is communicated, documented, and shared, then communicate this information to patients at risk and their family members or care partners.
- Decide how to integrate practice changes in current workflows.
- Determine staff knowledge and possible biases about fall assessment and prevention.
- Use consistent data collection methods before and after changes are made to your fall prevention and injury protection plan:
  - Clearly define within your institution what constitutes a patient fall (see Measuring outcomes later in this APSS).
  - Note that defining falls may cause the measured number of falls to rise at first. High-reliability organizations understand that this is not a reflection of staff negligence, but of better data collection policies.

Clearly define what constitutes a patient fall

Ganz 2013, Miake-Lye 2013, Registered Nurses Association of Ontario

- Leaders must accept that with clearer definitions of patient falls, there will likely be an increase in falls in the early days of the program. High-reliability organizations understand that this is not a reflection of staff negligence, but of better data collection policies.
- Define the types of falls:
  - Physiological (anticipated): Most in-hospital falls belong to this category. These are falls that occur in patients who have risk factors for falls that can be identified in advance, such as altered mental status, abnormal gait, frequent toileting needs, or high-risk medications.
  - Physiological (unanticipated): These are falls that occur in a patient who is otherwise at low fall risk, because of an event whose timing could not be anticipated, such as a seizure, stroke, or syncopal episode.
  - Accidental: These falls occur in an otherwise low-risk patient due to an environmental hazard. Improving environmental safety will help reduce fall risk in these patients but is helpful for all patients.
- Categorize falls with injury:
  - No apparent injury.
  - Minor injury: Bruises or abrasions as a result of the fall.
  - Moderate injury: An injury that causes tube or line displacement, a fracture, or a laceration that requires repair.
  - Major injury: Injury that requires surgery or a move to intensive care unit for monitoring a life-threatening injury.
  - Death.
Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: http://patient.sm/eWyqJQ

Leaders must plan for and incorporate a technology strategy to maximize the utilization of AI within their organization to create safer environments.

Technology in the field of fall prevention and protection from injury has advanced in the utilization of artificial intelligence (AI) with predictive modeling:

- Data and data analytic systems capture and utilize patient information through:
  - Wearables (Goodwin et al., 2014)
  - Sensors in garments and footwear
  - Smart technology embedded within beds, chairs, commodes and other durable medical equipment
- Predictive modeling is being embedded into alert systems such as communication and nurse call, and into electronic healthcare records
- Data analytics will drive advances in fall prevention and protection from injury (Baus et al., 2016)

Technology is also advancing into the physical environment with systems designed to create safer environments. New advancements utilize high performance monitoring systems to reduce physical sitters needed for individual observation (Mccurley and Pittman, 2014).

In the field of fall prevention and protection from injury, there is a focused approach to restore muscle strength and balance:

- In the inpatient arena, technology has influenced advancements in rehabilitation equipment that is supporting earlier mobilization (Knutson, 2017)
- In the outpatient arena, exercising and classes such as Tai chi have provided methods to help individuals at high risk for a fall with an overall approach to strengthen muscles.

While these classes are good, they are problematic for many patients. Emerging is 3D technology and interactive games which have the potential to be customizable to the individual capabilities.

Approach technology use with the understanding that it is multifocal, evolutionary, and not static in both use and understanding. Investments of resources both capital and human are ongoing and need to be planned for as such (Hamm, Money, Atwal, and Paraskevopoulos, 2016).

Electronic Health Records can provide meaningful data that can inform predictive modeling, advances in patient safety and further application of evidence into practice. It is only through interoperability of clinical systems that this can be achieved.

<table>
<thead>
<tr>
<th>System or practice</th>
<th>Available technology</th>
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<tbody>
<tr>
<td>ONC Meaningful Use Certified EHR system</td>
<td></td>
</tr>
<tr>
<td>Electronic Health Record (EHR) System</td>
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</tbody>
</table>
• Bed Connection to Nurse Call with priority for fall alarm
• Public health reporting systems for newborn screening

*Company has signed some form of the Open Data Pledge. Find more information on the Patient Safety Movement Foundation website: http://patient.sm/wXRMFV

## Measuring outcomes

### Maternal Falls with injury

**Falls with injury**
The definitions of a “fall” and a “fall with harm” from the state of Pennsylvania are:

- A fall is defined as any unplanned descent to the floor (or other horizontal surface such as a chair or table) with or without injury to the patient
- A fall with harm is defined as any fall that requires more than first-aid care. Treatment beyond first-aid care includes a laceration that requires physician intervention (e.g., sutures), more serious injury (e.g., fracture), or death.

### Outcome measure formula

**Numerator:** Falls with injury

**Denominator:** Total number of adjusted patient days
- This measure is usually displayed as Total Falls with injury / Adjusted Patient Days *1,000

### Infant Falls

**Numerator:** Infant falls or drops with or without injury

**Denominator:** 10,000 births

### Metric recommendations

**Direct Impact:** All patients

**Lives Spared Harm:**
Lives Spared Harm =
(Falls Rate\_baseline - Falls Rate\_measurement) x Adjusted Patient Days\_measurement

**Lives Saved:**
Lives Saved = Lives Spared Harm *0.055

### Notes

Adjusted Patient Days is defined as:
(Inpatient Revenue + Outpatient Revenue + (Miscellaneous Revenue) / (Inpatient Revenue))
x Total Patient Days

### 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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on the available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

## Workgroup

### Co-Chairs
- **Martie Moore**
  - Medline
- **Karen Curtiss**
  - CampaignZERO.org, Families for Patient Safety

### Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

- **Hania Alim**
  - Patient Safety Movement Foundation
- **Faisal Almubarak**
  - Advocate
- ***Steven Barker**
  - Patient Safety Movement Foundation; Masimo
- **Michel Bennett**
  - Patient Safety Movement Foundation (formerly)
- **Haylie Coffey**
  - Blue Ridge Healthcare Hospitals, Inc.
- **Karen Curtiss**
  - CampaignZERO: Families for Patient Safety
- **Martin Hatlie**
  - Medstar
- **Sherry Henricks**
  - Henricks Coaching & Consulting, LLC
- **Mickie Kidd**
  - Advent Health
- **Wendy Knecht**
  - Advocate
- **Michelle Lindwall**
  - Advocate
- **Ariana Longley**
  - Patient Safety Movement Foundation
- **Jacob Lopez**
  - Patient Safety Movement Foundation (formerly)
- **Olivia Lounsbury**
  - Patient Safety Movement Foundation
- **Janice Morse**
  - Utah College of Nursing
- **Theresa O’Hollaren**
  - West-Com NCS
- **Patricia Palmietto**
  - Wachter
- **Donna Prosser**
  - Patient Safety Movement Foundation
- **Rachael Raynes**
  - Patient Safety Movement Foundation
- **Jay Roque**
  - Medline
- **Allison Sandera**
  - Florida Hospital Association
- **Jennifer Tatro**
  - UC Health
- **Kathleen Trieb**
  - University of Vermont Health Network
- **Mary Waldo**
  - Providence Health
References


Appendix A: Revised knowledge-to-action framework

![Revised Knowledge-to-Action Framework Diagram]

- Select, Tailor, Implement Interventions & Implementation Strategies
- Chapter 4: Implementation strategies
- Assess Facilitators and Barriers to Chapter 3: Knowledge Use
  - Identification of barriers and facilitators
  - How to maximize and overcome
- Adapt Knowledge to Local Context
  - Chapter 2, Part A: Setting up infrastructure for implementation of BPG
  - Initial identification of stakeholders
- Stakeholders
  - Chapter 2, Part B: Define stakeholders and vested interest
  - Stakeholder analysis process
  - Stakeholder tools
- Resources
  - Chapter 2, Part C: Business Case
- RMAQ Resources
- Monitor Knowledge Use & Evaluate Outcomes
- Chapter 5: Identify key indicators
  - Conceptualization of Knowledge
  - Evaluating patient and related outcomes
- Sustain Knowledge Use
- Chapter 4
- Identification Problem
- Identify, Review, Select Knowledge
- Chapter 1: Identify gaps using quality improvement process and data
  - Identification of key knowledge (BPQ)

Understanding the Knowledge-to-Action Process

A two-step process:

1. Knowledge Creation:
   - Identification of critical evidence results in knowledge products (e.g., BPGs)
2. Action Cycle:
   - Process in which the knowledge created is implemented, evaluated and sustained
   - Based on a synthesis of evidence-based theories on formal change processes
   - The Knowledge-to-Action process is not always sequential. Many phases may occur or need to be considered simultaneously.

Adapted from ‘Knowledge Translation in Health Care: Moving from Evidence to Practice.’ S. Sten, J. Temow, and I. Graham. Copyright 2009 by Blackwell Publishing Ltd.
Appendix B: Toolkits and additional resources

  www.ahrq.gov/professionals/systems/hospital/fallpxtoolkit/index.html

- Australian Commission on Safety and Quality in Healthcare. Guidebook for Preventing Falls and Harm from Falls in Older People: Australian Hospitals. 

- CampaignZERO: Families for Patient Safety, www.CampaignZERO.org, Information and checklists for families to help them partner with care providers to prevent falls, infections and other hospital acquired conditions.

- ECRI Institute, Falls. ECRI. www.ecri.org/components/HRC/Pages/SafSec2.aspx

- Health Research & Educational Trust. Preventing patient falls: A systematic approach from the Joint Commission Center for Transforming Healthcare project. 
  www.hpoe.org/preventingfalls

  iu.instructure.com/courses/1491754/files/56997226/download?wrap=1


  rnao.ca/sites/rnao-ca/files/bpg/Preventing_Falls_FINAL_WEB.pdf


How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for NGT placement and verification. In it, you’ll find

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Leadership plan .................................................................................. 546
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APSS #15: Nasogastric tube placement and verification

**Executive summary checklist**

A nasogastric tube (NGT) is a tube inserted into a patient’s nose and down into their stomach to drain stomach contents or to give nutrition (feeding), fluids, and medicine. The person inserting the tube uses blind placement, which means they don’t know where the tube is going in the patient’s body as they push it in. As a result, NGTs can be misplaced and lead to serious patient harm and death.

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

**Engage staff and use data to find areas for improvement**

- □ Specifically train all staff who place NGTs in this procedure
- □ Train all staff who read radiographs to use a report template with the following 4 criteria:
  - □ Does the tube path follow the esophagus and avoid contours of the bronchi?
  - □ Does the tube clearly bisect the carina or the bronchi?
  - □ Does the tube cross the diaphragm in the midline?
  - □ Is the tip clearly visible below the left hemi-diaphragm?
- □ Create a mandatory reporting system to track NGT misplacements as a percentage of all tubes placed

**Ensure best patient care**

- □ Use only NGTs that:
  - □ Are radio-opaque throughout their length
  - □ Have external centimeter (cm) markings for detection of post-insertion tube movement
- □ Follow best practices for NGT placement and prior to first use:
  - □ Before inserting the NGT, accurately measure the length of the NGT prior to using the NEMU (Nose→Earlobe→Mid- Umbilicus) method
  - □ Prior to first use, confirm NG placement with pH of gastric aspirate the range of 1.0 to 5.5
  - □ Use an abdominal radiograph if indicated (pH >5.5 or high-risk patient listed below)
- □ Follow best practices after confirmation of NGT placement:
  - □ Document NGT confirmation and the method of confirmation (pH or radiograph) in the EMR
  - □ After confirmation, secure tubes to the patient so the cm mark is visible at the nose or lips
    - □ If no cm marks are available mark the tube with indelible ink
    - □ Document this cm mark in the medical record and as part of the physical exam
    - □ Use this point of reference to gauge movement of the tube
  - □ Observe for signs of respiratory distress, gagging, or vomiting post-tube placement
    - □ Strongly consider removing the NGT if these signs are present as the tube may have been dislodged into the airway or further into the lungs
What we know about NGT placement and verification

NGTs are commonly used in clinical practice. Studies have shown:

- In one day at 63 institutions, 24% of hospitalized infants and children needed NGTs, including an orogastric (OG) (tube placed through the mouth), nasogastric (NG), or transpyloric (tube placed in the upper small bowel) tube (Lyman et al., 2015)
- From 2011-2016, over 3 million NG or OG tubes were used in the United Kingdom (UK) (Parker, 2016)

Addressing nasogastric tube placement and verification helps create a safety culture, which is a culture that promotes patient safety and quality of care while reducing preventable risks and harms.

The problems with NGT placement and verification

As a result of blind placement, misplaced tubes happen in the esophagus, duodenum (the first part of the small intestines), or lungs. Studies show NGT misplacement can cause serious harm to patients:

- In adult patients, NGT misplacement causes serious harm in 1 to 3% of tubes placed (Gilbertson, Rogers and Ukoumunne, 2011; Bourgault and Halm, 2009)
- In infants, 59% NGTs are misplaced, with most tubes misplaced in the esophagus (October and Hardart, 2009)
- The Pennsylvania Patient Safety Authority documented 4137 NGT misplacements into the lung from 2011-2016 with 56 were noted as causing serious patient harm. In this same report there were two deaths (Wallace, 2017). Injuries from NGT misplacement include:
  - Pneumothorax (a buildup of air in the pleural space that surrounds the lung, which causes part or all of the lung to collapse)
  - Feeding formula given into the lung
  - Esophageal perforation (hole in the esophagus)
  - Death (Gilbertson, Rogers and Ukoumunne, 2011; Bourgault and Halm, 2009)
- Injuries from NGT misplacement include:
  - Pneumothorax (a buildup of air in the pleural space that surrounds the lung, which causes part or all of the lung to collapse)
  - Feeding formula given into the lung
  - Esophageal perforation (hole in the esophagus)
  - Death (Gilbertson, Rogers and Ukoumunne, 2011; Bourgault and Halm, 2009)

Failure to detect misplaced NGTs are due to:

- Use of non-evidence-based methods to confirm initial placement (auscultation or aspiration)
- Failure to recognize when an NGT has changed position
- Failure to properly read an abdominal radiograph
- Failure to accurately interpret an electromagnetic device screen (October and Hardart, 2009; Powers et al., 2013; Metheny and Meert, 2017)
The evidence for NGT placement best practices
A recent publication from the American Society for Parenteral and Enteral Nutrition detailed best practices for NGT placement verification in children that includes a process for NGT placement verification (Irving et al., 2018). Prior to this document, pediatric organizations failed to find any guidance for NGT placement verification in infants and children. This document closely follows the National Health Service (NHS) recommendations and guidance for best practices.

Leadership plan

Show leadership’s commitment to NGT placement and verification
- Identify and learn about performance gaps in their organization related to the use of evidence-based methods to verify NGT placement
- Use best practice guidelines when they exist
- Be engaged and show their own commitment to the new process change - senior leaders, directors, physicians, managers, and unit leaders have a significant role in the process improvement process by mandating practice change
- All leadership and healthcare professionals use root cause analysis of events involving NGT misplacement to identify performance gaps in their own care area and fully understand the need for change

Create the infrastructure needed to make changes
- Healthcare leadership support process changes, such as to:
  - Provide needed resources
  - Remove barriers
  - Give their time and attention
  - Encourage process improvement
- Healthcare leadership assist with the action plan, such as to:
  - Create clearly defined and measurable goals
  - Effectively communicate and collaborate
  - Encourage clinical/safety leadership and offer support during the change period

Engage staff
- Administrators recognize the impact of NGT misplacement that results in patient harm or death on the healthcare professional and provide services to the healthcare professional that help with emotional healing
- Sustain change by building acceptance and accountability - those responsible for putting the proposed changes into practice must accept them
- Use patient stories - in written and video form - to identify gaps and inspire change in your staff. For example, the story of Grant Lars Visscher, son of Deahna and Rich Visscher, is a compelling story that can be viewed and shared for free: patient.sm/Deahna-visscher--tube.
Action plan

Use safe equipment
- Use NGTs that are radio-opaque throughout their length and have external cm length markings to detect post-insertion tube movement
- When checking pH, use a product that is licensed for medical use

Provide staff training
- Train all staff who place NGTs. The training should include:
  - Use evidence-based procedures for guidance on NGT insertion and placement verification.
  - Knowledge of contra-indications for bedside placement, such as basilar skull fracture
  - Awareness of clinical situations that place patients at high-risk for misplacements, such as increased work of breathing or tachypnea
  - Awareness that signs and symptoms of misplacement could be:
    - Immediate, such as circumoral cyanosis, coughing, choking, and dyspnea
    - Delayed
    - Non-existent until the patient’s condition worsens - staff should not take the absence of signs and symptoms as confirmation the tube is correctly placed
  - When technology is utilized demonstrated skill in the use of technology to assist with placement (see ‘Technology Plan’ below)
- Train all staff who read radiographs to confirm NGT placement using ‘4 criteria’ (seek expert radiologist advice for detail of local training, but in brief):
  - Does the tube path follow the oesophagus and avoid the contours of the bronchi?
  - Does the tube clearly bisect the carina or the bronchi?
  - Does it cross the diaphragm in the midline?
  - Is the tip clearly visible below the left hemi-diaphragm rather than solely viewing the tip of the NGT?
- When product changes occur, educate staff on the new NGT and how it is different from the previous product
- For a free video to teach healthcare providers NGT placement, visit: [http://patient.sm/3bOu3b](http://patient.sm/3bOu3b)

Create protocols
- Create a mandatory reporting system to capture the frequency of NGT misplacement and patient outcome
- Use evidence-based procedures for guidance on NGT insertion and placement verification, including guidance on when a patient is considered high risk for misplacement - the procedure should include a comment to encourage critical thinking skills when assessing a patient during placement, immediately after, or at any time the NGT is in place and a patient’s condition worsens

Place NGT
- To get an accurate measurement of insertion length, use the NEMU method (Nose→Earlobe→Mid- Umbilicus) for children and adults
• Position the patient properly. Particularly, put their head into anatomic position during the insertion

Confirm placement before first use
• Upon initial NGT insertion, check the pH is within the desired range of 1-5.5:
  o Aspirate 3-8 ml of gastric fluid to obtain specimen for pH with stylet in place (in neonates and smaller pediatrics, a stylet may not have been used for placement, and it may not be possible to obtain 3 mL)
  o To remove the stylet after confirmation, instill water
  o You may need to instill water prior to NGT insertion to allow for stylet removal due to the narrow bore of the tube. Withdraw and waste the fluid before obtaining a specimen for pH measurement. Normal saline and water have an alkaline pH.
  o Use of acid suppressing medicines is not a contra-indication to pH measurement - if the pH is > 5.5 follow the process
  o If unable to obtain an aspirate, turn the patient on their left side if possible and after 10-20 minutes, try again to obtain fluid from the NGT
• If unable to obtain an aspirate within the required range of 1-5.5, do not use the tube until a radiograph is done to confirm placement
• When a radiograph is used to confirm placement, it should:
  o Follow the tube from the chest to below the diaphragm and give a visual of the tip of the NGT
  o Include a report template that documents all the following:
    • Does the tube path follow the oesophagus and avoid the contours of the bronchi?
    • Does the tube clearly bisect the carina or the bronchi?
    • Does it cross the diaphragm in the midline?
    • Is the tip clearly visible below the left hemi-diaphragm?
  o Have a comment that the tube is appropriately placed for use
  o Include a check that the radiograph is of the correct patient and the most recent radiograph taken
• For adults and certain infants and children, consider a radiograph even if pH is in the required range when the patient:
  o Is severely obtunded (has an altered level of consciousness)
  o Has an endotracheal tube
  o Is clinically unstable after NGT re-insertion post resuscitation
  o Has clinical deterioration soon after NGT placement

Reconfirm NGT placement after initial use
• Secure the tube to the patient so the cm mark is visible at the snaries - document this mark in the medical record and use it as a point of reference for movement of the tube
• Use pH to re-confirm placement especially if the securement device has become dislodged or the tube is not at the reference cm mark
• “When in doubt, pull it out!” - when in doubt of correct placement, remove and replace the tube
Do supplementary checks on NGT placement
The AACN recommends using 2 or more bedside methods to predict tube location at these time points:

- During insertion
- Before feeding
- At 4 hour intervals after feeding has started
- When there is any interruption in feeding
- For a decompression tube, an abrupt decrease in output warrants reconfirmation of placement

Below are 3 methods for supplementary checks. **Do not use these methods to confirm correct placement:**

- Observe for signs of respiratory distress such as coughing, choking, desaturation, and dyspnea
  - If patient has signs of respiratory distress, remove and re-insert tube
  - However, the patient may not have signs of respiratory distress when the tube is accidentally placed in the airway, especially if the patient has an impaired level of consciousness
- Observe for a change in the marked reading of the tube at the lip/naris or change in length of external portion of the tube (e.g., the length not inserted in the patient)
  - There are many reasons that a feeding tubes may become dislocated during use
  - Check tube location at regular intervals while the tube is being used for feeding or medicine
  - Observe and record the length of the external portion of the NGT to help detect tube migration
- Observe visual characteristics of aspirate for signs the tube moved from stomach to small bowel - there may be a more marked difference in appearance
  - Do not use this method to try to distinguish between gastric and respiratory secretions - there is not always a marked difference in appearance

**Do not use these practices to verify NGT placement**
The following non-evidence-based practices are misleading and should never be used to verify NGT placement:

- Auscultation (listening to sounds from the stomach, heart, lungs, or other organs)
- Visual inspection of fluid from the tube
- Observation of bubbles - this method is not reliable
- Litmus paper
The following section highlights best practices and emerging technologies used to assist accurate NGT placement and verification. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: [http://patient.sm/7hAR0s](http://patient.sm/7hAR0s)

<table>
<thead>
<tr>
<th>Best Practices</th>
<th>Overview</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| **pH testing** | • Collect aspirate through NGT and analyze at bedside using an appropriate pH strip  
  • Common first-line method for confirming NGT placement  
  • Gastric placement is confirmed if reading is equal to or below 5.5 | • pH measurement can be skewed by gastric contents, including:  
  • Enteral formula  
  • Acid suppressing medicines  
  • Requires accurate color perception  
  • Considered Point of Care testing |
| **Abdominal X-ray** | • X-ray to confirm NGT tip is visible below the diaphragm, at least 10cm for adults or beyond the gastro-esophageal junction for infants and children  
  • Considered the gold standard for initial placement confirmation | • X-rays can be misinterpreted  
  • 45% of harm events associated with NGT placement reported by the UK National Patient Safety Agency from 2005-2010 were caused by misinterpreted x-rays  
  • Often avoided in pediatric settings to decrease the cumulative effects of radiation exposure |
The following table shows methods with limited evidence or unclear benefit. These methods require further research. Some U.S. guidelines, research, and teaching methods have not kept up with advances in other parts of the world. Global studies are referenced below.

<table>
<thead>
<tr>
<th>Emerging Technologies</th>
<th>Overview</th>
<th>Evidence/Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biochemical markers</td>
<td>• Laboratory tests for bilirubin, pepsin, and trypsin can be used to compliment pH testing to confirm placement</td>
<td>• Not a bedside test</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Not widely validated in a variety of clinical settings</td>
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<tr>
<td></td>
<td></td>
<td>• Demonstrated in a 15-patient feasibility study of gastric-fed patients receiving mechanical ventilation (Schallom et al., 2015)</td>
</tr>
</tbody>
</table>
| Capnography/colorimetric capnometry | • Both measure carbon dioxide (CO2)  
  • Commonly used to confirm endotracheal tube (ETT) placement  
  • Not to be used as a single method of placement confirmation  
  • Unreliable in neonates and smaller pediatric patients. | • Will not differentiate between gastric and small bowel placement.                                    |
|                             |                                                                                                                                            | • Effectively rules out pulmonary misplacement.                                                         |
|                             |                                                                                                                                            | • In a 100-patient study, colorimetric capnography correctly ruled out tracheobronchial insertion (Meyer, et al., 2009) |
|                             |                                                                                                                                            | • In a 40-patient study, colorimetric capnometry was consistent with x-ray in 97.5% of cases (Erzincanli, Zaybak, and Guler, 2017) |
|                             |                                                                                                                                            | • In a meta-analysis of nine clinical trials involving a total of 651 insertions, gastric placement was correctly identified in 88-100% of cases. (Chau, et al., 2011) |
## Direct anatomical visualization (camera)

- A camera embedded in the tip of the NGT provides real-time images of anatomical landmarks in the GI or respiratory tract as the tube advances
  - May aid in placement, early identification, and timely correction of tracheobronchial insertion

- Can visualize both gastric and post-pyloric placement.
  - A 45-patient study of adult ICU and step-down patients found 98% agreement between visualized anatomical landmarks and X-ray (Wischmeyer, McMoon, Waldron, and Dye, 2018)
  - A 20-patient study of adult ICU patients showed 100% agreement between anatomical visualization and X-ray (Mizzi, et al. 2017)
  - Both studies reported near-miss respiratory tract insertion in 20-35% of cases, but the NGT was repositioned without patient harm. (Wischmeyer, McMoon, Waldron, and Dye, 2018; Mizzi, et al. 2017)
  - No published clinical evidence in pediatric populations

## Electromagnetic Placement Device

- Uses electromagnetic sensors in a stylet to provide a visual representation of the NGT tip relative to an external receiving unit placed over the patient’s xiphoid process.
  - In 2018, the FDA recommended competency training for all staff using this device and a second method to verify NGT placement, such as pH or radiograph.

- A 2018 report documented 1 adverse event (pneumothorax) in 7081 placements using this device. (Powers et al., 2018)
  - Harm events are associated with misinterpretation of the visual representations
    - 2 patient deaths and 2 moderate harm events described in a 2013 NHS Patient Safety Alert
    - 51 serious harm events, including 11 patient deaths were described in a Letter to Health Care Providers issued by the FDA in 2018.
  - No published clinical evidence in pediatric populations for NGT placement verification.
| Ultrasound | • Imaging method that uses high-frequency sound waves to produce images of structures within the body  
  • Most useful to show progress of the tube through the esophagus | • Requires skilled sonographers  
• Effective in adult ICU patients with large bore feeding tubes  
• In a 56-patient study, NGT images were obtained in 92.8% of cases, but in one case failed to identify a tracheal placement. (Gok, Kilicasian, and Yosunkaya, 2015)  
• In a 41-patient study, ultrasound correctly identified 38 proper placements. (Nedel, Jost, and Filho, 2017)  
• Demonstrated in pediatric populations  
• A study of 21 pediatric patients found 100% agreement between abdominal ultrasound and x-ray  
• Larger scale studies are needed |
Measuring outcomes

**Topic:** NGT misplacement

**Serious Safety Event (SSE) Rate:** Rate of NG tube misplacements per 10,000 NG tube insertions

**Outcome Measure Formula:**

**Numerator:** Number of misplaced NG tubes

**Denominator:** Total number of NG tubes inserted

Rate is typically displayed as: misplaced NG tubes per 10,000 NG tube insertions

**Metric recommendations:**

**Direct Impact:**
All patients

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

**Lives spared harm:**
Lives spared harm = (Rate of NG tube misplacement _baseline - Rate of NG tube misplacement _measurement) X NG tube insertions _measurement

**Lives saved:**
Lives saved = (NG tube misplacement mortality rate _baseline - NG tube misplacement mortality rate _measurement) X NG tube misplacements _measurement

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

**Notes:**

**Data Collection:**
Data may be captured from your electronic medical record if a discrete data element exists for NG tube placement and/or misplacement.

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 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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

Workgroup

Co-Chairs
Beth Lyman  
Children’s Mercy Hospital
Deahna Visscher  
Advocate

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Steven J. Barker  
Patient Safety Movement Foundation; Masimo
Michel Bennett  
Patient Safety Movement Foundation (formerly)
Robin Betts  
Kaiser Permanente
Haylie Coffey  
Carolinas HealthCare System Blue Ridge
Mitchell Goldstein  
Loma Linda University
Kim Gorsuch  
Cancer Treatment Centers of America
Frances Healey  
NHS Improvement
Larissa Kozloff Naves  
Centro Universitário Unimonte
Ariana Longley  
Patient Safety Movement Foundation
Jacob Lopez  
Patient Safety Movement Foundation (formerly)
Olivia Lounsbury  
Patient Safety Movement Foundation
Carol McGinnis  
Sanford Health Systems
Renae Moomjian  
Acacia Consultant
Bill Nadeau  
Cardinal Health
William Peruzzi  
Henry Ford Health System
Christine Peyton  
Children’s Hospital Colorado
Donna Prosser  
Patient Safety Movement Foundation
Sundary Sankaran  
Kaiser Permanente
Caroline Stade  
University Children’s Hospital Babel
Jennifer Tatro  
UCHealth Southern Colorado
*Stephen Thorpe  
CME Medical
References


Actionable Patient Safety Solutions (APSS) #16: Person and family engagement

How to use this guide
This guide gives actions and resources for creating and sustaining practices for patient and family engagement. In it, you’ll find:

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Executive summary checklist

“Person and family engagement goes beyond informed consent. It is about proactive communication and partnered decisionmaking between healthcare providers and patients, families, and caregivers. It is about building a care relationship that is based on trust and inclusion of individual values and beliefs” (CMS, n.d.)

An effective program to implement and sustain PFE should include the following actionable steps (HRET, n.d.). Use this checklist to help you prioritize your actions and measure your organization’s progress in each area.

Create an action plan

☐ Include PFE as a priority in organization-wide patient safety strategies
  ☐ Make PFE action items part of these strategic requirements to determine safe care and enhanced outcomes
☐ Develop and implement consistent internal communications about the importance of effective PFE—beginning with management—to ensure all staff see the connection between PFE and outcomes and safety
☐ Develop and integrate PFE education in new-hire orientation and regularly with staff to ensure that expectations are clear, engaging, and consistent
  ☐ Training should be held on an ongoing regular scheduled basis

Engage staff and use data to find areas for improvement

☐ Ensure that all members of the care team understand the importance of listening to the patient and their family members’ questions and concerns
☐ Assess strengths and gaps in your organization’s PFE efforts by using this checklist:
  ☐ Request feedback from your senior leadership team, staff, patients, and families about your organization’s PFE efforts
  ☐ Assess policies, processes, position descriptions, and training programs to determine whether PFE is included
  ☐ Talk about findings and conclusions with leadership, staff, and patients to create awareness and lay the groundwork for improvement efforts
☐ Deploy a system to implement PFE and monitor progress on improving PFE using the following:
  ☐ Develop an infrastructure that brings the patient and family’s voice systemically into your patient safety improvement work, such as:
    ☐ Appoint patients who identify as patients or patient advocates to your governing body
    ☐ Establish patient and family advisory bodies that contribute to organizational safety initiatives
    ☐ Include patient advocate input into improvement committees or root cause analysis teams
    ☐ Establish a functional area in your organization whose role and accountability is to engage patients and families
☐ Select measures that will allow you to see whether processes and patient safety outcomes are changing
☐ Ensure systems are in place so that data can be collected and shared
☐ Compile results in a format that is easy-to-understand and monitor
☐ Share results with staff, senior leadership, board, community, and the public
☐ Use patient stories – in written and video form – to help teach and inspire change in your staff
What is person and family engagement?

Person and family engagement (PFE) is an underutilized resource for achieving the goal of zero patient harm. Definitions of PFE vary. Angela Coulter put it well when describing the intention of PFE to “promote and support active patient and public involvement in health and healthcare and to strengthen their influence on healthcare decisions, at both the individual and collective levels.” (Coulter, 2011).

What we know about person and family engagement

The problems with patient safety and why they matter.

Despite widespread recognition of patient safety as a public health issue since 1999, preventable patient harm still happens. Estimates suggest that the number of people harmed is increasing, although arguably the larger and more alarming estimates now are a product of more effective measurement.

Studies show:

- Deaths due to medical errors in hospitals across the U.S. were estimated at 180,000 each year by the landmark Harvard Medical Practice Study in 1984 (Leape, 1995).
- A 2013 study by John James, a NASA toxicologist, estimates that the number of US deaths due to medical error are between 210,000 and 440,000 annually, making it the 3rd largest cause of preventable death (James, 2013).
- U.S. hospital deaths attributed to medical error are 250,000, reinforcing the finding of 3rd largest cause of preventable death (Makary, 2016).

Analyses of error in other U.S. healthcare settings underscore that unsafe care is prevalent and systemic. In a series of reports from 2008 to 2018, The Office of the Inspector General (OIG) of the US Department of Health and Human Services found that adverse events and temporary harm events are common, endanger patient health, and are costly to the Medicare program. In a 2010 study, OIG found that 27 percent of hospitalized Medicare beneficiaries experienced such events, costing Medicare approximately $4.4 billion a year. OIG then expanded on this work by examining post-acute-care settings, finding that 33 percent of Medicare beneficiaries in skilled nursing facilities, 29 percent of Medicare beneficiaries in rehabilitation hospitals and 46% of beneficiaries in long term care hospitals experienced harm.

Research from other countries confirms that the problem is international. Using data from the 2016 Global Burden of Disease study in 137 low and middle income countries, researchers estimated that 5 million deaths were attributable to poor quality care, significantly more than the 3.6 deaths caused by lack of access to care. (Kruk et al., 2018)

Existing research still lacks the ability to reliably estimate preventable harm due to missed, delayed, or miscommunicated diagnoses.

Whatever the estimates, the challenge before us is huge and touches millions of people worldwide. Collaborative efforts among healthcare provider organizations, thought leaders and policymakers, payors, innovators and researchers, educators, nonprofit/non-governmental advocacy groups, product makers, and people who use healthcare can make a difference.

Through focused attention and aligned efforts in the U.S. driven by the Centers for Medicare
and Medicaid Services (CMS), measurable patient harm was reduced by 21% between 2010 and 2015, which led to:

- 125,000 fewer deaths
- 3 million fewer injuries
- $28 billion in saved costs

At the local level, collaboration between the public health sector, hospitals, and outcome improvement experts reduced hospital readmissions by 7,000 in Minnesota between 2011 and 2013, enabling patients in Minnesota to spend 28,120 nights sleeping in their own beds instead of the hospital, and helped reduce healthcare costs by more than $55 million (AHRQ, 2016)

**Person and family engagement**

PFE is an underutilized natural resource for improving the safety of care. Healthcare users and their family members play significant roles in managing care and often encounter aspects of care that providers and researchers miss. If their observations, insights, and lessons learned are overlooked in safety improvement, an organization loses important opportunities to prevent harm. In a 2013 editorial, then Health Affairs Editor Susan Dentzer recognized the value of PFE in describing it as the “blockbuster drug” of the 21st Century, observing:

> “Even in an age of hype, calling something ‘the blockbuster drug of the century’ grabs our attention. In this case, the ‘drug’ is actually a concept—patient activation and engagement—that should have formed the heart of health care all along.”

There is ample evidence demonstrating that patients who are actively engaged as partners in managing their own long-lasting healthcare conditions achieve measurably better outcomes. Moreover, healthcare users or those who help loved ones are typically highly motivated to partner with their healthcare providers to improve safety. Their experiences bring an urgency to the patient safety movement that propels action by generating empathy—they engage our hearts as well as our minds and hands. In 2006, the World Health Organization captured this urgent offer to partner in the London Declaration of its Patients for Patient Safety group, a core component of its Global Patient Safety Programme (WHO, 2006).

Growing excitement over the potential for PFE strategies and tactics to measurably reduce harm and improve outcomes has generated many white papers, frameworks, and toolkits designed to engage healthcare users as partners in care—notably, as subject matter experts in safety and quality improvement initiatives, organizational governance, and the development of policies and procedures. Hospitals, healthcare systems, and ambulatory clinics that have engaged their users of care in improvement work and at the governance level report significant change in growing and sustaining a culture of safety.

A culture of safety 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

**The evidence for PFE**

The leading framework for PFE was published by Carman and colleagues in 2013 (go to Figure 1), and outlines opportunities for engagement at 3 levels:
- Direct care
- Organizational design and governance
  - Applies to healthcare providers
- Policymaking
  - Applies to government agencies, research bodies, and non-profit organizations

**Figure 1:** Framework for Patient and Family Engagement (Carman et al., 2013)

**Other common PFE frameworks include:**
- Health Information and Management Systems Society, Patient Engagement Framework
- American Hospital Association, Engaging Health Care Users: A Framework for Healthy Individuals and Communities
- FasterCures Patient Perspective Value Framework
- The Guiding Framework on Patient and Family Engaged Care from the National Academy of Medicine (Appendix A)

Guided by the Carman framework, in 2013 the U.S. CMS developed and deployed 5 PFE metrics in a nationwide effort to reduce 10 Hospital Acquired Conditions (HACs) and readmissions as an integral part of its Partnership for Patients (PfP) campaign. The 5 hospital-based PFE metrics are expanded upon in the Action plan of this Actionable Patient Safety Solutions (APSS).

Verified results show that hospitals with robust PFE accomplished a greater reduction in HAC frequency and did so at a faster rate. Based on these initial results, in 2015, 6 PFE metrics were deployed by CMS in the ambulatory care sector as part of its Transforming Clinical Practice
Initiative (TCPI). The 6 ambulatory care-based metrics are explained in detail in the Action plan of this APSS. Research and evidence continues to demonstrate the impacts of PFE on achieving zero patient harm. For example, there is a strong correlation with family involvement and a reduced rate of in-hospital falls. This led CMS to incorporate PFE into its overall Quality Strategy in 2016. Many hospitals and healthcare systems that have prioritized patient safety are building patient and family advisory councils (PFACs) or other infrastructure that embed PFE strategies. However, some hospitals and clinical practices have yet to incorporate robust PFE into their patient safety programs.

Education about PFE
System improvement and patient advocates also emphasize the importance of education about PFE in multiple settings, including professional education in medicine, nursing, pharmacy, and other healthcare fields. General education about using healthcare safely should also be prioritized, in primary or secondary school curricula as well as libraries, online forums, or other venues for adult education.

All educational efforts should address the needs of vulnerable populations, including those with:

- Low literacy
- Low health literacy
- Disabilities
- Cognitive or mental health challenges
- Limited access to or inability to afford healthcare services
- Limited access to or inability to use information technology

Leadership plan
It’s important that your healthcare organization commit to, and invest in, a culture of safety and transparency. This starts with, and is dependent upon, governance and executive leadership that is actively engaged and committed to achieving zero harm. A robust PFE program can help organizational leaders both build and sustain the culture of safety.

To successfully engage patients and families in safety at the point of care and in safety improvement work, leaders must take these key actions. The leadership plan for PFE incorporates and builds on the Culture of Safety Leadership Plan created in APSS #1.

Show leadership’s commitment to PFE

- Hospital governance and senior administrative leadership must commit to investigating and become familiar with this major performance gap in their own organizations. Senior leaders cannot merely be “on board” with patient safety—they must own it.
- Your hospital boards 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 and Epstein, 2010).
- Hospital governance, senior administrative leadership, and clinical/safety leadership must close their own performance gap by implementing a proactive, comprehensive safety culture action plan
- Healthcare leadership (clinical/safety) must reinforce their commitment by taking an active role, such as to:
• Champion process improvement
• Give their time, attention, and focus to remove barriers
• Remove barriers
• Provide necessary resources

• Healthcare leadership must support your organization’s action plan, such as to:
  • Shape a vision of the future
    • Provide clearly defined goals
    • Support staff as they work through improvement initiatives
    • Measure results
    • Communicate progress towards your goals

• There are many types of leaders within a healthcare organization, and for PFE process improvements 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 PFE performance must be valued and reflected in compensation plans so that leaders have direct personal accountability for results

Create the infrastructure needed to make changes

• Ensure your organization has a clear definition of PFE
• Discuss PFE with your senior leadership team so that they understand that it matters to you and the organization
• Request participation from your board, your staff, and representative patients and families about what your organization will look like if it’s successfully engaging patients and families
• Make improving PFE an organizational goal
• Establish infrastructure in your organization that creates pathways for PFE participation in safety improvement work
  • For example, Imperial College London has outlined their clear method for Patient and Public Involvement programs within the NHS in their five-year patient and public involvement found here: http://patient.sm/Tzp6ds
• Establish a shared vision and goals between safety and patient experience leaders so that PFE pursuits are aligned with outcomes and actions are transparent
• Allocate time in meetings with senior leadership, staff, and the board to hear and tell stories about engagement success and shortcomings
• Utilize patient stories – in written and video format – to help teach and inspire change in your staff:
  • One example of an inspiring story is that of Michael Seres.
    • It was filmed by the Patient Safety Movement Foundation and can be viewed for free here: http://patient.sm/VULt2F
    • Video from Safe Care Campaign’s Patient Perspective Series: http://patient.sm/LEZjr9
**Action plan**

**Embed PFE in governance and operations**

Healthcare organizations should use the Carman framework or an alternative framework to implement a PFE program that engages patients or their family members at multiple levels, including point of care, policy and governance, CMS currently is driving PFE through its Hospital Improvement Innovation Network (HIIN) program, using 5 metrics to track progress:

1. **Preadmission Planning Checklist** [point of care]: Hospital has a physical planning checklist that is discussed with every patient who has a scheduled admission
2. **Shift Change Huddles OR Bedside Reporting** [point of care]: Hospital conducts shift change huddles or bedside reporting with patients and family members in all feasible cases
3. **Designated PFE Leader** [policy & protocol]: Hospital has a designated individual (or individuals) with leadership responsibility and accountability for PFE
4. **PFAC or Representative on Hospital Committee** [policy & protocol]: Hospital has an active Patient and Family Advisory Council (PFAC) OR at least one patient who serves on a patient safety or quality improvement committee or team
5. **Patient Representative(s) on the Board of Directors** [governance]: Hospital has one or more patient(s) who serve on a governing and/or leadership board as a patient representative

Hospitals and multi-site systems should consider using the same program and metrics. In non-acute care clinics or other ambulatory care delivery sites, a 6 part PFE practice plan should be considered.

1. **Support for patient and family voices** [point of care]: Are there policies, procedures, and actions taken to support patient and family participation in governance or operational decision-making of the practice (Patient and Family Advisory Councils, Practice Improvement Teams, Board Representatives, etc.)?
2. **Shared decision-making** [point of care]: Does the practice support shared-decision making by training and ensuring clinical teams integrate patient-identified goals, preferences, concerns, and desired outcomes into the treatment plan (e.g. those based on the individual’s culture, language, spiritual, social determinants, etc.)?
3. **Patient activation** [point of care]: Does the practice utilize a tool to assess and measure patient activation?
4. **Active e-Tool** [policy & procedure]: Does the practice use an e-tool (patient portal of other E-Connectivity technology) that is accessible to both patients and clinicians and that shares information such as test results, medication lists, vitals and other information and patient record data?
5. **Health literacy survey** [policy & procedure]: Is a health literacy patient survey being used by the practice (e.g. CAHPS Health Literacy Item Set)?
6. **Medication management** [governance]: Does the clinical team work with the patient and family to support their patient/caregiver management of medications?

At the organizational design and governance level, healthcare organizations should consider engaging healthcare users in improvement efforts and measure progress in the following areas (you may choose one or more):

- Preventing Adverse Drug Events
- Preventing Catheter-Associated Urinary Tract Infections (CAUTI)
• Preventing Central Line Associated Bloodstream Infections (CLABSI)
• Preventing Falls and Falls out of Bed
• Preventing Obstetrical Adverse Events
• Preventing Pressure Ulcers
• Preventing Surgical Site Infections
• Preventing Venous Thromboembolism (VTE)
• Reducing Hospital Readmissions
• Preventing Clostridium difficile (c-diff)
• Ensuring Airway Safety
• Preventing Sepsis and Septic Shock
• Preventing Hospital Acquired Acute Renal Failure
• Preventing Ventilator-Associated Pneumonia (VAP)
• Teaching Practical Skills for Managing Critical Test Results
• Preventing iatrogenic Delirium
• Preventing Procedural Harm

• Preventing Undue Exposure to Radiation
• Monitoring for Opioid-induced Respiratory Depression
• Advancing Hospital Culture of Safety
• Preventing Methicillin-resistant Staphylococcus aureus (MRSA)
• Teaching Effective Pain Management Practices and Behaviors and Addressing the Opioid Crisis
• Define and Advance Child-Friendly Care Practices
• Ensuring and/or Advancing Antibiotic Stewardship
• Preventing Diagnostic Error
• Reducing Health Care Disparities
• Preventing Malnutrition
• Preventing Multi-Drug Resistant Organisms

Technology plan
These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: https://patient.sm/ydmHKI

Information and communication technologies
The use of information and communication technology is a particularly fertile area of innovation that is being used to engage patients. Examples include:

• Electronic patient portals
• Smartphone apps
  o PatientAider mobile app http://patient.sm/f6MnWH
  o Patient Safety Advisor (English) and Dr. Rafael (Portuguese) mobile app http://patient.sm/BIAlR5
• Email
• Texting pathways

OpenNotes and personal health records
OpenNotes is an international movement advocating patient access to all aspects of their electronic health records—including physician notes and diagnostic tests. Supporters believe that providing access to notes is transformative in empowering patients, families, and caregivers to feel more in control of their healthcare decisions and improve the quality and safety of care
Researchers in the OpenNotes community are collaborating closely with health systems, healthcare professionals, and millions of patients around the world to understand the effects of fully transparent medical care on communication, engagement, safety, costs, and the overall quality of care.

Personal health records are also an international movement to give each consumer a complete, consumer-controlled, consumer-centered, unified, lifetime electronic health record. Supporters believe that each consumer should have a complete electronic health record in one place that is updated automatically after every encounter with a provider. The complete record is then available if the patient ever needs to see a new provider, such as with referrals from their regular provider, if the patient changes insurance, or relocates to another city or country.

With personal health records, family members and caregivers can have access as representatives to the patient’s unified health record—so they can advocate and care for the patient when necessary.

- Personal health records can store patient-generated health data (PGHD) including the patient’s goals and preferences for healthcare.
- Personal health records promote safer care when they are available to telehealth providers seeing the patient for the first time over a video connection.
- If the patient is unable to give consent, emergency providers can access the patient’s unified record when giving life-saving treatment.
- All providers should be sure that their electronic health record systems automatically send a copy to the patient’s personal health record whenever new information is generated.

Many companies are producing technological solutions designed to advance PFE. Healthcare organizations can use the HIMSS PFE framework displayed below to track innovation in this space (Figure 2). However, patient advocates also cite the digital divide and urge that PFE implementers be aware that many people are not proficient using information technology or don’t have access to it, and should take steps to ensure that these patients are not left behind.

- Healthcare organization should also consider using their Serious Safety Event reporting system, or any alternative or complementary reporting systems used to track patient safety outcomes.
- When possible, healthcare organizations should consider integrating patient complaints, the narrative portions of patient satisfaction surveys, or other mechanisms that patients and families use to communicate concerns about patient safety events.

**Personal health records**

Personal health records are also an international movement to give each consumer a complete, consumer-controlled, consumer-centered, unified, lifetime electronic health record. Supporters believe that each consumer should have a complete electronic health record in one place that is updated automatically after every encounter with a provider. The complete record is then available if the patient ever needs to see a new provider, such as with referrals from their regular provider, if the patient changes insurance, or relocates to another city or country.

With personal health records, family members and caregivers can have access as representatives to the patient’s unified health record—so they can advocate and care for the patient when necessary.

- Personal health records can store patient-generated health data (PGHD) including the patient’s goals and preferences for healthcare.
• Personal health records promote safer care when they are available to telehealth providers seeing the patient for the first time over a video connection
• If the patient is unable to give consent, emergency providers can access the patient’s unified record when giving life-saving treatment
• All providers should be sure that their electronic health record systems automatically send a copy to the patient’s personal health record whenever new information is generated

Many companies are producing technological solutions designed to advance PFE. Healthcare organizations can use the HIMSS PFE framework displayed below to track innovation in this space (Figure 2). However, patient advocates also cite the digital divide and urge that PFE implementers be aware that many people are not proficient using information technology or don’t have access to it, and should take steps to ensure that these patients are not left behind.

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Measuring outcomes

Hospitals and health systems should consider using the PFE metrics outlined above in the Action Plan section.

Referenced resources

1. PFE resources are easy to find online but it’s important to incorporate them along the continuum of care
   o You can encourage PFE by providing updated resources and conversing with patients and family members about how they may utilize the information
   o The following resources have been identified as useful by patients and/or their family members to be used by the hospital:
     • An Empowered Patient
       [http://patient.sm/41kUFL](http://patient.sm/41kUFL)
       Engaged Patients is a national campaign under the guidance of the Empowered Patient Coalition nonprofit with the vision that all patients and their loved ones have free access to the tools and the resources they need to be fully informed and participating members of their health care teams
     • CampaignZERO: Families for Patient Safety
       [http://patient.sm/dw789V](http://patient.sm/dw789V)
       CampaignZERO is a national non-profit organization that offers resources to patients, families and providers to advance PFE for patient safety through 4 main PFE initiatives:
       a. Free checklists for patients’ families to help them support their loved ones’ medical care in partnership with all care providers. CampaignZERO’s checklists, written in simple terms (AMA recommended 6th grade literacy level/below), provide simple “how-to’s” to: Prevent the most common hospital acquired conditions: infections, falls, medication errors, blood clots and more.
       b. Participate in shared decision-making for recommended surgery and other treatment plans
c. Participate in discharge planning and post-discharge support to prevent readmissions.

- Community-based patient safety education through its national speaker network of professional patient advocates, see PatientSafetySpeakers.org.
- Provider PFE training workshops based on CampaignZERO’s Safe & Sound Tools for Family Engagement in Patient Centered Care, endorsed by QSEN and offered free of charge through the Medline Innovation Institute
  - In-Patient PFE Education Tools (electronic and print) to inform and activate patients’ family members to help prevent HACs and readmissions, [http://patient.sm/dw789V](http://patient.sm/dw789V)
  - Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families [http://patient.sm/2G3fCz](http://patient.sm/2G3fCz)
    
    Content last reviewed April 2018. Agency for Healthcare Research and Quality, Rockville, MD
  - AHRQ Question Builder tool for patients [http://patient.sm/ZjZC3r](http://patient.sm/ZjZC3r)
  - Access requires registration, but it is grant supported so there is no cost to users
  - OpenNotes movement [http://patient.sm/0luwWP](http://patient.sm/0luwWP)
  - PfP Strategic Vision Roadmap for Patient and Family Engagement [http://patient.sm/Bszlah](http://patient.sm/Bszlah)
  - Four Habits [http://patient.sm/U8elwM](http://patient.sm/U8elwM)

2. Education: everyone from youth to the most experienced clinician has an opportunity to improve healthcare safety through increased PFE:

- You can contribute by educating others within your area of influence:
  - Educating future leaders in patient safety [http://patient.sm/0FypVX](http://patient.sm/0FypVX)
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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs
Martin Hatlie MedStar
Vonda Vaden Bates Patient Safety Movement Foundation, 10th Dot

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions
Jill Arnold Maternal Safety Foundation
Steve Barker Patient Safety Movement Foundation, Masimo
Victoria Baskett Victoria Baskett Patient Safety Foundation
Michel Bennett Patient Safety Movement Foundation (formerly)
Cindy Cassity Baylor Scott & White Health
Aline Chibana Brazilian Patient Safety Foundation
Amy Cohen The University of Vermont Health Network
Karen Curtiss CampaignZERO, Families for Patient Safety
Laura Enright Advocate
Victor Grazette Virginia Hospital Center
Kari Hamlin Hackensack Medical Center
Diane Hopkins Patient Safety Movement Foundation
Kori Jew Patient Safety Movement Foundation
Arthur Kanowitz Securisyn
Audrey Kennedy Children’s Mercy Kansas City
Edwin Loftin Parrish Medical Center
References


Actionable Patient Safety Solutions (APSS) #18:

Post-operative delirium in older adults

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for monitoring for opioid-induced respiratory depression. In it, you’ll find:

- Executive summary checklist................................. 576
- What we know about delirium in older adults .......... 578
- Leadership and implementation plan ...................... 586
- Action plan .......................................................... 587
- Technology plan .................................................. 589
- Patient, carer & family engagement ....................... 590
- Measuring outcomes ............................................. 591
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Delirium in older patients following anesthesia and surgery is frequent and often goes undiagnosed, is a significant source of short and long-term morbidity and mortality, and leads to increased cost of care (American Geriatrics Society Expert Panel on Postoperative Delirium in Older Adults). It is important to ensure that older patients and their caregivers are informed about risks of delirium and how it may be prevented (Berger, et al., 2018; Mahanna-Gabrielli, et al., 2018). Steps to consider when implementing a delirium prevention and management strategy in a healthcare organization include:

- Establish an Oversight Committee which oversees pre-hospital and admission screening programs, multidisciplinary care programs and perioperative assessment, prevention, and care strategies. The committee reports through safety and quality care pathways.
- Develop a hospital-wide education program, targeted appropriately to relevant clinical areas, with the intent of increasing awareness of the importance of identifying cognitive impairment and delirium, and what strategies can be used to support and best manage such patients.
- This should incorporate local/national/international recommended best practice standards and tools where they exist
- Implement liaison with relevant local medical practitioners (primary care / family medicine / general practitioners) for pre-hospital and post-discharge planning. Such planning includes assessment, optimization, implementation of appropriate referral pathways, and post-discharge medication management.
- Ensure that the patient, carers and/or family are engaged at all stages of care and can be involved with support for the at risk individual.
- Establish hospital resources including protocols and guidelines (listed below) for delirium prevention and management by identifying risk factors for delirium, minimizing trigger factors and optimizing assessment and care in the perioperative environment, including high dependency units (HDUs) and intensive care units (ICUs) again drawing on any local/national or international standards or resources that may exist
- Screening tools administered by suitably trained personnel prior to or on admission and during the postoperative period for cognitive decline and delirium
- Checklists for risk identification (Predisposing factors)
  - Conduct discussions with patients and caregivers about the possibility of postoperative delirium, the risks associated with delirium and the importance of its prevention.
- Checklists for trigger factor minimization (Precipitating Factors)
  - Emphasizing multicomponent / multidisciplinary interventions in high risk patients (Hshieh, et al., 2018); including surgery, geriatrics, anesthesiology, nursing, allied health practitioners and carers/family members
  - Intraoperative and perioperative guidelines which use best practice and evidence-based strategies to minimize the risk of postoperative delirium
☐ Assessment tools for ICU and ward use for bedside (point of care) delirium screening; include awareness of hyperactive, hypoactive and mixed presentations

☐ Management guidelines for delirium once diagnosed, based on the diagnosis and treatment of contributing factors; including minimization of restraints or antipsychotic medications unless the patient or staff are at risk of harm.

☐ Discharge protocols to communicate to patients and caregivers relevant issues relating to perioperative delirium.

☐ Discharge protocols for primary caregivers and other providers.

☐ Referral pathways for psychogeriatric consultation or memory clinics if concerns are identified as appropriate

☐ Record cognitive screening and delirium assessments in clinical records (paper, electronic) in a manner which can be retrieved and audited for prevalence, incidence and intervention effectiveness and for monitoring the patient course during hospitalization

☐ Regularly report delirium incidence to the oversight committee and in relevant hospital communications

☐ Continually ensure that all staff are aware of the delirium reduction program and educated in its implementation.

☐ Regular program auditing
What we know about delirium in older adults

What is delirium?
Delirium is an acute and fluctuating disturbance in thinking, characterized by inattention, confusion and often hallucinations and/or changes in consciousness (American Psychological Association, 2013). A person suffering from delirium may be restless or agitated, but alternatively may be quiet and withdrawn. It can be described as a form of “acute brain failure.” Not only can delirium be distressing for the patient and loved ones, but it has been shown to be associated with poor short-term and long-term outcomes (O’Regan, et al., 2013; Rudolph & Marcantonio, 2011; Gleason, et al., 2015; Inouye, et al., 2016).

Delirium can occur at any age, but this APSS is focusing on delirium in older (65y or more) hospitalized adults having surgery and anesthesia because it is very common in this group, especially when admission to an intensive care unit occurs.

What is the significance of Postoperative Delirium (POD)?

In healthcare:
Delirium is associated with serious clinical consequences including (O’Regan, et al., 2013; Rudolph & Marcantonio, 2011; Gleason, et al., 2015; Inouye, et al., 2016):

- Behavioral disturbances, which if agitated may result in physical harm to the patient or those around them.
- Interruption to acute care by disruption of infusions or failure to comply with treatment.
- Increased complications following surgery, including falls and chest and wound infections.
- Prolonged hospital length of stay.
- Increased need for higher dependency care post discharge.
- Increased risk of acute-care readmission within 30 days.
- Increased risk of intermediate and longer-term cognitive decline (Inouye, et al., 2016; Saczynski, et al., 2012), including dementia (Lingehall, et al., 2017)
- An association with increased mortality.

By 2050, half of all anesthetics and surgical procedures will be provided to those aged 65 years or more. Thus, millions of individuals at high-risk of delirium and its consequences will undergo the precipitating event of surgery and anesthesia every year.

Apart from the personal impact, for hospitalized patients overall, the cost of an episode of acute care is increased 2.5 times by the occurrence of delirium, increasing the cost of healthcare in the United States by over $125 billion dollars every year (Inouye, Wastendorp, & Saczynski, 2014; Brown, et al., 2016) This health-care burden includes the cost of readmission to hospital within 30 days.

It is estimated that up to 40% of hospital-related episodes of delirium are preventable (Inouye, et al., 2014).

For the patient:
Older individuals undergoing surgery and anesthesia have a high risk of experiencing delirium during their hospitalization, especially following major or emergency operations. Patients undergo anesthesia and surgery in order to improve their quality of life, reduce pain or aid disease diagnosis and management. It is now well recognized, but not widely known in the
community, that disorders of cognition occur frequently in older patients following surgical procedures. What is critically important is that delirium should be prevented if possible. Preventing delirium in the older patient will lead to improved health outcomes, including reduced complications, improved recovery, and a likely decrease in the development of later cognitive decline, with reduced mortality and potentially improved long-term health benefits.

For carers (family / caregivers / care providers):
Observing someone you care for experiencing delirium can be very distressing for family, caregivers and nurses. In fact, carers and family members of a delirious patient may experience levels of distress similar to that experienced by the patient, and this distress may persist for 12 months or longer (Patridge, et al., 2019).

Nearly two-thirds of older post-operative patients experience some form of delirium, and it is more likely to occur in patients who already have some cognitive impairment. It is important for caregivers to contribute to planning perioperative care by informing clinicians of any memory or thinking concerns, prior episodes of delirium, and assisting with programs before, during and after the patient’s hospital stay that are designed to reduce risk (Mahanna-Gabrielli, et al., 2019). It is also important for carers and/or families to be involved in discharge care and planning as patients may be discharged from hospital still experiencing hypoactive delirium, even following day case surgery.

Predisposing Factors for Postoperative Delirium: Identifying Risk for POD
Patients who present to the hospital with any of the following factors are at an increased risk for post-operative delirium (American Geriatrics Society Expert Panel on Postoperative Delirium in Older Adults, 2015):

- Increasing Age
- Frailty
- Polypharmacy
- Cerebrovascular disease
- Major cavity surgery (e.g., abdominal, thoracic)
- Emergency surgery
- Metabolic disturbances
- Pre-existing cognitive impairment
- A history of prior POD

At the time of hospital admission, these risk factors should be identified and the treatment team alerted to the need for a delirium-risk care plan. Some risk factors, such as polypharmacy or metabolic disturbances, may be mitigated given sufficient time.

Predictive tools in the general hospital surgical population:
Screening for the risk of developing delirium:
A number of tools with published performance data have been reviewed (Lindroth, et al., 2018). Not all are designed for postoperative risk. Common features included are pre-existing cognitive impairment, age, and general health status. Factors to consider when selecting a tool for routine use in any healthcare environment include use of variables and assessments that are readily available in clinical practice and are feasible to administer without extensive training or interpretation (Lindroth, et al., 2018). Examples include:
AWOL (Douglas, et al., 2013; Brown, et al., 2017)

The AWOL prediction rule was derived by assigning 1 point to each of 4 items assessed upon admission that were independently associated with the development of delirium:

- A: Age ≥ 80 years
- W: Unable to spell “World” backward,
- O: DisOrientation to place
- L: Higher iLness severity

Higher scores were associated with higher rates of delirium with a score of 2 or higher indicating a 5% or higher risk of delirium (ROC AUC 0.69 in the validation cohort).

The AWOL-S variant takes surgical complexity into account.

NSQIP-derived predictive risk in hip fracture patients (Kim, Li, & Kim, 2019).

This is a 9-feature, 20 point maximum risk index for delirium following surgery for fractured neck of femur (ROC AUC 0.77):

- preoperative delirium (8 points);
- preoperative dementia (3 points);
- age (0–3 points);
- medical co-management (1 point);
- American Society of Anesthesiologists (ASA) physical status III-V (1 point);
- functional dependence (1 point);
- smoking (1 point);
- systemic inflammatory response syndrome/ sepsis/septic shock (1 point);
- and preoperative use of mobility aid (1 point);

Screening for cognitive impairment:

Cognitive impairment is a well-validated risk factor for developing post-operative delirium. A number of tools and resources are available. Commonly used tests such as the Mini-Mental State Examination are able to detect possible dementia but are less sensitive to milder forms of cognitive impairment. Simple tests include the Montreal Cognitive Assessment (MoCA) (Ciesielska, et al., 2016), MiniCog (Quitoriano & Hamm, 2017) and TICS (Cook, Marsiske, & McCoy, 2009) which are more sensitive to subtle impairment.

Screening for the clinical presence of delirium: (see later section)

Prediction of Delirium in ICU:

There are several assessment tools that can, with variable precision, predict the development of delirium in ICU patients (including post-operative patients) from various weighted clinical features. All models have been found to have moderate to good predictive abilities. While the features in Pre-DELIRIC (recalibrated) (Table 1, left column (Van de Boogaard, et al., 2014)) were most accurate, the early predictive model (Table 1, center column (Wassenaar, et al., 2015)) although slightly less sensitive had the benefit that it could be applied early in the ICU admission and may allow for timely preventive measures (Green, et al., 2019).
Table 1. Variables included in selected predictive models of ICU delirium (Green, et al., 2019).

**Precipitating Factors for Postoperative Delirium**

There are many factors which may precipitate delirium, especially in patients already at risk. Many are preventable, so a delirium care-plan needs to identify and manage as many of these as possible (White, et al., 2019; Scottish Intercollegiate Guidelines Network, 2019).

- Pain
  - Poorly controlled pain
  - Sedating analgesics, especially opioids
- Disorientation
  - An unfamiliar environment
  - Unfamiliar people
  - Lack of sensory aids, for example, glasses or hearing aids
- Sleep disturbance
- Sedating drugs
  - Especially benzodiazepines
- Polypharmacy
  - Especially drugs with anticholinergic side effects
- Drug withdrawal
  - e.g benzodiazepines, opioids, gabapentinoids
- Dehydration and metabolic disturbances
- Local Infections and Sepsis
- Indwelling catheters
  - Especially urinary catheters
- Physical restraints
Preventive strategies to decrease POD incidence

Up to 65% older post-operative patients suffer some form of delirium following a surgical procedure, especially if requiring ICU admission (Marcantonio, 2017). Because delirium is associated with increased morbidity; mortality; persistent physical and cognitive decline; and overall healthcare costs, prevention of this complication is of paramount importance (Berger, et al., 2018; Gleason, et al., 2015; Brown, et al., 2016; Aldecoa, et al., 2017).

There is evidence that delirium can be prevented or reduced with multicomponent and multidisciplinary strategies, especially when targeted at individuals identified as high risk (Hshieh, et al., 2018; Zhang, et al., 2013; Siddiqi, et al., 2016). Prevention involves attention to predisposing and precipitating factors along the entire clinical pathway (American Geriatrics Social Expert Panel on Postoperative Delirium in Older Adults, 2015):

Prior to hospital admission (or upon hospital admission for emergencies or day-cases)

Elective surgical patients should undergo an appropriate full history and examination either prior to or on admission to hospital which includes the identification of predisposing factors for delirium such as:

- Pre-existing cognitive impairment (history, memory complaint (patient or informant), screening tests) (Berger, et al., 2018)
- Prior experience of postoperative delirium or neurocognitive decline
- Other factors identified by risk assessment tools eg AWOL score (above) (Brown, et al., 2017)

Pharmacological review, ideally by a geriatrician or pharmacist to identify polypharmacy, drug withdrawal risk and potential drug interactions

Patient, family (or carer) involvement with concerns and support - including ensuring the provision of sensory aids (glasses, hearing aids)

Prior to the operative procedure

Factors as above if not completed.

Cognition assessment (eg MoCA, MinCog) and frailty assessment.

Delirium screening test (eg 4-AT or AWOL-S, see below), with more comprehensive testing or referral if positive.

Provide awareness to ward, clinical staff and family/carers if the patient is deemed to be at risk or cognitively impaired.

Immediate preoperative period (in-hospital)

Avoid prolonged fasting, dehydration or metabolic disturbance.

Avoid precipitating factors eg benzodiazepines

Anesthesia strategies

There are many factors which can trigger or precipitate delirium in the postoperative period, and it is unlikely that modification of any one factor in isolation will have a profound effect on outcome, especially in patients with multiple comorbidities.

General principles are to avoid excessive drug exposure, minimize stress, maximize pain control and facilitate early mobilization and return to normal function (White, et al., 2019).

There is no evidence that prophylactic antipsychotic medications decrease the incidence of
Delirium, and in fact may cause harm (Burry, et al., 2018)

**Type of anesthesia.** There is a lack of evidence to support that type of anesthesia (regional versus general) (Patel, et al., 2018) has a substantial impact on the incidence of POD. This is likely due to many factors involved including the presence of multiple risk factors and the use of sedatives to decrease psychological stress for patients. There is no consistent evidence to suggest a difference exists regarding delirium outcomes to guide choice regarding the administration of total intravenous anesthesia (TIVA) versus volatile agents (Royse, et al., 2011; Landoni, et al., 2019).

**Depth of anesthesia (dose of anesthetic).** Avoiding excessively deep anesthesia by titrating anesthetic agents can be achieved clinically, or supported by processed frontal EEG-based (pEEG) neuromonitoring or age-adjusted minimum alveolar concentration for volatile agents. This has been recommended in a number of guidelines (American Geriatrics Society Expert Panel on Postoperative Delirium in Older Adults, 2015; Berger, et l., 2018; Aldecoa, et al., 2017). The use of pEEG guided anesthesia results in lower doses of anesthetic agents being administered and decreased burst-suppression activity on the EEG, and a meta-analysis suggested a benefit in its use in reducing incident delirium (MacKenzie, et al., 2018; Luo & Zou, 2018). Subsequently, a large randomized controlled trial failed to confirm a benefit in this outcome - noting that the intervention was confined to volatile agents, and burst-suppression still occurred frequently in both groups (Wildes, et al., 2019). Similarly, a study in patients having hip fracture repair did not find a difference in incident delirium in patients undergoing deep or light sedation (with BIS pEEG monitoring in both groups) (Sieber, et al., 2018). Possible benefit in POD reduction with the use of intraoperative EEG monitoring awaits clarification by further studies comparing the specific targeting of pEEG and/or burst-suppression levels in appropriately controlled and randomized groups (Abbott & Pearse, 2019).

**Cerebral perfusion.** Cerebral perfusion monitoring and support has a plausible physiological basis, and hypotension has been associated with increased incidence of stroke (Wijeysundera, et al., 2014). A 2018 best practices statement published by the American Society of Anesthesiologists Brain Health Initiative also suggested that optimizing intraoperative cerebral perfusion may improve outcomes (Berger, et al., 2018). Limited trial data suggests that avoidance of significant blood pressure excursions (either hyper- or hypo-tension) may be important (Hori, et al., 2014; Hori, et al., 2016; Brown, et al., 2019). Near infrared spectroscopy-based (NIRS) regional cerebral perfusion monitoring may be used to provide an indirect indicator of frontal cortex perfusion. To date there are limited studies of sufficient size or quality to confirm a strong beneficial impact of NIRS on delirium or neurocognitive outcomes either during surgery (Yu, et al., 2018) or in the ICU (Bendahan, et al., 2018).

**Specific drugs:**
Dexmedetomidine is a potent alpha-2 adrenoceptor agonist with sedative and analgesic properties. Dexmedetomidine given postoperatively, predominantly in the ICU, has been shown to reduce the incidence of postoperative delirium in cardiac and non-cardiac surgery patients (Duan, et al., 2018). It is still uncertain that intraoperative administration on its own is of benefit, and further trials are awaited (Deiner, et al., 2017; Wu, et al., 2018).

There is growing evidence that peri-operative administration of an alpha-2 agonist (dexmedetomidine) may have efficacy in the prevention and treatment of post-operative delirium in ICU patients (Wu, et al., 2018; Flukiger, et al., 2018).

Ketamine. An early trial suggested that administering a single small dose of ketamine (ie 0.5 mg/kg) at the beginning of cardiac surgery may decrease the incidence POD, however a
meta-analysis (Hovaguimian, et al., 2018) and a large RCT failed to demonstrate any benefit in delirium reduction in major surgery (Avidan, et al., 2017).

**Post-operative care**

Daily non-pharmacologic interventions include early mobilization, noise reduction, orientation (day, time, place), reducing polypharmacy, use of hearing and visual aids and maintenance or restoration of normal sleep-wake cycles (Scottish Intercollegiate Guidelines Network, 2019). Sleep deprivation is especially prominent in surgical intensive care patients who tend to attain an average of less than 2 hours of sleep per day (Aurell & Elmqvist, 1985). In this circumstance, maintaining more normal sleep-wake cycles pharmacologically has also been shown to be helpful in preventing postoperative delirium (Aizawa, et al., 2002). Soothing music therapy has also been noted to decrease the severity of delirium, to some degree, in older joint replacement patients (McCaffrey, 2009).

The ABCDEF bundle (Assess, prevent and manage pain, Both spontaneous awakening trials (SAT) and spontaneous breathing trials (SBT), Choice of analgesia and sedation, Delirium: assess, prevent and manage, Early mobility and exercise, and Family engagement and empowerment) is effective in reducing the incidence of delirium in the ICU and involves multidisciplinary clinicians and families (Pun, et al., 2019). This applies to patients of all ages. The use of a portion of the ABCDEF bundle is successful in reducing the risk of poor outcome in a dose-dependent manner.

Dexmedetomidine. As noted above, dexmedetomidine has been shown to decrease the incidence of delirium in elderly cardiovascular surgery patients by more than 50% when administered upon admission to the ICU and continued until the next post-operative day (Duan, et al., 2018). Other studies suggest that another drug (clonidine) in the same class of drugs (alpha-2 agonists) may produce similar results (Rubino, et al., 2010). Alternatively, antipsychotics, both typical (haloperidol) and atypical (risperidone, olanzapine) have little benefit in preventing delirium (Wu, et al., 2019) and should only be used in treatment if considered essential for safe care (Burry, et al., 2018; Oh, et al., 2017).

**Identification of the presence of delirium**

Opinions vary widely on the most appropriate screening tool for delirium in hospitalized patients, noting that patients may manifest hypoactive or hyperactive psychomotor forms. It should be noted that a screening tool is not diagnostic and needs to be sensitive rather than specific. Any tool should also be easy and quick to administer, have a high inter-rater reliability and ideally need minimal training. A patient who screens positive for delirium should have an escalated care plan including appropriate support and treatment strategies, have the managing medical team notified, and be considered for geriatric, neuropsychiatric or psychological referral.

Screening tools should be applied pre-operatively, especially to patients identified as high risk (see predisposing factors above). This can include at the time of pre-admission assessment, or in a modified form at the time of admission to hospital - especially for an acute or emergency procedure. In the latter situation, quick pre-screening questions testing orientation may be sensitive enough to trigger a more specific test be used.

There are many screening tools available of varying ease of use, and sensitivity and specificity (Scottish Intercollegiate Guidelines Network, 2019). Screening tools aid risk assessment and can guide ‘next steps’ including clinical intervention and support and/or referral. Simple one or two questions tests such as the Single Question to Identify Delirium (SQID) are usually based on orientation to time and place (Hendry, et al., 2016) and have only moderate sensitivity and specificity.
When applying tests for delirium, especially in the perioperative/ICU setting, an assessment of the state of alertness of the patient should be part of this and made using a tool such as the Richmond Agitation and Sedation Scale (RASS) (Aldecoa, et al., 2017). This is because delirium can present in different psychomotor forms (ie hyperactive versus hypocative (and mixed). Some specific tests for delirium can then be applied and include:

**4AT**
The 4AT is a screening instrument designed for rapid (< 2 mins) initial assessment of delirium and cognitive impairment using 4 test domains. A total score of 4 or more (maximum 12) suggests delirium but is not diagnostic. Sensitivity is 86-100%; specificity is 65-82%. Any score >0 suggests possible cognitive impairment (http://patient.sm/LRwgGe).

**3D-CAM**
The 3D-CAM is a derivative of the Confusion Assessment Method CAM, taking less time (under 5 mins) and requiring less operator training. Sensitivity is 66-100%; specificity is 90-99% (Marcantonio, et al., 2014).

**Nu-DESC**
The Nursing Delirium Screening Scale (Nu-DESC) is designed to be completed quickly with minimal training using nurse administration (Gaudreau, et al., 2005). It comprises an observational five-item scale. Sensitivity is 32-96%; specificity is 69-92% (Scottish Intercollegiate Guidelines Network, 2019).

The gold standard for diagnosis of POD is by an appropriately qualified physician according to the DSM-5 criteria. For suitably trained experts (or research), tools that may be used include the CAM, Comprehensive Geriatric Assessment or DRS-R-98 (Delirium Rating Scale- Revised). For non-experts options include (with appropriate training): 3D-CAM; CAM-ICU (only validated in ICU).

**Implementation of optimal management plans for POD**
Delirium, once diagnosed, should be managed promptly as for any other acute medical condition. A pre-determined escalated care plan should be implemented including appropriate treatment strategies, the managing medical team must be notified, and the patient considered for geriatric, psychiatric or psychological referral. Follow-up plans must also be in place.

- Elements of acute care include:
  - Making all staff (and family) interacting with the patient aware of the patient’s cognitive state.
  - Reviewing potential precipitating factors (see above) and correcting any abnormalities.
  - Reviewing the patient’s environment to ensure it is safe, calm and supportive for orientation.
  - Regularly re-evaluating at least once per nursing shift and at discharge
  - Reducing the use of pharmacologic interventions or physical restraints unless the patient or staff are at risk of harm (usually from excessive agitation).

**Documentation and reporting of POD incidence**
Delirium episodes when diagnosed should be entered in the patient’s medical record (ideally in a specific section in an Electronic Medical Record), and the managing medical team must be notified. It is essential that the patient and their family and/or carers (as appropriate) are

Discharge documentation should include mention of any episodes of delirium.

**Leadership and Implementation Plan**

In order to build an effective and sustainable postoperative delirium prevention program, it is necessary to engage members from key stakeholder groups across the perioperative continuum. Such a program is truly a team effort with many stakeholders, and requires broad support and buy-in. Much of the work to prevent postoperative delirium occurs prior to hospital admission, and on the ward or in the ICU after surgery.

**Key Points**

- Formation of a leadership group such as an Executive Implementation Committee (eg Cognitive Care Oversight Committee) to initiate and support policy change and implementation (incl content experts / broad representation / ideally change management) including medical, nursing, allied health, pharmacy, informatics and patient/carer representation.
- The committee chair should be an appropriately experienced clinician.
- Consultation must involve all relevant stakeholders including members of the wider community.
- Resources need to be allocated (staff time / IT / educators).
- EMR should be leveraged to trigger reminders / alerts (medication/need for consults) / order-sets.
- Time course for implementation needs to be mapped with an expectation of months to years.

**Possible stakeholders (and suggested roles) include:**

**All phases**

- Hospital / health system leadership
  - support, time, funding
- Family and/or carers

**Prior to admission**

- Anesthesia preoperative clinic
  - screening for frailty, cognitive dysfunction, nutritional status, etc; delirium prevention education
- Surgical clinics
  - screening for frailty, cognitive dysfunction, nutritional status, etc; delirium prevention education
- Pharmacy review of medications
- Social workers, case workers
  - discharge planning
- Dieticians, Physiotherapy, Occupational Therapy
  - preoperative optimization
• Geriatricians, palliative care providers
  o medical optimization, surgical decision-making and goals of care support

**Perioperative**

• Preoperative nursing
  o screening or identification of high-risk patients, keeping sensory aids accessible to patient, patient/family education

• Anesthesia providers
  o choice of anesthetic technique, use of appropriate monitoring, best-practice intraoperative care

• Recovery room nursing
  o delirium screening, appropriate medication administration, non-pharmacologic delirium prevention measures, communicating delirium risk to ward or ICU nurse, patient/family education

**Postoperative**

• Surgical teams, ICU teams
  o ordering of diagnostic / prevention measures, appropriate medication prescribing, appropriate consultation and hand-over

• Ward and ICU nursing
  o delirium screening, non-pharmacologic delirium prevention/treatment measures, patient/family education

• Physiotherapy / Occupational Therapy staff
  o early mobilization, discharge planning

• Pharmacists
  o medication review

• Dieticians
  o nutrition advice

• Case workers/social workers
  o discharge planning

• Geriatricians, palliative care providers
  o medical consultation, assistance with goals of care and symptom management

• Caregivers and family members of the patient
  o monitor and report changes in mental status, actively support early mobilization and other non-pharmacological prevention measures

**Action Plan**

Following the information outlined in preventive strategies (above), recommended specific actions relating to implementation of a delirium prevention program include (American Geriatrics Society Expert Panel on Postoperative Delirium in Older Adults, 2015; Scottish Intercollegiate Guidelines Network, 2019; Aldecoa, et al., 2017):

1. During the development of educational resources and protocols/guidelines, Include a Patient Family Advisory Committee (PFAC) representative on the Delirium Workgroups/Committees.
2. All patients over age 65 should be informed of the risks following an operation of developing POD including confusion, inattention, and memory problems. This discussion should include mention of post-discharge care and involve other family members and/or carers where appropriate.

3. Baseline cognition should be objectively evaluated with a brief screening tool during preoperative evaluation in all patients over the age of 65 and in any patient with risk factors for preexisting cognitive impairment.
   3.1. Tools include: MiniCog; MoCA, TICS (see above).
   3.2. The 4AT can also be used as a sensitive but not specific tool for assessing cognitive impairment.

4. A management plan should be implemented for patients at risk, focusing on reducing precipitating events

5. Perioperative care
   5.1. Implement a strategy for avoiding excessive anesthesia dosing
      5.1.1. Consider monitoring depth of anesthesia using pEEG including processed frontal EEG / burst suppression indices (Siddiqi, et al., 2016)
      5.1.2. Monitoring age-adjusted end-tidal MAC fraction
   5.2. Avoid relative hypotension
   5.3. Maintain normothermia
   5.4. Provide adequate pain assessment and treatment
      5.4.1. Use strategies to minimize opioid-based analgesia
   5.5. Identified at-risk patients should not leave the recovery room without being screened for POD
      5.5.1. If positive, patients should not be discharged to the ward without having started specific interventions to modify precipitating factors for delirium.
   5.6. In the postoperative and ICU setting, it is important that both a sedation/agitation tool such as the Richmond Agitation-Sedation Scale (RASS) and a delirium screening tool are used

6. For routine implementation, it is mandatory to train the team on the basic features of delirium as well as the features of any tools that will be used.

7. On the postoperative ward, POD should be monitored at least once per shift in higher risk patients, due to the fluctuating course of POD.
   7.1. A high sensitivity (to detect POD as early as possible) may be achieved with tests such as the SQID, the Nursing Delirium Screening Scale (Nu-DESC) or the 4AT (see above for details) n.b. the Confusion Assessment Method (CAM) is sensitive and specific but needs specific training and takes longer.

8. Pre-discharge screening for POD should be done in all at risk patients or patients who have had an episode of POD.

9. Manage delirium with a multidisciplinary and multifactor approach

10. Discharge planning should include notification to the patient’s primary physician (GP) if an episode of POD was detected or if baseline cognitive impairment was found.

**Suggested considerations**

1. Implement fast track surgery (ERAS program) with early mobilization and discharge to
2. Avoid routine premedication with benzodiazepines for at-risk patients except for patients with severe anxiety

**Technology plan**

Technology is an enabler of good clinical care. In some cases technology is the only practical means by which some objectives can be achieved (eg EMR medication alerts or audit; online tools). In many cases recommendations for the use of technology are based on ‘best practice’ recommendations, awaiting further evidence (eg pEEG monitoring) and in others, possible applications of technology are listed as they are ‘emerging’ (eg motion tracking or regional cerebral oximetry).

**Technology can support**

- EMR - linkages / alerts
- On-line tools (home assessment / tablet)
- clinical assessment of cognitive impairment
- bedside diagnosis of POD
- risk minimization strategies, including:
  - Preoperative risk assessment and postoperative diagnosis checklists
  - Electronic medication management (with warnings)
  - Optimizing intraoperative depth of anesthesia control including EEG-based and MAC-o based anesthetic titration (best practice recommendation)
  - Optimizing cerebral perfusion (specific evidence weak)
- Audit and review

<table>
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<tr>
<th>System or Practice</th>
<th>Available technology</th>
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| Preoperative clinical risk assessment and screening of cognitive impairment should be performed and documented in patients > 65 years of age or at high risk of postoperative cognitive impairment | • On-line risk assessment questionnaire  
  • On-line / tablet-based cognitive tests  
    o For use by clinical staff and / or patients |
| Screening for Postoperative Delirium                     | • On-line / tablet-based cognitive tests  
  o For use by clinical staff |
  • Simple tests  
  • Quick to apply  
  • Minimal training needed  
  • Sensitive (not necessarily specific)
### Diagnosis of postoperative delirium should:
- Be performed by a healthcare provider trained to perform delirium assessments using accepted diagnostic tools (listed above)
- Include assessments for hyperactive, hypoactive, and mixed subtypes (includes application of the Richmond Agitation and Sedation Scale)

### Employing brain monitoring strategies
- Avoidance of deep anesthesia (and sedation) during surgery
- Optimize cerebral perfusion
- Monitoring for low cerebral perfusion / oxygenation (intra-operative and ICU)

### Titrate volatile anesthesia to appropriate age-adjusted minimum alveolar concentration (MAC)
- Titrate volatile and intravenous anesthesia using processed EEG-based technology (best practice recommendations based on limited evidence)
  - Avoidance of burst-suppression EEG which may reflect anesthesia excess
- Optimize cerebral perfusion (best practice recommendation)
  - Specific technology eg regional Cerebral Oximetry (NIRS) (low level evidence currently)
- Limited ICU evidence only for post-operative use

### End-tidal anesthetic agent monitoring (best practice recommendation)
- Eye tracking
- Motion / activity tracking

### Built into EMR system reports

### Future technologies: Activity monitoring
- Eye tracking
- Motion / activity tracking

### Patient, Carer & Family Engagement

The inclusion of a patient’s family and/or support persons (friends and other support) in a patient’s care planning preoperatively and while in the hospital is vital to providing complete care for the patient and provides an opportunity to implement delirium prevention strategies (Mahanna-Gabrielli, et al., 2019). Include STOP & THINK, family engagement strategies.

For patients identified at risk in the preoperative period, provide education to the patient and support persons on postoperative delirium, potential risks and preventative measures. Informed consent should include risks of postoperative delirium based on pre-operative screening (Berger, et al., 2018; Hogan, Scenning & Hogan, 2018).
Risk reduction strategies include inviting a carer or family member to be with the patient at risk of delirium throughout as much of the perioperative period as possible - this includes accompanying the patient to the OR holding/preparation area and being present in the post-anaesthesia care unit (recovery room) as they emerge from anaesthesia. The benefits of orientation at these times with a familiar person present may be significant.

For patients identified with postoperative delirium provide education to support persons regarding postoperative delirium and management of postoperative delirium, especially nonpharmacological interventions. Engage support person(s) in nonpharmacological interventions as appropriate, including bedside presence and ongoing post-discharge support.

During the development of educational resources and protocols/guidelines, include a Patient Family Advisory Committee (PFAC) representative on the Delirium Workgroups/Committees. In the development of educational materials/handouts and protocols for patients and support persons, engage with the Patient, Family Advisory Committee (PFAC) to review educational materials from a patient’s perspective.

Public Awareness: Provide public education on Postoperative delirium to include signs, symptoms and treatment. Incorporating patient and family stories is a powerful way to engage practitioners and how they perceive the issue of delirium.

**Measuring outcomes**

To evaluate the effectiveness of the early identification, prevention and management of older patients at risk for postoperative delirium, key process and outcome metrics need to be documented. Key population subgroups might include emergency versus elective patients, identified high-risk versus low-risk, and different surgical specialties.

**Topic:** postoperative delirium

**Outcome Measure Formula:**

**Numerator:** Number of surgical patients, 65 years and older, who develop postoperative delirium

**Denominator:** Number of surgical patients, 65 years and older,

Rate is typically displayed as: Number of surgical patients, 65 years and older, who develop postoperative delirium per 1,000 surgical patients, 65 years and older,

**Outcome Measure Formula 2:**

**Numerator:** Number of surgical patients, 65 years and older, who require readmission within 30 days of surgery who have experienced post-operative delirium in their primary care episode

**Denominator:** Number of surgical patients, 65 years and older.

Rate is typically displayed as: Number of surgical patients, 65 years and older, who require readmission for post-operative delirium within 30 days per 1,000 surgical patients, 65 years and older.

**Process Measure Formula:**

Numerator: Number of surgical patients, 65 years and older, who are screened pre-operatively for cognitive impairment and/or delirium
Denominator: Number of surgical patients, 65 years and older, 
Rate is typically displayed as: Number of surgical patients, 65 years and older, who are screened pre-operatively for cognitive impairment and/or delirium per 1,000 surgical patients, 65 years and older,

Process Measure Formula 2:  
Numerator: Number of surgical patients, 65 years and older, who are evaluated post-operatively for delirium at prescribed intervals using standardized clinical assessment tool  
Denominator: Number of surgical patients, 65 years and older, 
Rate is typically displayed as: Number of surgical patients, 65 years and older, who are evaluated post-operatively for delirium at prescribed intervals using standardized clinical assessment tool per 1,000 surgical patients, 65 years and older,

Process Measure Formula 3:  
Numerator: Number of surgical patients, 65 years and older, with positive delirium screens who receive postoperative preventative interventions (pharmacologic and nonpharmacologic)  
Denominator: Number of surgical patients, 65 years and older, with positive delirium screens 
Rate is typically displayed as: Number of surgical patients, 65 years and older, who receive postoperative preventative interventions (pharmacologic and nonpharmacologic) per 1,000 surgical patients, 65 years and older, with positive delirium screens

Metric recommendations:  
Direct Impact: surgical patients, 65 years and older,  
Elimination of patient harm: As measured by 1) elimination of postoperative delirium among surgical patients, 65 years and older, or 2) reduction in time from onset of delirium symptoms post-operatively to implementation of treatment protocols/guidelines.  
Lives spared harm:  
Lives spared harm = (postoperative delirium rate_baseline - postoperative delirium rate_measurement) x surgical patients, 65 years and older_measurement  
Lives saved:  
Lives saved = (surgical patients, 65 years and older, postoperative delirium mortality rate_baseline - surgical patients, 65 years and older, postoperative delirium mortality rate_measurement) × surgical patients, 65 years and older, postoperative delirium cases_measurement

Notes:  
Limitations: It may be difficult to define the patient population. Pre Screening should be helpful in determining if there is a pre-existing condition such as dementia versus postoperative delirium.  
Data Collection:  
Manual chart review of surgical patients, 65 years and older, with any of the following post-operative delirium diagnosis codes:  
CM Diagnosis Code F05 - Delirium due to known physiological condition or the following codes with any diagnosis and a POA of No: R404, R410, R440, R441, R443
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 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.

Workgroup
Co-Chairs
David Scott St. Vincent’s Hospital, Melbourne
Cheryl Misak University of Toronto

Members
This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Steve Barker Masimo; Patient Safety Movement Foundation
Julie Barr Stanford University
Robin Betts Kaiser Permanente
Dan Cole University of California, Los Angeles
Anne Donovan University of California, San Francisco
Lis Evered St. Vincent’s Hospital, Melbourne
Lee Fleisher University of Pennsylvania
Adrian Gelb University of California, San Francisco
Lisa Helfand Comfortable in My Thick Skin
Ariana Longley Patient Safety Movement Foundation
Olivia Lounsbury Patient Safety Movement Foundation
Armando Nahum Safe Care Campaign
Donna Prosser Patient Safety Movement Foundation
Mike Ramsay Baylor Scott & White Health
Sundary Sankaran Kaiser Permanente
Jonathan Stewart BETA Healthcare Group
Jennifer Tatro UC Health
Kerry Tomlin Medtronic
Kimberly Won Chapman University
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