Patient Safety in the Cardiac Operating Room: What Can, Will, and Might Make Patients Safer and You Happier?

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Learning Objectives:
As a result of completing this activity, the participant will be able to
- Describe the current state and limitations of safety science as it relates to communication, culture, and environment in the operating room
- Incorporate current safety principles into operating room practice
- Differentiate latent errors in a care delivery system from adverse patient events

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The cardiac operating room (OR) is a complex environment consisting of four teams of providers—surgeons, nurses, perfusionists, and anesthesiologists—and where a myriad of complicated equipment is often crammed into a space that might not have been designed for this purpose.

Despite the obstacles, mortality and morbidity from cardiac surgery have steadily decreased over the past decade. Inevitably, however, humans continue to make errors. Gawande and colleagues found that adverse events occurred in 12% of cardiac surgical operations, compared with only 3% in a general surgery population. Some 28,000 of the 350,000 cardiac surgical patients in the United States each year will have an adverse, preventable event.

Preventable errors are not related to failure of technical skill, training, or knowledge, but represent cognitive, system, or teamwork failures. Jim Reason, the renowned human factors engineer, was the first to propose a simplified model of error, now referred to as the “Swiss cheese” model. This model eloquently describes how hidden—or, in human factors terminology, latent—errors can line up to create actual errors or patient harm. In one example, originally outlined by Pronovost et al., a patient suffered from a venous air embolism not because a doctor was careless, but because there were many hidden failures, often termed latent failures, that added up to create a catastrophe. In this example, components of latent error included poor communication, lack of protocols or lack of knowledge of protocols, inadequate training, and fear of retribution if the nurse spoke up. Resilient systems are designed to reduce the number of latent errors. If there are fewer latent errors, the holes in the Swiss cheese for an error to pass through are harder to align.
The Systems Engineering Initiative for Patient Safety (SEIPS) model, now in generation 2.0, describes the healthcare delivery system and its complex interactions (Figure 2). The work system comprises the tools and technologies we use, the tasks we complete, the physical environment in which we work, the organizational structure, and finally the people—patients and healthcare workers. The interactions of these complex parts, both with each other and with themselves, define the work system. This system then defines a care process. Finally, the care processes define and determine the outcomes. Poor equipment, poor organizational structure, and ill-defined, poorly executed tasks will lead to poor processes and adverse patient outcomes. Summarized nicely by Holden et al., “According to the work system model, a person (who can be a caregiver or the patient) performs a range of tasks using various tools and technologies. The performance of these tasks occurs within a certain physical environment and under specific organizational conditions.” In other words, all systems are perfectly designed to achieve the results they get.

Communication failures that occurred primarily between caregivers accounted for 87% of the system failures that led to an out-of-court malpractice settlement. Breakdowns in teamwork result in surgical disruptions and consequent technical failures and adverse patient outcomes. Even minor events, those that are easy to recover from and are seemingly trivial, reduce the team’s ability to recover from major events. In one study, the greater the number of minor events that occurred, the longer was the operation and the more the providers’ performance suffered. In short, the little things matter a lot.

To design a system that reduces latent errors and minimizes disruptions means the system must communicate well both within and between teams, incorporate an environment that is designed to minimize errors, and foster a culture in which safety is the number one priority.

For an outstanding review of patient safety in cardiac surgery, please refer to the recently published Scientific Statement on the subject from the American Heart Association. What follows is a simplified summary of the full document.

THE PHYSICAL ENVIRONMENT

The physical environment in which cardiac surgery occurs includes not only the tools and technologies that we use to do our work, but also the physical placement of these tools, their alarms and displays, and the characteristics of lighting, noise, vibration, temperature, physical layout and available space, and air quality. Arguably no place in the healthcare system incorporates more tools and technologies into one space, and no place uses more at the same time. Little work has been done to identify the optimal configuration and interaction of equipment in the OR. Rather, objects have been increasingly added to an already crowded room with little thought to integration. As a result, we have simply built larger and larger ORs, crowded with wires, cords, and display screens, creating what has been termed the “spaghetti syndrome” (Supplemental Digital Content 2, http://links.lww.com/ASA/A559).

Pennathur et al., using data collected from the Flawless Operative Cardiovascular Unified Systems (FOCUS) Locating Errors through Networked Surveillance (LENS) study, have investigated the role of technology in creating hazards and offer a framework to explain and categorize these errors. Technology is problematic with regard to design and function, how the organization interacts with the equipment through purchasing or training, and how a device is incorporated into the physical environment (Supplemental Digital Content 3, http://links.lww.com/ASA/A560). Poor design and function or poor interaction between technologies impacts the providers’ cognitive task load; the more we struggle with our equipment, the more our brains are distracted from the patient.

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In a review of hazards in cardiac surgery, Martinez et al. identified four ways in which machines cause harm: (1) misuse (poor training or negligence); (2) the inherent risks of using the device; (3) poor maintenance and upkeep; and (4) poor machine design. Table 1 demonstrates concrete examples of each type of possible machine harm.

A human factors analysis of modern-day cardiopulmonary bypass pumps found that information displays suffer from placement, legibility, and format problems; components are poorly integrated into the machine; and the alarms are too loud or too quiet. Alarms, designed to alert the team to an abnormal condition, occur at an “alarming” rate of 3.59 per case, or 1.2 per minute, and 90% are false positive. This
quickly leads to alarm fatigue, as well as increasing the noise level, which has been implicated in disruptions and even surgical site infections. A recent editorial in JAMA suggests that alarm systems should be redesigned to (1) create clear, priority-based sounds and alerts, (2) provide clinical information at the time of care, and (3) incorporate the Bayesian nature of clinical decision making to create an intelligent and integrated system that helps clinicians piece together disparate pieces of information. Information systems (monitors, electronic medical record systems, alarms) are not integrated, and do not provide the comprehensive physiological disease model that is optimal for patient safety.

From this review of the hazards associated with tools and technologies as well as the physical environment, it is clear that interventions to mitigate these hazards must include the system as a whole. The science of human factors engineering has begun investigating how these complicated technologies are incorporated into the OR, but this work is in its infancy.

We have much to learn about the ideal space and ideal layout. Although architects suggest that the ideal OR is at least 600 square feet (650 square feet for cases requiring cardiopulmonary bypass), there are admittedly few data to suggest what is best. Sterile fields must be far enough from the OR walls as to not risk contamination; but how far is far enough? The guiding principles for optimal OR design, as summarized by Killen, are as follows: (1) standardize the location of the head of the table and the handedness of the room; (2) provide adequate space for equipment and for the staff to move around; (3) maintain focus on the patient; (4) ensure that all staff have a line of sight to the patient at all times; and (5) use technology to help workflow. Solving such issues as the “spaghetti syndrome” of wires and cables and the increased microbial count associated with frequent door openings will take a coordinated and concerted effort. Reduction of distraction, noise, and door openings by controlling traffic patterns has been recommended by the Association of Perioperative Registered Nurses.

Data such as that provided by the Realizing Improved Patient Care through Human centered Operating Room Design (RIPCHORD) study group provide a framework and methodology that could be used to help understand traffic patterns in the OR and determine optimal positioning of booms and equipment. As each of these problems (noise, alarms, equipment position, and personnel traffic) is studied, high-fidelity simulation offers an opportunity to evaluate possible solutions (Supplemental Digital Content 4, http://links.lww.com/ASA/A561).

SAFETY CULTURE

An organization’s safety culture refers to those collective behaviors and values that influence its ability to identify and mitigate hazards and systemic conditions that contribute to error. Safety culture has been stated to be “the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization’s health and safety management.” Although senior leadership is critical in establishing a safety-oriented culture, it is the frontline providers who...
must be fully engaged in creating a climate of quality and safety.

A culture that permits disruptive behavior among healthcare workers directly impacts patient safety. Disruptive behavior is common, reported by three quarters of physicians and nurses, and cuts across all disciplines. Respondents to a survey reported witnessing disruptive behaviors in 75% of surgeons, 64% of anesthesiologists, and 59% of nurses. More than 80% reported loss of concentration, communication failures, and poor patient safety as a result of disruptive behavior.

There are few tested methods for improving an organization’s culture. Thankfully, simple interventions to improve communication in the cardiac OR, such as checklists, briefings, and teamwork training, are typically associated with improvements in safety attitudes of OR personnel, as well as patient safety. The Comprehensive Unit-based Safety Program (CUSP), created in the Armstrong Institute for Patient Safety and Quality at Johns Hopkins University, is a safety culture program that has been successfully tested in intensive care units and recently in the OR. CUSP is a five-step iterative process that includes: (1) educating staff on the science of safety; (2) identifying defects; (3) involving senior executives to work with staff to prioritize safety and provide resources to eliminate hazards; (4) learning from studying 1 defect per month; and (5) implementing teamwork and improvement tools with intermittent quantitative assessments of culture. CUSP is integrated into the organization’s strategic plan but defers to frontline workers, giving them autonomy to identify and rectify safety hazards. Use of the CUSP approach together with specific checklists resulted in virtual elimination of catheter infections, a significant decrease in ventilator-associated pneumonia, and significant improvements in teamwork climates.

Communication failures are common and have been implicated as a cause of error and adverse outcomes in both general and cardiac surgery. Research in aviation and the military has demonstrated that team training can facilitate improved coordination and enhanced performance. Tools that teach teams how to perform and communicate better show promise. A trial of an evidence-based, government-sponsored program called Team Strategies and Tools to Enourage Performance and Patient Safety (Team STEPPS) has been conducted in the Veterans Administration system with success. However, the results of increased teamwork and a reduction in errors were difficult to sustain and were lost within 12 months. The frequency of retraining required to sustain improvements in team performance is not known. It is vital to realize the following: that teams should be trained as teams and not as individuals; that use of simulated scenarios is effective; that both executive leadership and nurse managers are critical to effective implementation; and that repetition, continued coaching, or both are required to strengthen and maintain benefits.

Today, the integration of and improvements realized with the checklist is no secret to all of us practicing medicine. The World Health Organization’s Surgical Safety Checklist combined with JACHO’s timeout process has been shown to decrease surgical error and reduce mortality when used appropriately. Experts argue that it is the adaptive work of the team, rather than the technology of a checklist, that generates improvements in patient safety. Nonetheless, in the Netherlands, where checklist compliance was mandated, overall mortality decreased from 3.13 to 2.85%. Arguably the most important part of the checklist process that is underutilized but most important to improving communication is the preoperative briefing and the postoperative debriefing. Used often and consistently, they have been shown to reduce surgical error and decrease distractions. Thankfully, the simple act of conducting briefings has been shown to increase teamwork behavior and team performance. The debriefing allows members of the medical team to assess what went well and what did not, to coalesce as a team, and to improve their
Structured communication between two or more teams of people is an effective method to reduce errors, especially in stressful environments. Techniques such as using words for letters (Alpha, Bravo, Charlie) or saying the individual digits of a number can reduce ambiguity, enhance clarity, and specify the intended recipient. Structured communication between the perfusionist and surgeon was clearly shown to reduce the number of miscommunications between the two roles at key times during a cardiac operation. Models of structured communication between teams at all points of an operation have not been designed or studied. Pilots recognize a 10,000 foot ceiling below which no extraneous conversation can occur. There is no time during an operation when a “sterile cockpit” can be identified and adhered to (Figure 3). This author is convinced that structured communication at key points in the operation is our answer to the sterile cockpit. However, we are a long way from understanding when and how these conversations should happen.

American Heart Association recommendations for improving teamwork and communication include the following (reprinted with permission. Circulation 2013; 128:1139–1169. © 2013, American Heart Association Inc.):

1. Checklists and/or briefings should be implemented in every cardiac surgery case, and postoperative debriefings should be encouraged by leadership in cardiac ORs (Class I; Level of Evidence B).
2. Team training to improve communication, leadership, and situational awareness should be implemented in cardiac ORs and should involve all members of the cardiac operative team (Class I; Level of Evidence B).
3. Formal handoff protocols should be implemented during transfer of the care of cardiac surgical patients to new medical personnel (Class I; Level of Evidence B).
4. It is reasonable to conduct event scenario training that involves the complete cardiac surgery team for significant and rare nonroutine events (i.e., emergency oxygenator change-out) on a regular basis (Class IIa; Level of Evidence C).
5. It is reasonable to conduct future studies of teamwork and communication that (a) investigate optimal communication models (e.g., briefings and structured communication protocols in the cardiac surgical OR); (b) investigate team-training models to determine the “best product” for use in the cardiac OR; (c) investigate impediments to implementation of formal training in teamwork and communication skills; (d) include long-term studies of the sustained impact of such training on provider outcomes (e.g., attitudes regarding safety, compliance with best practices, and communication skills); (e) investigate the efficacy of formal training in teamwork and communication skills in improving patient outcomes (e.g., satisfaction, blood product use, infections, intensive care unit readmissions, mortality, and costs); and (f) include establishment of an anonymous national multidisciplinary event-reporting system to obtain data about events and near-misses (Class IIa; Level of Evidence C).

REFERENCES


“The same situation keeps producing the same errors . . . even though quite different people are involved. That surely indicates we are dealing with error prone circumstances rather than error prone people. We are dealing with error traps.”

Cable Management
Work Arounds
Slips and falls

Equipment Design

Poor use of space

Noise

Traffic

Alarms