Actionable Patient Safety Solutions (APSS)

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Actionable Patient Safety Solutions (APSS) #1:

Culture of safety

How to use this guide

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

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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.
- ☐ Make sure leadership and staff can all 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
- 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 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.

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.

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 1st Actionable Patient Safety Solution (APSS) 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.
- 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
- 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
- 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 process improvement to truly be successful, leadership commitment and action are required at all levels. The board, senior leadership, physicians, pharmacy and nurse directors, managers, unit leaders, and patient advocates all have important roles and need to be engaged in specific behaviors that support staff to provide safer care.
- Safety culture and performance must be valued and reflected in compensation plans, 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. that allows anonymous reporting of unsafe conditions without fear of reprisal. Anonymous event reporting will show that your 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

- Encourage staff to 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 do safety rounds to identify potentially unsafe conditions

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.
- Collect and review data about common causes you find 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

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.
- Develop comprehensive internal communications plans around safety goals:
  - Thoughtfully, consistently, and openly communicate 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

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 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.

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
- A 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 will include:
  - National Patient Safety Awareness Week
  - Newsletters, emails, and videos
  - Case studies
  - Meetings and huddles
  - Simulations (where available)
  - Participation in a patient safety organization (PSO) to enhance sharing and learning from safety events

Measuring outcomes

Topic:

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 events, state reportable events, or hospital acquired conditions (HACs)

Lives spared harm:
Lives spared harm =
(SSE rate_baseline – SSE rate_measurement) x adjusted patient days_measurement

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

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

Notes:

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

Inpatient revenue + outpatient revenue + ((miscellaneous revenue) / (inpatient revenue)) x 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.

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Actionable Patient Safety Solutions (APSS) #2A:

Hand hygiene

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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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 soap 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 Protocol, 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:
  - ☐ 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
  - ☐ Craft education for patients, family members, and visitors
  - ☐ Conduct performance evaluation and give feedback
- ☐ The protocol should include training for patients and family members when they are admitted and encouraging 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
- ☐ DO should not be used for measurement of hand hygiene rates because it's been shown to be inaccurate and unreliable in multiple studies (Srigley, et al, 2014) (Scheithauer et al., 2009)

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 Protocol
- ☐ 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 infections that patients may get from devices used in healthcare, such as catheters or ventilators. 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 (Organization and others, 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 and secret shoppers 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.

- Pacing Event on May 25, 2017, Partnership for Patients Pacing Event Hand Hygiene and HAIs.

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
  - Curate stories based on your own organization's culture
  - 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 ("Joint Commission Center for Transforming Healthcare. Joint commission resources hot topics in health care—transitions of care: the need for a more effective approach to continuing patient care", 2012). 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 protocols

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 your staff by modeling and ask your staff to teach-back the concepts
2. Admission nurses should teach the concepts with daily reminders by other staff nurses
   a. Family and visitors can also be taught as needed
3. Use print materials to strengthen teaching

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 reporting 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

User must decide based on what is best for their institution and culture

Feature Set	Options These options have their respective advantages and organizations must decide what is right for them based on the evidence and knowledge of their culture and staff.
What standard of care is measured	Tracks World Health Organization (WHO) 5 Moments for Hand Hygiene (Steed et al., 2011) (Diller, 2013) OR Wash in/Wash Out (Kelly, et al., 2015)
Hand hygiene products used requirement	Universal system (deployment of the technology requires no hand hygiene product change required) OR HH Brand Specific (deployment of the technology does require use of a specific brand)
Compliance data reporting level	Group, Unit, Department Level, Individual Level, or Both
System functionality	Gentle Reminders for healthcare workers and Patient Awareness Function; Auto Push Reports via email (eliminates the need to log on to access the system)
System infrastructure	Stand alone or Real Time Locating System (RTLS) Application
Financial model	Capital expense Subscription/annual fee model or hybrid

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: **patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

For a list of suppliers that meet criteria above, visit The Electronic Hand Hygiene Compliance Organization (EHCO), Inc. website (**www.EHCOhealth.org**).

EHCO is a 501C6 not for profit industry association focused on the public health and patient safety issues associated with poor hand hygiene, is a resource for the evidence in support of adoption of electronic monitoring.

System or Practice	Available Technology
Electronic monitoring of hand hygiene behavior	Clean Hands/Safe Hands **cleanhands- safehands.com/** Stanley Healthcare **stanleyhealthcare.com/solutions/health-systems/patient-safety/hand-hygiene-compliance-monitoring**

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 as 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 members are required to disclose any potential conflicts of interest.

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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 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) #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:

Executive summary checklist 32
What we know about CAUTI 33
Leadership plan 34
Action plan 35
Technology plan 35
Measuring outcomes 36
Conflicts of interest disclosure 37
Workgroup 37
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Patient Safety
MOVEMENT

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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 the most common healthcare-associated infection (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 (Maki & Tambyah, 2001):

- 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 tract infections (UTIs) are the most common HAIs, making up to 40% of infections reported in acute care hospitals (Edwards *et al.*, 2009). 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 appropriate indications
- Compliance with evidence-based guidelines, such as:
  - Surgical Care Improvement Project (SCIP-Inf-9) requires urinary catheter removal on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD 2)
- 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
- 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
     - 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
  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
  - Craft stories based on your organization's culture
  - You'll find examples of impactful stories at:
    - Patient Safety Movement Foundation **youtube.com/0x2020**

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 technologies to address CAUTIs in your organization:

System or Practice	Available Technology
An anti-infective Foley catheter kit Ensure there are enhanced components to prepare, insert and maintain a safe urinary catheter.	BARDEX I.C. Advance Complete Care Trays

Measuring outcomes

Topic

Catheter-associated urinary tract infections (CAUTI)

Rate of patients with CAUTI per 1,000 urinary catheter-days – all in-patient 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-days for all patients that have an urinary catheter (2-calendar days or more) in all tracked units

**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:

$Lives = (CAUTI\ RATE_{baseline} - CAUTI\ Rate_{measurement}) \times (Urinary\ Catheter)\ days_{baseline}$

Lives Saved:

Lives Saved = Lives Spared Harm X Mortality Rate

Notes

To meet the NHSN definitions, infections must be validated using the hospital acquired infection (HAI) standards (CDC, 2015). 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:

CAUTI and urinary catheter-days can be collected through surveillance (at least once per month) or gathered through electronic documentation. Denominator documented electronically must match manual counts (+/- 5%) for a 3 month validation period.

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

SIR = Observed CAUTI/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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Actionable Patient Safety Solutions (APSS) #2C:

Surgical site infections (SSI)

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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Leadership plan 45
Action plan 45
Measuring outcomes 48
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Patient Safety
MOVEMENT

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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 (Ban et al., 2017; 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 **youtu.be/TVtTEerE0vo**

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 that includes the repeated use of:
  - Chlorhexidine gluconate (CHG)
  - Antimicrobial soap
- 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
  - 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 antiseptic agents—FDA approved or cleared—and approved by your organization's infection control staff:
  - The purpose of skin antiseptic agents is to significantly lower microorganisms on intact skin
  - Skin antiseptic agents should be used for all pre-operative skin preparation
  - Skin antiseptic 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 antiseptic agents
  - These practices ensure that an appropriate therapeutic dose covers and is maintained across the entirety of the skin surface
- Educate peri-operative staff on:
  - The safe application and use of skin antiseptic agents
  - The benefits of skin antiseptics—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:
  - A single-use hair clipper
  - 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/**

System or Practice	Available Technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)	
Skin antiseptic activity	• 3M Duraprep • Carefusion Chloraprep
Supportive intra-operative wound protection	• Applied Medical Alexis • 3M SteriDrape
Actively clean and remove infectious contamination from the surgical incision	• CleanCision Wound Retraction and Protection System (Suh *et al.*, 2017)

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data- pledges/

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

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:

Lives Spared Harm = (SSI Rate $_{baseline}$ *- SSI Rate* $_{measurement}$ *) X Operative Procedures* $_{baseline}$

Lives Saved:

Lives Saved = Spared Harm X 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:

SIR = 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 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 0.028 (28 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* $_{measurement}$ *) X Operative Procedures* $_{baseline}$

Lives Saved:

Lives Saved = Spared Harm X 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 = 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

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 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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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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Patient Safety MOVEMENT

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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, 2010). 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
  - ☐ Use cuffed endotracheal tube with in-line or subglottic suctioning
  - ☐ 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
  - ☐ 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 (SCCM 2017 Statistics; DeLassence, *et al.*, 2002)
- The crude mortality rate for VAP is between 20% and 60%—incidence ranges from 4% to 48% (Cook, 1998, Heyland, 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 Peptic Ulcer Disease (PUD) prophylaxis
- Use Deep Venous Thrombosis (DVT) prophylaxis
- Recommend daily oral care with chlorhexidine
- Follow hand hygiene procedures before and after touching a patient

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 Solution (APSS) 8B - Unplanned Extubation Technology plan.

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:

System or Practice	Available Technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)	
Implement endotracheal tubes designed to drain subglottic secretions	
If endotracheal tubes designed to drain subglottic secretions are not available	• Consider use of the Vyaire Medical Tri-Flo Subglottic Suction System
Implement oral hygiene products	• Include the use of Chlorhexidine • Such as SAGE Q-Care Rx Oral Cleansing and Suctioning Systems or HALYARD or Medline Oral Care Kits with CHG
Implement electronic surveillance technologies that support antimicrobial stewardship	• In late onset cases of VAP, bacteria is often multidrug resistant, and can have great clinical and economic challenges

Implement Electronic Measurement of hand hygiene compliance	• See APSS #2A to learn more

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: **https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

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:

$Lives = (VAP\ Rate_{baseline} - VAP\ Rate_{measurement}) \times Ventilator\ days_{baseline}$

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 (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, 2015). *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.

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Actionable Patient Safety Solutions (APSS) #2E:

Clostridium difficile infection (CDI)

How to use this guide

This guide gives actions and resources for creating and sustaining safe practices for clostridium difficile infection (CDI). In it, you'll find:

Executive summary checklist 66
What we know about CDIs 68
Leadership plan 69
Action plan 70
Technology plan 71
Measuring outcomes 72
Conflicts of interest disclosure 73
Workgroup 73
References 75

Patient Safety
MOVEMENT

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Executive summary checklist

Clostridium difficile—or C. diff, for short— is a bacterium that can cause symptoms ranging from diarrhea to life-threatening swelling 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).

Patients can become infected with a clostridium difficile infection (CDI) if they touch items or surfaces that are contaminated with feces and then touch their mouth 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 infection rates in healthcare settings
  - ☐ Go to APSS #3A to learn more
- ☐ Maintain contact precautions for duration of diarrhea
- ☐ 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:
  - ☐ Clorox Healthcare Bleach Germicidal Wipes
  - ☐ Xenex UV Light Disinfection System
- ☐ Create education 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 alcohol products to disinfect equipment
- ☐ 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 your staff

What we know about CDIs

Clostridium difficile infections

Clostridium difficile—or C. diff, for short— is a bacterium that can cause symptoms ranging from diarrhea to life-threatening swelling 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 antibiotic-associated diarrhea (AAD) and it accounts for 15-25% of all episodes of AAD
- C. diff infections can cause many diseases, including:
  - Pseudomembranous colitis (PMC)
  - Toxic megacolon
  - Perforations of the colon
  - Sepsis
  - Sometimes, death

Symptoms include:

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

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

- With antibiotic exposure
- With proton pump inhibitors
- With Immunocompromising conditions
- Who've had gastrointestinal surgery
- Who spend more time in healthcare settings
- That may have a serious underlying illness
- Who are elderly

How is CDI spread?

C. diff is spread among patients through feces. Patients can become infected if they touch items or surfaces that are contaminated with feces and then touch their mouth 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 rubs (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 gloving and after degloving (WHO, n.d.).

- 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—for about 10 days
- 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 in your organization should be familiar with the differences between C. diff colonization and infection:

- Clostridium difficile colonization:
  - Patient doesn't show clinical symptoms
  - Patient tests positive for C. diff organism and/or its toxin
  - More common than CDI
- Clostridium difficile infection:
  - Patient shows clinical symptoms
  - Patient tests positive for the C. diff organism and/or its toxin

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.

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 CDIs.

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

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 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

Create, establish, and consistently implement CDI prevention guidelines that focus on educating:

- Healthcare providers
- Patients and their families
- Surveillance
- Hand hygiene
- Contact and isolation precautions

Prevention guidelines must also include the establishment of an antimicrobial stewardship program (CDC, 2012; WHO, n.d.).

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

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

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 equipment

- Practice standardized hand hygiene (Oughton, 2009; WHO, n.d.)
  - 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 rubs, 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 the appropriate 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 (EPA, 2014)
    - 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

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:

System or Practice	Available Technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)	

Support proper surface cleaning and utilize as part of a defined environmental control best practice program	
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

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: **patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

Measuring outcomes

Topic

Healthcare-associated Clostridium Difficile Infection Rate (CDiff)

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 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:

$$\textit{Lives Spared Harm} = (\textit{CDI Rate}_{\textit{baseline}} - \textit{CDI Rate}_{\textit{measurement}}) \times \textit{Patient Days}_{\textit{baseline}}$$

Lives Saved:

$$\textit{Lives Saved} = \textit{Spared Harm} \times \textit{Mortality Rate}$$

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

CDiff 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 (ICU), specialty care areas (SCA), step-down units, wards, and chronic care units. Surveillance will NOT be performed in Neonatal Intensive Care Units (NICU), Specialty Care Nurseries (SCN), babies in LDRP, 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 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). 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 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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Actionable Patient Safety Solutions (APSS) #2F:

Central line-associated blood-stream infections (CLABSI)

How to use this guide

This guide gives actions and resources for creating and sustaining safe practices for CLABSI. In it, you'll find:

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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

Ensure best patient care

- ☐ During insertion of a central catheter, doctors should always:
  - ☐ Perform a "time-out"
  - ☐ Wash their hands with soap
  - ☐ Clean the patient's skin with appropriate antiseptic
  - ☐ 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), such as:
  - ☐ Arrow International PSI Kit with Integral Hemostasis Valve/Side Port
  - ☐ Arrow International Pressure Injectable Quad-Lumen Central Venous Catheterization Kit with Blue FlexTip
  - ☐ ARROWg+ard Blue PLUS Catheter and Sharps Safety Features
  - ☐ 3M Tegaderm chlorhexidine gluconate (CHG) dress
- ☐ 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) when CLABSIs are identified in 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 - 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 75,000 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):

- Heavy bacterial colonization at the insertion site
- Catheter is placed in the arm or leg rather than 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 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 (Vonberg *et al*., 2006). 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 as much as $23,000 per case (Scott, 2009).

Preventing CLABSIs

CLABSIs and other HAIs, however, are mostly preventable. Interventions that focus on reducing CLABSIs have resulted in reductions ranging from 38% to 71% (Pronovost, *et. al.*, 2003). 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*., 2011)
- 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 checklist

- Monitoring the continued need for intravascular access on a daily basis
- 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
  - 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: https://youtu.be/-DNuFp6KDVM

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—gowns, mask, gloves, and hair covering
- Cover patients with a sterile drape, except for a very small hole where the central line goes in
- 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)

    - 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)
    - 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)
    - Go to APSS #2A Hand Hygiene to learn more
- Use ultrasound guidance for all non-emergent central line placements
- For directly inserted central lines, avoid veins in arm and leg, which are more likely to get infected than veins in chest
- 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
    - 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
- When inserting near the lungs, ensure line aspirates blood to ensure proper catheter placement
- Apply a sterile dressing to the site
- Use a prepackaged or filled insertion cart, tray, or box – cart/tray/box that contains all the necessary supplies
- Use an insertion checklist with staff empowerment to stop non-emergent procedure:
    - Include a checklist to ensure adherence to proper practices
- Use a full sterile barrier for providers and patients:
    - 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
    - Use a sterile sleeve to protect pulmonary artery catheters during insertion
- Provide insertion training for all providers

Maintenance

- Perform daily assessments of need for line and remove when no longer needed:
    - Have daily discussion of line necessity, functionality, and utilization including bedside and medical care team members
        - Healthcare personnel that are properly trained should be doing the maintenance on the central line
    - 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
        - Consider bundling labs and line entries

    - Consider documentation as best practice
        - Document that the discussion occurred 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 rounds
- Send monthly data to team and leadership
    - Celebrate successes
    - Perform in-depth case reviews when infections do occur
    - Identify the risks that could've been avoided and modifications needed moving forward, if any
    - Use a systematic approach to review all hospital-acquired CLABSIs

Standardized access procedure

- Go to Hand Hygiene details in APSS #2A
- Disinfect cap before all line entries by scrubbing with an appropriate antiseptic and accessing the port only with sterile devices
- 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
    - 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 drape

In the neonatal ICU:

- Create a monthly report-out at team/quality committee and leadership meetings
- Implement standardized central venous catheter (CVC) practices:
    - Insertion checklist
    - Daily assessment
    - Electronic health record prompt to remove catheter based on feeding volume

    - 24-hour catheter tubing change, experienced nurses only
    - Enhanced nursing education and competency for CVC care

Provide staff training

- Nursing education—care and maintenance bundle
- Neonatal ICU nursing education—enhanced and competency for CVC care
- Central Line Simulation Program
    - Develop education for attendings, residents, and nurses
    - Key Curriculum Concepts—reinforcement
        - Hand hygiene
        - Appropriate gowning and gloving
    - Key Curriculum Concepts—new
        - Standardized central line insertion best practice
            - Ultrasound guided cannulation
        - Updated 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 education document (see **Figure 1** below)

My CVL Plan

My name is: **Today's Date is:** **Bed Spot:**

Central line #1 My type of central line is a:_____ _____ lumens	Central line #2 My type of central line is a:_____ _____ lumens
❑ I have a positive blood culture from my line	❑ I have a positive blood culture from my line
My central line is _____ days old	My central line is _____ days old
Do I still need my central line? _____	Do I still need my central line? _____
My central line is accessed _____ times per shift ❑ Which of my IV meds can go to oral dosing? ❑ Can we decrease my frequency of blood work? ❑ Do I have a PIV we could use instead?	My central line is accessed _____ times per shift ❑ Which of my IV meds can go to oral dosing? ❑ Can we decrease my frequency of blood work? ❑ Do I have a PIV we could use instead?
❑ Both lumens pull back and flush well	❑ Both lumens pull back and flush well
❑ My central line site is clean and intact	❑ My central line site is clean and intact
My next dressing is due:	My next dressing is due:
What can we do today to prevent a central line infection:	**What can we do today to prevent a central line infection:**

Figure 1: My CVL Plan (developed by Hospital for Sick Children, Toronto)

Quality process measures and metrics

- Complete documentation elements
  - Number of operator attempts per line placement
  - % of patients with site disinfection per protocol
  - % insertion with completed checklist
- Bundle compliance – insertion and maintenance to be measured separately
  - % of line insertions following all bundle components
  - Hospitals can choose to include additional bundle components. Including more than 5 may confuse and overwhelm providers.
- 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/**

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

System or Practice	Available Technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)	
A central venous catheterization (CVC) kit to prepare, insert and maintain a safe central line. • Kits can be custom designed to fit the needs of one hospital or hospital system. • Two such kits are used at the University of Vermont Medical Center and have been included:	• Arrow International PSI Kit with Integral Hemostasis Valve/Side Port • Arrow International Pressure Injectable Quad- Lumen Central Venous Catheterization Kit with Blue FlexTip • ARROWg+ard Blue PLUS Catheter and Sharps Safety Features
Electronic Hand Hygiene Compliance technology • ensure accurate and reliable measurement, feedback and improvement of this essential performance indicator	• Go to APSS 2A to learn more

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: **https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

Measuring outcomes

Topic:

Central line-associated bloodstream infections (CLABSI)

Rate of CLABSI (healthcare-associated primary bloodstream infection (BSI)) in a patient that had a central line within the 2 calendar days before the development of the BSI and that is not related to an infection at another site.

Outcome measure formula:

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

Denominator: Device days or patient days

Rate is typically displayed as CLABSI/1000 Line 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:

Lives = (CLABSI Rate $_{baseline}$ *- CLABSI Rate* $_{measurement}$ *) X Line days* $_{baseline}$ || *Patient Days* $_{baseline}$

Lives Saved:

Lives Saved = Lives Spared Harm X 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, 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). 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.

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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 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) #3A:

Medication errors

How to use this guide

This guide gives actions and resources for creating and sustaining safe practices for reducing medication errors. In it, you'll find:

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Executive summary checklist

Medication errors are major causes of inpatient harm and death. Medication errors are preventable adverse events due to wrong medicine use including:

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

Ensure best patient care

- ☐ Create a multidisciplinary team to lead the project, including physicians, nurses, pharmacists, and information technology personnel
- ☐ Use systematic protocols for medicine 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:
    - ☐ The BD Intelliport Medication Management System
    - ☐ First Databank FDB MedKnowledge drug library system
    - ☐ Other drug dosing solutions such as Monarch Medical Technologies solution for calculating IV & SubQ insulin doses
  - ☐ Use barcoding for identification in the medicine administration process
  - ☐ Check patient's allergy profile before prescribing medicine
  - ☐ Ensure appropriate training and safe operation of automated infusion technologies
  - ☐ Distinguish "look-alike, sound-alike" medicines by 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 Physician Order Entry (CPOE), reporting systems and quality assurance reports to audit compliance
- ☐ Use Clinical Decision Support Systems (CDSS) 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).

Addressing medical 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 medicines are often critically ill and taking multiple medicines, which further increases the chance of error and adverse events.
- Surgery has high rates of medication errors with a higher severity level (NQF, 2010). This is due to a high-stress environment and lack of computerized order entry, pharmacy approval, 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 medicine safety plan that follows the National Quality Forum (NQF) safe practices (NQF, 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." (IHI, 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:
  https://youtu.be/9jmULQ_m04o

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, 2011)
- Create and deliver monthly or quarterly education on medication error and patient safety updates

Create protocols

- Create a universal checklist for medicine administration that includes:
  - Patient name
  - List of patient's current medicines
  - Medicine to be given and its:
    - Dose
    - Route
    - Timing
    - Documentation
- Systematize tools and practices, including checklists, for:
  - Patient allergy and medicine interaction checks on every patient
  - CPOE (Computerized physician order entry)
  - Medicine barcoding
  - Patient education and adherence
  - Correct and on-time medication administration (ISMP, 2011)
- Practice hand hygiene when giving medicine as tablets, capsules, and pills by hand, such as wearing gloves instead of bare hands
- Use standardized order sets where possible
- Review medicine labels and redesign as needed (Practices, n.d.)
- Prepare medicine 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
  - Training and safe use of intravenous infusion pumps
  - Use of medicine dispensing cabinets (ISMP, 2011)
  - Adult IV Push Medications
  - High-Alert Medications

- Ensure that all FDA and USP regulations are met and followed by either in-house production or third party vendor as part of a standardized process for compounding sterile medicines (Practices, n.d.)
- Follow the APSS#4 guidelines for continuous monitoring of all patients who are receiving parenteral narcotics or other sedative drugs
- Practice CDC Guidelines for single use injections - one solution, one patient, one syringe
- Use FDA Manufactured Single Use Injection Kits (SUIK) when available

Ensure safety during transitions of care

- Consider the following high-risk medicine groups:
  1. Opioids
     a. Consider all pain medicines including over the counter
     b. Concern for over-using tylenol
  2. Anti-diabetics
     a. Resume Metformin, confirm kidney function appropriate
     b. Adjust insulin based on food intake
  3. Anticoagulation/Antiplatelet
     a. INR levels, renal function, OTC medicine use (NSAIDs)
  4. Antibiotics
     a. Appropriate duration of therapy
     b. Labs ordered (vancomycin follow up)
     c. Home health ordered
- Coordinate appropriate follow up and monitoring, such as:
  - Labs: INR, Digoxin levels, electrolytes, blood sugar, vancomycin troughs, thyroid levels
  - Chronic disease state management, such as heart failure, asthma, and COPD
- Confirm medicine dose for any changes in health status, including changes in:
  - Weight
  - Renal and liver function
  - Functions that could affect the patient's ability to take medicine by mouth, injection, or inhalation
- Confirm needed medical equipment is ordered, such as a nebulizer, diabetic supplies, and IV antibiotic
- Evaluate for high risk disease states
  - Check patients comply with core measures and immunizations when appropriate (Stroke, MI, Heart Failure)
  - 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/

System or practice	Available technology
All settings	
ONC Meaningful Use Cert ified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Electronic Prescribing (eRx) • Electronic Prior Authorization (ePA)	
Electronic Medication Administration Record (eMAR) system with pharmacy and bedside barcoding capabilities	First Databank FDB MedKnowledge system (First Databank, 2014)
FDA approved clinical decision support solution for medication therapy recommendation	Monarch Medical Technologies* Endotool Solutions for insulin
Infusion pumps that wirelessly communicate data back to the electronic eMAR	
Patient and medication barcoding system	
CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE (Metzger et al., 2010; Leung et al., 2013)	Leapfrog CPOE Evaluation Tool (Leapfrog, 2016)
Drug libraries	
Pharmacy workflow manager	DoseEdge from Baxter Healthcare*

Surgery environment	
IV injectable doses, audible and visual feedback for each syringe attached with measurement of dose, allergy alerts and more accurate and timely documentation wireless to the anesthesia information system	BD Intelliport* Medication Management System.
Continuous physiologic monitoring on patients receiving IV medications to provide an early indication of deterioration due to a medication error	Masimo* rainbow Acoustic Monitoring (Mimoz et al., 2012)
Pharmacy	
Pharmacy robots to reduce safety problems associated with providers drawing up their own medications, and risks associated with contamination from outsourced compounders	BAXA Intellifil Robot
Utilize single use injection kits or pre-mixed sterile solutions	• Asclemed USA Inc., Injection Kits • Nubratori RX, Pre-mixed sterile solutions
Other considerations	
"End-to-end" smart pump system, or other electronic pump systems	

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: **https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

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 medicine).

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 medicine or class of medicines)

**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 medicines

Lives spared harm:

Lives Spared Harm = (ADE Rate $_{baseline}$ *- ADE Rate* $_{measurement}$ *) X Doses or Adjusted Patient Days* $_{baseline}$

Lives saved:

Lives Saved = Lives Spared Harm x Mortality Rate

Notes

Top medicine 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 medicines)
6. Injectable medicines

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 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 and a medication errors reporting program, MERP).

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

If medicine usage information is not available, 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 (NLM, 2015)

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 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 Adverse Drug Events 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.

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Actionable Patient Safety Solutions (APSS) #3B:

Antimicrobial stewardship

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:

Executive summary checklist 108
What we know about antimicrobial stewardship 109
Leadership plan 110
Action plan 110
Technology plan 115
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Patient Safety
MOVEMENT

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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 infection prevention, infectious disease professionals from Medicine, Surgery, Pharmacy, Microbiology Laboratory, Nursing, and Information Technology
- ☐ Create ways to educate clinicians regarding ASP initiatives and progress

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

- 20% of adverse drug events (Lesar, 1997; JAMA 2017)
- 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)
- *Clostridium 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 SB 1311 that requires all general acute care hospitals in California to create a physician supervised multidisciplinary Antimicrobial Stewardship committee by July 1, 2015 (CLI, 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 Antimicrobial Stewardship Programs in place

A successful ASP committee includes the following members:

- Infectious disease (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 antibiotics
- Identify and reduce risks of developing, acquiring, and transmitting infections
- Reduce healthcare costs and toxicities with antimicrobials and inappropriate therapy

- Prevent adverse drug events
- 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 infectious disease training)
  - Actionable program components (e.g., prospective audit, automatic discontinuation orders)
  - Monitoring of microbial resistance and infection patterns
  - Reporting of and education about ASP findings to hospital staff (physicians, nurses, pharmacists, etc.)

Engage staff

- Protect and approve time for 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 (APS)

- Create a multidisciplinary team that includes:
  - ID-trained physician
  - ID-trained or clinical pharmacist
  - Microbiologist

- Infection control technologists
- Information technologists (CDC, 2015)

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

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

	Restrictive program ASP	**Prospective audit with feedback ASP**
What is it?	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 approval by .	In this program, a retrospective (hours to days) review of antimicrobial orders takes place for targeted and in some institutions non - targeted antimicrobials for appropriateness. It is also common to find programs that use a hybrid approach in which audit and feedback are employed along with a restricted formulary.
Pros	Offers direct oversight in the use of restricted antimicrobials Reduces pathogen resistance within the hospital and communities Reduces hospital LOS Reduces risks of antimicrobial-related side effects and drug-drug interactions	Avoids loss of autonomy Offers the chance to educate individuals rather than only restrict use.
Cons	Requires personnel to be available around-the-clock Physicians may see this as a loss of autonomy 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) 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	Compliance is often voluntary (Dellit, 2007) 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

Create pharmacy driven protocols

Pharmacy intervention	Rationale	Minimal resources required	Dedicated resources required
Protocols for changes from intravenous (IV) to oral (PO) antibiotic therapy in appropriate situations	• Decrease cost • Decrease hospital stay • Reduce line infections	Pharmacist	Clinical Stability Criteria for IV to PO: • Afebrile • Stable heart rate • Stable respiratory rate • Systolic blood pressure >90 mm Hg • O2 saturation >90% (O2 partial pressure >60 mm Hg) • Functional GI • Normal mental status • Lab results received identifying pathogen
Antimicrobial dosage adjustments in case of organ dysfunction	• Avoid toxicities	Pharmacist	
Dose optimization (pharmacokinetics/ pharmacodynamics) to trea organisms with reduced susceptibility	• Avoid toxicities • Optimize PK/PD • Improve patient outcomes		
Automatic alerts where therapy might be unneeded	• Avoid toxicities • Decrease costs	IT	
Time-sensitive automatic stop orders for specific antibiotic prescriptions	• Decrease cost • Decrease unneeded antimicrobial use • Decrease resistance	IT	
Start necessary treatment for patients who should be getting antibiotics	The delay of an active antibiotic increases mortality		

Institution specific antimicrobial stewardship guidelines	• Based on antimicrobial resistance patterns at your institution • Align with ASP initiatives • Provide a resource		

Create microbiology lab protocols

Pharmacy intervention	Rationale	Minimal resources required	Dedicated resources required
Location specific antibiogram (hospital-specific) once or twice a year		Microbiology lab	
Rapid diagnostics, such as: • Multiplex PCR • Matrix Assisted laser desorption/ ionization-time of flight (MALDI-TOF)	• Decrease time to appropriate antibiotics • Decrease unneeded antimicrobial use		
Use procalcitonin level measurement	• Tissues make procalcitonin during bacterial infection • Evidence Decrease unneeded antibiotic use • Shorten length of therapy		

Automatic testing and reporting of tigecycline and colistin or newer agents if formulary (ceftazidime/ avibactam, meropenem/ vaborbactam, eravacycline) for Carbapenem Resistant Enterobacteriaceae (CRE) isolates	• Increase in carbapenem resistance		
Reporting of minocycline susceptibility for *Acinetobacter* isolates	• Minocycline susceptibility remains high in most institutions against multi-drug resistant		
Selective susceptibility reporting/SDD	Selective reporting is a process of withholding susceptibility results from selected categories of antibiotics 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 1st generation cephalosporin but is susceptible to cefotaxime, other broader agents such as cefepime, meropenem, or ceftaroline could be withheld and made available.	Microbiology Lab	

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/

System or Practice	Available Technology	Evidence
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: Computerized Physician Order Entry (CPOE) Drug-drug interaction check Drug-allergy interaction check Clinical Decision Support tools (CDS)		• Increases in patient safety • Cost savings • Decreased time on ASP activities (Kullar and Goff, 2014; Evans *et al.*, 1998)
CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE	Leapfrog CPOE Evaluation Tool (Leapfrog Group, 2016)	
Drug Libraries (Metzger *et al.*, 2010; Leung *et al.*, 2013)		
Pharmacy Workflow Manager	DoseEdge from Baxter Healthcare*	

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website:

https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/

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
- 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)
- Clostridium difficile infection (CDI) - but just measuring CDI is not all encompassing (For a playbook to more comprehensively reduce CDI please see APSS #2C)

Outcome measure formula

The calculation is: (DDDs / patient days) * 1000. Recent guidelines from the Infectious Disease Society of America, recommend the use of days of therapy (DOT) per 1000 patient days over DDD, with DDD being an alternative at institutions that cannot collect DOT data.

Conflicts of interest disclosure

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Actionable Patient Safety Solutions (APSS) #3C:

Severe hypoglycemia

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 121

Leadership plan 122

Action plan 122

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Patient Safety MOVEMENT

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Executive summary checklist

Severe hypoglycemia (SH) is a low blood glucose level that requires the help of another person to recover. A blood glucose level less than 40 mg/dL is considered SH and likely to cause harm in a hospital 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, medicine 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 medicine (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

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
- ☐ 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 hospital and nursing units based on performance quality scorecards

What we know about severe hypoglycemia

SH can cause disorientation, unusual behavior, and death. 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 hospital setting. In a 2009 survey of 575 hospitals, 5.7% of all point-of-care blood glucose (BG) tests showed hypoglycemia (<70 mg/dL) tests (Swanson *et al.*, 2011). Causes of hypoglycemia for inpatients include:

- Too much insulin dose
- Inappropriate timing of insulin or anti-diabetes therapy
- Unaddressed previous hypoglycemia
- Changes in nutritional regimen
- Creatinine clearance changes
- Steroid dose (Deal et al., 2011)
- Failure to monitor BG
- Communication between physicians, pharmacists, and nurses

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 severe hypoglycemia 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 et al., 2011; DiNardo et al., 2006)

Preventing SH

Early management of mild hypoglycemia can prevent SH. For example, adjusting the patient's anti-diabetic regimens after treatment of hypoglycemia.

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, including awareness, accountability, ability, and action (NQF, 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: **https://www.youtube.com/0X2020**

Action plan

Ensure accountability

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

Create protocols and provide staff training

- Create a systematic approach to reducing SH to:
  - Identify events and prioritize
  - 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 a 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 known and assumed solutions to hypoglycemia (e.g., "STOP Hypoglycemia!")
  - Kickoff reception for safety initiative
  - 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

Track and analyze your progress

- Investigate events and collect causative factors to consider as part of analysis tool, such as:
  - Insulin stacking
  - Wrong drug, dose, route, patient, or time
  - Insufficient glucose monitoring
  - Basal heavy regimen
  - Decreased nutritional intake
  - Event related to outpatient or emergency department medicine administration
  - Event while treating elevated potassium
  - Glucose trend not recognized
  - High dose sliding scale insulin
  - Home regimen continued as inpatient
  - Much lower steroid dose
  - Sulfonylurea-related hypoglycemia
  - Insulin administration and food intake not in sync
  - POC glucose reading not linked to insulin administration
  - POC glucose reading not in sync with food intake
- A pharmacist and/or nurse reviews analysis tool forms in a timely manner (e.g., 72 hours) for causative factors and communicates findings with doctors
- 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
- Share strategies and use informed interventions on target floors and patients

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/

System or practice	Available technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS) • Of setting restrictions for the prescribing of U-500 Regular Insulin to only specialists and under special circumstances in CPOE	
Glycemic management clinical decision support for insulin therapy recommendation, based on individual responses to insulin and designed for mitigation of all types of hypoglycemia	• Includes all of the following bullet points with significant additional safety features
Real-time surveillance method for informatics alerts:	• "High-Risk Sulfonylurea Alert" • "Hypoglycemia Risk Alert"
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 causative factors of hypoglycemia, 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 clinical decision support for insulin therapy recommendation, based on individual patient's response to insulin and designed for relief of all types of hypoglycemia	• Monarch Medical Technologies* Endotool Solutions
CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE	• Leapfrog CPOE Evaluation Tool
Drug libraries	• Injectables, or comparable systems
Pharmacy Workflow Manager	• DoseEdge from Baxter Healthcare*

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data- pledges/

Conflicts of interest disclosure

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Appendix A: Summary of Foundational Best Practices (Moghissi et al., 2009)

Intervention	Rationale
Raise awareness of hypoglycemia	Initiatives to raise awareness on preventable harm have improved patient care
Real time analysis (48 hours)	• Pharmacy surveillance system provides information of when and where these events occur, but not why they occur • Many hospitals have lowered harm rate using real time analysis
Create and use diabetes management team	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
Provide prescriber with tools to use as a dosing guide	• AACE/ADA suggests a systems approach for management of inpatient glycemic control • Can create reasonable and achievable glycemic management goals
Nursing education process	• AACE/ADA noted a lack of ownership in diabetes care due to insufficient knowledge or confidence in diabetes management • Ongoing education and training can improve care

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 POC 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)

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

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 Medicine" 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 medicine on their formulary have not addressed patients who may use it from home
- Hospitals feel that the medicine not on their formulary will protect them from ADEs – but non-formulary does not equal 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:

Executive summary checklist 132

What we know about pediatric adverse drug events 133

Leadership plan 134

Action plan 135

Technology plan 138

Measuring outcomes 139

Conflicts of interest disclosure 139

Workgroup 139

References 140

Patient Safety MOVEMENT

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Executive summary checklist

Pediatric adverse drug events (pADEs) are harm and injury caused by medicine 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 medicine, 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 medicine 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 medicine reconciliation, allergy checking, interaction checking, and dose range checking with alerts
- ☐ Use a double-check process of medicine verification before dispensing high-risk medicines
- ☐ Ensure open communication and standardize medicine handoffs between healthcare teams at shift changes
- ☐ Use 'smart' drug infusion pumps with drug libraries that include pediatric standardized medicine amounts for all weight ranges

Engage staff and use data to find areas for improvement

- ☐ Use pediatric-specific technologies such as eBroselow (or equivalent) 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 medicine 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
- Dilution of stock medicine solutions
- Immature renal and hepatic functions
- Limited ability to communicate side effects (Kaushal et al., 2001; Poole et al., 2008)
- Some drugs do not have an FDA-specific indication for children - more than 70% of the drugs used in pediatrics have not been studied in age-specific populations to assess patient safety (Poole et al., 2008; Lindell-Osuagwu et al., 2009)

Problems with the standard treatment

Most medicine 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 professional must often prepare medicines 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 medicines are not prepared in the pharmacy (i.e., prepared by frontline caregivers), 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 et al., 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 15.7 per 1000 patient-days
- 22% of all pADEs could be prevented and 17.8% could have been identified earlier (Takata et al., 2008)

Preventing pediatric adverse drug events

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, 2001). 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, infrastructural 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 medicine 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)

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

- Electronic Health Records (EHR)
- CPOE
- Barcode medication administration (BCMA)
- Bar code assisted medication preparation system (BCMP)
- Smart pump infusion technology (Manias, 2014; Laresen, 2005; Morriss, 2009; Tourel, 2012; Mason, 2014; Morriss, 2011; Hardmeier, 2014; King, 2003; Leung, 2015; Manrique-Rodriguez, 2016; Rinke, 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 medicines, 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, 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 medicines to children (ISMP, 2003; 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; https://www.solutionsforpatientsafety.org/)
- 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 medicine evaluation, selection, and use (Joint Commission, 2008; ISMP, 2003)
- 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 medicine 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 PPAG include (Bhatt-Mehta et al., 2013):
  - 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.
- Create pharmacist-driven processes, such as:
  - Admission medicine histories and reconciliation process for pediatric patients (Provine et al., 2014)
  - Discharge prescription review program, led by a clinical pharmacist (with pediatric training preferred), to ensure the doses are the same to those prepared in the hospital (Christiansen et al., 2008)
  - A double- and triple-check system for high alert medicines to ensure the "5 Rights", appropriate medicine selection, accurate excipients, dose, and concentrations of liquid medicine prior to compounding and dispensing them
- Standardize equipment and measurement systems throughout the institution, such as smart infusion pumps and weight scales for pediatric patients (Stucky, 2003)
- Ensure best practices are used for syringe pumps with medicines that require low infusion rates (<5 mL per hour) (FDA, 2016; Sherwin, 2014)

Create protocols

- Prevent timing errors in medicine 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 medicines to the minimum needed (Joint Commission, 2008; Irwin et al., 2008; Hilmas et al., 2009; Murray et al., 2014; Larsen et al., 2005)
- Weigh all pediatric patients in kilograms 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 medicines for pediatric patients based on your types of pediatric population, infrastructure, and unique features (Doherty and Donnell, 2012; Glanzmann 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 medicine therapies
- Create CPOE order sets to help standardize care and medicine therapy for specific pediatric disease states (Potts et al., 2003)
- Embed a pediatric trigger toolkit in the CPOE as an alert system for prescribers when medicines are ordered out of range, or are duplicate therapies (Takata, 2008; Burch, 2011; Call, 2014) – it should electronically identify high risk medicines 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; Halsyamani et al., 2006; Manias et al., 2015; Manias et al., 2009; Apker et al., 2007)

Provide staff training

- 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 medicines 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., 2012)
- 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 medicines for pediatric patients (Benavides et al., 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 syringeinfusionsafety.org

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 et al., 2011; Stratton et al., 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 medicines 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 et al., 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:

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

System or Practice	Available Technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following abilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)	
Standardized measuring tools for liquid pediatric oral medicine	• Oral syringes with better accuracy (Yin, 2016) • Provide measuring tools closely matched to prescribed dose (Yin, 2017)

Bar coded medication process for pediatric medicine products (e.g., multi-dose or unit-dose vials, compounded, and/or repackaged) (ASHP, n.d.;.Eiland LS *et al*., 2018)	• Use a bar code assisted medication preparation system (BCMP) for intravenous sterile compounding in pharmacy, such as:
	  • Baxter's* DoseEdge Pharmacy Workflow Manager
	  • BD's Cato Medication Workflow Solutions
	  • Omnicell's i.v.SOFT Assist
	• Use an electronic aid to help those who compound parenteral medicines on their own to standardized concentrations for fluid balance considerations for small patients and patients with fluid restriction (Damhoff, 2014)
	• eBroselow* System (or equivalent)
	• 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).
	  • Codonics* Safe Label System
	  • BD Intelliport Medication Management System

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website:

https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/

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.

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Actionable Patient Safety Solutions (APSS) #3E:

Standardize and safeguard medicine administration

How to use this guide

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

What we know about medicine administration 146
Leadership plan 147
Action plan 147
Technology plan 149
Measuring outcomes..... 150
Conflicts of interest disclosure 150
Workgroup 150
References 151

Patient Safety
MOVEMENT

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Executive summary checklist

Healthcare providers need to safely and quickly deliver medicines 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 medicine 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, and administration

Ensure best patient care

- ☐ Use the potential of the newest, barcode-enabled, mobile medicine safety tools
- ☐ Educate staff about and use of a universal checklist for all medicine administration
- ☐ Follow protocols to create a "mobile 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 EMR
  - ☐ Is supplemented with barcode access points that eliminate the need for math or memorization at acute ordering, medicine preparation, and delivery
  - ☐ Can be integrated into your systemic response to acute medicine shortages
- ☐ Use patient stories – in written and video form – to teach and inspire change in your staff

What we know about medicine administration

Medicine 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 medicine administrations, and 1 in every 2 surgeries, resulted in a medication error or an adverse drug event (harm and injury caused by medicine) (Nanji et al., 2016).

Most medical 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 medical 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 care providers (Kaufmann et al., 2012)
- There are 10 times more mathematical errors due to incorrect calculations for children than adults

Preventing medication errors

A standardized system for medicine administration can reduce incorrect calculation errors and miscalculation in the absence of the EHR. There are a variety of approaches to standardize medicine 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 medicine administration.

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

Show leadership's commitment to standardized medicine 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 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 medicine 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 medicine 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 medicine administration log book from the mobile app (drug, dose, time of administration, ROA, and patient) – 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 sync medicine shortages with alternative medicines 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 medicine shortages and alternatives

- Get rid of information silos about medicine shortage information through the above points

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/

System or practice	Available technology
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: • Have wireless capability • Work offline • Synchronize the downtime data back into the EHR when the system goes back online • Include basic documentation functionalities, such as time-stamped text logs, that work with existing electronic systems • Be capable of syncing medicine shortages with compatible alternative medicines • Provide relevant medicine information (weight, drug, drug concentration, ROA, and indication) • Be manufacturer and EHR agnostic • Be a knowledge-based mobile tool for checking medicines and indications • Provide updated information and alerts about medicine shortages • Have free access for all users	• SafeDosePro* • Drug Shortages (app by the FDA) • RxShortages

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website:

https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/

Measuring outcomes

The measure of adverse drug events. See APSS #3A for more information.

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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Actionable Patient Safety Solutions (APSS) #3F:

Drug shortages

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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What we know about drug shortages 155
Leadership plan 157
Action plan 157
Technology plan 159
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Patient Safety
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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 (Kantajarian, 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., 2015; Kumar, 2006; Dorsey & Thompson et al., 2009; Pendergast & Sher, 2005; Traynor, 2010; Fox & Tyler et al., 2009; General Accounting Office, 2002; Eggerston, 2010; Mazer-Amirshahi & Goyal et al., 2001-2016) and around the world (Bochenek & Abilova, 2018; Iacobucci, 2017; De Weerdt & De Rijdt et al., 2017; Yang & Wu et al., 2016; Aksheikh & Seoane-Vazquez et al., 2016). The World Health Organization also considers drug shortages as a global problem and has discussed the need for a global notification system (Jarosawski & Azaiez, et al., 2016). Drug shortages happen with all therapeutic classes including:

- Therapeutic products
- Preventive products
- Diagnostic products (Fox & Birt et al., 2009)
- Routinely recommended vaccines (CDC, 2004; CDC, 2004; CDC, 2002; CDC, 2002; CDC, 2000; "Vaccines and Preventable Diseases")
- Biologics ("Vaccines and Preventable Diseases")
- Parenteral nutrition (Ziesenitz & Mazer-Amirshahi et al., 2017)
- Saline water (Holcombe & Mattox et al., 2018)
- Orphan drugs (Donaldson & Goodchild, 2013)

As of September 1, 2018, the following drug shortages were reported:

- The US Food and Drug Administration (FDA) reported 109 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 8 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 26 drug shortages in the same date, including cytarabine that was also reported by the EMA.

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 et al., 2003; Fox & Tyler et al., 2003; Eggertson, 2010). Pharmaceutical shortages may have a profound effect on patient outcomes (Fox & Tyler et al., 2002; Hampton, 2007; National Vaccine Advisory Committee, 2003; Lukmanji & Sauro, 2018; Omorodion & Algahtani, 2017; Furlow, 2017; Donohue & Angus, 2017; Lau & Khazanie, 2016; Findlay & Taylor, 2017; Gupta & Dhruva et al., 2017):

- Patients may stop use of an essential product, miss doses, or defer use until the shortage ends (Kumar, 2006; Dorsey & Thompson, 2009; Pendergrast & Sher, 2005; CDC, 2004; CDC, 2002; CDC, 2002)
- Medicine changes due to pharmaceutical shortages can increase prescribing, dispensing, and administration errors, and reduce patient adherence (Fox & Tyler, 2003; Baumer & Clark et al., 2015; Pendergrast & Sher et al., 2004)
- Drug shortages suddenly change formularies, clinical practice, and clinical decision-support systems to disrupt 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 health care costs (Flannery & Pandya, 2017; Fox & Tyler et al., 2017; Alevizakos & Detsis et al., 2016; Iacobucci, 2017; De Weerdt & De Rijdt, et al., 2017; Strausbaugh & Jernigan et al., 2001)
- Patients often need to switch to more expensive alternatives (Kumar, 2006; Dorsey & Thompson, 2009; Pendergrast & Sher, 2005; Hampton, 2007; Hendricks & Singha, 2005)

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 & Clark et al., 2004; Traynor, 2010; Fox & Tyler, et al., 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 evidence the need for prevention. Once a shortage happens, mitigation strategies are difficult and costly and fail to address the health and economic effects of the shortage (Baumer & Clark et al., 2004; Pendergrast & Sher et al., 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

Hospital contracts with Group Purchasing Organizations (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).

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 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 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

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 group purchasing organization 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
- 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:
    - Set up prevention programs
    - Reduce the incidence and duration of shortages
    - Establish responsibilities for the effects of drugs 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 your 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 (Kantarjian). The process for managing drug shortages should include:
    - Assess the details and potential duration of the shortage
    - Assess and manage inventory hand and potential drug supply sources
    - Approve alternative therapies
    - Define alternative clinical pathways for care of patients affected by drug shortages
    - Address ethical considerations related to the allocation of drugs in short supply
    - 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/

System or practice	Available technology
All settings	
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Electronic Prescribing (eRx) • Electronic Prior Authorization (ePA)	
Electronic Medication Administration Record (eMAR) system with pharmacy and bedside barcoding capabilities	• First Databank FDB MedKnowledge system (First Databank, 2014)
FDA approved clinical decision support solution for medication therapy recommendation	• Monarch Medical Technologies Endotool* Solutions for insulin
Infusion pumps that wirelessly communicate data back to the electronic eMAR	
Patient and medicine barcoding system	• Codonics Safety Labeling System*; or • BD Intelliport Labeler; or • Single Use Injection Vials and Kits
CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE (Metzger *et al.*, 2010; Leung *et al.*, 2013)	• Leapfrog CPOE Evaluation Tool (Leapfrog, 2016)

Drug libraries	

Pharmacy Workflow Manager	• DoseEdge from Baxter Healthcare*
Surgery environment	
• IV injectable doses • Audible and visual feedback for each syringe attached with measurement of dose • Allergy alerts • More accurate and timely documentation wireless to the anesthesia information system	• BD Intelliport Medication Management System • Masimo rainbow Acoustic Monitoring* • Philips* • GE Healthcare* • Side-stream end-tidal carbon dioxide monitoring: o Oridion o Masimo o Respironics
Continuous physiologic monitoring on patients receiving IV medicine to provide an early signs of deterioration due to a medication error	
Pharmacy environment	
Pharmacy robots to reduce safety problems with providers drawing up their own medicines, and risks associated with contamination from outsourced compounders	BAXA Intellifil Robot
Single Use Injection Kits or Pre-mixed sterile solutions	Asclemed USA Inc., Injection Kits Nubratori RX, 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

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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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Patient Safety MOVEMENT

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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

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), SpO_2, 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

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 *et al.*, 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; SAMHSA, 2008; McPherson, 2008; Jarzyna *et al.*, 2011; Ferrell *et al.*, 2010).

Adverse effects associated with opioids not only include respiratory depression, but also hyperalgesia, early development of tolerance, ileus (inability of the intestine to move food or waste), nausea and vomiting, and delayed recovery. If these adverse events lead to death or serious harm to a patient, they are labeled as "failure to rescue."

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 (IOM, 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 (administered through vein or IV, usually) opioids, and using a system to notify caregivers when alarming conditions occur (Weinger *et al.*, 2011).

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 (CMS, 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 *et al.*, 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.

A landmark study published in January 2010 by Dartmouth-Hitchcock Medical Center demonstrated that clinicians using Masimo SET measure through motion and low perfusion pulse oximetry and Patient SafetyNet 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 *et al.*, 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 *et al.*, 2012). They also reported savings of $58,459 saved per patient who was not transferred to the ICU in the original orthopedic unit ($76,044 vs. $17,585), equating to **$1.48 million in annual 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. 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.

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 (NQF, 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

- 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 patient admits and discharges from continuous monitoring

Use opioid alternatives in your pain management protocols

- 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-steroidals - acetaminophen, low dose ketamine, dexmedetomidine, intravenous lidocaine, and intravenous magnesium (ASA, 2012)

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, such as with a Masimo SET.
- 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:
  - 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
  - For most children:
    - Set PR alarm for below 70 and above 120
    - Set SpO_2 alarm for below 84% (McGrath, Pyke, & 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, 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.*, 2008)

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 using the following technologies:

System or Practice	Available technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)	
Continuous pulse oximetry • Adhesive pulse oximetry sensor connected with pulse oximetry technology proven to 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	• Masimo* SET pulse oximetry, in a standalone bedside device or integrated in one of over 100 multi-parameter bedside monintors (Taenzer *et al.*,2010)
Continuous respiratory rate monitoring • 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	• Masimo* rainbow Acoustic Monitoring (Mimoz *et al.*, 2012)

Remote monitoring and notification system • Remote monitoring with direct clinician alert capability compatible with recommended pulse	• Masimo* Patient SafetyNet EarlySense Contact Free Monitoring System **OR** • Comparable multi-parameter monitoring system Direct clinician alert through dedicated paging systems or existing hospital mobile device notification system
Network	• Medical-grade wireless network suitable to permit reliable, continuous remote monitoring and documentation during ambulation and/or transport • Alternatively, use a wired network which allows surveillance of patients while they are in bed, but not while they are in an ambulance

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: **patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

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-9-CM or ICD-10-CM diagnosis code for acute respiratory failure
- Any listed ICD-9-CM or 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)

Denominator: Elective surgical discharges, for patients ages 18 years and older, with any-listed ICD-9-CM or 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-9-CM or ICD-10-CM diagnosis code (or secondary diagnosis present on admission) for acute respiratory failure (see above)
- With any listed ICD-9-CM or ICD-10-CM diagnosis codes for:
  - Neuromuscular disorder
  - Degenerative neurological disorder
- With any listed ICD-9-CM or ICD-10-PCS procedure codes:
  - That involve the face (when appropriate) and any-listed ICD-9-CM or 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)
- MDC 5 (diseases/disorders of circulatory system)
- MDC 14 (pregnancy, childbirth, and puerperium)

Metric recommendations

Direct Impact: All elective surgical patients

Lives Spared Harm:

Lives Spared Harm = (PSI #11 Rate $_{baseline}$ *- PSI #11 Rate* $_{measurement}$ *) X 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, 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 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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Actionable Patient Safety Solutions (APSS) #5:

Patient blood management

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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What is patient blood management? 179

What we know about patient blood management 179

Leadership plan 181

Action plan 181

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Patient Safety MOVEMENT

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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 *et al.*, 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.*, 2011). 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 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**)

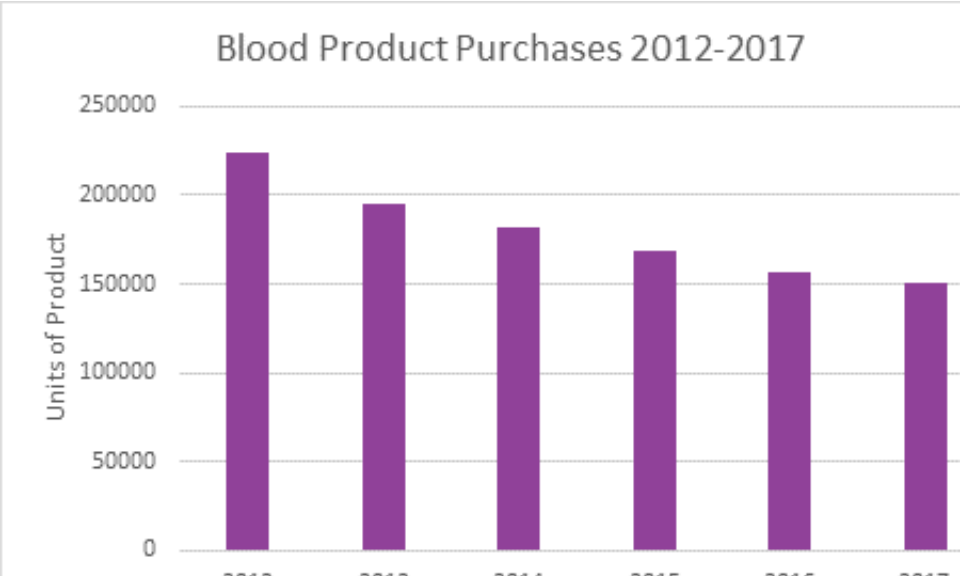

Figure 1: The reduction in blood product used over the last 5 years at the Wolff Center, which reduced costs by $10M by implementing the 6-point strategy for PBM

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 *et al.*, 2016; Moskowitz et al, 2010; Leahy *et al.*, 2014; Theusinger *et al.*, 2014; Freedman, 2014; Oliver *et al.*, 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 (NQF, 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 *et al.*, 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**)

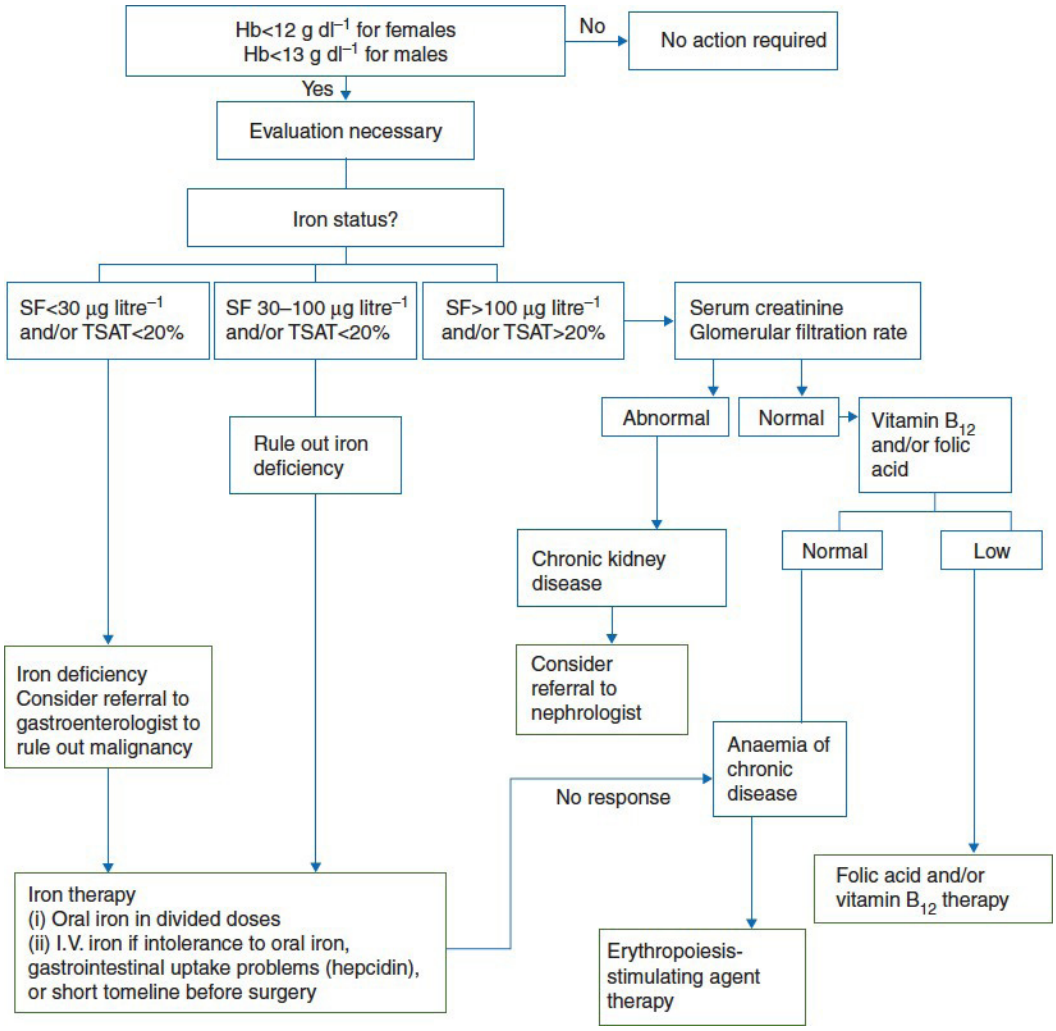

Figure 2: Preoperative anemia management workup algorithm (Goodnough *et al.*, 2011) to optimize coagulation and reduce bleeding

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

System or Practice	Available technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • 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	• SpHb adhesive sensors connected to rainbow SET monitors with SpHb, OR • A multi-parameter patient monitor with SpHb including but not limited to: o Dräger* M540/Infinity Acute Care System o Welch Allyn* CVSM, Fukuda Denshi 8500 o Saadat Aria and Alborz monitors o GE* o Philips* o Nellcor* N-600x o INVOS* Cerebral/Somatio Oximeter
Cell recovery technology in the operating room	• Cobe • Haemonetics **OR** • Other equivalent devices
Point of care coagulation testing	• iStat • TEG • ROTEM

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	

*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/

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 *et al.*, 2011):

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

Population	Non -Anaemia*	Anaemia*		
		Mild[a]	Moderate	Severe
Children 6 - 59 months of age	110 or higher	100-109	70-99	lower than 70
Children 5 - 11 years of age	115 or higher	110-114	80-109	lower than 80
Children 12 - 14 years of age	120 or higher	110-119	80-109	lower than 80
Non-pregnant women (15 years of age and above)	120 or higher	110-119	80-109	lower than 80
Pregnant women	110 or higher	100-109	70-99	lower than 70
Men (15 years of age and above)	130 or higher	110-129	80-109	lower than 80

± 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.

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Actionable Patient Safety Solutions (APSS) #6:

Hand-off communications

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:

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Patient Safety MOVEMENT

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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.

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. 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 3 issues that make checklists mandatory: workload stress, distractors, 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.

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:
    - As role models, leadership must 'walk the walk' when it comes to supporting process improvement across an organization
    - 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
    - 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/ssWSoN00yxI**

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**
    - 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**
  - Solicit support and active involvement in the plan to improve HOCs, obtain buy-in and build accountability for the outcomes
  - Identify a leader for the HOC initiative, which is critical to the success of the project
  - 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

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 in **Appendix B**.

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/**

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:

System or practice	Available technologies
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: Computerized Physician Order Entry (CPOE) Drug-drug interaction check Drug-allergy interaction check Clinical Decision Support tools (CDS) Workflow customization Incorporation of hand-off checklists	
Support the efficient utilization and data capture of the checklist methods	CareInSync Carebook iPatient SignOut by Fluent Medical
Support clinician communication	Vocera Hand-Off Communications Vocera Care Transitions Doctella*

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	PatientAider

*Company has signed some form of the Open Data Pledge. More information can be found on the Patient Safety Movement Foundation website: **https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

Conflicts of interest disclosure

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Appendix A: Hand-off communications (HOC) checklists

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 (reference: "The Checklist Manifesto").

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**
  - Patient is very ill and may even be an emergency situation
  - Fatigue is very common: "I was up all night on-call"
  - Multiple priorities: "This is not my only patient!"
- **Distractors**
  - Noise and hallway traffic during rounds
  - Pagers going off during hand-off communication
  - Emergency arises on a different patient
- **Increased level of complexity**
  - Electronic Medical Record (EMR) requirements
  - Compliance documentation
  - 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**.

This appendix include an example checklist for lists below that are marked with an *.

From emergency department to:

1. Hospital ward team
2. Operating room*
3. Anesthesiology team
4. Surgery team*
5. Critical care unit*
6. Testing unit (radiology, etc.)

From hospital unit (ward or ICU) to:

7. Operating room
8. Outpatient clinic*
9. Long-term care unit
10. Testing unit (radiology, etc.)
11. Home (discharge instructions) *
12. Within same unit:
    Shift changes*
    Medications management during transitions*

From operating room to:

13. Post-anesthesia care unit (PACU)
14. Hospital unit (ward or ICU)*
15. Home (ambulance or surgery)*

From paramedics to:

16. Emergency department*
17. Hospital unit (ward, ICU)
18. Long-term care unit

Emergency department to operating room checklist

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)

Initial transitional care contact

- ☐ Patient name
- ☐ Date of contact

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)

Medication reconciliation

- ☐ Medication list updated
- ☐ New medication list given to patient

Referrals

- ☐ None needed
- ☐ Referrals made

Community resources identified for patient/family

- ☐ None needed
- ☐ Home health agency
- ☐ Assisted living
- ☐ Hospice
- ☐ Support group
- ☐ Education program

Durable medical equipment ordered

- ☐ None needed
- ☐ DME ordered

Additional communication delivered or planned

- ☐ Family/caregiver
- ☐ Specialists
- ☐ Other

Patient education

- ☐ Topics discussed
- ☐ Handouts given
- ☐ Date initial transitional care contact was made

SBAR Shift change checklist

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 to hospital unit checklist

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)

- ☐ 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 101°F
  - ☐ 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

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

- ☐ Bathing and any other: frequency and assistance/supervision required

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 surgery checklist

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

Emergency department to critical care unit checklist

Illness severity

- ☐ Unstable/Watch/Stable/Discharging (structured)

Findings

- ☐ Chief complaint
- ☐ Vitals:
  - ☐ HR (beats/min)
  - ☐ BP (sys/Dis; mL Mercury)
  - ☐ PulseOx (O_2Sat)
  - ☐ 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

- ☐ 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

I-PASS hand-off checklist and components

I	**Illness severity**	• Stable, "watcher," unstable
P	**Patient summary**	• Summary statement • Events leading up to admission • Hospital course • Ongoing assessment • Plan
A	**Action list**	• To do list • Timeline and ownership
S	**Situation awareness and contingency planning**	• Know what's going on • Plan for what might happen
S	**Synthesis by receiver**	• Receiver summarizes what was heard • Asks questions • Restates key action/to do items

Appendix B: Joint commission standards

Following the rationale described in the "Leadership Plan" section above, this HOC APSS:

- Incorporates the applicable "Standards" and their included "Elements of Performance" from The Joint Commission's documented hospital accreditation standards (cited above) as its Action Plan foundation
- Does not originate HOC mistake mitigation Practice Plan standards and practices in addition to, and potentially inconsistent with, those stipulated by The Joint Commission

In fact, 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 (The Joint Commission. "Appendix K. Key Patient Safety Requirements," Comprehensive Accreditation Manual for Hospitals, 2017 (Joint Commission Resources, Oak Brook Terrace, IL, USA, 2012), pp. PS-23 - PS-50 (**http://bit.ly/2eNCrLK**)).

We list the Joint Commission's standard statements below, grouped by critical HOC elements. Note that some standards apply to multiple HOC elements.

Standards that apply to timely detection of the potentially problematic clinical events:

IC.01.03.01	The hospital identifies risks for acquiring and transmitting infections
LD.03.02.01	The hospital uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality
EC.04.01.01	The hospital collects information to monitor conditions in the environment
LD.03.03.01	Leaders use hospital-wide planning to establish structures and processes that focus on safety and quality
MM.07.01.03	The hospital responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors
MS.08.01.01	The organized medical staff defines the circumstances requiring monitoring and evaluation of a practitioner's professional performance
PI.01.01.01	The hospital collects data to monitor its performance
PI.02.01.01	The hospital compiles and analyzes data
PI.03.01.01	The hospital improves performance on an ongoing basis

Standards that apply to the prompt execution of the appropriate corrective action(s):

APR.09.02.01	Any individual who provides care, treatment, and services can report concerns about safety or the quality of care to The Joint Commission without retaliatory action from the hospital
LD.02.04.01	The hospital manages conflict between leadership groups to protect the quality and safety of care
LD.03.04.01	The hospital communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties
LD.03.06.01	Those who work in the hospital are focused on improving safety and quality
LD.04.04.05	The hospital has an organization-wide, integrated patient safety program within its performance improvement activities
MM.08.01.01	The hospital evaluates the effectiveness of its medication management system

MS.09.01.01	The organized medical staff, pursuant to the medical staff bylaws, evaluates and acts on reported concerns regarding a privileged practitioner's clinical practice and/or competence
NR.02.01.01	The nurse executive directs the hospital's nursing services

Standards that apply to comprehensive enforcement of administrative and clinical process standards and practices:

APR.09.01.01	The hospital notifies the public it serves about how to contact its hospital management and The Joint Commission to report concerns about patient safety and quality of care
LD.02.01.01	The mission, vision, and goals of the hospital support the safety and quality of care, treatment, and services
LD.03.01.01	Leaders create and maintain a culture of safety and quality throughout the hospital
LD.03.05.01	Leaders implement changes in existing processes to improve the performance of the hospital
LD.04.01.01	The hospital complies with law and regulation
LD.04.01.05	The hospital effectively manages its programs, services, sites, or departments
LD.04.04.01	Leaders establish priorities for performance improvement (refer to the "Performance Improvement" [PI] chapter)
LD.04.04.05	The hospital has an organization-wide, integrated patient safety program within its performance improvement activities
PI.01.01.01	The hospital collects data to monitor its performance
RI.01.01.01	The hospital respects, protects, and promotes patient rights
RI.01.01.03	The hospital respects the patient's right to receive information in a manner he or she understands
RI.01.02.01	The hospital respects the patient's right to participate in decisions about his or her care, treatment, and services
RI.01.03.01	The hospital honors the patient's right to give or withhold informed consent
RI.01.05.01	The hospital addresses patient decisions about care, treatment, and services received at the end of life
RI.02.01.01	The hospital informs the patient about his or her responsibilities related to his or her care, treatment, and services

The remainder of this section details an HOC mistake mitigation practice plan with these characteristics:

- Addresses the 3 HoC mistake mitigation requirements: completeness, accuracy, and timeliness
- Incorporates by reference and is compatible with the applicable Patient Safety System (PS) Standards of The Joint Commission cited above in this section
- Includes activities to buy or to build an IT solution that adhere to generally accepted management standards for IT solution development and management:
    - Modeled on content published by Online Resource Center, Villanova University. "The Processes of Project Management," Project Management, Copyright 2017, viewed July 26, 2017 (http://bit.ly/2w1c6xe)

- Includes optional but strongly recommended activities for conducting an APSS HOC project in the context of comparative effectiveness research (CER) [Agency for Healthcare Research & Quality, USA DHHS, "What is the [Comparative Effectiveness] Research Process?," viewed 7/29/2017 (http://bit.ly/2uI5LJv)], in order to substantiate the expected positive transformation from HoC per current standards of care, assumed to be best practice, to IT-enabled HOC accomplished per the guidance in this HOC APSS

Actionable Patient Safety Solutions (APSS) #7A:

Optimal neonatal oxygen targeting

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:

Executive summary checklist 222
What we know about neonatal oxygen targeting ... 224
Leadership plan 227
Action plan 227
Technology plan 228
Measuring outcomes 229
Conflicts of interest disclosure 230
Workgroup 230
References 231

Patient Safety
MOVEMENT

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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
  - o Examples: Bird, Carefusion, Precision Medical's low-flow and high-flow oxygen-air blenders
- ☐ 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 SpO_2 for a preterm baby breathing supplemental oxygen should not exceed 95%
  - ☐ The SpO_2 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 SpO_2 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 SpO_2 alarm should be set to 95%, depending on the infant
- ☐ The low SpO_2 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 SpO_2 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 et al., 2007; Klinger et al., 2005; Sola, 2008; Sola et al., 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% O_2) unnecessarily
- Do not measure FiO_2
- Do not adequately monitor oxygen saturation (SpO_2) levels

  (Baquero et al., 2011; Shah et al., 2012; Bizzarro et al., 2013; Chow et al., 2003; Deulofeut et al., 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 et al., 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 et al., 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_2 target ranges are difficult to maintain for more than 50-60% of the time (Fiore, 2014).

To date, the "perfect" SpO_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_2 intention to treat (85-89%) or higher target SpO_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 et al., 2008; Askie et al., 2011).

A recent presentation by Askie et al. (Cochrane review) 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_2 of 85-89%. There are several issues that suggest extreme caution should be used in the interpretation of these randomized controlled trials (Manja et al., 2015; Lakshminrusimha et al., 2015; Schmidt et al., 2014).

In a recent meta-analysis (Askie et al., 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_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 (Bizzaro M., 2018) mentions that SpO_2 of 91-95% may be better than 85-89%, but that, in clinical practice, SpO_2 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 SpO_2 range for each infant will depend on the type of SpO_2 monitor used, gestational age, postnatal age, hemoglobin A concentration, hemoglobin level, oxygen content, cardiac output, clinical diagnosis, and illness severity (Castillo et al., 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 SpO_2 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 SpO_2 alarms rather than to "mental SpO_2 target ranges or intention to treat"
- Given the limitations of SpO_2 and the uncertainty about the ideal SpO_2 intention to treat for infants of extremely low birth weight, wider alarm limits are easier to target
- The lower alarm limit:
  - Generally needs to extend somewhat below the lower SpO_2 chosen as the intention to treat
  - Must take into account practical and clinical considerations, and the steepness of the oxygen saturation curve at lower saturations
  - For extremely low birth weight infants, should be set no lower than 85%, although 86-87% may also be appropriate
- The upper alarm limit:
  - 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 (NQF, 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

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:
  - **Establish oxygen levels:**
    - SpO_2 for a preterm baby breathing supplemental oxygen should not exceed 95%
    - 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 SpO_2 dips below 88%, avoid responding in a way that may cause hyperoxia or high saturation
  - **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 SpO_2 alarm to 95%, depending on the infant
    - Set the low 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 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/**

Select technologies that have been shown to improve neonatal oxygen targeting include:

System or Practice	Available technology
Use blenders in all circumstances when administering oxygen, including the delivery room	Precision Medical's low-flow and high-flow oxygen-air blenders
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	
For pulse oximetry, select equipment that: • Can measure through motion and low perfusion conditions to avoid inaccurate measurements/ false alarms and identify true alarms • Is proven effective for neonatal oxygen targeting	Masimo* SET pulse oximetry (until another technology is proven to be equivalent)

*Company has signed some form of the Open Data Pledge. Find more information on the Patient Safety Movement Foundation website: **https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

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 SpO_2 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 SpO_2 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.

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Actionable Patient Safety Solutions (APSS) #7B:

Failure to detect critical congenital heart disease (CCHD) in newborns

How to use this guide

This guide gives actions and resources for creating and sustaining a plan to reduce your organization's failure to detect critical congenital heart disease (CCHD) in newborns. In it, you'll find:

Executive summary checklist 236
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Patient Safety
MOVEMENT

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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 and typically takes place during the 1st year of life. Use this checklist to help you prioritize your actions and measure your organization's progress in detecting CCHD in newborns.

Create a universal pulse oximetry screening program

- ☐ Choose a proven technology that can accurately monitor and read through during motion and low perfusion
  - o Example: Masimo SET pulse oximetry (until another technology is proven to be equivalent)
- ☐ 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:
    - ☐ **SpO_2 of less than 90% from any site, or SpO_2 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 SpO_2 measurements between the right hand and either foot.** For these results, take 2nd and 3rd measurements as described in the items above.
  - ☐ Take a perfusion index (PI) measurement:
    - ☐ **For a PI measurement of less than 0.7**, increase the need for assessment
    - ☐ **For a PI measurement of less than 0.4**, assess the baby immediately
- ☐ 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
- ☐ 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 et al., 2015). CCHD causes (Hoffman 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 et al., 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 et al., 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 (de-Wahl Granelli et al., 2009).

- 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 et al. reported similarly positive results from a prospective study using SET 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 PI 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 SpO_2 values from pulse oximetry.

However, an additional SET pulse oximetry measurement, PI, may help detect CCHD with obstructions to aortic outflow. It is an assessment of strength of perfusion at the monitored site.

In a 2007 study, Granelli showed that adding abnormal PI 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 PI to the screening criteria may also result in an increase in false positives (Granelli, 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. Peterson et al., 2013 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 SpO_2 is less than 90% in either limb, the infant needs to be assessed immediately
- If 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 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: **https://youtu.be/VXK02w6aR14**

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.
  - Take a PI measurement:
    - **For a PI 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:
  - Proper screening methods
  - Strategies for family education and engagement
  - Follow-up investigation protocols for positive screens
  - Public health results reporting policy
- Implement optimization and workflow guidelines to ensure staff is adequately screening, such as:
  - As a quality indicator, each week randomly assess the number of babies that should have been screened but were not
  - Communicate with staff and, based on results, implement measures to improve processes in order to meet the goal of screening all newborns
  - 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/**

Select technologies that have been shown to improve neonatal oxygen targeting include:

System or Practice	Available technology
Pulse oximetry technologies that are effective in helping clinicians screen for CCHD	• Masimo* SET measure-through motion and low perfusion pulse oximetry • SET pulse oximetry is available in: o Standalone monitors (Rad-5, Rad-57, Radical-7, Rad-87) o Over 100 devices from over 50 companies including Atom, Drager*, Fukuda Denshi, GE*, Mindray, Nihon Koden, Philips*, Spacelabs, and Welch Allyn*
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	• Eve app on the Radical-7 (this device CE Marked but has not received U.S. FDA 510k)
• Public health reporting systems for newborn screening	• Oz Systems newborn screening or automated reporting with Oz BabyBundle

*Company has signed some form of the Open Data Pledge. Find more information on the Patient Safety Movement Foundation website: **https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

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

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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Actionable Patient Safety Solutions (APSS) #8A:

Safer airway management

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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What we know about airway management 251
Leadership plan 253
Action plan 254
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Patient Safety MOVEMENT

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Executive summary checklist

Major causes of patient morbidity and mortality include delays or failure to secure a patient's airway, recognize if an airway is malpositioned, and to maintain an airway (such as by unplanned extubation, where the airway comes out on its own or the patient pulls it out – see APSS #8B). These are all high priorities for airway safety efforts.

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, ICU, hospitalist, and anesthesiology physician leader
  - ☐ 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 a physician anesthesiologist/intensivist/neonatologist, develop a comprehensive airway toolkit method (such as the Safer Airway Bundle):
  - ☐ Start in the 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, 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 attempts, esophageal intubation, SpO2 less than 90% or a decline of greater than 10%, and dental or soft tissue injury
  - ☐ 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 airway problems
  - ☐ Select and use the correct course of action
  - ☐ Understand when and how to call for expert help, such as from Anesthesiology
- ☐ 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 operating room, including: pre-hospital emergency medical services (EMS), emergency departments (EDs), intensive care units (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 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 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 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 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
- Many failed attempts to secure the airway
- Failure to correctly secure the endotracheal tube, 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 with anesthesia (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, 2013; Natt, 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.

  For example, missed airways in the EMS setting have been reported to be as high as 52% (Hubble et al., 2010). Airway management can be successfully performed by paramedics in the field (success rates as high as 97.7%), but variations in training, techniques, and technology lead to many systems with reduced provider competence and low intubation success rates (47.6%).

- 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.

  VL allows the approach to airway management in the EMS setting to undergo a dramatic transformation (Chemsian et al., 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 et al., 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). It leads to a high likelihood of death.

  Waveform capnography can identify an endotracheal tube that has not been placed correctly in the trachea and should be readily available to avoid preventable deaths. Yet some EMS agencies have not yet adopted waveform capnography.

- **Unplanned extubation**

  Unplanned extubation, both in the field and in the hospital, is an avoidable and costly problem. It happens in over 7% of patients who undergo mechanical ventilation in the ICU and the 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.

Because of underreporting, 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
- 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 Improved Health Initiative (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 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
- 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://youtu.be/3F7WDS00acY**

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**

Actions for EMS Advanced Cardiac Life Support (ACLS) Units

- Use an SGA device for initial treatment of cardiac arrest and as a rescue device for failed or difficult intubation
- Use Video Laryngoscopy (VL) as your main device for endotracheal intubation
- 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 **www.emerg.org**

Actions for hospitals

- Establish high-reliability as the driving principle for airway 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 systems should include the key components listed in this chart.

(Source: www.saferairway.org)

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)

	Solution and key features		Level of recommendation	Safety rationale	Reference source
1	**Failed Airway Protocol/ Pathway (FAP)** Alternative term is "Difficult Airway Pathway" (DAP)		Mandate	FAP should be operational, standardized, and actionable. Creates a team approach.	
	A	Choose a simple format (3-4 key steps) that can be known & used by all team members	Mandate	Aligns teams to focus on major vulnerabilities and key actions	NAP4
	B	Integrate "awake" non-paralyzed intubation into difficult airway pathway for ED/ICU	Highly recommend	Essential practice not commonly performed in EM	ASA, DAS
	C	Include Video Laryngoscopic (VL) intubation for ED/ICU			
	D	Standardize throughout hospital	Highly recommend	Validated safety practice	

	Solution and key features		Level of recommendation	Safety rationale	Reference source
2	**Airway Equipment**				
	A	**Choose a consolidated Airway Cart** (standardized) 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) and general unit settings.	Mandate	Avoids critical delays, assures equipment availability, and prompt access. Workspace with references.	ASA
	B	**Cart components** Organize the cart to support FAP progression of need.	Highly Recommend	Reinforces FAP and increases reliability	
	1	Oral (mouth) and nasal (nose) airways			
	2	Full face masks			
	3	Nasal CPAP mask			
	4	Video laryngoscope (VL) – in room and ready for all intubations	Mandate	Gives higher 1st pass success and is an essential airway tool	ASA, NAP4
	5	Bougie type introducer catheters and stylets	Mandate	Critical adjunct	ASA
	6	Supraglottic airway devices (SGDs) – appropriately sized to meet needs of patient population	Mandate		ASA
		a. Laryngeal mask airways (LMAs)	Mandate	Essential Rescue Device	ASA
		– LMAs with intubation capability	Highly recommend	Allows conversion to ETT	ASA
		– LMAs with gastric access capability	Recommend	Lowers aspiration risk	
		b. King airway/ combitube – alternative to LMA or rescue for LMA	Highly Recommend	Key rescue device option	

	7	Cricothyrotomy kits (simple surgical)	Mandate	High reliability kits	ASA
	8	Needle jet ventilation kits/sets – for pediatric patients under age 10and adults, Use in ED/ICU after failure of VL, DL, SGA and BVM.	Mandate		ASA
	9	Continuous Waveform Capnography – maintained on all intubated patients including ED/ICU/ Transports and with central monitoring enabled	Mandate	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.	AHA 2010 AARC (2003), ACEP, NAP4, AAGBI, ICS, EBA
	10	Endoscope (flexible fiberoptic scope or video scope) and/or optical stylets – in ED/ ICU at all times	Mandate	Essential for awake intubation, SGA conversion. Video scope preferred.	ASA
	11	LED blades/handles for direct laryngoscopy – replace bulb models with single-use models, which may be better	Highly recommend	10x brighter, higher reliability, and better visibility	Anes-thesia
	12	Devices or systems for securing airway in patient – to avoid unplanned extubation	Highly recommend	High rates of unplanned extubation (UE) in ED, ICU, and Transport settings	

	Solution and key features		Level of recommendation	Safety rationale	Reference source
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 ear to sternal notch, head elevated laryngoscopy position (HELP), and ramped position in obese patients (Levitan et al., 2003)	Mandate	Critical but commonly overlooked	ASA
	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	Ann Emer Med
	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.	
	F	Use BIPAP/CPAP pre-oxygenation in patients with persistent hypoxia	Highly recommend	Useful with persistent hypoxia in obesity, CHF, other	Ann Emer Med

	G	Use delayed sequence intubation with Ketamine – use for agitated patients with hypoxia	Recommend	Important for allowing pre-oxygenation	Ann Emer Med
	H	Quickly use SGA if DL/ VL failed			
	I	Place SGA during codes (cardiac/respiratory arrest)	Highly recommend	Assures open airway, prompt easy placement, and avoids resuscitation delay	
	J	Quickly use surgical cricothyrotomy if VL/DL, SGA, BVM failed. Only qualified personnel should use this.			
	K	Use flexible fiberoptic scope to convert SGA to ETT	Highly recommend	Blind techniques with only 65% 1st pass success rate	NAP4
	L	Use awake fiberoptic intubation (AFOI) or other non-paralyzed intubation techniques. Use for intubations that may be difficult or highly difficult.	Highly recommend	Essential practice that is not commonly performed in EM	ASA , DAS, NAP4
	M	Immediately use and maintain Continuous Waveform Capnography – on all intubated patients	Mandate	SEE Equipment above	See references above
	N	Optimize sedation and restraint protocols to minimize unplanned extubations (UEs)	Highly recommend	Patients who are under sedation or agitated are at risk for airway loss (UE)	AJCC
	O	Formalize system for optimally securing ETT (Tube holders for adults, C- Collar infants in transport)	Highly recommend	UE causes high death rates – reportedly as high as 7%. High risk in pediatric patients.s	

	P	Implement a System for flagging identified difficult airway patients in electronic health records (EHR) system	Highly recommend	Many EHR systems are able to flag difficult airway patients, but flagging is not developed or used	
	Q	Use extubation guidelines	Highly recommend		
	R	Implement system for tracking and reviewing QA data from intubations or UEs – see Airway Registry	Highly recommend	Safety reporting systems have shown low yield for near-miss events from fear of punishment	
	S	Use strategies for avoiding peri-intubation hypotension	Highly recommend	Use IVF, positioning, and pressers in high-risk groups	
	T	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**)			

	Solution and key features		Level of recommendation	Safety rationale	Reference source
4	**Team training**		Mandate		
	A	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.	Mandate		
	B	Promote teamwork and clear communication – include a plan for sharing, open communication, and debriefing	Mandate		
	C	System for ensuring that practitioners are trained and credentialed in airway management			

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:

System or Practice	Available technology
ONC Meaningful Use Certified Electronic Health Record (EHR) System An effective EHR System should include: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)	
Laryngoscopes 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 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	• GlideScope (Verathon) • C-MAC (Storz) • McGrath (Medtronic)* • King Vision (Ambu)
Fiberscopes 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 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.	Supraglottic devices permitting gastric decompression include: • LMA ProSeal or Supreme (LMA) • AuraGain (Ambu) • (MedtronicCovidien)* • King LT-D (King) • iGel (Intersurgical) • AirQ (Cookgas) The Aintree Intubation Catheter (Cook Medical) allows for exchange of supraglottic airway to endotracheal tube using a flexible fiberscope

Waveform Capnography 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	• Masimo* • Medtronic* (Oridion/Covidien) • Nonin • Philips* (Respironics) • Welch Allyn*
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 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/

Measuring outcomes

Tracking will help your organizations improvement and helps hospitals and evaluate your progresshow 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.

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.

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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, 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

Actionable Patient Safety Solutions (APSS) #8B:

Unplanned extubation (UE)

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:

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Patient Safety
MOVEMENT

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Executive summary checklist

Unplanned extubation (UE) is the unintentional removal of a patient's breathing tube, either by self-removal (self-extubation) or accidental removal due to an external force (accidental extubation) that causes the tube to become dislodged. UE, both in the field and in the hospital, is a common and costly problem. It results in significant morbidity and mortality. Although much of the information in this document relates to adult and pediatric patients, this document currently addresses adult patients only. A specific APSS addressing the pediatric and neonatal population is under development.

Use this checklist to help you 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:
  - ☐ VP of Quality/Safety
  - ☐ Physician, nursing, and respiratory care team leaders across all hospital units to ensure recognition of the problem and support development of systems that will eliminate UE and its associated complications, especially preventable deaths
  - ☐ Neonatal, Pediatric, and Anethesiology representation (expertise) is vital
- ☐ 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 of management of the difficult airway patient
- ☐ Implement Clinical Best Practices for Preventing UE:
  - ☐ Standardize tracheal tube restraint devices, using the most proven methods and devices
  - ☐ 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 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 goal of eliminating preventable deaths from UE and ultimately eliminating all incidents of UE:

- ☐ Require 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

Unplanned extubation, both in the field and in the hospital, is a common and costly problem. An extensive review of 50 studies revealed that:

- 7.3% (range: 0.5% - 35.8%) of adult endotracheally intubated Intensive Care Unit (ICU) patients have an UE (daSilva, Anesthesia & Analgesia, 2012)
- 1.65 million adult patients are intubated and mechanically ventilated each year in U.S. 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 yearly, in U.S. adult ICUs alone
- Based on morbidity and mortality data, those 120,000 UEs yearly would result in over 33,000 deaths (DeLassence, et al., 2002)
- UE increases the incidence of pneumonia from 14% to 30% (DeLassence, et al., 2002), which would result in over 36,000 pneumonias
- UE more than doubles the average ICU stay (DeLassence, et al., 2002), increasing 9 days to 18 days (DeLassence, et al., 2002)
- Complications of UEs in adult ICUs results in over $4.9 billion in unnecessary healthcare costs (Dasta et al., 2005; Needham and Provost, 2005).

The need to accurately track UE

Although the incidence of UE is likely higher in emergency medical services (EMS) settings due to the difficulties of transporting critically ill patients in a chaotic environment, UE is not tracked in most EMS systems. Similarly, most hospitals do not track UE. 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 incidences.

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, safety and 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 reducing the incidence of UE with a goal of zero preventable deaths
- Raise awareness regarding the seriousness of UE – champion efforts to raise awareness regarding the seriousness (frequency and costliness) 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 incidence rate, develop an organizational story and use the skill set of storytelling to raise organizational 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 should consist of the following:

- VP of Quality/Safety
- Physician, nursing, and respiratory care team leaders from ED, OR/PACU, and ICU
- Neonatal/Pediatric representation (expertise) is crucial – APSSs are currently being developed for 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://youtu.be/v8PV4mDWVWc**

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 2-6 cm above the carina). Proper 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 (>2 cm) total movement of the tube
- 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)
- 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 that the endotracheal tube is correctly positioned and the patient is being adequately ventilated via waveform capnography. 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, the tube should be immediately repositioned, UE should be considered as the cause of the arrest and a root cause analysis of the 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

- UE should be considered through an event review as the cause of any cardiac arrest and if determined to be the cause of death a true root cause analysis should be performed
- 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:
    - Review all incidents of UE
    - Determine root causes, which may include:
        - Inadequate stabilization of the endotracheal tube
        - Inadequate sedation (chemical restraint)
        - Inadequate physical restraint
    - 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 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
- EMS airway provider 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:

System or Practice	Available technology
ONC Meaningful Use Certified Electronic Health Record (EHR) System An effective EHR System should include: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS) • ETT depth alerts for documentation of placement that is outside the normal range • An alert if >6 hours since the patient completed and passed a spontaneous breathing trial	
Standardize tracheal tube restraint devices The current methods and devices for stabilizing endotracheal tubes include: • Adhesive tape • Cotton twill ties • Multiple commercial devices The current 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. Other considerations, such as ease of use or ability to prevent skin breakdown should be secondary considerations. 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 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 In adults, the stabilizer should, at minimum, prevent clinically significant movement (>2 cm) 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.	
Waveform Capnography Mandate the use of Waveform Capnography in ALL intubated patients to ensure rapid recognition of a malpositioned tracheal tube. 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.	

*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/

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:
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 EHR 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 (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"?
    - 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 EHR to collect information to learn about new or specific trends identified by staff

Extubation may occur as a planned or unplanned event:

- A **planned extubation** occurs when a physician orders the removal of the endotracheal tube and the extubation proceeds in a controlled manner
- A **UE** is defined as removal of a patient's endotracheal tube without a physician's order and the extubation occurs in an uncontrolled manner. UE may occur from either patient self-extubation or accidental extubation by an external force.

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 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.
- 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:
    - 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
    - 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
    - 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 all incidents of UE is 28% (deLassence 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.

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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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Patient Safety MOVEMENT

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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.

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 administration, nursing, physicians, and pharmacy
- ☐ Create a sepsis dashboard for your organization's leadership

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 teams)
- ☐ Formalize processes to screen patients for signs of sepsis throughout the entire institution
- ☐ 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/Septic shock workflow
  - ☐ Mortality prediction: qSOFA (or "Level of Risk")
- ☐ Create a process for case reviews for outliers
- ☐ 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)

Engage staff and track data on your progress

- ☐ 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)
- ☐ Use 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
- ☐ Use patient stories – in written and video formats – to identify gaps and inspire change in your staff

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 M, Deutschman CS, Seymour CW, et al: The Sepsis Definitions Task Force The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). (*JAMA*, Feb 22, 2016) and www.esicm.org/article-review-sepsis-3-depascale)

Sepsis is a growing threat worldwide, and the most common cause of death in U.S. hospitals:

- Sepsis cases have increased in the U.S. from 621,000 in the year 2000 to 1,141,000 in 2008 (Centers for Disease Control and Prevention, 2017)
- According to the World Sepsis Day Newsletter, "preventing infections and fighting sepsis to save 800,000 lives each year" (GSA, 2016)
- At least 10-15% of sepsis deaths could be prevented through vaccination and hygienic measures
- Severe sepsis is estimated to affect 750,000 people annually in the U.S. and has a 28.6% mortality rate – it kills more people than stroke and pneumonia
- As many as 87% of sepsis cases originate in the community (http://jamanetwork.com/journals/jama/fullarticle/2654187)
- 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 (http://www.ncbi.nlm.nih.gov/pubmed/16625125).

Preventing morbidity and mortality through early detection of sepsis

Hospitals and healthcare institutions need to do all that is practicable to eliminate hospital-acquired infections. Early detection of sepsis, with the timely administration of appropriate fluids and antibiotics, appear to be the most important factors in reducing morbidity and mortality from 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.

The evidence for early detection of sepsis

Early treatment of sepsis, severe sepsis, or septic shock with quantitative fluid resuscitation has been shown to improve patient outcomes in multiple studies (Rivers et al., 2001; Levy et al., 2010), as has early treatment with antibiotics. Multiple instruments have been developed to screen for sepsis (Kumar et al., 2006; Ferrer et al., 2009; Álvaro Castellanos-Ortega et al., 2010).

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 intervention in sepsis has been found to improve patient outcomes and mortality rates but relies on completion of screening for rapid identification and communication of the results to the team members who can initiate appropriate treatments. It is the care delivered by the multidisciplinary team that is effective in improving patient outcomes.

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, n.d.)
- 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 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:
  - The filmed stories of Kate Hallisy and Rory Staunton:
    - Kate Hallisy: **https://youtu.be/VArcgHurgpY**
    - Rory Staunton: **https://youtu.be/cypQFXPrQD4**
  - Joshua Nahum's story: **https://youtu.be/DTHbiwHlN6E**
  - Sepsis Alliance Faces of Sepsis Videos: **https://youtu.be/12Qbnn6XfH0**

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 criteriaTemperature > 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
  - 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 (**Figure 1**)
- 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.)

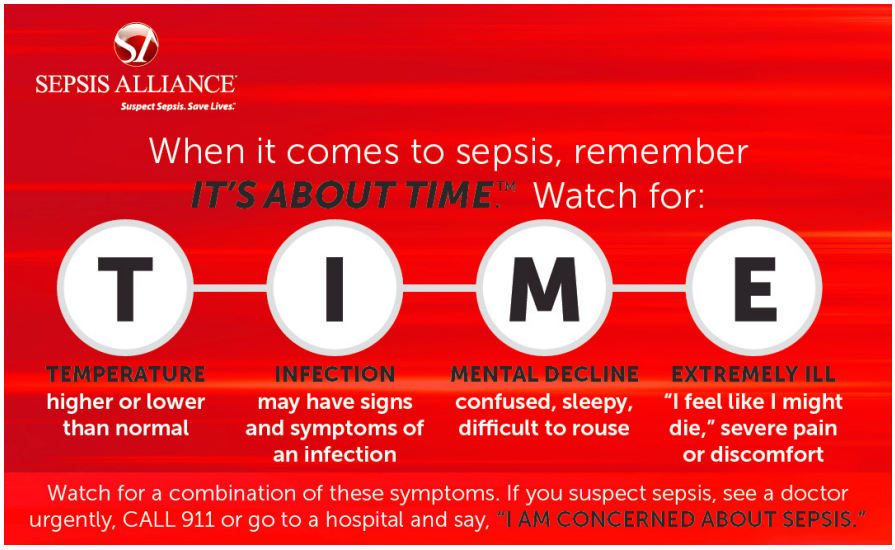

Figure 1: Graphic Courtesy of Sepsis Alliance

Create protocols for communication

- Use standardized protocols for patient/family engagement/communication, including:
  - Coordinate with family or caregiver to reduce sepsis risk factors and identify clinical indicators at first sign
  - Disclose all sepsis related events
  - Provide an explanation as to why and how the sepsis occurred
  - Explain how the effects of sepsis will be minimized
  - 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:
  - 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.
  - Obtain blood cultures prior to administration of antibiotics
  - Administer broad spectrum antibiotics
  - Administer 30 mL/kg crystalloid for hypotension or lactate ≥4 mmol/L
  - 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):
  - 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
- Remeasure lactate if initial lactate was elevated

Offer sepsis resources to the public

Innovative ways to engage patients and families as safety partners are critical to improve sepsis 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 of sepsis, which hinders their ability to recognize and report early signs of the disease. More than 40% of U.S. adults have NEVER heard of sepsis (Sepsis Alliance, 2017).

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 the injuries and deaths from sepsis. Sepsis survivors and their loved ones need assistance in coping during the immediate recovery period and in knowing what to expect during the oftentimes protracted post-sepsis healing process. Here are resources you can share with the public:

- **Sepsis Alliance** resources:
  - Sepsis 911 Education Toolkit to raise sepsis awareness in your community: www.sepsis.org/resources/sepsis-911
  - Resources for those diagnosed with sepsis: http://www.sepsis.org/resources/diagnosed_with_sepsis/
  - If a loved one has sepsis: http://www.sepsis.org/resources/how_to_help/
  - Life after sepsis: http://www.sepsis.org/life_after_sepsis/
  - Sepsis Information Guides : https://www.sepsis.org/resources/sepsis-information-guides/
  - Share your story on Faces of Sepsis: https://www.sepsis.org/faces/
- **Engaged Patients** (Empowered Patient Coalition) Empowered Patient Signs of Sepsis Fact Sheet (free with registration): http://engagedpatients.org/empowered-patient-signs-sepsis-fact-sheet/

- Sepsis resources from the **Centers for Disease Control and Prevention (CDC)**: http://www.cdc.gov/sepsis/basic
- **National Institutes of Health (NIH)** Sepsis Fact Sheet: https://www.nigms.nih.gov/education/pages/factsheet_sepsis.aspx

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: https://www.sepsis.org/sepsis-first-response
  - Sepsis Coordinator Network: https://sepsiscoordinatornetwork.org
  - Sepsis: Across the Continuum of Care webinars for healthcare professionals: https://www.sepsiswebinar.org
  - Sepsis 911 Education Toolkit to raise sepsis awareness in your community: www.sepsis.org/resources/sepsis-911
  - Life after sepsis: http://www.sepsis.org/life_after_sepsis/
  - Posters and infographics: https://www.sepsis.org/resources/infographics/
- Sepsis resources from the CDC: https://www.cdc.gov/sepsis/education/hcp-resources.html
- **Center for Medicare and Medicaid Services (CMS)** Webinar SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock: v5.3a Measure Updates: https://www.qualityreportingcenter.com/wp-content/uploads/2018/02/IQR_slides_Sepsis_v5.3a_20180227_vFINAL508.pdf
- **Surviving Sepsis Campaign**: http://www.survivingsepsis.org/Pages/default.aspx

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/**

System or Practice	Available technology
Electronic Health Record (EHR)	• Ambient Clinical: DART System
Continuous pulse oximetry	• 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

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 $Rate_{baseline}$ – Mortality Ratemeasurement) X $Patients_{baseline}$

*$Patients_{baseline}$: 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.

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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 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?

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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What we know about sepsis detection and treatment for LMICs 303

Leadership plan 304

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Examples of a sepsis screening and management tool for LMICs 310

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Appendix A: A modified sepsis screening tool for LMICs with 3 entry points 313

Patient Safety MOVEMENT

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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, 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**).

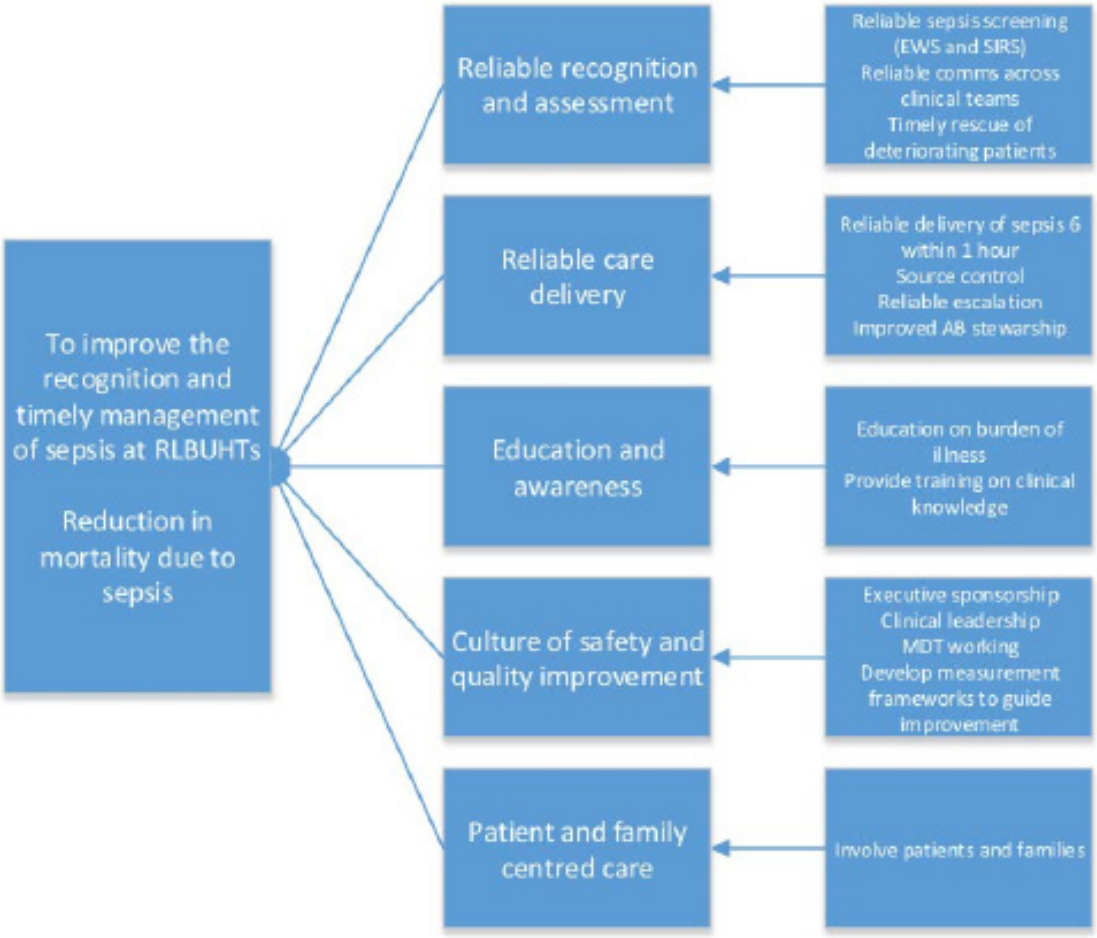

Figure 1: Driver diagram for sepsis (courtesy of The Royal Liverpool and Broadgreen University Hospitals NHS Trust (RLBUHTs))

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

The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Sepsis Strategy

Mission					
To continuously transform sepsis care across The Royal Liverpool and Broadgreen University Hospitals NHS Trust					
Vision					
Provide a gold standard of care for every patient, every time	To be the best performing Trust in the region within 12 months, based upon AQ and national CQUIN	Best performing Trust nationally within the next five years, based upon national CQUIN			
Values					
Patient centred	Professional	Open and engaged	Collaborative	Creative	
Objectives					
Reduce mortality by 20% for patients with severe sepsis and septic shock	Consistent use of sepsis pathway and consistent care	Mandatory sepsis training for all staff	Reduced length of stay	Robust triage process in ED and AMU that incorporates sepsis treatment and care	
Strategy					
Establishment of a patient group	Recruitment and development of a sepsis nurse team based within the emergency floor	Collaboration with the local health economy including CCG and Liverpool Community Health	Pre alert from North West Ambulance Service (NWAS) within the emergency floor to alert about potential severe sepsis and septic shock patients	Continued, real time robust data collection and audit, disseminating lessons learned	Targeted education including simulation for clinical staff

Figure 2: Sepsis Strategy (courtesy of The Royal Liverpool and Broadgreen University Hospitals NHS Trust (RLBUHTs))

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**).

	2016	2017
Screening for sepsis	0.52	0.85
Antibiotics within 1 hour	0.49	0.62
Lives saved		548 estimated

Figure 3: Example of data

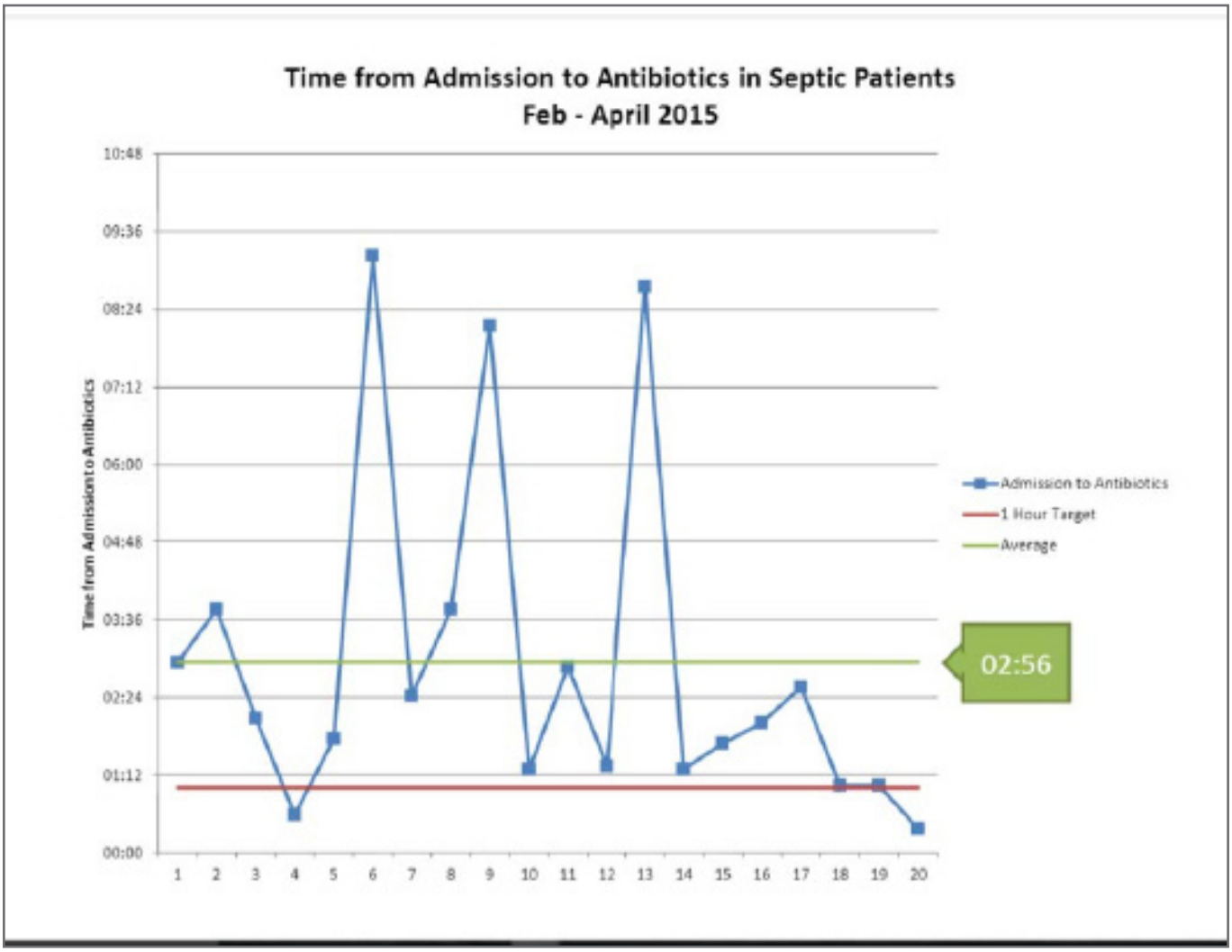

Figure 4: Example of use of data

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**
- Resources for those diagnosed with sepsis: **http://www.sepsis.org/resources/diagnosed_with_sepsis/**
- If a loved one has sepsis: **http://www.sepsis.org/resources/how_to_help/**
- Life after sepsis: **http://www.sepsis.org/life_after_sepsis/**
- Faces of Sepsis video from Sepsis Alliance: **http://www.sepsis.org/resources/**
- Kate Hallisy's story, as told by her mother, Julia: **http://youtube/VArcgHurgpY**
- Empowered Patient Signs of Sepsis Fact Sheet (free with registration): **http://engagedpatients.org/empowered- patient-signs-sepsis-fact-sheet/**
- Sepsis resources from the CDC: **http://www.cdc.gov/sepsis/basic/**
- NIH Sepsis Fact Sheet: **https://www.nigms.nih.gov/education/pages/factsheet_sepsis.aspx**

Other useful information for your organization

- Surviving Sepsis Campaign guidelines – Recommendations for Sepsis Management in resource limited settings (Reference): **http://patient.sm/Sepsis-management-limited-resources**
- 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_2 is greater than 90% on room air, or
    - SpO_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_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.

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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)
- ☐ SpO_2 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 & 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 316
What we know about in-hospital cardiac arrest 318
Leadership plan 320
Action plan 321
Technology plan 322
Measuring outcomes 324
Conflicts of interest disclosure 325
Workgroup 325
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Executive summary checklist

One-third of inpatient deaths may be preventable by improving practice, such as better recognizing deterioration in patients and optimizing resuscitation strategies.

Checklist for care systems

- ☐ Convene an institutional multi-disciplinary Resuscitation Outcomes Steering Committee (ROSC), including physicians, nurses, respiratory therapists, and administrators who will have primary responsibility for the resuscitation program

Use data strategically

- ☐ Create a formal mechanism for the use of input data (afferents) to influence output actions (efferents)
  - ☐ Afferents should include **external** sources of information, such as guidelines and scientific literature, and **internal** (institutional) data
  - ☐ The ROSC should have input into the ways efferents respond to afferent data
- ☐ Present efferent data to the hospital medical executive board on a regular basis, such as monthly or quarterly
- ☐ Target the most prevalent causes of cardiac arrest
- ☐ Consider available evidence, technology, and continuous quality improvement (CQI) data when developing resuscitation protocols

Improve prevention and care

- ☐ Use technology and clinical data to develop an early warning system to recognize patients who are at risk of cardiac arrest:
  - ☐ Perfusion technologies, which include:
    - ☐ Vital signs
    - ☐ Sphygmomanometry
    - ☐ ECG
    - ☐ Capnometry
    - ☐ Clinical assessment (mental status, capillary refill, pulse quality, extremity temperature)
    - ☐ Pulse oximetry, including:
      - ☐ Related perfusion indices
      - ☐ Measures of acidosis (pH, base deficit, lactate, anion gap)
      - ☐ Newer modalities (near-infrared spectroscopy, orthogonal polarization, heart-rate variability)
  - ☐ Oxygenation technologies, which include:
    - ☐ Vital signs
    - ☐ Pulse oximetry
    - ☐ Blood gas analysis
    - ☐ Near-infrared spectroscopy
    - ☐ Clinical assessment

- ☐ Ventilation technologies, which include:
  - ☐ Vital signs
  - ☐ Respiratory volumetrics (tidal volume, respiratory rate)
  - ☐ Blood gas analysis
  - ☐ Capnometry
  - ☐ Capnography, such as with Masimo, Medtronic (Oridion/Covidien), Nonin, Philips (Respironics), and Welch Allyn
  - ☐ Apnea monitoring, such as with Respiratory Motion ExSprion
  - ☐ Clinical assessment
- ☐ Focus post-resuscitative care on:
  - ☐ Delivery of optimal supportive critical care
  - ☐ Consideration of targeted temperature management and early coronary revascularization

Create a culture of safety

- ☐ Engage individual providers and enhance their personal sense of ownership and accountability
- ☐ Use patient stories, in written and video form, to identify gaps and inspire change in your staff

Checklist for cardiac arrest resuscitation training

- ☐ Implement an evidence-based institutional cardiac arrest resuscitation training program, such as Advanced Resuscitation Training (ART)
- ☐ Use provider training that ensures optimal prevention and resuscitation performance and is specific to provider roles, clinical units, and technology
- ☐ Emphasize the importance of optimal cardiopulmonary resuscitation (CPR) to increase survival from cardiac arrest
- ☐ Teach clinicians:
  - ☐ The indications to initiate compressions
  - ☐ The proper compression rate, depth, and recoil
  - ☐ Integration of compressions and ventilations, per institutional standards
- ☐ Train resuscitation leaders to recognize and maintain optimal CPR. This may involve the integration of available technology, including:
  - ☐ Use of sensors to measure compression rate, depth, and recoil, which are available but require additional training for effective implementation and use
  - ☐ Use of end-tidal carbon dioxide ($EtCO_2$) as a surrogate for cardiac output during cardiac arrest. Absolute values as well as changes in $EtCO_2$ provide information regarding chest compression performance and prognosis.
  - ☐ Use of mechanical chest compression devices to provide consistent compressions

What we know about in-hospital cardiac arrest

In-hospital cardiac arrest is the sudden loss of heart function, breathing, and consciousness. It is a major preventable cause of patient harm and death, and outcomes have been largely unchanged for decades.

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
- Improve CPR performance by staff

This APSS gives recommendations to:

- Improve care systems, including use of data to inform an early-warning system to identify patients at risk of cardiac arrest
- Apply the ART program to improve staff CPR capability
- Integrating technology into clinical practice

Staff CPR skills are inadequate

The foundation for successful resuscitation from cardiac arrest is the performance of high quality CPR. The literature documents suboptimal performance of CPR by both hospital and out-of-hospital providers:

- First responders are often reluctant to initiate chest compressions. This leads to prolonged "down times" with absent perfusion and worsens prognosis from cardiac arrest. This may reflect uncertainty with regard to patient perfusion status or a lack of appreciation for the importance of early CPR.
- There are often frequent and prolonged interruptions in chest compressions. This leads to a rapid decrease in cardiac output and lowers the likelihood of a return of spontaneous circulation. Interruptions in chest compressions are typically performed to prioritize other tasks, such as rhythm analysis, defibrillation, airway management, vascular access, or intubation, and may reflect a lack of appreciation for the relative importance of chest compressions.
- Chest compressions are generally too fast and shallow, with poor chest wall recoil. This severely compromises cardiac output during CPR.
- Ventilations are generally too fast. This increases intrathoracic pressure and decreases cardiac output during CPR.

CPR training is inadequate

The primary mechanism for maintaining resuscitation competency for most institutions is limited to a biennial (every 2 years) completion of the American Heart Association life support training courses: Advanced Cardiac Life Support (ACLS) and Basic Life Support (BLS) (Neumar et al., 2010).

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 tremendous potential to improve outcomes
- There is no emphasis on arrest prevention, which is where the most opportunity exists for improving clinical outcomes in the hospital setting

An institutional resuscitation program should target preventable deaths as well as optimal resuscitation performance. Each of the core elements described below (steering committee, afferents, and efferents) should reflect and be adapted to your institution. In addition, the core elements should be linked together in an institutional closed-loop performance improvement system.

Advanced Resuscitation Training (ART): A solution to improve CPR skills

ART was developed in 2007 at the University of California at San Diego (UCSD) and represents the archetype for an institutional resuscitation program.

The ART program is 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 (Figure 1). Ownership and accountability are transferred to the institution, enhancing both relevance and engagement.

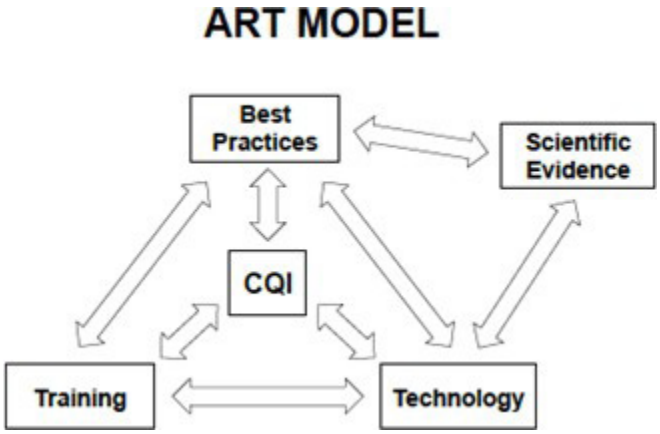

Figure 1: ART model

Components of the ART model

Critical paradigms at the heart of the ART program

The ART Matrix represents a **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.

The Matrix also allows for **consolidation of 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. This integration is crucial for effective hospital leadership, outcomes tracking, and training efficiency.

The Matrix is based on the ART Integrated Model of Physiology, which identifies **3 physiological processes** – perfusion, oxygenation, ventilation – that define the optimal approach to clinical practice, CQI data collection, technology, and training.

Early detection of deterioration is critical for arrest prevention (Nolan *et al.*, 2010). Most approaches involve a critical tradeoff between sensitivity and specificity, with a measurable incidence of over- or under-use of rapid response team resources, limiting overall effectiveness. The ART model employs a stepwise approach to early detection that maximizes both sensitivity and specificity and integrates clinical data, technology, and hospital processes.

Each Matrix category is associated with specific static and dynamic risk factors, which in turn suggest particular strategies for vital sign assessment and sensors/technology. Patterns that suggest deterioration trigger a targeted diagnostic and therapeutic approach to both improve specificity and potentially reverse deterioration.

Integrative practice

The integrative nature of the ART program is a key component to its effectiveness. In addition to integrating clinical practice, science, technology, CQI, and training, ART also brings together multiple hospital provider types and initiatives, allowing leadership integration and enhancing efficiency.

Finally, regular access for all clinical providers to ART training helps address institutional resuscitation and patient safety needs.

Increased efficiency and performance

Various aspects of critical care, technical procedures, and surveillance should be recalibrated to use ART paradigms and terminology. This makes training more efficient and enhances clinical performance and recall during stressful resuscitation events.

Embed the ART approach to risk factor assessment – both static and dynamic – into patient care records and hospital policies and procedures. This will help institutionalize its integrated approach to surveillance and monitoring:

- Static risk factors include those factors that do not vary throughout the admission, such as obesity, advanced age, immunocompromised status, and presence of pneumonia
- Dynamic risk factors vary as part of a typical hospital course, such as medications administered, procedures, and sleep/wake status

The evidence for the ART program

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 tripled
- Life support expenditures have been reduced by 25%
- Return on investment has been more than 10-fold, with potential savings in reduced cost-of-care, medicolegal payouts, and improved reimbursement for pay-for-performance/value-based purchasing

Leadership plan

Show leadership's commitment to improving staff CPR skills

- Hospital administration and clinical leadership must commit to supporting the development and maintenance of an institutional resuscitation program, including support for program leadership and a commitment to provider training
- Establish a ROSC: A multi-disciplinary institutional group that is primarily responsible for

the program. This group should have both ownership and accountability for outcomes and should have access to afferent data and input into the efferent response.

- Reporting from the institutional ROSC should be upward to institutional leaders; horizontal to other committees, hospital units, and service lines; and downstream to providers
- Base ART program implementation on the principles of the Society of Hospital Medicine's Mentored Implementation Program, which has demonstrated effective change management in multiple patient safety initiatives

Support implementation of ART with funding and infrastructure

- Administration should provide financial support. This may exist as supplemental training, which would require new expenditures.
- Alternatively, you may find tremendous cost savings in reallocating existing life support and other training toward an ART program
- Provide any additional infrastructure support from patient safety and risk management entities

Engage staff

- Engage individual providers and enhance their personal sense of ownership and accountability. This can be accomplished by:
  - Engagement and public support of the institutional ROSC and their activities by hospital leaders, and broad representation of various hospital groups on the ROSC
  - Effectively modifying training content to address provider-specific needs and issues, and giving routine feedback of institutional resuscitation data. Ultimately, this program should become the primary vehicle to reduce preventable deaths and ensure an institutional culture of safety.
- Use patient stories, in written and video form, to identify gaps and inspire change in your staff

Action plan

Implement training, technology, and data analysis to improve outcomes

- Provide training based on provider type (MD, RN, pharmacist, RT) and practice unit. Based on the ART philosophy of "adaptive" training, this allows provider subgroups to receive training relevant to their patient population, resources, and role expectations.
- Develop an institutional treatment algorithm and simulation training to help reintegrate providers who have received this adaptive training
- Develop a treatment algorithm based on institutional capabilities, technology, CQI needs, and clinical leader interpretation of scientific evidence
- Develop a simulation that combines cognitive and psychomotor skills and allows integration and teamwork training, including optimal communication
- Apply the ART approach to CQI:
  - Define specific data elements that identify opportunities for training and algorithm modification
  - Ensure CQI efforts document clinical outcomes, which are relayed back to providers to enhance ownership and accountability

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:

System or practice	Available technology
ONC Meaningful Use Certified Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)	

System or practice	Available technology
Perfusion: • Vital signs • Sphygmomanometry • ECG • Capnometry • Clinical assessment (mental status, capillary refill, pulse quality, extremity temperature) • Pulse oximetry including related perfusion indices • Laboratory measures of acidosis (pH, base deficit, lactate, anion gap) • Newer modalities (near-infrared spectroscopy, orthogonal polarization, heart-rate variability)	• 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)

Oxygenation:
• Vital signs pulse oximetry
• Blood gas analysis
• Near-infrared spectroscopy
	• Implement noninvasive and continuous hemoglobin monitoring (Ehrenfeld; WFN)
	  o SpHb adhesive sensors connected to Masimo* Radical-7 with SpHb, or a multi-parameter patient monitor with SpHb, including but not limited to:
	  • Dräger* M540/Infinity Acute Care System
	  • Welch Allyn* CVSM
	  • Fukuda Denshi 8500
	  • Saadat Aria* and Alborz monitors
	  • BMEYE ccNexfin

System or practice	Available technology

Ventilation:
• Vital signs
• Respiratory volumetrics (tidal volume, respiratory rate)
• Blood gas analysis
• Capnometry
• Capnography
• Apnea monitoring
	• Capnography
	• Apnea Monitoring
	  o Respiratory Motion's ExSpiron
	• 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
	  • Masimo* rainbow acoustic monitoring
	OR
	  o Sidestream end tidal carbon dioxide monitoring

Remote monitoring with direct clinician alert capability compatible with recommended pulse oximetry technology	• Masimo* Patient SafetyNet, or comparable multi-parameter monitoring system
Direct clinician alert through dedicated paging systems or hospital notification system	

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: **patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

Measuring outcomes

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 Spared Harm = (ARD Rate $_{baseline}$ *– ARD Rate* $_{measured}$ *x Admissions* $_{measured}$

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.

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Actionable Patient Safety Solutions (APSS) #11A:

Postpartum hemorrhage (PPH)

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:

Executive summary checklist 330
What we know about PPH 332
Leadership plan 334
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Technology plan 335
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Executive summary checklist

PPH is the most common problem in 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 like PPH in their healthcare system

Establish readiness for PPH in every unit

- ☐ Create a hemorrhage cart with supplies, checklists, and instruction cards for intrauterine balloons and compression sutures based on the recommendations referenced
- ☐ Ensure teams have immediate access to hemorrhage medications such as a uterotonic medication kit (drugs that induce contraction in 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, unit-based drills (with post-drill debriefs)

Recognize and prevent in every PPH patient

- ☐ 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 to PPH

- ☐ 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 PPH

- ☐ 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 causes of maternal morbidity and mortality (Callaghan *et al.*, 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 *et al.*, 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 results in poor outcomes. Early recognition of PPH and a timely, coordinated intervention are essential to reduce associated morbidity and mortality.

Causes and risk factors for PPH

The most common cause 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 (the premature separation of the placenta from the wall of the uterus, with blood trapped inside the uterus) or retroperitoneal hemorrhage (when blood is 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
- The lack of clear guidelines for measuring blood loss during childbirth often leads to underestimation and a clinician may not diagnose primary PPH

More information about PPH

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 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 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 problems 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 et a., 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 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://safehealthcareforeverywoman.org/patient-safety-bundles/obstetric-hemorrhage/

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/**

System or practice
ONC Meaningful Use Certified Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)
Close monitoring of hemodynamics such as heart rate and blood pressure
Ultrasound technology for assessment of retained products, retained placenta, or abruption

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.

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.

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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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Patient Safety MOVEMENT

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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

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

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 *et al.*, 2014).

Approximately 15-17% of all maternal mortality is caused by hypertensive disorders which include: chronic (pre-existing) 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 (Merkatz & Thompson, 1990; 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, mm Hg) ≥140/90 mm Hg prior to the 20th week of pregnancy, and leads to complications in 5% of all pregnancies (Seely & Maxwell, 2007; Druzin *et al.*, 2013; Yanit *et al.*, 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 (Leddy *et al.*, 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 also be the first presentation.

There is an **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. Committee Opinion No. 692. American College of Obstetricians and Gynecologists. Obstet Gynecol2017:129:e90–5).

In the past, the focus was placed on the prevention of eclamptic seizures, which is associated with an increase in both neonatal and maternal morbidity and mortality. Eclamptic seizures can be prevented through the administration of magnesium sulfate (Sibai, 2004; MTCG, 2002; Duley *et al.*, 2003; 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, preeclamptic mothers 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 & 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. Committee Opinion No. 692. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2017:129:e90–5).

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).

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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 (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 problems 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 *et al.*, 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 *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 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: **youtu.be/dyh46iIcmkQ**.

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/**

System or practice
ONC Meaningful Use Certified Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)
Blood pressure measurement devices

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:
Lives Spared Harm = (SMM Rate $_{baseline}$ *- SMM Rate* $_{measurement}$*) X Denominator* $_{baseline}$

Note

Since this is a morbidity measure, the lives saved calculation is not applicable.

Data collection

HDD File (ICD9/ICD10)

Topic 2: SMM (excluding transfusion codes) among preeclampsia cases

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:
Lives Spared Harm = (SMM Rate $_{baseline}$ *- SMM Rate* $_{measurement}$*) X Denominator* $_{baseline}$

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 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.

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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:

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Patient Safety MOVEMENT

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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, 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.

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, 2007; Spong, 2012)
- ☐ Optimize patient and family engagement (Declercq, 2017). 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; Bisognano, 2014; Hodnett Group, 2013). 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)/Society for Maternal Fetal Medicine (SMFM), 2014, ACOG, 2017) 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, 2008), including:
  - ☐ Interpretation
  - ☐ Documentation using The National Institute of Child Health and Human Development (NICHD) terminology
  - ☐ 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, 2008; Hofmeyr, 2015)

Respond

- ☐ Have available an in-house maternity healthcare provider or alternative coverage that guarantees timely and effective responses to problems that may occur in labor (Rosenstein, 2015; Iriye, 2013; Nijagal 2015)
- ☐ 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; Zhang, 2010)
- ☐ Adopt policies that outline standard responses to abnormal fetal heart rate patterns and uterine activity (Clark, 2013)
- ☐ Make available specialized expertise and techniques to lessen the need for c-section birth (Hollier, 2008; Barrett, 2013) such as:
  - ☐ Breech version
  - ☐ Instrumented 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 1.3 million of the procedures are performed annually (HCUP, 2014)
- 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.*, 2017)

Among the population of first-time mothers with low-risk births (also called Nulliparous, Term, Singleton, Vertex (NTSV)), 25.7% give birth by cesarean, which is a 40% increase since 1997 (Martin *et al.*, 2017). C-section rates have also increased globally (Betran *et al.*, 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 *et al.*, 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 *et al.*, 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)
- 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 *et al.*, 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 *et al.*, 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 1:333 (Belfort *et al.*, 2010).

Women who want vaginal birth after cesarean can't obtain it

Nearly 88% of the approximate 604,000 women with a history of a prior cesarean who gave birth in the U.S. in 2016 did so by c-section (Driscoll, 2017).

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).

This drop 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).

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 *et al.*, 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 pilot program, with a goal of scaling back cesarean birth over-utilization while maintaining safety for mothers and infants, rapidly lowered NTSV cesarean rates in several California hospitals and established 2 separate baselines for infants and mothers.

Coordinated by the CMQCC, 3 hospitals seeking to lower their NTSV rates collected data on balancing measures, including the National Quality Forum's Unexpected Newborn Complications measure and 3rd- and 4th-degree perineal lacerations occurring in vaginal births (Lagrew *et al.*, 2017). The hospitals averaged reductions of:

- 18.6% in their NTSV rates in 2015
- 24.5% in newborn complications
- 4.7% in 3rd- and 4th-degree perineal lacerations

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)
- Carolinas Health System, headquartered in North Carolina (Bell *et al.*, 2017)
- Brazil's Hospital Israelita Albert Einstein (HIAE) (IHI, 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

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/**

System or practice
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.

System or practice
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.
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 2 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

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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Actionable Patient Safety Solutions (APSS) #12A:

Venous Thromboembolism (VTE)

How to use this guide

This guide gives actions and resources for creating and sustaining safe practices for VTE. In it, you'll find:

Executive summary checklist 372
What we know about VTEs 374
Leadership plan 374
Action plan 375
Technology plan 376
Measuring outcomes 378
Conflicts of interest disclosure 380
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Patient Safety
MOVEMENT

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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 for VTE among patients hospitalized with:
  - ☐ Injury to vein: fracture, surgery
  - ☐ Slow blood flow: bedrest, limited mobility, paralysis
  - ☐ Increased estrogen: birth control, pregnancy and recent childbirth, hormone replacement therapy
  - ☐ Chronic illness: cancer, heart/lung disease, atrial fibrillation, inflammatory bowel disease (Crohn's Disease and ulcerative colitis)
  - ☐ Other: personal or family history of DVT/PE, age, obesity, central lines, or clotting disorders
- ☐ 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)
  - ☐ Patient mobility

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

The problems with standard treatments for VTEs

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 (PCAST, 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 (ONC, 2014). A healthcare institution must maintain a high level of clinical suspicion to diagnose VTE.

Prevention of VTEs

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.

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, 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: **youtu.be/cLbncqbBYg0.**

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
    - Pharmacological prophylaxis ordered
        - Pharmacological prophylaxis missed doses
        - Patient refusal of pharmacological prophylaxis
    - Mechanical prophylaxis ordered
        - Patient refusal of mechanical prophylaxis
    - Patient mobility
- Identify gaps in care that promote VTE development

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
    - 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
    - Consider adopting VTE power plans/order sets
    - Continue VTE prophylaxis past discharge if recommended

- Ensure timely and reliable delivery of pharmacological and/or mechanical prophylaxis as indicated
  - Track and find trends in missed doses and patient refusals
  - 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
  - Educate staff without the information needed on VTE prophylaxis
  - Consider yearly competence in VTE
  - 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)
  - 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

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/**

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 Physician 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
- Jobst 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
- Flotron/Flotron DVT system-thigh
- Impulse pump-thigh
- Intermittent pneumatic compression stockings
- Intermittent compression device (ICD)
- KCI stockings
- Leg pumpers
- PAS (Pulsatile anti-embolic stockings)
- Plexipulse-calf/thigh
- Pneumatic intermittent impulse compression device
- Rapid inflation asymmetrical compression (RIAC) devices
- Sequential compression device
- Sequential pneumatic hose
- Thromboguard
- Thrombus pumps-calf/thigh
- Vascutherm
- VasoPress DVT System
- Venodyne boots-calf/thigh
- Leg pumpers

- PAS (Pulsatile anti-embolic stockings)
- Plexipulse-calf/thigh
- Pneumatic intermittent impulse compression device
- 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 $\text{Rate}_{\text{baseline}}$ - VTE or PE $\text{Rate}_{\text{measurement}}$) X Total Patient $\text{Days}_{\text{baseline}}$

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

PfP Hospital Acquired Condition (HAC) for 2010-2014	Estimated Additional Cost per HAC (2010 dollars)	Estimated Additional Inpatient Mortality per HAC
Adverse Drug Events	$5,000	.020
Catheter-Associated Urinary Tract Infections	$1,000	.023
Central Line-Associated Bloodstream Infections	$17,000	.185
Falls	$7,234	.055
Obstetric Adverse Events	$3,000	.0015
Pressure Ulcers	$17,000	.072
Surgical Site Infections	$21,000	.028
Ventilator-Associated Pneumonia	$21,000	.144
Postoperative Venous Thromboembolism	$8,000	.104

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

ICD10: I8010, I8011, I8012, I8013, I80201, I80202, I80203, I80209, I80211, I80212, I80213, I80219, I80222, I80223, I80229, I80231, I80232, I80233, I80239, I80291, I80292, I80293, I80299, I82401, I82402, I82403. I82409, I82411, I82412, I82413, I82419, I82421, I82422, I82423, I82429, I82431, I82432, I82433,I82439, I824Y1, I824Y2, I824Y3, I824Y9, I2602, I2609, I2692, I2699

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 $Rate_{measurement}$) X Total Patient $Days_{baseline}$

Lives saved:
Lives Saved = Lives Spared Harm X 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.

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Appendix A

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)

5 points	3 points	2 points	1 point
☐ Stroke (in the previous month) ☐ Fracture of the hip, pelvis, or leg ☐ Elective arthroplasty ☐ Acute spinal cord injury (in the previous month)	☐ Age≥ 75 years ☐ Prior episodes of VTE ☐ Positive family history for VTE ☐ Prothrombin 20210 A ☐ Factor V Leiden ☐ Lupus anticoagulants ☐ Anticardiolipin antibodies ☐ High homocysteine in the blood ☐ Heparin induced thrombocytopenia ☐ Other congenital or acquired thrombophilia	☐ Age: 61-74 years ☐ Arthroscopic surgery ☐ Laparoscopy lasting more than 45 minutes ☐ General surgery lasting more than 45 minutes ☐ Cancer ☐ Plaster cast ☐ Bed bound for more than 72 hours ☐ Central venous access	☐ Age 41-60 years ☐ BMI > 25 Kg/m2 ☐ Minor surgery ☐ Edema in the lower extremities ☐ Varicose veins ☐ Pregnancy ☐ Post-partum ☐ Oral contraceptive ☐ Hormonal therapy ☐ Unexplained or recurrent abortion ☐ Sepsis (in the previous month) ☐ Serious lung disease such as pneumonia (in the previous month) ☐ Abnormal pulmonary function test ☐ Acute myocardial infarction ☐ Congestive heart failure (in the previous month) ☐ Bed rest ☐ Inflammatory bowel disease

Scoring and Recommended Prophylaxis (Gould et al., 2012)

Caprini Score	Risk	VTE Incidence	Recommended Prophylaxis
0-2	Very low-low	<1.5%	Early ambulation, IPC
3-4	Moderate	3%	LMWH; UFH; or IPC *If high bleeding risk, IPC until bleeding risk diminishes.*
5-8	High	6%	LMWH + IPC; or UFH + IPC *If high bleeding risk, IPC until bleeding risk diminishes.*
>8	Very high	6.5-18.3%	LMWH + IPC; or UFH + IPC *If high bleeding risk, IPC until bleeding risk diminishes.* *Consider extended duration prophylaxis.*

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 Predictiction score for VTE among hospitalized patients (Barbar et al., 2010). A score of:

- ≥4: high risk of VTE
- ≤4: low risk for VTE.

Variable	Score
Active cancer	3
Previous VTE	3
Decreased mobility	3
Thrombophilia	3
Previous trauma or surgery within that last month	2
Age≥ 70	1
Heart and/or respiratory failure	1
Ischemic stroke or acute myocardial infarction	1
Acute rheumatologic disorder and/or acute infection	1
Obesity	1
Hormonal therapy	1

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

Variable	Score
Prior episode of VTE	3
Thrombophilia	3
Malignancy	1
Age more than 60 years	1

Interpretation of the IMPROVE Predictive Score

Score	Predicted VTE risk through 3 months
0	0.5%
1	1.0%
2	1.7%
3	3.1%
4	5.4%
5-8	11%

IMPROVE Associative Score

Variable	Score
Prior episode of VTE	3
Thrombophilia	2
Paralysis of the lower extremity during the hospitalization	2
Current malignancy	2
Immobilization for at least 7 days	1
ICU or CCU admission	1
Age more than 60 years	1

Interpretation of the IMPROVE Associative Score

Score	Predicted VTE risk through 3 months
0	0.4%
1	0.6%
2	1.0%
3	1.7%
4	2.9%
5-10	7.2%

Actionable Patient Safety Solutions (APSS) #12B:

Air Embolism

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:

Executive summary checklist 390
What we know about air embolism 391
Leadership plan 392
Action plan 393
Technology plan 395
Measuring outcomes 396
Conflicts of interest disclosure 396
Workgroup 396
References 397

Patient Safety
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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 (such as ClearLine IV)
- ☐ 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 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: **patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/**

Consider implementing the following technologies:

System or Practice	Available Technology
ONC Meaningful Use-Certified Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician 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 ClearLine or equivalent 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

*Company has signed some form of the Open Data Pledge, more information can be found on the Patient Safety Movement Foundation website: **https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/**

Measuring outcomes

- Consider:
  - Functional status assessment (pre and post)
  - Process measures to help facilities identify leading indicators of success

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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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:

Executive summary checklist 402

What we know about mental health and patient safety 403

Leadership plan 404

Action plan 405

Technology plan 414

Measuring outcomes 417

Conflicts of interest disclosure 417

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Patient Safety
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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 et al., 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
  - ☐ Code white frequency
  - ☐ 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 et al., 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 et al., 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

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 et al., 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 & 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

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:
  - 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 et al., 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
  - Develop a guide for staff and physicians to determine appropriate family and supports to be involved in care planning
  - 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
  - Protect time to engage in patient comfort planning
- Produce capability
  - Educate staff on:
    - How to leverage comfort planning
    - How to engage patients to identify their triggers
    - When to seek additional resources
  - Educate families on:
    - How to support positive behaviors
    - How to identify triggers
    - When to ask for assistance

- Give motivation
  - Highlight the importance of patient involvement in patient outcomes
  - Empower staff to proactively assess and include patients in their treatment
  - Empower family involvement, if appropriate
- Track outcomes
  - 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
  - The story of Glenn Saarinen is an inspiring story produced by the Patient Safety Movement Foundation
    - It can be viewed for free here: **youtu.be/tUxvgL2rqMw**

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)**

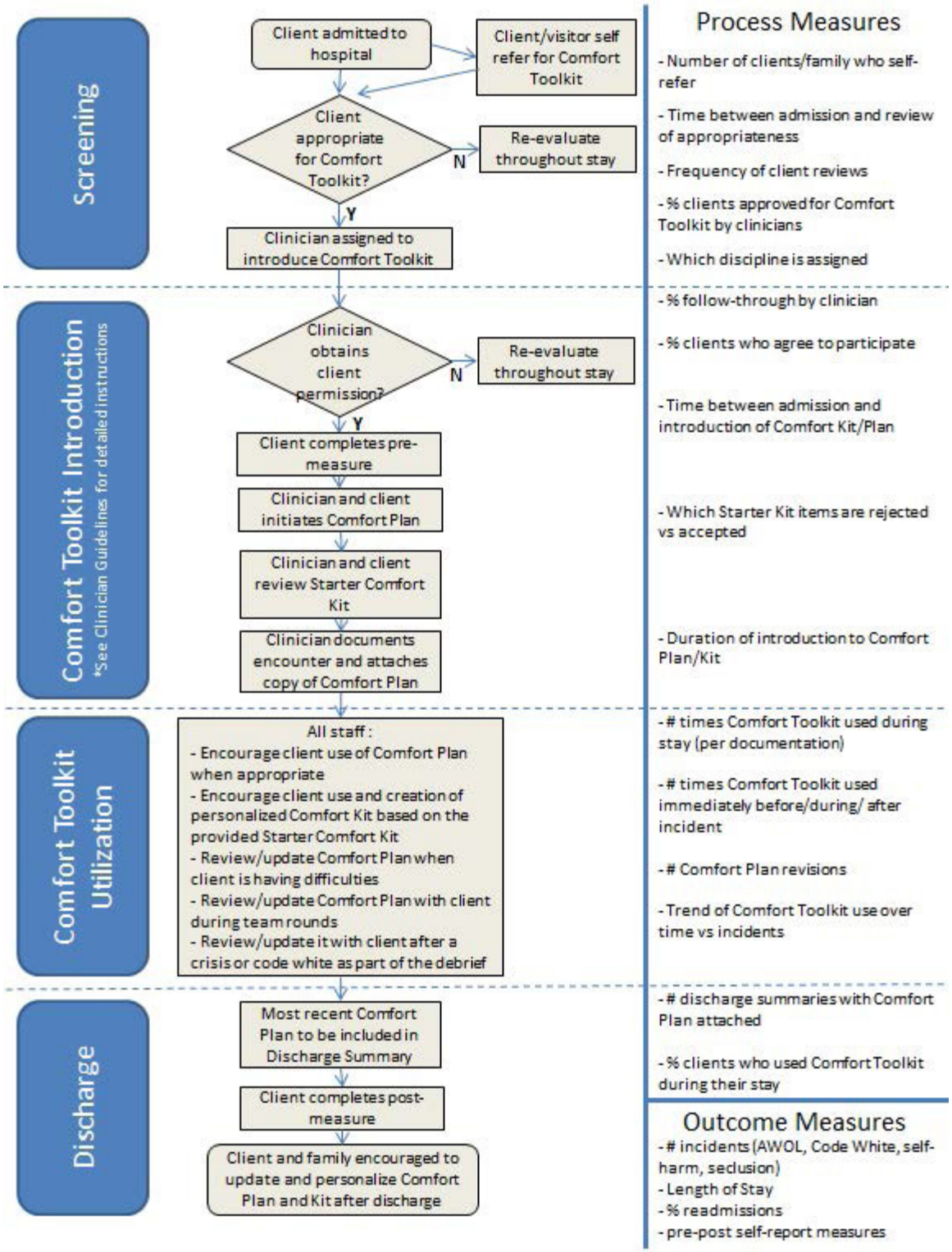


Figure 1: Comfort Plan: Collaborative Creation Guidelines and Process Measures

Vancouver CoastalHealth
Promoting wellness. Ensuring care.

Comfort Plan

Name:_____ **Date:**_____

A comfort plan is a way of identifying ways to cope with intense emotions. This plan is made by you to help you feel comfortable & safe.

When a challenge happens:

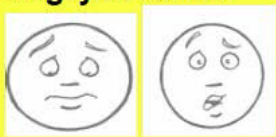
	What I can notice	What others notice	What I can do	How others can help
I am in crisis				
I am feeling a bit angry/anxious 				
I am feeling good				

Figure 2: Comfort Plan Template (Courtesy of: Vancouver Coastal Health)

Comfort Plan Guide

When a Challenge Happens… WHAT TO DO

People	Places
• Talk or sit quietly with a staff member • Something others can say to help me calm down is: ____ • Talk to another resident/friend • Call a supportive friend/family member • Be around other people	• Sit by the care team station • Go to my room • Go outside • Be in soft/low light • Go to a quiet space • Sit in the TV room
Strategies	**Activities**
• Breathing techniques • Grounding exercises • Distraction activities • Hope statements • Naming my goals • Mindfulness • Progressive muscle relaxation • Guided imagery • Meditation • Body scan • Positive affirmations • Yoga	• Listen to music/radio • Go for a walk • Run/exercise • Spend time with a pet • Spend time alone • Write/journal/read/do art • Stretch/do yoga • Clean my room • Do something to stay busy • Play music • Watch TV • Do a word search/crossword/Sudoku
Calming/comforting sensory ideas	**Alerting/distracting sensory ideas**
Touch & Temperature • Wrap myself in a warm or heavy blanket • Drink a cup of tea or warm milk *Auditory/Listening* • Listen to soft/slow music • Relaxation or meditation CDs *Vision/Looking* • Look at pictures that calm me • Watch things in nature (trees, clouds) *Olfactory/Smelling* • The smell of herbal tea or mint • The smell of chocolate • The smell of baking or other food *Gustatory/Tasting/Chewing* • Drinking tea • Chewy toffee or candy • Chocolate • Chewing gum	*Touch & Temperature* • Lie down with a cold face cloth or ice • Splash cold water on my face • Have a cold drink *Auditory/Listening* • Listen to loud/fast music • Be around people talking *Vision/Looking* • Look through magazines *Olfactory/Smelling* • The smell of coffee • Citrus smells • Shower with good smelling soap *Gustatory/Tasting/Chewing* • Drinking something carbonated • Strong mints • Crunchy foods • Sour candy or fruit

Figure 3: Comfort Plan Guide (Courtesy of Vancouver Coastal Health)

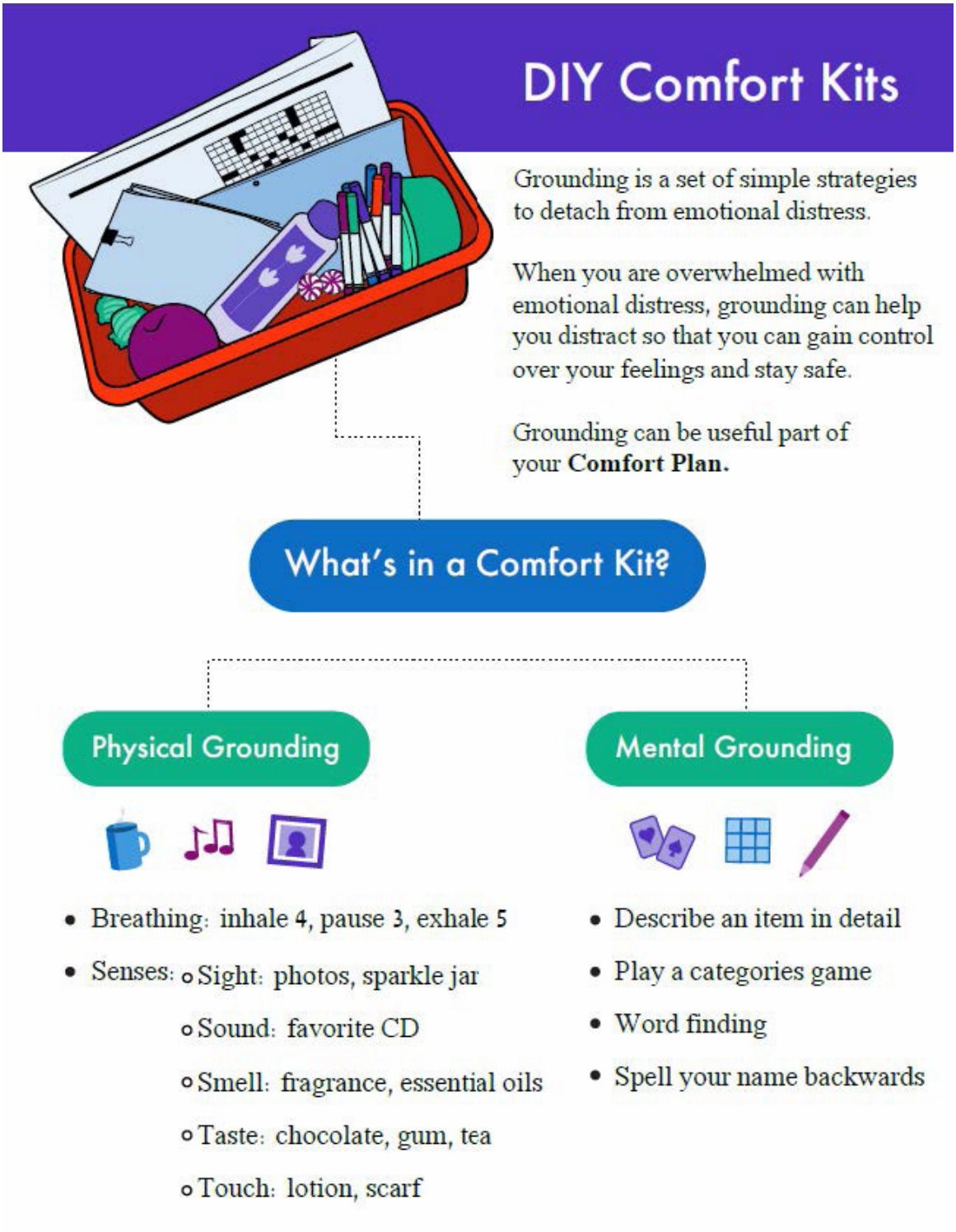


Figure 4: DIY Comfort Kits (Courtesy of Vancouver Coastal Health)

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
    - The Comfort Plan is initiated by one clinician but should be used by all clinicians managing the patient's care
    - It's important to document the status of the Comfort toolkit for other staff
    - Comfort Plan copy is attached in patient chart
        - Update with revised versions
    - Clinical notes should be written about when and how the Toolkit was used
5. Promote ongoing use of the Comfort Plan and Kit:
    - 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
    - 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

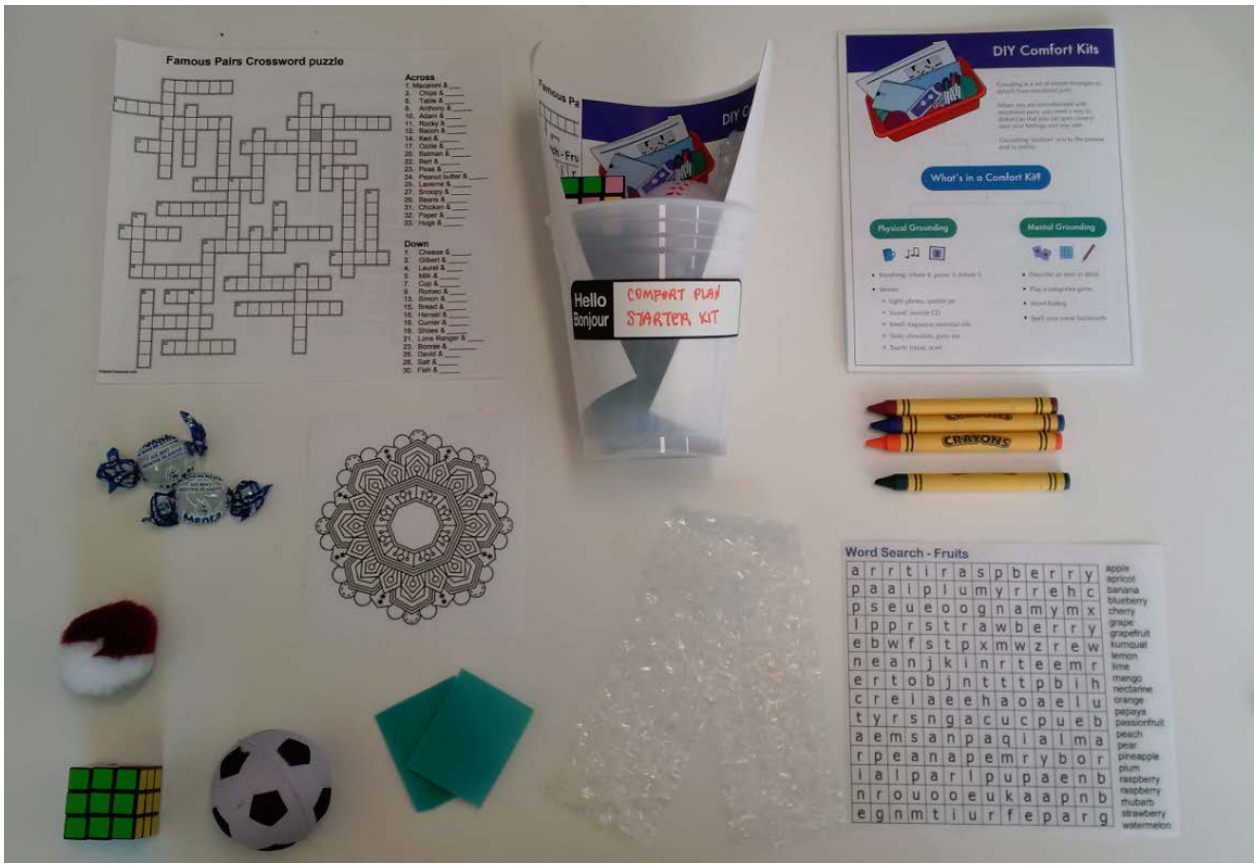


Figure 5: Example of $2 Starter Comfort Kit

Table 1: Cost of Starter Comfort Kit

Item	Price CAD (when purchased in bulk)
DIY Comfort Kit Instruction Sheet (photocopy)	$0.01
Crosswords, Word Searches, Mandalas (photocopy)	$0.04
Stress Ball	$0.90
Rubik's cube	$0.40
Pom pom	$0.05
Velcro strip	$0.05
Bubble wrap	$0.05
Crayons	$0.40
Candy	$0.05
Cup (container)	$0.05

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

System or Practice	Available Technology
Psychiatric settings vary widely, please adapt as necessary for your area	
Tech tools for building patient awareness about mood state:	
Physiological measures • Heart rate • Blood Pressure	• Mobile nursing medical cart • Smartwatch: Heart Rate Monitor • Smartphone App for measuring blood pressure or heart rate • Traditional heart rate monitors and blood pressure cuffs
Symptom rating/mood diary	• Websites and smartphone apps for tracking mood and symptoms
Tech Tools for Grounding	
Daily reminders to engage in self-care	• Smartphone App for tracking gratitude
Physical grounding	• Smartphone App for tactile sensory modulation, e.g., acupressure • Smartphone App for breathing exercises • Smartphone App for stretching • MP3, Ipod, or cellphone as a music player • Hand held video games • MP3 preloaded with soothing music • MP3 preloaded with guided meditation
Mental grounding	• Smartphone App for meditation • Smartphone App for cognitive games and exercises

The following 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?

   _____

   _____

   _____

Measuring outcomes

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 = $(AE_{baseline} - AE_{intervention}) \times patient\ days_{intervention}$

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.

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Actionable Patient Safety Solutions (APSS) #14:

Falls and fall prevention

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:

Executive summary checklist 422

What we know about falls and fall prevention 423

Leadership plan 425

Action plan 427

Technology plan 431

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Patient Safety
MOVEMENT

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Executive summary checklist

Patient falls are a major cause of inpatient injury and even death. Healthcare administration must develop, revise, and support the plan through the following actionable steps ("Preventing falls in hospitals: a toolkit for improving quality of care.", 2013; Boushon et al., 2008):

Use data to find areas for improvement

- ☐ Assess your existing fall prevention and protection from injury policies, procedures, protocols, and education in relation to current evidence and emerging research
- ☐ 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
  - ☐ 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 training for the patient and their family on preventing falls before, during, and after a patient's hospital stay (see examples at CampaignZERO.org)

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, unit manager, frontline nursing staff, 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

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. Consistently educate newly-admitted patients and their advocates on how important they are to reducing and avoiding 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; 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 people at risk for a fall and fall injuries
- The risks and benefits for the person should be considered in partnership with patients and their advocates when implementing interventions to fall prevention and protection from injury

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 (HRET, 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 interventions tailored to an individual patient's identified risks. In addition, systematic reporting and analysis of falls incidents are important components of a fall's 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 succeed 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 monitors fall risk (Degelau 2012). The tool provides the probability of an anticipated physiological fall but does not inform caregivers what to do about it (Morse 1989).

- **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. 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 ("Knowledge Translation in Health Care: Moving from Evidence to Practice", 2009). 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 (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 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 2012, Degelau 2012, France 2017, Ganz 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 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 a 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: **youtu.be/npAC2DJClgA**

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 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 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 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:
  - 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.

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

Patient-specific	Environmental	Situational	Organizational
Impaired gait Impaired cognition Forgetfulness Poor judgment Impulsiveness Sedation/recent surgery Impaired vision Weakness, especially in the legs Hypotension Depression Urinary incontinence Acute event (e.g., MI, PE) Certain medications (sedatives, opioids, SSRIs) On a new med with potential side effects including dizziness or confusion Prior history of fall/s History of vertigo Low/drop in oxygen saturation rate Normally uses a cane or walker to get around	Furniture on wheels Cluttered pathways Poor lighting Slippery floors Height of furniture Unit layout making it difficult to see patients from nurses' station Medical devices (IV poles, indwelling urinary catheters)	Leaning forward Reaching up Transferring on/off a bed or chair	Staffing: • Numbers • Knowledge • Skill mix • Attitudes Types of Policies: • Hourly rounding • Toileting schedules • Type of fall prevention program Available equipment purchases: • Bed/chair alarms • Transfer equipment • Surveillance video monitoring • Non-slip cushions • Low/very low beds • Seating

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 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/**

Leaders must plan for and incorporate a technology strategy to maximize the utilization of AI within their organization to create safer environments (for Health Solutions, 2014).

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, 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 et al., 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.

System or practice	Available technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System	
• Bed Connection to Nurse Call with priority for fall alarm	• Te Nurse call systems • West-Com • Rauland • Hill-Rom • Ascom • Hill-Rom • Linet • Stryker • Umano
• Public health reporting systems for newborn screening	• Oz Systems newborn screening or automated reporting with Oz BabyBundle

*Company has signed some form of the Open Data Pledge. Find more information on the Patient Safety Movement Foundation website: https://patientsafetymovement.org/partners/open-data-pledges/view-all-open-data-pledges/

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.

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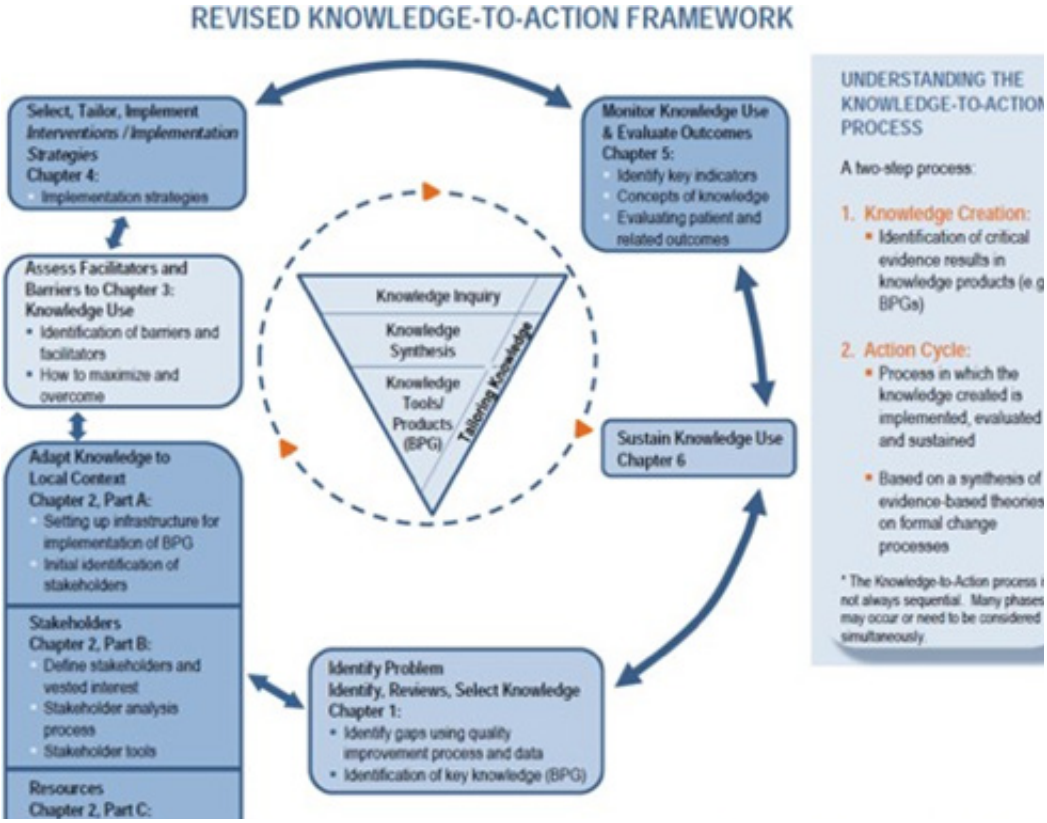
Appendix A: Revised knowledge-to-action framework



Appendix B: Toolkits and additional resources

- Agency for Healthcare Research and Quality. AHRQ. Preventing falls in hospitals. A toolkit for improving quality of care. **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. **www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/com-pubs_FallsGuidelinesCommunity**
- 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**
- Institute for Clinical Systems Improvement. Health Care Protocol: Prevention of Falls (Acute Care). **www.icsi.org. iu.instructure.com/courses/1491754/files/56997226/download?wrap=1**
- National Council on Aging. Falls and Fall-Related Injuries Among Older Adults, A Practical Guide to State Coalition Building to Address a Growing Public Health Issue. **www.ncoa.org/wp-content/uploads/Falls- Prevention-Coalition-Toolkit.pdf**
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Actionable Patient Safety Solutions (APSS) #15:

Nasogastric tube (NGT) placement and verification

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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What we know about NGT placement and verification 441

Leadership plan 442

Action plan 442

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Patient Safety MOVEMENT

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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 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 place

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
- ☐ 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
    - ☐ 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
    - ☐ 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 44 NGT misplacements into the lung from 2011- 2013 with 24 were noted as serious patient harm (Powers, Fischer, Ziemba-Davis, Brown and Phillips, 2013)
- 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, Fischer, Ziemba-Davis, Brown and Phillips, 2013)

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, Rempel, Lyman, Sevilla, Northington, Guenter, 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:
  - 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
- 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: **youtu.be/k8aH0TyJYhc**

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
- 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:
  - Take aspiration of 3-8 ml of gastric fluid to obtain specimen for pH with stylet in place
  - To remove the stylet after confirmation, instill water
  - In infants and children, you may need to instill water prior to NGT insertion to allow for stylet removal due to the narrow bore of the tube – you withdraw and waste the water before obtaining a specimen for pH measurement. Do not use normal saline to flush an NGT as it has an acidic pH.

  - Use of acid suppressing medicines is not a contra-indication to pH measurement -if the pH is > 5.5 follow the process
  - 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:
  - Follow the tube from the chest to below the diaphragm and give a visual of the tip of the NGT
  - Include a report that documents all '4 criteria':
    - 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?
  - Have a comment that the tube is appropriately placed for use
  - 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:
  - Is severely obtunded (has an altered level of consciousness)
  - Has an endotracheal tube
  - Is clinically unstable after NGT re-insertion post resuscitation
  - 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 snare – 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

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, 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 change in length of external portion of the tube
  - 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 would be a more marked difference in appearance
  - Do not use this method to try to distinguish between gastric and respiratory secretions – there is not 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 heart, lungs, or other organs)
- Visual inspection of fluid from the tube
- Observation of bubbles - this method is not reliable
- Litmus paper

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/**

System or practice	Available technology proven to show benefit	Limitations
Methods to confirm NGT placement	pH testing • The **first-line method** for bedside checking of NGT placement • Recommended cut-off point of less than or equal to 5.5 (If using whole number increments, the cut-off is less than or equal to 5)	• pH measurement can be skewed by the presence of enteral formula • It can also be unreliable if the patient is on acid suppressing medicines, but those medicines are not a contra-indication to pH testing • The clinician cannot be color blind
	X-ray • The **gold standard** for initial NGT placement • Often avoided in pediatric settings to decrease the cumulative effects of radiation exposure	• X-rays are not fool-proof • Between 2005 to 2010, 45% of all cases of harm caused by a misplaced NGT reported by the UK National Patient Safety Agency were due to misinterpreted X-rays - however, none of the cases used the '4 criteria' and relied on viewing tip placement

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.

Technology with limited evidence or unclear benefit	**Limitations**	**Research**
Biochemical markers • Pepsin, bilirubin, and typsin	Currently no bedside tests available but laboratory tests for bilirubin, pepsin and trypsin levels have been used together with pH to confirm placement	Most current research of these markers are as a proxy to discern gastric reflux from aspiration of oral secretions in critically ill patients (Schallom 2015)
Capnography/ colorimetric capnometry	• More studies are needed on capnography • It can only discern if the tube is not in the lung - does not verify tube is not in the small bowel • Typically used in a critical care setting	• A study of 100 mechanically ventilated patients that compared ausculation to capnography to detect NGT placement with abdominal radiograph found 100% agreement with abdominal radiograph. (Meyer, et al., 2009) • A meta-analysis of capnography to detect pulmonary placement of an NGT found it to be reliable in detecting accidental pulmonary placement of an NGT in mechanically ventilated patients (Chau, et al., 2011) • Another study compared capnography, auscultation to abdominal radiograph and found excellent agreement between US and radiography. Auscultation was accurate 83% when compared to radiography. Authors note capnography only confirms non-pulmonary placement. (Erzincanili, et al., 2017)

Ultrasound	• Useful to show progress of the tube through the oesophagus
	• There are issues to use it to verify that the tip is in the stomach
	• Use depends on operators who are skilled in sonography
	• Most of the research is done in critically ill adults who have larger bore feeding tubes.
		• A study of 56 critically ill adults looked at passage of the NGT from the level of the esophagus. Results showed good agreement with abdominal radiograph in52 out of 56. Some subjects required tracheal pressure to get the desired view. (Gok, 2015)
		• A study of 21 critically ill patients ages 1-18 years compared US to abdominal radiography with NGTs placed within the stomach. All US were done by the same radiologist. (Atalay 2016)
		• A study of 41 critically ill, mechanically ventilated adult patients found:
		  • Time to verification of tube placement was 46min for US vs 162min for abdominal radiograph
		  • 3 tubes were improperly placed (not defined by authors) and were all identified by US (Nedel 2017)

Electromagnetic tracing (EM)	• Depends on operator expertise in using the unit and interpreting the screen- the NHS and FDA recommend competency training for anyone using EM and use of another verification method, such as pH or radiograph • Not widely used for NGT placement in the US--most studies look at post-pyloric placement. • There are no published studies of EM use to guide nasogastric tube placement in children to date and only one study of its use to guide in adults (NICE, 2016)	• A 2013 Patient Safety Alert from the NHS describes 2 patient deaths and 2 patient events with moderate harm due to mis- interpretation of the visualization screen • In 2018, the FDA reported 51 pneumothorax with 11 deaths from January 2012 to July 2017

Visualisation technology:
IRIS camera Cardinal website
	• Newer technology more widely used in Europe
	• The tube has a camera in the tube tip.that allows for direct visualization of the respiratory and upper GI tract anatomy - the camera size in the tube tip limits use in children
	• Requires operator expertise
	• Most helpful for NGT placement as opposed to postpyloric tube placement
		• One Italian study with 20 sedated patients found:
		  • The camera showed the trachea just 35% of the time and gastric mucosa 90% of the time
		  • Use of the camera for re-verification of placement only worked for 3 days post insertion (Mizzi 2017)
		• A U.S. study of 45 patients found the camera identified gastric mucosa in 93% of insertions, and identified one tube as misplaced (Wischmeyer 2018)

Measuring outcomes

At this time, hospitals are not looking at NGT placement as a preventable complication. APSS recommends political pressure to make sure hospitals have a specific process in place so that errors do not occur.

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.

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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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What we know about person and family engagement 458

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Patient Safety MOVEMENT

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Executive summary checklist

Person and family engagement (PFE) is an underutilized resource for achieving the goal of zero patient harm. 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 patient experience and patient safety education in new-hire orientation and regular staff to ensure that expectations about PFE 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 listen to the patient and their family members' questions and concerns, and avoid being short or brief with patients
- ☐ 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 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 problem may be getting worse not better, 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)
- U.S. hospital deaths attributed to medical error are 250,000, making it the 3rd largest cause of preventable death (Makary, 2016).

Existing research still lacks the ability to reliably estimate preventable harm due to missed, wrong, or miscommunicated diagnoses. Data on harm due to medical error in non-acute care settings is purely speculation.

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.

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 organization

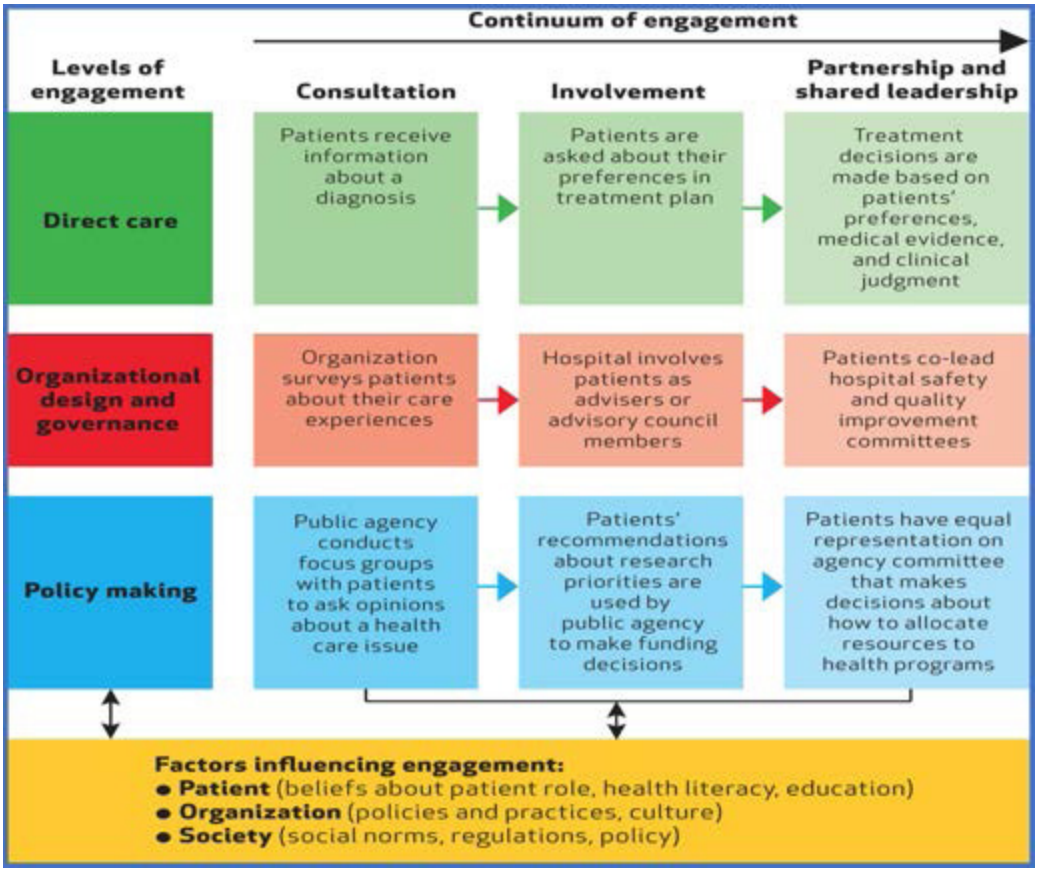

Figure 1: Framework for Patient and Family Engagement (Carman et al., 2013)

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 is also being advocated 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 & 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
    - 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 process improvement to truly be successful, leadership commitment and action are required at all levels. The board, senior leadership, physicians, pharmacy and nurse directors, managers, unit leaders, and patient advocates all have important roles and need to be engaged in specific behaviors that support staff to provide safer care.
- Safety culture and performance must be valued and reflected in compensation plans so that leaders have direct personal accountability for results

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
- 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: https://youtu.be/3idHnsslsf

Action plan

Ensure accountability

Healthcare organizations should consider using the Carman framework or an alternative framework to implement a PFE program that engages patients or their family members at 2 levels:

1. Avoiding preventable harm in their own care [Level: Direct Care], and
2. Serving as organizational advisors on operational improvement work or as contributors to Board of Governors oversight on patient safety [Level: Organizational Design and Governance]

Create protocols and provide staff training

Healthcare organizations should consider establishing a PFE infrastructure that aligns with and advances the innovations currently being driven by CMS through hospitals participating in the Partnership for Patients Hospital Improvement Innovation Networks (HIINs).

In hospitals and multi-site systems, 5 PFE metrics have been developed to ensure that hospitals have structures and practices that enable active patient and family partnership at 3 levels of the hospital setting, including: point of care, policy, and governance.

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

In non-acute care clinics or other ambulatory care delivery sites, a 6 part PFE practice plan should be considered.

1. Use of a tool to assess patient readiness to be "activated" as a partner in the patient's own care

   [Level: direct care]
2. Use of a tool to assess a patient's degree of health literacy

   [Level: direct care]
3. Use of a tool to support shared decision-making between patients and their providers
4. Establishment of a process to support medication use

   [Level: direct care]
5. Use of a technological platform to communicate with or provide information to patients

   [Level: direct care]

6. Establishing a Patient and Family Advisory Council or equivalent infrastructure to include patient input into safety improvement work

   [Level: organization design & governance]

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

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
- Email
- Texting pathways
- OpenNotes
  - 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

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
  - Innovations such as MedStar Health's "We Want to Know" platform specifically designed to prompt complaints and suggestion from users of care, show promising results:
    - Patients in the MedStar system are reporting patient safety events or aspects of events that hospital staff have failed to report ("We Want to Know patient reporting program", n.d.)

Measuring outcomes

If you want to improve PFE opportunities, researchers suggest that your organization could:

- Make access to medical records easy and transferable to unify care
- Have a patient on the hospital board
- Involve volunteers to teach how to avoid hospital infections, ask questions, and keep track of medications

Referenced resources

- PFE resources are easy to find online but it's important to incorporate them along the continuum of care
  - You can encourage PFE by providing updated resources and conversing with patients and family members about how they may utilize the information
  - The following resources have been identified as useful by patients and/or their family members to be used by the hospital:
    - An Empowered Patient
      www.EmpoweredPatientCoalition.org
    - Patient Aider
      patientsafetymovement.org/patientaider
    - CampaignZERO: Families for Patient Safety
      www.CampaignZERO.org
      CampaignZERO is a national initiative that offers free checklists to help families partner with their loved ones' medical care providers to prevent the most

common hospital acquired conditions: infections, falls, medication errors, blood clots and more. It also offers community patient safety education through its national speaker network of professional patient advocates.

- EngagedPatients:
  engagedpatients.org/
  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
- Minnesota Alliance for Patient Safety, You: Your Own Best Medicine:
  ownbestmedicine.mn
- Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families
  www.ahrq.gov/professionals/quality-patient- safety/patient-family-engagement/pfeprimarycare/index.html
  Content last reviewed April 2018. Agency for Healthcare Research and Quality, Rockville, MD
- Guide to Patient and Family Engagement in Hospital Quality and Safety. www.ahrq.gov/professionals/systems/hospital/engagingfamilies/index.html
  Content last reviewed February 2017. Agency for Healthcare Research and Quality, Rockville, MD
- AHRQ Question Builder tool for patients
  www.ahrq.gov/patients- consumers/question-builder.html
- Motivational interviewing tools. patient.sm/acp-interviewing-tools
  Access requires registration, but it is grant supported so there is no cost to users
- OpenNotes movement
  www.opennotes.org
- PfP Strategic Vision Roadmap for Patient and Family Engagement
  patient.sm/pfp-strategic-roadmap
- Harnessing Evidence and Experience to Change Culture: A Guiding Framework for Patient and Family Engaged Care (National Academy of Medicine)
  patient.sm/NAM-Patient-Family-Engaged-Care
- Four Habits
  www.ndep.nih.gov/assets/The-Four-Habits-Model-508.pdf
- American Hospital Association's Health Research and Educational Trust (AHA HRET) Patient and Family Engagement Resource Compendium
  www.hret- hiin.org/Resources/pfe/16/patient-and-family-engagement-pfe-resource- compendium.pdf

- 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
      www.ncbi.nlm.nih.gov/pmc/articles/PMC4181734/
    - The WHO Multi-Professional Patient Safety Curriculum Guide
      www.who.int/patientsafety/education/curriculum/Curriculum_Tools/en/

- Academy for Emerging Leaders in Patient Safety
  thetellurideexperience.org
- Canadian Patient Safety Institute, Patient Safety Education Program Core Curriculum
  www.patientsafetyinstitute.ca/en/education/PatientSafetyEducationProgra m/PatientSafetyEducationCurriculum/Pages/default.aspx

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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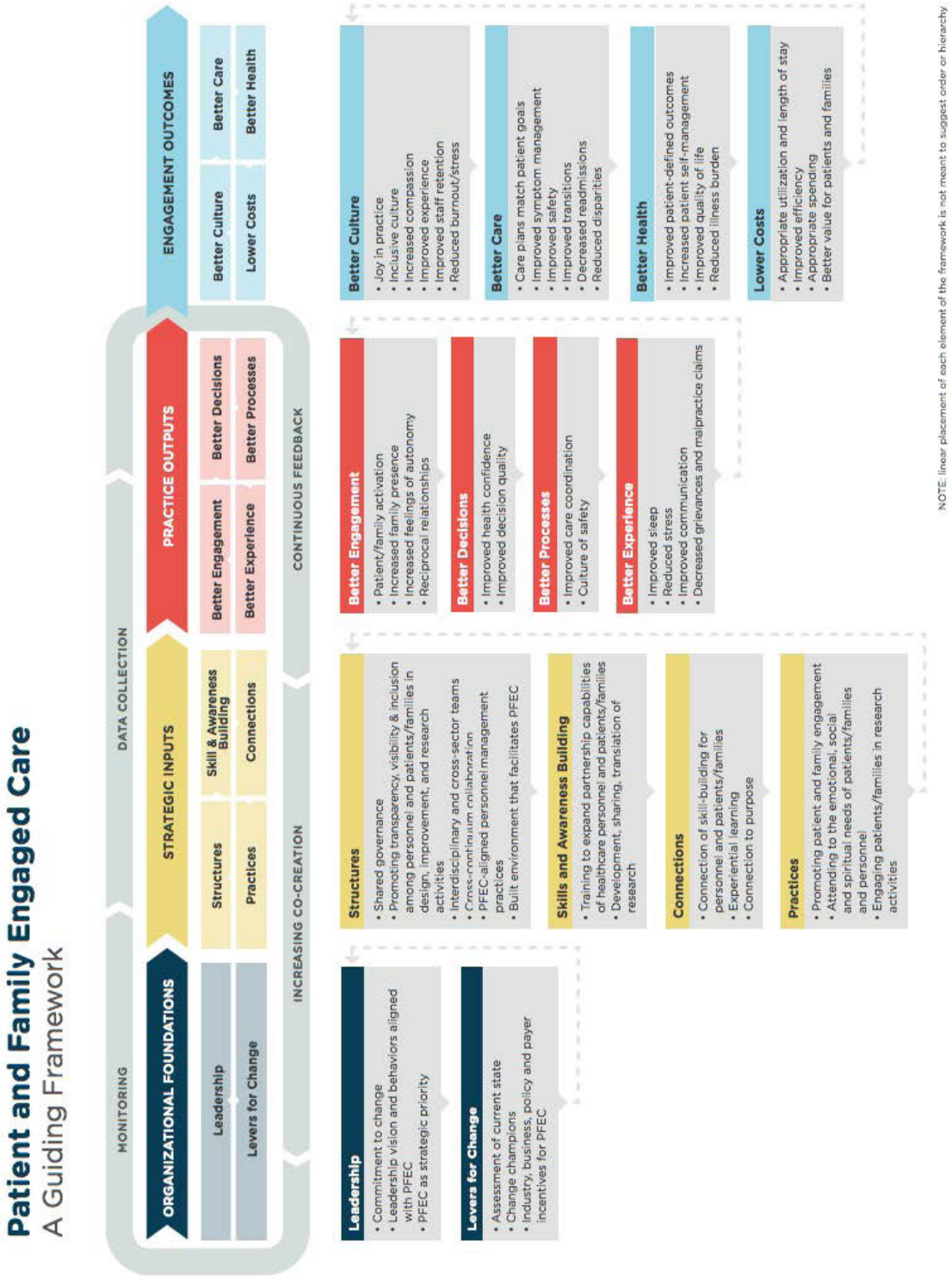
Appendix A



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