

Preventing Harm in the ICU—Building a Culture of Safety and Engaging Patients and Families

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Objective: Preventing harm remains a persistent challenge in the ICU despite evidence-based practices known to reduce the prevalence of adverse events. This review seeks to describe the critical role of safety culture and patient and family engagement in successful quality improvement initiatives in the ICU. We review the evidence supporting the impact of safety culture and provide practical guidance for those wishing to implement initiatives aimed at improving safety culture and more effectively integrate patients and families in such efforts.

Data Sources: Literature review using PubMed including evaluation of key studies assessing large-scale quality improvement efforts in the ICU, impact of safety culture on patient outcomes, methodologies for quality improvement commonly used in healthcare, and patient and family engagement. Print and web-based resources from leading patient safety organizations were also searched.

Study Selection: Our group completed a review of original studies, review articles, book chapters, and recommendations from leading patient safety organizations.

Data Extraction: Our group determined by consensus which resources would best inform this review.

Data Synthesis: A strong safety culture is associated with reduced adverse events, lower mortality rates, and lower costs. Quality improvement efforts have been shown to be more effective and sustainable when paired with a strong safety culture. Different methodologies exist for quality improvement in the ICU; a thoughtful approach to implementation that engages frontline providers and administrative leadership is essential for success. Efforts to substantively include patients and families in the processes of quality improvement work in the ICU should be expanded.

Conclusions: Efforts to establish a culture of safety and meaningfully engage patients and families should form the foundation for all safety interventions in the ICU. This review describes an approach that integrates components of several proven quality improvement methodologies to enhance safety culture in the ICU and highlights opportunities to include patients and families. (*Crit Care Med* 2017; XX:00–00)

Key Words: critical care; harm reduction; patient engagement; patient safety; safety culture

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Preventable harm remains a major contributor to ICU morbidity and mortality despite immense efforts at both the local and national level (1). The landmark report from the Institute of Medicine “To Err is Human” estimated that up to 98,000 lives are lost per year due to medical errors in the United States alone (2). A more recent review suggests the number of deaths due to preventable harm in hospitalized patients may be as high as 400,000 per year and that between 2 and 4 million nonlethal preventable adverse events occur each year (3, 4). Although both of these studies suffered from methodologic concerns and the number of people dying needlessly is sadly unknown, preventable harm remains a significant problem. Medical errors and deaths due to preventable harms are more common in the ICU due to the severity of illness, complexity of care, and number of therapies provided in this environment (1, 5, 6).

Healthcare is broadening the types of harms that are deemed preventable. For example, central line-associated bloodstream infection (CLABSI), ventilator-associated pneumonia (VAP), delirium, and venous thromboembolism, once considered inevitable, are now largely deemed preventable, though still account for a large share of preventable harm in the ICU. In addition, loss of respect and dignity was previously not considered a harm but is emerging as an important, preventable harm (7, 8). The most successful large scale efforts to reduce harm in the ICU have included programs that focus on creating a culture of safety (9). Establishing a successful quality improvement (QI) program in the ICU requires building a foundation for success by first creating a culture of safety that effectively and meaningfully engages clinicians, patients, and families. Engaging patients and families in safety culture is of utmost importance since patients have been shown to be a crucial source of information in the reporting of adverse events and can offer insights not available through traditional mechanisms (10). Successful efforts to reduce harm generally start with the goal of zero harm and then work backward to design and implement a multifaceted intervention, working at multiple levels in the organization, to realize that goal. This review will outline the evidence that positive safety culture has a meaningful impact on clinical outcomes and QI efforts in the ICU, describe an approach to enhancing safety culture which integrates commonly used QI methodologies, and highlight mechanisms to engage patients and families as partners in delivering safe care.

SAFETY CULTURE MATTERS

One of the most successful ICU QI projects to date was the Michigan Keystone Project which focused on improving a number of aspects of ICU care including reducing the rate of CLABSI in greater than 100 ICUs across Michigan (9). This intervention focused not only on implementing and standardizing simple practices that were already known to reduce the incidence of CLABSI and VAP but also incorporated interventions that addressed the complex social structure of the ICU in order to improve the safety culture. The investigators began by launching the Comprehensive Unit-based Safety Program (CUSP) in the ICUs—a QI framework focused on safety culture that engages both frontline providers and senior leadership in using a systematic approach to prevent harm (11). They subsequently addressed workflow issues, created and implemented a checklist of safety interventions for central line insertion, tracked, monitored, and shared data, and empowered all ICU staff to intervene if providers did not adhere to the checklist components. In the end, not only did the project dramatically reduce the incidence of CLABSI during the study period, but also demonstrated improvement in teamwork climate and safety culture as assessed using the Safety Attitudes Questionnaire (SAQ) following implementation of CUSP (11). Both the reduction in CLABSI and the improvement in safety culture were sustained over time (11, 12). In addition, expected mortality was reduced beyond that expected by the elimination of CLABSI (13).

An analysis of the Michigan Keystone project concluded that a critical component that led to its success was reframing CLABSI as a “social problem,” allowing for the ICU team to “accept collective responsibility for their outcomes.” The authors also cited using the central line insertion checklist as a social tool to overcome the traditional hierarchical structure and thus empower nurses to speak up and correct physician behavior (14). In fact, given the efficacy of the individual interventions used in the bundle, some authors have postulated that a failure to reduce the rate of CLABSI would have been more indicative of a failure of the program to change provider behavior than a failure of the bundle itself (15). The authors also highlight the importance of integrating local, unit-based teams that offer “grassroots features” with senior program leadership (14). By first focusing on improving the safety culture of the ICUs in the study, the authors were able to effectively implement evidence-based approaches to reduce harm and to sustain them over time. The Keystone program was spread state by state across the United States. Today, through the efforts of many, ICU CLABSI is down 80% in U.S. hospitals (16).

Positive measures of safety culture have been associated with lower rates of adverse events in other settings, as well (17, 18). In a cross-sectional study of 91 hospitals, those that scored better on measures of safety climate had a lower relative incidence of adverse events (17). Importantly, the authors also found that positive perceptions of patient safety climate as reported by frontline personnel were more strongly associated with a lower risk of experiencing safety events than perceptions reported by senior managers (17). A similar analysis of survey data from 179 hospitals found that a more positive patient safety culture was associated with fewer adverse events (18).

Interventions designed specifically to improve safety culture can have meaningful clinical impact on patient safety. In a large, urban children’s hospital, the implementation of a comprehensive patient safety program focused on improving safety culture resulted in substantial reductions in preventable harm, hospital mortality, and associated costs (19). The program, based on the Institute for Healthcare Improvement (IHI) model for improvement, included safety training for all staff and implementation of specific programs to improve the safety culture. These included the creation of a “safety coach” program to train and support frontline providers and the creation of “multidisciplinary microsystem-based teams.” In another intervention targeting 118 ICUs in Brazil, the implementation of a QI framework consisting of education, the use of checklists, clinician prompts, and goal setting during multidisciplinary rounds demonstrated improved adherence to numerous evidence-based practices known to reduce harm in the ICU and improved measures of teamwork and safety culture but did not result in improved mortality (20).

In contrast, an intervention that sought to implement the Society of Critical Care Medicine “ABCDE bundle” across five ICUs included a robust education component for providers (21). However, the authors describe significant barriers to adoption of the bundle that related to safety culture. They cited the power differential between physicians and other providers,

the belief among some in the ICU that the bundle was only beneficial to inexperienced providers, and a lack of adoption by some physicians. This highlights the critical importance of safety culture in creating a fertile environment for change that extends beyond efforts aimed at provider education.

Indeed, improvement in safety culture has also been shown to be associated with greater impact of a surgical QI program. Use of the Surgical Safety Checklist reduced both complications and mortality in patients undergoing noncardiac surgery across a diverse group of hospitals (22). An analysis of the safety culture at each study site was undertaken and revealed significant improvements following implementation (23). Interestingly, the change in perception of safety climate and teamwork was correlated with the degree of improvement in both mortality and complications suggesting that improving safety culture enhances the impact of a QI intervention.

CREATING A CULTURE OF SAFETY IN THE ICU

An ICU environment optimally primed to deliver safe care is an ideal shared by all ICU clinicians, staff, and managers and is an expectation of patients and families. Several established methodologies exist to organize and support QI and safety work to achieve a culture of safety. Examples of these methodologies include Lean management (originating from the Toyota

Production System), IHI-QI, and CUSP, each with extensive applications in critical care and healthcare, in general (24–26). Each of these methodologies includes principles of strong system design, the goals and benefits of which may extend beyond safety to include high efficiency and value. These principles enable organizations to perform with high reliability in the complex healthcare system while engaging those who interact with the system. A strong culture of safety forms a solid foundation for continuous improvement work.

Common principles span all three methodologies despite differing terminology and techniques (Table 1). For example, each emphasizes mistake-proofing—that is, designing systems that make errors impossible. In Lean, this is called “poka-yoke” and is often accomplished through automation; complementary IHI and CUSP standardization tools include checklists, independent checks, and forcing functions to prevent “defects” from causing errors and harm (25–27). Similarly, rapid cycle improvements—such as Plan-Do-Study-Act (PDSA)—are used as tests of change across methodologies (25). Conversely, although all three employ frontline clinicians and staff to develop solutions to identified problems, CUSP also relies on frontline staff to identify opportunities for improvement work (24). Any of these methodologies may be used to foster a culture of safety and as a platform for continuous improvement; therefore, level of institutional support, available resources, implementation scope,

TABLE 1. Comparison of Quality and Safety Methodologies

Domain	Lean (26)	Institute for Healthcare Improvement-Quality Improvement (25)	Comprehensive Unit-Based Safety Program (24)
Typical level of implementation	Organization/institution	Any	Individual unit
Improvement model	<ul style="list-style-type: none"> Continuous improvement (Kaizen) workshops within value streams Understand the current situation in the workplace (gemba): observe and gather data, review the value stream, perform time studies Develop improvements: generate ideas Test ideas and implement the new plan: plan-Do-Check-Act Develop new standards 	<ul style="list-style-type: none"> Model for improvement Aim: What are we trying to accomplish? Measures: How will we know that a change is an improvement? Changes: What changes can we make that will result in improvement? Rapid cycle improvement: Plan-Do-Study-Act 	<ul style="list-style-type: none"> Learning from defects process What happened? Why did it happen? What will you do to reduce the risk of recurrence? How will you know the risk is reduced?
Team members	<ul style="list-style-type: none"> Frontline clinicians and staff Patient/family member(s) Fresh eye(s) Team leader Workshop leader Process owner(s) Project sponsor(s) Executive sponsor(s) Lean coach 	<ul style="list-style-type: none"> Day-to-day leader Technical expert Clinical leader Project sponsor 	<ul style="list-style-type: none"> Frontline clinicians and staff Patient/family member(s) Unit champion (unit team lead) Content specialist(s) Project champions Stakeholders Nurse or unit educator(s) Unit manager/director Hospital safety/quality officer(s) Executive sponsor

(Continued)

TABLE 1. (Continued). Comparison of Quality and Safety Methodologies

Domain	Lean (26)	Institute for Healthcare Improvement-Quality Improvement (25)	Comprehensive Unit-Based Safety Program (24)
Improvement origin and target	<ul style="list-style-type: none"> Institutional strategic plan Value stream map Team charter (A3-T document) Target progress report and results sheet (A4-KW document) 	<ul style="list-style-type: none"> Patient safety leadership WalkRounds Nonpunitive reporting system Selecting aims <ul style="list-style-type: none"> Safe Effective Patient-centered Timely Efficient Equitable 	<ul style="list-style-type: none"> Staff Safety Assessment (two question survey) completed by frontline clinicians and staff Safety issues worksheet for senior executive partnership
Strategies	<ul style="list-style-type: none"> 5S (sort, set in order, shine, standardize, sustain) Eliminate waste (muda) <ul style="list-style-type: none"> Transport Inventory Movement Waiting Overproduction Overprocessing Defects Level production (heijunka) Just-in-time <ul style="list-style-type: none"> Keep up with demand ("takt" time) Use visual signals (kanban) Pull from downstream Create flow Intelligent automation (jidoka) <ul style="list-style-type: none"> Build in quality Visually broadcast problems (andon) Mistake-proof (poka-yoke) Stop-the-line (e.g., upon safety concern identification) Determine root cause (five whys) Establish standard work and standard work in progress Policy deployment (hoshin kanri) 	<ul style="list-style-type: none"> Change concepts <ul style="list-style-type: none"> Eliminate waste Improve work flow Optimize inventory Change the work environment Producer/customer interface Manage time Focus on variation Error proofing Focus on the product or service 	<ul style="list-style-type: none"> Principles of safe design (applied to technical and teamwork) <ul style="list-style-type: none"> Standardize Create independent checks Learn from defects Address system-level contributing factors Identify defects by creating situational awareness (sensemaking) Seek diverse and independent input Apply teamwork and communication tools Use strong error-prevention strategies (e.g., forcing functions)
Study using methodology and outcomes	McCulloch et al (28): A "Lean" Intervention in a Surgical Emergency Unit (patient safety processes, adverse events)	Brilli et al (19): Implementation of a Comprehensive Patient Safety Program in a Children's Hospital (preventable harm and associated costs, hospital mortality)	Pronovost et al (9, 11): Michigan Keystone Project (central line-associated bloodstream infection, safety culture)

and affiliations may guide the selection of one or a combination of strategies. Reengineering is another form of process improvement that is more drastic in its approach and involves radical redesign of processes in contrast to the incremental changes in the more traditional QI methodologies described in this review.

The model for organizational change outlined in the Michigan Keystone project used a simple construct of four Es (Engage, Educate, Execute, and Evaluate) to lead change at the front lines and in administration (11). Using this model as a guide, we expand upon it to outline a general framework for establishing a culture of safety in the ICU, merging components from each of the three aforementioned methodologies.

Engage

The first step of creating a culture of safety is engaging key stakeholders as successful culture change requires significant buy-in. Creating a lasting culture of safety necessitates engagement from frontline clinicians and staff to middle managers to the executive level. Engaging frontline clinicians may be accomplished by demonstrating a need for safe systems through unit-specific narrative examples and empowering them to enact change by equipping them with tools to improve the systems that support their work. Engagement may also be impacted by team structure. Involving frontline clinicians in leadership roles (e.g., as Unit or Project Champions in CUSP), taking on

team-based projects, and fostering transdisciplinary collaboration are integral to creating a culture of safety. Referencing the organization's strategic plan and engaging an executive sponsor who can help align improvement work with institutional priorities can help to garner institutional support. Engagement of the executive sponsor can be sustained with executive presence in the workplace (e.g., WalkRounds, workplace [gemba] walk, and patient safety leadership rounds) (24, 29, 30). Because there is potential for frontline clinicians to initially feel uncomfortable with executive presence, it is important to emphasize that WalkRounds focus on observing processes rather than people; they should be used to inspire improvement opportunities and conducted in a positive and nonpunitive manner.

Educate

Regardless of the methodology used, training material is readily available both online and in print. As many ICU stakeholders as possible should receive safety education specific to their role in safety, trainees include frontline clinicians and staff of all disciplines, managers, executive sponsors, and patients and families including those who are part of a patient-family advisory council (PFAC), which is discussed later. At a minimum, safety culture training should cover the science of safety and principles of safe design, terminology (e.g., defect, "harm"), systems thinking, waste elimination, implementation science, communication, and shared decision-making (27, 29).

Given that positive safety culture is "characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures," training should include communication and teamwork skills to foster respect for peers, subordinates, patients, and families alike (31). A robust safety culture embraces viewpoints from all disciplines and ranks and flattens the rigid hierarchy often present in medicine. In a culture of safety, anyone, including a patient or family member, is empowered to "stop the line" when "something does not feel right (26)." Collaboration between people of different disciplines and ranks on specific projects may foster the development of respect for one another as they work toward the common, overarching goal of safety.

Execution

The essential component of a successful culture of safety is a framework that empowers and enables frontline clinicians, staff, and even patients and families to prevent harm by improving processes. First, establish a system for project idea submission—this can be as simple as a suggestion box located somewhere in the ICU. Project selection may be done by weighing unit- and organization-specific factors, such as institutional priorities, scope, potential for harm, prevalence, and perceived benefit. It may be prudent to select "low-hanging fruit" for "early wins" in a new safety program but large initiatives can also be successful. Tracking project progress with visual aids (e.g., *Kanban* or huddle boards) is one way to be transparent in project selection and progress, create accountability, and promote engagement (32).

The project team should include a representative from each discipline involved in the specific process being evaluated and those who will be affected by its solution. Team members should include frontline clinicians and staff with expertise in the area, managers, and an administrative leader who is ultimately responsible for the project's success and whose primary role is to remove barriers (33). The intentional use of transdisciplinary teams for focused problem solving is one mechanism by which a more collaborative atmosphere can be fostered.

Project execution using a structured process will reinforce educational concepts and guide intervention design and implementation. For example, the CUSP "Learning From Defects" tool will direct team members to identify contributing factors and develop high-yield solutions (27). Other examples include "Kaizen" workshop "standard work" and the IHI model for improvement (25, 26). Both large- and small-scale improvement ideas should be encouraged. All methodologies use small tests of change using the PDSA cycle as a means of incremental, continuous improvement.

Evaluate

Evaluation of safety culture and specific project impacts are essential to achieve and maintain a culture of safety in the ICU. Safety climate can be assessed using a validated survey tool, such as the SAQ, which encompasses domains of teamwork climate, safety climate, perceptions of management, job satisfaction, working conditions, and stress recognition (34). Measurement prior to and following program implementation may highlight the impact on safety culture, especially as coimplementation of a CUSP program with a QI intervention has been associated with greater gains in safety culture, working conditions, and job satisfaction (35, 36). The quantitative utility of incident report data is limited by underreporting. However, qualitative analysis of data, including near-misses, may contribute to safety assessment.

As a safety culture and the systems that support it mature, improvement work becomes inherent and integrated. High-reliability organizations in other industries view safety not as a series of projects but as an integrated operating management system that includes governance, leadership, management, information technology, capacity building, human resources, and learning, all working together to ensure safety. Healthcare is just beginning to explore these integrated models (37). Sustaining a culture of safety requires dedicated leadership and an infrastructure that may require resource allocation. Improvement projects should include evaluation for impact on project-specific safety aims, and these measures may be indicative of overall safety culture. Disseminating solutions and results of improvement work back to clinicians and staff can enhance engagement and foster a sense of empowerment. Additionally, these results can be used to demonstrate efficacy locally and to advocate for support from administrative leadership. In an ideal scenario, both senior leaders and frontline clinicians are able to see the benefits of such efforts in a tangible way.

ENGAGING PATIENTS AND FAMILIES IN THE CULTURE OF SAFETY

Patient and family engagement (PFE) has been defined as “patients, families, their representatives, and health professionals working in active partnership at various levels across the healthcare system—direct care, organizational design and governance, and policy making—to improve health and health care (38).” PFE requires a multidimensional framework within a continuum of engagement—consultation, involvement, and ultimately partnership/shared leadership—across the different levels of the healthcare system. Engaging patients and families in safety work in the ICU represents an underutilized but critical opportunity to enhance culture. This requires incremental work to achieve deep integration into routine care processes.

In modern practice, patients are routinely engaged in their own care through education about their health status and shared decision-making regarding treatment plans. Brown et al (39) have expanded on the definition of PFE and described five core components of PFE in the ICU: collaboration, respect and dignity, activation and participation, information sharing, and decision-making. The National Patient Safety Foundation has identified patients and families as a key target for engagement in a culture of safety (29, 40). Extensive efforts are ongoing to use technology in this domain. The creation of electronic portals allows patients to access parts of their medical record such as laboratory results and provider documentation. More work is needed to define optimal methods of engagement, especially for patients/families without access to or familiarity with technology and patients without family or surrogate support. Other opportunities to engage patients and families in care include involvement on interdisciplinary rounds, regular two-way communication with healthcare teams, shared decision-making, and open ICU visitation hours. Maintaining open ICU access and family presence in the setting of resuscitation events has been associated with decreased anxiety and posttraumatic stress disorder among family members with minimal disruptions in organization of care highlighting the impact these changes can affect (41, 42).

However, integration of patients and families into QI efforts has been limited. The next crucial step is including them in organizational design and governance in order to enhance safety and the patient experience (43). This must go beyond the use of surveys, which have already been broadly adopted as a means to consult patients about their experience. It requires including them as members of a hospitals’ Board of Trustees and committees, and as advisors and partnering with them as participants and leaders of QI efforts in the ICU setting. But, this requires education and support for staff to adapt to this new paradigm (44). One mechanism to engage patients and families in care organization is by establishing PFACs (29, 45). A PFAC is a group of patients, family members, and clinicians who partner to improve safety and the patient experience. Organizations seeking to create a PFAC can reference a step-by-step toolkit developed by the Agency for Healthcare Research and Quality (40). It is important, however, to not only establish a PFAC but also empower the council to pursue meaningful projects. Continued expansion of patient and family involvement into all

areas of care design and improvement has been recommended, as well as engagement with development of health policy (45).

CONCLUSIONS

Preventable harm remains a significant challenge in contemporary ICUs. Both traditional clinical harms and newly recognized nontraditional harms have significant effects on patient and family outcomes after critical illness. A strong safety culture is an integral part of successful quality initiatives and is required to achieve a sustained improvement in patient outcomes. Interventions designed to improve safety culture in the ICU should therefore form the foundation of a comprehensive patient safety program. Culture change has been described as an “evolutionary cycle” and requires sustained engagement in a multifaceted, collaborative manner across multiple levels of an organization (46). Numerous methodologies exist which can provide a framework for safety work, but a thoughtful approach to implementation is required to achieve effective and sustainable change. Finally, engaging with patients and families both at the individual and at the organizational level will offer substantial impact on the patient and family experience and also on the safety culture as a whole.

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Appendix 1: Additional Project Emerge Collaborators

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