CHAPTER 10 ■ QUALITY ASSURANCE, SAFETY, AND OUTCOMES

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Several Institute of Medicine (IOM) reports raised the nation’s awareness about a significant problem with patient safety in health care (1,2). These reports stated that the number of deaths attributed to medical errors per year is between 44,000 and 98,000, and highlighted that the systems in which patients receive care were to blame rather than frontline caregivers. While many efforts have been made to improve patient safety, there is still little evidence showing systematic improvements in safety since these IOM reports (3). However, efforts have been severely limited by a scarce understanding of the science of patient safety and a lack of rigorous methodologies to design and implement changes and monitor progress.

Patient safety is a broad and relatively new area of research that cannot be covered in one chapter. Thus, regulatory strategies and details of error reporting will not be covered herein. The goal of this chapter is to present a practical framework infused with an evidence-based medicine approach that health care professionals may use to implement patient safety improvement efforts. To accomplish this goal, we will begin by explaining the science of patient safety, which is the foundation for understanding where errors occur and how to identify the factors contributing to these errors. After presenting this foundation, we will review a model with four active or latent failures, but the avenues to communicate these failures for system redesign either are not known or are not available.  

SCIENCE OF PATIENT SAFETY

Similar to any field of investigation, there is a science to patient safety that warrants understanding in order to effectively and efficiently research safety in health care organizations. A summary of the tenets of the science of safety includes that humans are fallible, broken systems—rather than individuals—allow errors and leaders have the power to fix broken systems (Table 10.1). For this science, a system is a set of interdependent elements that interact to achieve a shared aim. There are two human elements that interact within a system: The frontline staff, who does the work, and management, who has the power to design, control, and redesign the work. In order to fix a broken system, we must first identify the failure(s). Over a decade ago, James Reason, among others, introduced the human factor’s analysis and classified system failures as either active or latent (4). Active failures are actions involving direct patient contact by frontline staff that have an immediate adverse effect on patients. These failures occur closest to the patient and are not a reflection of a health care worker’s professional ability. Latent failures are managerial or organizational in nature in which the adverse event is not immediately evident. Frontline caregivers are often aware of active and latent failures, but the avenues to communicate these failures for system redesign either are not known or are not available.
There are safety mechanisms inherently built into health care by nature of its purpose—to improve an individual's health. For example, medications are used to relieve symptoms or resolve an illness. Patients may have a medication allergy—the presence and nature of which is a ubiquitous question of medical practice. Medications are used to relieve symptoms or resolve an illness. Patients may have a medication allergy—

The science of safety teaches that:
- Fallibility is part of the human condition.
- We cannot change the human condition.
- Harm is the result of a cascade of broken systems.
- Therefore, in order to improve safety, the system must be the focus, rather than individuals who make errors.
- Individuals can change the systems under which people work.
- We must focus on interpersonal communication, and accept the responsibility for the system in which we work.
- Leaders control the potential to change systems.

A Medication Error Story

A patient is administered ampicillin despite a documented allergy to penicillins. On cursory review, the physician who wrote the order and the nurse who administered the medication are at fault because they failed to remember, or check for, any medication allergies. Further, multiple caregivers not involved in the event condemned the negligent actions of these bedside caregivers.

Detailed Investigation

However, the event needed a more in-depth investigation with appropriate lenses to identify the system failures that resulted in this error. First, let us review the circumstances leading up to the error through the eyes of the caregivers involved.

The patient was exhibiting signs of pneumonia. The bedside nurse knew that administering an antibiotic within 1 hour would dramatically improve the patient’s outcome, and timely antibiotic administration a core measure for pneumonia therapy mandated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). On further discussion with the staff, investigators uncovered that the nurse’s concern over administering the antibiotic quickly was perpetuated by a broken fax machine and tube system. This was troubling because orders were faxed to pharmacy, and medications were sent from the pharmacy through a tube system for a quick turnaround. In addition, the person employed to run errands had been cut to save money. Because the system to obtain medications quickly failed, the nurse borrowed the ampicillin from another patient.

Analysis

This case illustrates how each step aligned to achieve a catastrophic outcome. Unfortunately, by borrowing the antibiotic from another patient, the pharmacy was bypassed and a crucial safety check of potential medications allergies was missed. This example is powerful because:
- It demonstrates the frontline caregiver’s commitment to quality and patient safety (i.e., timely antibiotic administration for pneumonia).
- It uncovers the real defects that resulted in the event (i.e., broken fax, broken tube system, runner abolished, pharmacy safety check bypassed).
- It provides obvious solutions to fix the problem (i.e., fix the fax machine and tube system, and consider reinstating the runner position).

It is important to recognize that fixing broken systems often takes resources. Health care organizations must consider the marginal costs and benefits of implementing—as well as not implementing—patient safety initiatives. Thus, it is important to have a system to prioritize where the greatest hazards exist. Indeed, in the real world, correcting one problem may introduce new hazards (unintended consequences) or—due to the consumption of scarce resources—result in not correcting another. As such, organizations should ensure that the impact of their patient safety improvement efforts is evaluated.

As illustrated in the above example, systems in health care are exceedingly complex. Efforts to improve a system are often difficult to implement and can introduce new hazards.
Frontline caregivers are not the only individuals that are blamed for mistakes. Bad outcomes are often blamed on a patient’s medical condition or age (e.g., too old or too young), complexity of an operation (e.g., multiple-procedure operation), or devices in place that are sources of infection (e.g., ventilator). Nevertheless, the science of safety has taught us that many bad outcomes traditionally attributed to patients may be caused by system factors that influence the organization and delivery of care. For example, intensive care unit (ICU) physician and nurse staffing, teamwork, and communication have been shown to impact patient mortality (5,6).

**Pearls for Quality and Safety Initiatives**

Through our efforts to improve safety in health care, we have learned many lessons:

- First, experiences from large health care organizations have taught us that the context in which care is delivered (culture) is a key element in making safety a reality.
- Second, safety interventions must be goal directed and patient centered. Small-scale efforts that target a particular unit and subpopulation of patients (e.g., ICU) are more often successful than large-scale efforts that try to improve care throughout a health system.
- Third, frontline caregivers must understand the science of safety and evaluate safety risks with lenses that see hazardous systems, and not incompetent people.
- Fourth, the efforts of frontline staff must be concrete and goal oriented, with a measurable intervention or outcome.
- Fifth, local leaders need to understand the science and culture of safety and support the efforts of frontline caregivers.

**HOW TO EVALUATE PROGRESS IN PATIENT SAFETY**

**Measuring Safety**

The first step toward improving patient safety is the ability to measure progress to improve patient safety. Health care currently has few scientifically sound or feasible measures or the tools required to accomplish this task. We have borrowed tools from other disciplines—for example, organizational psychology, sociology, and human-factors engineering—that have developed basic safety-related principles. As Brennan et al. noted in a recent article (7), health care has borrowed the basic science of safety from other disciplines, but needs to further develop the tools required to accomplish this task.

To quantify improvement one must measure and remeasure to show positive change. Unfortunately, patient safety efforts cannot always be evaluated with a valid rate. To be valid as a rate, a measure must have a clearly defined numerator (i.e., population at risk), and method of surveillance in which bias is minimized. With safety, most events are rare, what we are measuring is not clearly defined, and our surveillance systems are poorly developed; all of these introduce bias (14).

Moreover, the variables that we do try to measure coexist with other variables that also affect patient safety and make isolation more difficult. For example, measuring caregiver compliance with effective use of briefings before critical tasks can be affected by teamwork, communication, or the culture of safety (15). Consequently, health care has turned to the Donabedian model of quality to measure safety (16). This model evaluates structure (i.e., organization of care), its connection to process (i.e., what is done), and influence on outcomes. We have added safety culture (i.e., the context in which care is delivered) to this model because of its importance in effectively implementing any interventions. While most measures of quality focus on process or outcomes, many patient safety measures focus on the structure (e.g., staffing) and culture (e.g., staff perceptions of safety) in which the process of care occurs. In addition, cultural variables, such as communication and teamwork, are doubly important, given that both are leading contributing factors in all sentinel events (www.jointcommission.org).

The IOM expressed the need to address culture, and the National Quality Forum (www.qualityforum.org) recommended that health care organizations measure culture annually (1). The Safety Attitudes Questionnaire (SAQ) is a valid and reliable instrument that assesses the frontline caregiver’s perceptions of safety culture (17). Furthermore, results from SAQ administrations at the Johns Hopkins Hospital and in over 70 hospitals in the Michigan Keystone ICU project (18) found that better perceptions of teamwork and safety in a clinical area can be achieved through specific interventions (19,20). In addition, these interventions (e.g., daily goals checklist, care bundles, and the Comprehensive Unit-based Safety Program) have been associated with lower rates of nurse turnover, catheter-related bloodstream infection (CRBSI), decubitus ulcer, and in-hospital mortality (21,22).

To move forward with patient safety efforts, a measurement model is needed to determine whether patients are safer. The model described below is adapted from Donabedian, with the addition of a safety culture parameter. Researchers at the School of Medicine at Johns Hopkins University developed and tested this model in over 200 ICUs across the United States as part of ongoing collaborative projects (18,23).

**How Do We Know That We Are Safer?**

The key question to reliably answer, particularly as we implement improvement interventions, is whether patients are safer. Despite all of the publicity generated by IOM reports on patient safety and all of the efforts made to improve patient safety, many question the empiric evidence claiming that safety has improved (7,14,24,25). With a few exceptions, most efforts to date do not provide a clear answer as to whether patients are safer now than at the start of the patient safety movement. This deficiency is partly due to the relative novelty of safety as a science, as well as the methodologic challenges of rigorous measurement and data collection.

Measuring compliance with process measures (e.g., four therapies known to reduce ventilator-associated pneumonia) or monitoring outcomes (e.g., decreased CRBSI rates) is the most advanced methodology to evaluate whether or not we are safer. However, not all safety interventions can be measured as rates, and evaluating “changes made” can be difficult. In this section, we will outline a model that uses two rate-based measures and two measures that cannot produce valid rates of patient safety; all four are equally important.
The model we developed focuses on measures of safety rather than broader measures of quality. It has been used at the Johns Hopkins Hospital and in over 100 ICUs in the state of Michigan (23). Four methodologically validated questions are the basic outline for this model and cover the domains of health care that affect safety (i.e., structure, process, outcomes, and culture).

How Often Do We Harm Patients? (Outcome Measure, Valid Rate)
Understandably, patient outcomes have been a ubiquitous focus in health care for centuries. When measuring harm, however, it is important to make sure that the harm you are measuring is preventable with appropriate interventions. If you measure an inevitable outcome, your data will not be reliable or valid (26). A good example—and possibly the only valid measure of harm at this time—is catheter-related bloodstream infections, because most are preventable. In addition, a solid infrastructure is in place to reliably measure harm rates (i.e., hospital infection control departments and Centers for Disease Control and Prevention guidelines) and significantly reduce infections (22,27,28).

How Often Do We Do What We Should? (Process Measure, Valid Rate)
A process measure is an indicator of whether patients reliably receive evidence-based interventions known to prevent complications in the targeted outcome. For example, washing your hands and applying chlorhexidine to sterilize the site before a catheter line insertion are two of five sterilization processes known to reduce bloodstream infections. When measuring processes, it is essential to remember that patient factors, bias in measurement, and interventions that might prevent a complication all play a role in complications. Unfortunately, existing process measures only capture acute myocardial infarction, congestive heart failure, and pneumonia; in many hospitals, this accounts for a small percentage of discharges (29). It will be extremely important to focus research efforts on more scientifically sound process measures since “what we do” directly impacts care, and the closer a mistake is in proximity to the patient, the higher the risk for harm.

How Do We Know We’ve Learned from Our Defects/Mistakes? (Structural Measure, Nonrate)
In our patient safety efforts, whether we have learned from our previous defects has received the least attention. Structural interventions, however, can have a profound impact on patient safety. For example, intensivist staffing in critical care has been associated with a 30% relative reduction in hospital mortality (5). In addition, structure and process measures work together to produce an outcome.

The use of validated tools, such as the Learning from Defect (LFD) tool, can help hospitals evaluate how care is organized and delivered to evaluate whether interventions are improving safety. Defects can be identified through various venues (e.g., morbidity and mortality conferences, incident reporting systems). The main goal of the LFD tool is to extensively investigate a small number of defects and make significant system changes based on the findings—dig an inch wide and a mile deep. To assess if a hospital, department, or clinical area has learned from a defect investigation, measure whether the recommendations made to avoid harm were actually implemented.

How Well Have We Created a Culture of Safety? (Cultural Measure, Nonrate)
As we discussed earlier, safety culture in health care is the context in which care is delivered. The beliefs, values, and opinions of the organizations’ leaders and managers strongly influence safety culture. Safety culture is a measure of how caregivers communicate and interact, and strongly influences patient outcomes (www.jointcommission.org) (30). Validated tools, such as the SAQ (17), assess the caregiver’s perceptions of safety climate in his or her clinical area. The SAQ includes six domains that affect culture: Teamwork climate, safety climate, perceptions of management, stress recognition, job satisfaction, and working conditions. Culture should be measured annually and is best administered at the clinical care area level rather than hospitalwide, given the variation in assessments among clinical areas within a single hospital. Scores are most interpretable when presented as the percent of staff in a clinical area reporting positive culture scores. A good indication that a clinical area is safe is to have at least 80% of staff in that area reporting a positive safety culture.

FRAMEWORK FOR IMPROVING PATIENT SAFETY
There are two strategies in this framework to improve patient safety. One strategy focuses on the rate-based measures we discussed and the other addresses the non-rate-based measures. The rate-based measures will be described in the context of collaborative projects, because such projects or interventions involve reorganizing the delivery of care (i.e., process, or what we do) to improve patient outcomes. The non-rate-based measures will be described in the Comprehensive Unit-based Safety Program (CUSP) because CUSP focuses on the structure of an organization and its culture. Before describing a collaborative, we should mention that a single institution can implement this project.

Collaboratives
A collaborative involves the participation of multiple health care organizations in a structured program with a shared goal of improving an aspect of clinical care. For our patient safety framework, this also means the involvement of a multidisciplinary team from each patient care area or hospital participating in the collaborative. Teams will implement and evaluate interventions with support from other frontline staff in their care area. To succeed, organizations designing collaboratives should do the following:

- Identify one important clinical outcome for improvement (e.g., eliminate CRBSI).
- Assemble a team to manage the project, particularly data collection and coordination with the collaborative’s core research center.
- Educate all caregivers in the patient care areas participating in the best practices of care for their outcome, and measure compliance with the interventions at baseline.
Give teams suggestions to reach their goals, but encourage them to adapt implementation of the interventions to fit their culture and resources.

Limit time to implementation of an intervention.

As with all care improvement projects that are successful, measurement of baseline compliance and change over time are key data points to collect.

Collaboratives are successful when sites network to share existing knowledge and accomplish a common goal. Through group meetings and conference calls, teams can learn about best practices and innovative methods used by other teams to approach a problem or succeed. In addition, collaboratives bring a shared momentum that can increase sustainability (31,32). There are, of course, pitfalls to any project in a multicenter or single hospital setting. Some problems to consider and rectify, or adjust for, are:

- Inadequate resources
- Poor leadership support
- Vague expectations and objectives for team members
- Poor communication
- Complex study plans
- Inadequate management of data collection and data quality
- Wasted efforts to “reinvent the wheel” rather than adopt the practices proven effective by others

**Designing a Collaborative to Improve Health Care Safety**

Considering the benefits and pitfalls outlined above, designing a collaborative requires a culture (i.e., the set of values, attitudes, and beliefs of the group) with a shared consensus of safety, and an understanding of the science (i.e., the technical components of how care is organized and delivered) of patient safety. The following intervention design incorporates both components in simple and reproducible steps to improve patient safety; it has been validated in several large collaborative efforts (22,33):

1. Identify evidence-based interventions associated with an improved outcome through review of peer-reviewed publications.
2. Select goal-oriented interventions that have the biggest impact on outcomes and transform them into behaviors. For example, we identified five behaviors in the literature that reduce CRBSI: Handwashing, cleaning of the skin with chlorhexidine, use of full barrier precautions, avoidance of the femoral site, and removal of unnecessary lines. In selecting behaviors, the focus should be on interventions with the strongest treatment effect (i.e., lowest number needed to treat) and the lowest barrier to use. One would not, for example, start with controversial or burdensome interventions that most caregivers have not yet accepted.
3. Develop and implement measures that evaluate either the outcome or use of the behaviors or interventions.
4. Measure baseline performance and establish databases to facilitate accurate data management and timely feedback to teams.
5. Ensure that patients receive evidence-based interventions through four basic phases: Engagement, education, execution, and evaluation (Table 10.2).

This framework to improve patient safety has been applied with previously designed tools and interventions in the Michigan collaborative previously mentioned. This project implemented the five evidence-based behaviors to reduce CRBSI, as outlined above, as an intervention and achieved dramatic reductions in infection rates (22). This intervention also included a component to reduce complexity and introduce a redundant safety check. To decrease complexity, a line cart was introduced, which centralized, in one place, all of the supplies required to place a central catheter. In addition, a checklist of questions stayed with the cart to ensure compliance with the best practices for central catheter placement. The checklist is typically completed by a nurse and is added assurance that the operator washed his or her hands appropriately and draped the entire patient; used sterile gloves, mask, and gown; and maintained a sterile field while placing the catheter. The

| TABLE 10.2 |
|---|---|
| **CHANGE MODEL: HOW TO ENSURE PATIENTS RECEIVED EVIDENCE-BASED INTERVENTIONS** | **Catheter-related bloodstream infection (CRBSI) as example** |
| **Steps** | **What do you do?** |
| ENGAGE | Make the problem real. | Share local CRBSI infection rates. |
| EDUCATE | Develop an educational plan to reach all members of the caregiver team. | Present evidence-based practices at grand rounds, multidisciplinary team meetings, etc. |
| EXECUTE | Develop a safety culture. | Present information on how you will improve care, and measure that behavior or outcome. |
| | Reduce complexity of the processes. | Make certain that all equipment to do it right is easily available to the provider; put everything in one place (i.e., a line cart). |
| | Introduce redundancy in processes. | Introduce checklists that identify the key steps to reduce CRBSI. |
| | Have regular team meetings. | Develop a project plan focusing on one to two tasks a week. Identify who owns each step of the process. |
| EVALUATE | Measure and give feedback. | Develop a data collection plan and database to facilitate tracking of progress. |
| | | Provide real-time feedback. |
| | | Post progress in highly visible locations for all staff to see. |
| | | Identify causes of defects. |
A nurse is empowered to stop the procedure if a sterile technique is compromised. This intervention resulted in a 66% reduction in the overall CRBSI rate, with a median rate reduced from 2.7 per 1,000 catheter days prior to the intervention to 0 by month 5 and through month 18 of the postintervention.

**Comprehensive Unit-based Safety Program: A Strategy to Learn from Mistakes and Improve Culture (Nonrate Measures)**

The CUSP is a six-step program that has been tested and successfully used to improve the quality and safety in ICUs (Table 10.3) (10,21). It provides a structured approach to improve safety culture by educating staff about the science of safety, including staff in the process of identifying and mitigating hazards, partnering the unit with a leader who can make change happen, and providing tools to learn from defects and improve the organization of work (21).

### The Comprehensive Unit-based Safety Program in Detail

Safety culture is assessed in the first step of the CUSP and reassessed about 1 year after the CUSP is under way to evaluate the impact of the program on safety culture. The initial measure is a baseline assessment of staff perceptions of safety culture in their clinical area and their perceptions of the organization’s commitment to patient safety. The Safety Attitudes Questionnaire is the instrument used, and is perceived as the most valid, reliable, and widely used survey to measure culture (34). Education is a crucial next step since it provides staff with a new set of lenses to identify hazards and recommend system changes to improve care—knowledge fosters awareness. In the third step, the frontline staff identifies patient safety hazards in their clinical area and suggests interventions for improvement. There are other sources to identify hazards, such as patient safety reporting systems, morbidity and mortality conferences, or liability claims. However, the most powerful method of incident reporting is to ask staff how they think the next patient will be harmed, and how it can be prevented from happening.

In step four, a senior executive builds a partnership with a unit or clinical area. This involves monthly rounds on the

| TABLE 10.3 |
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| **STEPS IN THE COMPREHENSIVE UNIT-BASED SAFETY PROGRAM (CUSP)** |

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Measure safety climate (baseline). Assess safety culture in each clinical area through Safety Attitudes Questionnaire (SAQ) administered to all staff.</td>
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<tr>
<td>2.</td>
<td>View educational material. Educate all staff about the science of safety through lectures and other educational materials.</td>
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<td>3.</td>
<td>Complete forms identifying patient safety issues.</td>
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<td></td>
<td>• Ask all staff the following:</td>
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<td></td>
<td>□ Think about the last patient who would have been harmed without the staff intervening.</td>
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<td></td>
<td>□ How will the next patient be harmed?</td>
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<td></td>
<td>□ How can this harm be prevented or mitigated?</td>
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<td></td>
<td>• Establish incident reporting system.</td>
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<td></td>
<td>Have a monthly meeting of all staff in the clinical area with a senior executive to:</td>
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<td></td>
<td>■ Help prioritize safety efforts</td>
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<td></td>
<td>■ Remove barriers for system changes</td>
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<td></td>
<td>■ Provide resources</td>
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<td></td>
<td>■ Demonstrate hospital commitment to patient safety</td>
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<td></td>
<td>■ Foster relationship between senior leadership and staff</td>
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<tr>
<td>4.</td>
<td>A senior executive should be responsible for application of the CUSP in the intensive care unit.</td>
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<td>5.</td>
<td>Implement projects/improvements.</td>
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<td></td>
<td>• Select two to three safety issues to focus on at one time (based on step 3).</td>
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<tr>
<td></td>
<td>■ Simple goals:</td>
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<td></td>
<td>□ Reduce complexity in a process.</td>
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<td></td>
<td>□ Create independent redundancies to ensure that appropriate critical steps are done (i.e., have two or more staff check independent of one another).</td>
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<tr>
<td></td>
<td>■ Example: Medication reconciliation, an independent redundancy done at patient discharge to recheck appropriateness of orders</td>
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<tr>
<td>6.</td>
<td>Repeat measure of safety culture. Remeasure safety culture to see if the CUSP has been successful (i.e., scores improve).</td>
</tr>
</tbody>
</table>

unit with staff to help them prioritize safety efforts, ensure they have the resources to implement improvements, and hold them accountable for evaluating whether safety has improved. In the fifth step, we ask staff to learn from one defect a month, and implement one tool designed to improve care delivery per quarter (e.g., daily goals or morning briefing) to improve communication and teamwork (11,13).

Implementing the Comprehensive Unit-based Safety Program

To implement the CUSP, start by choosing one patient care area, such as the ICU. Next, assemble a patient safety team using staff from that clinical area; they will be responsible for oversight of the program. To be most effective, this team should include the ICU director or an ICU physician safety champion, the nurse manager, another ICU physician and nurse, a risk manager or patient safety officer, and a senior executive from the institution. We have found that the program works best if the physician and nurse who will lead the program have at least 20% of their time devoted to improving patient safety. The first unit will be your beta site; subsequent teams from other clinical areas should learn from its successes and failures. The ultimate goal is to have every area in your hospital organize and manage safety through the CUSP.

Evidence of Comprehensive Unit-based Safety Program Benefits

The CUSP has been associated with significant improvements in safety culture. For example, the percent of staff reporting a positive safety climate increased from 35% before the CUSP to 60% after the CUSP (21). In addition, teams identified and mitigated several specific hazards through the CUSP. For example, as a result of asking staff how the next patient will be harmed, and using the LFD tool, the ICU created a dedicated ICU transport team, implemented point-of-care pharmacists, implemented the daily goals sheet, labeled epidural catheters to prevent inadvertent IV connection, and standardized the equipment in transvenous pacing kits (31). Moreover, the use of the CUSP was also associated with a reduced length of stay and nurse turnover.

In summary, the CUSP has several benefits worthy of repeating:

- Improving safety culture is necessary for staff compliance in implementing any safety intervention or project.
- It is malleable enough to add improvement tools.
- It is a venue to introduce rigorous research methods.
- It is a learning laboratory to identify and mitigate hazards.
- It provides the potential to improve patient outcomes.

Improvement Tools

Through our efforts to improve patient safety, tools have been developed to reorganize the way care is delivered. For example, five interventions known to decrease morbidity, mortality, or duration of ventilator support were assembled in a ventilator bundle to improve care for mechanically ventilated patients (36). These interventions include:

- Elevating head of bed to greater than or equal to 30 degrees
- Utilization of appropriate sedation (i.e., patient able to follow simple commands)
- Appropriate stress ulcer prophylaxis (i.e., received medication)
- Appropriate deep vein thrombosis prophylaxis (i.e., received mechanical devices or medications for prevention)
- Daily assessment for extubation (i.e., evaluate with rapid shallow breathing index or trial of spontaneous ventilation)

We have organized our tools into a Patient Safety Toolbox, and provide an example of several tools in our ICU collaboratives (Table 10.4).

Learning from Defects

While patient safety reporting systems have been advocated as a strategy to improve safety, their benefits lie in the rich information reported about the incidents (14,35). We must learn from these incidents. The LFD tool is designed to guide in the investigation of an incident or defect (23). This tool guides the investigators to evaluate system defects (e.g., computer malfunction for physician order entry), offers a structured approach to share what went wrong, and outlines a plan to improve the defects and follow-up (i.e., close the loop) to evaluate whether care is safer. If the loop is not closed, the error will be repeated.

The LFD process is a condensed root cause analysis (RCA), however, the LFD can be implemented with fewer resources, can investigate near-misses that rarely trigger a hospital-level RCA, and can be done more frequently by more clinical areas or departments. The LFD tool is part of the CUSP, but can also be used to investigate liability claims, incidents reported to patient safety reporting systems, and incidents brought up at morbidity and mortality conferences. This is a one-page tool, divided into four sections that ask the following:

- What happened?
- What factors contributed or minimized the risk of patient harm?
- What actions can be taken to reduce the likelihood of a similar incident?
- How do we know that our actions improved safety?

One of the major advantages of the LFD is that it allows ICUs to analyze in real time any incident and produce a plan to improve safety. Examples of the LFD tool have been previously published (35). This tool has been used successfully in morbidity and mortality meetings, as well as performance improvement meetings, to structure discussions around the system failures that resulted in the defects and away from the traditional focus on health care provider inadequacies.

Improving Teamwork and Communication

Effective teamwork and communication are essential for high-quality and safe delivery of care to our patients. Teamwork and communication failures are the most common contributing factors for adverse events in the ICU, and a root cause of sentinel events throughout the health care system (37–39).
<table>
<thead>
<tr>
<th>Tool</th>
<th>Problem</th>
<th>Purpose</th>
<th>Who should use</th>
<th>How to use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving communication</td>
<td>Communication failures have resulted in patient harm, increased length of stay, and provider dissatisfaction.</td>
<td>Improve communication among care team and family members regarding the patient’s care plan</td>
<td>All health care providers involved in patient care (physician, nurse, nutritionist, respiratory therapist, etc.)</td>
<td>During morning rounds, the “team” reviews the days’ goals for each patient. The patient’s nurse keeps the DGS at the bedside. The form is revisited during the day as the care plan changes.</td>
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<tr>
<td>Daily goal sheet (DGS)</td>
<td></td>
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</tr>
<tr>
<td>Learning from a Defect (LFD) tool</td>
<td>Health care organizations can improve the way they evaluate and learn from defects.</td>
<td>Provide a structured approach to identify systems that contributed to the defect, and take action to fix the defect</td>
<td>All staff involved in the delivery of care; can be used to investigate incident reports, morbidity and mortality conferences, etc.</td>
<td>Complete on at least one defect per month. Review different defects from different sources. Take action to resolve the defect and follow up to ensure safety has improved.</td>
</tr>
<tr>
<td>Care improvement Bloodstream infection checklist</td>
<td>Catheter-related bloodstream infections (CRBSIs) are associated with increased morbidity, mortality, and cost of care.</td>
<td>Improve teamwork Comply with infection control practices Eliminate CRBSIs</td>
<td>Nurse at the bedside</td>
<td>Checklist to be completed by nurse. If operator fails to complete a step, the nurse will stop the process. Completed checklist is turned in to unit leader.</td>
</tr>
<tr>
<td>Ventilator bundle</td>
<td>Mechanical ventilation increases risk of complications (e.g., ventilator-associated pneumonia [VAP]), length of stay, and death. VAP incidence in ICU ranges from 10% to 60%</td>
<td>Eliminate VAP Reduce length of stay Reduce the risk of death</td>
<td>All staff involved in the delivery of care</td>
<td>Complete five interventions (described in text). Check off on DGS to ensure this is done daily.</td>
</tr>
</tbody>
</table>

Team training has the potential to improve teamwork and communication in health care, and has been used effectively in other high-risk industries (e.g., commercial aviation, nuclear power). While there are guidelines in the medical literature regarding methods to train effective teams, there are few programs designed specifically for health care workers. Implementing team training in health care will take time and resources to design and implement a curriculum and evaluate the effectiveness of the curriculum on team interactions. To implement teamwork training, health care organizations must commit to a long-term plan to integrate team training into their existing curriculum, including the use of interdisciplinary simulation that will be discussed later in this chapter.

Other methods to improve communication and teamwork that fit more easily into daily work are daily goals sheets, briefing and debriefing tools, and multidisciplinary rounds, which are well known to intensivists (8,9,13,20,41). These tools are relatively new, but the evidence supporting the benefits is increasing, and they all provide a method to standardize communication. We have demonstrated that improvements in teamwork culture, measured with the SAQ, were associated with decreased medication errors, ventilator-associated pneumonia and CRBSI rates, and ICU length of stay (13,22,36,42,43).

Daily Goals Sheet

The daily goals sheet has been used since July 2001 during multidisciplinary rounds in the ICUs at Johns Hopkins to improve communication (13). This tool is a one-page checklist that is completed every morning to document the establishment of the care plan, set goals, and review potential safety risks for each patient. The goals sheet stays with the patient, is updated as needed, and is used as an information sheet for all staff involved in the patient's care. While its history of use has been in the ICU, this checklist can be modified for use on regular floor or critical care units. The daily goals sheet is a tool to standardize communication and is designed to promote effective interdisciplinary communication and teamwork. Both have been used in the operating rooms, in sign-out from the ICU nursing staff to the intensivist, and between OR nursing and anesthesia coordinators (8,9,11). A briefing is a structured review of the case at hand among all team members before any task is undertaken with the patient. A debriefing occurs after a procedure or situation in which the team reviews what worked well, what failed, and what can be done better in the future.

Other Tools to Improve Safety

Testing Knowledge and Ability: Beyond See One, Do One, Teach One

Testing the knowledge and ability of health care workers will take coordination and resources. To more formally evaluate clinician knowledge, some institutions have a hospitalwide inpatient site for clinical care issues (e.g., protocols, guidelines for equipment use, knowledge and competency testing) that staff visit regularly. For example, to decrease CRBSIs in an ICU, frontline caregivers were required to complete an online
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training session and pass the assessment. Simulation offers a strategy to evaluate a trainee or staff’s ability or skill.

Simulation
Simulation is a powerful tool/technique that has been used in high-risk industries to improve safety and reduce errors (44,45). The benefits of simulation in health care have been described as follows (46):

- Frequent training for emergencies (crisis resource management [CRM])
- Teamwork training (a weak link in the whole process of patient safety)
- Skills training and evaluation of competency before a trainee touches a patient
- Testing of new procedures and usability of new devices

Health care takes place in a complex, high-stress environment that impacts human performance and patient outcomes. High-fidelity simulation allows us to not only examine human performance, but also analyze system-based problems. Although most of medical simulation is still new, it provides an opportunity to reorganize our “see one, do one, teach one” method of clinical training and better prepare trainees before they practice medicine. We need a more thorough evaluation of the impact of simulation on patient safety, but like other industries, the face validity of this tool is likely to drive change and impact outcome. This impact will be especially apparent in the training domain, both for technical and nontechnical or behavioral skills (communication skills, leadership, task management, teamwork, situational awareness, and decision making) (47,48). These behavioral skills are common contributors that underlie critical events in health care (49), although organizations have not developed methods to incorporate these needed skills in current training practices. Simulation allows trainees to practice in an environment that is safe for the trainee and the patient. In addition, trainees are exposed to common, rare, and crisis situations, and can practice learned competencies and receive immediate feedback about their performance (50,51).

SUMMARY

Patient safety as a science is a relatively new and broad field of research in health care that draws upon many disciplines. Many health care organizations have made concerted efforts to address the hazards that plague safety. Over the past several years, most of our efforts have investigated causes and executed interventions to improve patient safety. Only now are researchers beginning to discuss how to evaluate these interventions and determine if patients are indeed safer. To evaluate the impact of simulation on patient safety, but like other industries, the face validity of this tool is likely to drive change and impact outcome. This impact will be especially apparent in the training domain, both for technical and nontechnical or behavioral skills (communication skills, leadership, task management, teamwork, situational awareness, and decision making) (47,48). These behavioral skills are common contributors that underlie critical events in health care (49), although organizations have not developed methods to incorporate these needed skills in current training practices. Simulation allows trainees to practice in an environment that is safe for the trainee and the patient. In addition, trainees are exposed to common, rare, and crisis situations, and can practice learned competencies and receive immediate feedback about their performance (50,51).

To begin to improve patient safety we can implement collaborative projects and the Comprehensive Unit-based Safety Program. The CUSP fosters a culture of safety in that staff will understand the data to date, it seems reasonable that all ICUs should be routinely assessing their culture of safety.

Any safety program should provide a practical, goal-oriented set of tools that improve culture and lead to measurable improvements in patient safety, using the principles described in this article as a guide. Further research is necessary to identify other effective safety interventions. Links must be developed between the structural elements of health care delivery and patient safety outcomes. Some of these structural elements might include intense staffing models, presence of pharmacies, use of the CUSP, improved nurse-to-patient ratio, and implementation of patient safety reporting systems. Given the data to date, it seems reasonable that all ICUs should be routinely assessing their culture of safety.

Although work is necessary at the organizational level, the question of whether our patients are safer can be meaningfully answered. Significant and very exciting improvements are beginning to be implemented throughout the United States. The critical care community must continue to develop the science of safety and, to a certain extent, create it, but many of the foundations have clearly already been laid.

References