Patient Safety Science in Cardiothoracic Surgery: An Overview

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Introduction

Cardiothoracic surgeons have a rich history of quality improvement and a strong ethos of transparency and innovation allowing for the rapid diffusion of standards, techniques, and benchmarks. This approach has resulted in improvements in patient outcomes and in the recognition of our specialty as leading in quality and safety. The development of the Society of Thoracic Surgery’s databases is pivotal in driving much of the incremental improvements and refinements in techniques and processes of care by capturing important risk factors and by reporting risk-adjusted outcomes using methods that serve as the gold standard for other registries and clinical databases worldwide [1].

Although morbidity and mortality have continued to decrease over time, errors and preventable events continue to yield suboptimal outcomes [2]. Contemporary cardiothoracic surgical care is a complex sociotechnical system involving sophisticated techniques and equipment, health care professionals with varying levels of skills, and high-risk patients. We work in safety-critical environments where the complexity of care and the patients’ risk factors exponentially increase the potential for significant harm. Given this degree of complexity, optimal conditions are critical to successful outcomes. Because humans and poorly designed systems are vulnerable to error, a critical assessment of our systems of care and learning from other safety-critical industries are essential for improvement to continue. The traditional view that patient outcomes are related only to the surgeon’s technical skill has given way to an evolving and broader framework wherein health care outcomes are affected by a multitude of factors in a highly integrated and complex environment.

Adverse Events in Cardiothoracic Surgery

We make two implicit individual and organizational promises when patients entrust themselves to our care: first, to do everything possible to provide excellent care, and second, to do no harm. In some instances, patients do not get the care that is expected and are inadvertently harmed [2]. Deviations from established protocols, lapses, and nonobvious (“latent”) conditions are important elements contributing to harm. Not all errors result in adverse events, and not all such events are caused by error. As such, it is important to distinguish between preventable and nonpreventable events in understanding the nature of patient safety.

Two thirds of surgical adverse events occur in inpatients, and approximately half of these are preventable [3]. The incidence of adverse events among patients undergoing coronary artery bypass grafting or cardiac valve operations is 12.3% compared with 3% among all surgical admissions. Of the 4,828 reported incidents related to cardiac operations over a 4-year period in the United Kingdom’s National Reporting and Learning System, a voluntary web-based incident reporting system, 21% occur in the operating room; of these, 32% resulted in some level of patient harm [4]. Other investigators have also identified an alarming rate of safety hazards during cardiac operations [5]. On the basis of studies using structured observation, contextual inquiry, and extensive data capture using a systems engineering and human factors framework, hazards in the cardiac operating room are widespread and numerous opportunities exist for improvement focusing on fostering a culture of safety, increasing compliance with evidence-based practices, improving communication and teamwork, and developing a partnership among stakeholders.

A public inquiry of clinical failures in pediatric cardiac operations at the Bristol Royal Infirmary concluded that systemic factors had contributed to that organization’s inability to detect and correct problems [6]. The analysis highlighted the importance of strong and effective clinical governance, a strong quality improvement infrastructure, and a culture of transparency in mitigating patient harm. Ongoing surveillance for quality, routine audits, and an in-depth examination of adverse events, near misses, and other unsafe conditions are the hallmarks of a safety-focused organization.

Learning From Failure

One of the forerunners of modern industrial safety and accident investigation programs, Heinrich’s classic safety pyramid of industrial accidents proposed that for each major injury there were 29 minor injuries and 300 precursor events [7]. Although the exact ratio is disputed, examining unsafe situations and “near misses” prove to
be considerably more fertile than the more frequent practice of directing major improvement efforts based on the relatively few harmful events. At-risk behaviors and activities that are not consistent with safety protocols and training, such as bypassing preoperative checklists or lax patient verification practices, have a profound impact on a safety-oriented team culture.

Precursor events that contribute to harm appear to be ubiquitous in the cardiothoracic surgical environment. These events deviate from the expected and optimal course of a process, and they precede an adverse or catastrophic outcome. Examples include equipment failures, scheduling mixups, missing diagnostic test results, medication errors, and technical operative problems; these events are unrelated to patient characteristics.

A prospective study identified 1,627 precursor events in 464 cardiac operations [8]. Of these, 32% were considered major. Alarmingly, only 31% of these events were discussed by the team, whose members thereby missed opportunities for collective learning and team building. Furthermore, the number of precursor events had a strong association with the risk of death or near miss (Fig 1) [9] after adjustment for cardiopulmonary bypass time.

Efforts to prospectively identify conditions that pose potential or real risk to patients are not always standard practice in cardiac surgery [10]. Behaviors such as deviations from normal procedures and other seemingly minor events cause a cascade effect, resulting in distractions that lead to major events and poor outcomes.

Examining mortality rates in low-risk patients undergoing standard cardiac surgical procedures, investigators at Papworth Hospital concluded that preventable deaths were due to either inadequate myocardial protection or failures in communication [11]. After correction of the systemic factors identified initially, subsequent adverse events were isolated mainly to technical errors [12]. Thus, routine examination of deaths and “near misses” in low-risk groups may unmask pervasive systemic errors and weaknesses to be targeted for modification.

Learning from error can occur at both an individual and an organizational level through incident reporting and analysis. Incident Reporting Systems and Root-Cause Analyses are essential tools that enhance an organization’s ability to learn from error. Incidents are traditionally underreported as a result of the pervasive focus on individual blame, compounded by “hindsight bias.” Because the value of an Incident Reporting System is dependent on the culture of an organization, hospitals are able to learn from each event only when individuals feel psychologically safe to report problems without fear of reprimand. A properly conducted Root-Cause Analysis uses a structured, systematic approach to incident analysis, which takes into account the complex nature of the health care environment and recognizes that error is an inevitable component of social systems. The lessons learned through the use of these tools allow an organization to identify and eliminate unsafe conditions and help mitigate future patient harm.

The Science of Safety

Safety science is an interprofessional field, which has evolved from work conducted in a wide variety of industries that consider accident investigation, loss prevention, and risk management to be integral components of their mission. Many of the concepts emerging from this
field are directly applicable to the health care environment and specifically to cardiothoracic surgery.

The Skill, Rule, and Knowledge (SRK) based classification developed by Rasmussen [13] provides a useful framework for identifying the types of error likely to occur when different types of information processing are demanded of individuals, particularly under periods of duress. The SRK approach is based on the degree of conscious control exercised by an individual over a task. Skill-based errors such as slips and lapses occur when the action made is not what was intended. Rule-based mistakes are actions that match intentions but do not achieve their intended outcome because of the incorrect application of a rule or the inadequacy of a plan. Finally, knowledge-based mistakes are actions that do not achieve the desired outcome because of a gap in knowledge.

In general, theories of accident causation share three main themes: that humans make mistakes, that big accidents usually escalate from small events, and that most failures arise from organizational factors, not from isolated operator error. The industrial psychologist James Reason [14] proposes that most accidents can be traced to at least one of four failure domains: organizational influences, supervision, preconditions, and specific acts. In his Swiss Cheese Model, defenses against failure in human systems are modeled as a series of barriers represented as slices of Swiss cheese. The holes in each slice represent weaknesses that vary constantly in size and position. The system produces failures when the holes temporally align, allowing “a trajectory of accident opportunity” leading to failure. This model is used frequently in risk management strategies and underlies the principle of “layered security” used by many industries.

In the Normal Accident Theory, the sociologist Charles Perrow [15] proposes that accidents are inevitable in extremely complex systems. Unanticipated failures are “normally” expected, and therefore redundant subsystems or processes should provide an alternative way to accomplish a task if the primary process fails. The degree of flexibility in the coupling between processes determines whether errors are directly and immediately transmitted and magnified downstream. An error in a tightly coupled system such as cardiac surgery has a prompt and major impact on other interdependent processes and tasks. A salient example of tight coupling is the interaction between the perfusionist and the cardiac surgeon. Even small deviations in cardiopulmonary bypass pump operation can have immediate and catastrophic consequences. Tightly coupled systems such as those found in cardiothoracic surgery raise the odds that an error will result in patient harm unless redundant processes and actions can degrade or arrest the impact.

The ability to perform well under high-stakes, high-risk conditions is a fundamental skill of the cardiothoracic surgeon. Industries that function with very low rates of failure despite the high-risk nature of their environments have been described as High-Reliability Organizations (HRO) [16]. Examples of HRO include aircraft carriers, air traffic control systems, fire incident command systems, commercial aviation, and nuclear power operations. These organizations use complex processes to manage their complex work. HROs share many properties with other high-performance organizations, including a reliance on highly trained personnel, the need for continuous training and improvement, effective reward systems, and frequent process audits and analysis. Behaviors that make these HROs organizations unique include the incessant testing of assumptions and the anticipation of failure. They “hardwire” redundancies at critical points and institute a variety of checks and counterchecks as precaution against errors. Such an organization-wide sense of vulnerability is grounded in the collective mindfulness and high sensitivity to how the system functions as a whole. Table 1 lists the properties of HRO as described by Weick and Sutcliffe [16].

Because major adverse events are relatively rare, the practice of focusing exclusively on clinical outcomes as a proxy for safety gives surgeons and health care leaders a false sense that processes of care are reliable. Accentuated by a permissive approach toward clinical autonomy, this focus allows unjustified performance variations that go unrecognized until it is too late. Conformity with existing processes, a focus on efficiency, infrequent opportunities for learning, and information filtering lead team members to reject or excuse early warning signs of quality degradation. Although creating a state of collective mindfulness and maintaining vigilance require great effort and commitment, the HRO model can potentially transform cardiothoracic surgical care to achieve ultrasafe levels of performance.

Studies in human factors have enhanced the performance of many complex sociotechnical systems by using a rigorous multidisciplinary approach to the interface between humans, their environment, and technology. This approach is increasingly being applied with some advantage in surgical care. This approach is increasingly being applied with some advantage in surgical care.

Table 1. Characteristics of High-Reliability Organizations

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<td>• Preoccupation with failure: Maintaining continuous surveillance for early signs of failure</td>
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<td>• Reluctance to simplify: Simplifying complex processes may make the system vulnerable to failure</td>
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<td>• Sensitivity to operations: An awareness of the consequences that any change may have on the entire system</td>
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<tr>
<td>• Commitment to Resilience: Maintaining function during unexpected, demanding events</td>
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<td>Absorb strain and preserve operations despite adversity</td>
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<td>Maintain the ability to recover from unexpected events</td>
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<tr>
<td>Train for worse-case scenarios and learn from each precursor event, near miss, or failure</td>
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<tr>
<td>• Deference to expertise: Deferring to individuals with relevant knowledge, experience, and skill regardless of rank</td>
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(Adapted from Weick KE, Sutcliffe KM. Managing the unexpected: resilient performance in an age of uncertainty. 2nd ed. San Francisco: Jossey-Bass; 2007.)
success to the health care environment, specifically to high-risk surgical care [17–20].

The application of human factors science to the operating room and critical care environments requires tools focused on standardization and automation, simplification (but not oversimplification), and the creation of “forcing functions” and other types of constraints to minimize reliance on memory and to facilitate making the right choice [21, 22]. Incorporating redundancies in the system to limit the effects of failure and establishing closed-loop communication during critical processes are effective ways to achieve reliability and high performance in work systems such as the cardiothoracic operating room.

Using a human factors classification system in a cardiac operating room, Wiegmann and colleagues [23] identified a significant incidence of flow disruptions resulting from unnecessary interruptions and communication failures that were associated with an increased rate of surgical error. Categories of disruptions included teamwork, extraneous interruptions, equipment and technology, resource-based issues, and supervisory or training issues. The strongest predictor of subsequent error was failure in teamwork and communication.

Studies of error mitigation during operations suggest that the surgeon’s cognitive flexibility, adaptability and resiliency are pivotal to maintaining a team’s capacity to manage and recover from errors and unexpected problems [17, 18]. These qualities are dependent on a surgeon’s ability to remain calm during attempts to remedy problems under conditions that threaten patient safety. Additionally, surgeons play a critical role in facilitating work system changes and in buffering the impact of these events on members of the surgical team by fostering effective team coordination and adapting their surgical and communication style to optimize human capital and the collective skillsets of other team members.

Resilience Engineering, an approach to safety developed in industries such as firefighting, builds on the anticipation of error and failure [24]. Designing resilience into complex adaptive systems such as the “microsystem” (see below) of a cardiothoracic surgery team requires tradeoffs between efficiency and thoroughness [25]. Optimality, the ideal tradeoff point, preserves efficiency while allowing a team to recover from error by maintaining a tactical reserve of resources (ie, maintaining a “margin of maneuver”) to recover from unexpected events.

Several organizational models aim to redesign operational units to reliably maintain optimal performance. Emphasizing the strengths of both groups and individuals, a microsystem is the smallest replicable work unit with a common purpose within a larger organization [26]. A surgical microsystem, for example, might consist of a pediatric cardiac surgical team that includes the corresponding critical care unit and patient wards. This model incorporates both clinical and business aims and specific, measurable performance outcomes with a view toward continuous improvement through real-time collection, analysis, and sharing of information. Safety is one of the fundamental properties of a microsystem.

The qualities of clinical Microsystems are optimal for implementing strategy, leveraging information technology, and “hardwiring” other performance-enhancing practices into the service delivery process. Organizations using this approach must be willing to redesign workflows, reporting structures, and governance if they are to have an impact. Added benefits of this model include high levels of staff satisfaction, an enhanced level of empowerment, increased commitment toward established goals, and a passion for continuous learning and innovation.

### Safety Culture, Teamwork, and Communication

Culture can be defined as the set of shared values and beliefs that interact with an organization’s structure, practices, and control systems to produce behavioral norms [27]. Organizations with a strong safety culture explicitly recognize the high-risk nature of their work, and they demonstrate a collective determination to achieve consistently safe operation. A blame-free environment where individuals are able to report errors and near misses without fear of reprimand is an essential component. By contrast, organizations that punish the voicing of concerns, either directly or indirectly, and ignore close calls create a culture that threatens safety. These environments can allow “normal deviance” to emerge: unsafe behaviors and actions that have become routine and are no longer recognizable as violations of rules and protocols. A safety-minded culture encourages collaboration and a collective mindfulness across ranks and disciplines to seek effective solutions to patient safety problems.

Certain errors, however, demand accountability, and the “blame-free” approach has its limitations when behaviors are not congruent with a culture of safety. The Just Culture framework recognizes the difference between unintentional human errors, at-risk behaviors requiring correction, and reckless behavior such as willful disregard for safety procedures. The challenge of a just culture hinges on the proper balance between a nonpunitive, no-blame environment and individual accountability [28].

The safety climate of cardiac surgery teams was compared in one study with a large dataset of all types of surgery [29]. Cardiac surgery teams demonstrated a more positive safety climate than the all-type surgery cohort in teamwork-related measures within but not across hospital units. Measures of nonpunitive response to error received the lowest score in the cardiac surgery teams. Thus, there is considerable room for improvement in psychological safety and in communication with components of care residing outside the cardiac surgery operating room.

Team training programs such as Crew Resource Management and Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) use highly effective training strategies for reducing error [30–32]. These programs aim to enhance nontechnical skills by facilitating collaborative teamwork, improving timely communication, and achieving high levels of
situational awareness among team members. Using high-fidelity team simulation, crisis management training, checklists, and other tools, these programs can have a substantial impact on safety culture and team performance in many different settings.

The introduction of new technology and innovation is a hallmark of cardiothoracic surgery and requires effective teamwork. For instance, in examining the adoption of Port Access minimally invasive cardiac operations in 660 patients at 16 cardiac surgery centers, investigators found that factors relating to leadership and team dynamics had a greater impact on the successful adoption of new technology than factors such as skill, organizational resources, and experience [33]. The degree to which team members felt safe in speaking up was highly dependent on the leadership and attitude of the lead surgeon [34]. Behaviors exhibited by the team leader resulted in a quicker, more effective rate of adoption of complex new technology and were precipitated by such activities as preparation and training as a team and situation-specific changes in communication and coordination. Team familiarity and team stability were also important determinants of success [35]. By contrast, the reluctance of team members to share safety events with others as a result of rigid hierarchical team structures had a negative impact on team performance and patient outcomes.

A survey of pediatric cardiac surgery teams demonstrated that 29% of team members felt they had difficulty speaking up if they perceived a problem, and 41% felt unable to express disagreement. Additionally, individuals involved in an error were found to be profoundly affected by it and to carry a significant personal burden [36]. Thus, the quality of communication and information exchange has a direct impact on the quality of care and on the well-being of individual team members.

Communication failures are one of the most frequent root causes of sentinel events reported to the Joint Commission [37]. As many as 70% of these reports cite communication failure as a major contributing factor to error. Structured Communication refers to a portfolio of techniques used across a variety of disciplines designed to reduce ambiguity and increase efficiency in high-risk environments. The “sterile cockpit” approach to effective communication uses structured communication around critical events to reduce the possibility of error and enhance patient safety during cardiac surgical procedures.

Measuring the cognitive workload of various team members has demonstrated the considerable variation in the temporal distribution of high workload periods in cardiac surgery teams (Fig 2) [38]. The frequency of communication breakdowns per case decreased significantly (11.5 vs 7.3 breakdowns/case) after a structured verbal communication protocol was implemented. Thus, in addition to superior technical skills in the operating room, the cardiothoracic surgeon must possess well-developed, team-oriented, nontechnical skills to be an effective team leader and communicator (Table 2). Surgeons should avail themselves of every opportunity to develop and strengthen these skills and to promote these concepts, tools, and techniques from safety science among our peers and our professional community.

The Society of Thoracic Surgeons and Patient Safety

The Society established the Workforce on Patient Advocacy, Communications, and Patient Safety in 2003, later renamed the Workforce on Patient Safety. The Workforce has hosted a Patient Safety Symposium during the Society’s Annual Meeting since 2007 (Table 3). It also makes

Table 2. Attributes of Safety-Focused Surgical Teams

- Training together
- Consistent leadership
- Psychological safety and the ability for team members to voice concerns
- Clearly defined boundaries of actions and behaviors
- Role clarity among all members of the team
- Team structure is not rigidly hierarchical
- Team briefings in anticipation of problems
- Team debriefings to learn and improve
- Mechanisms for conflict resolution
- Shared accountability

Table 3. Themes and Topics Presented at the Annual Society of Thoracic Surgeons Patient Safety Symposium

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<th>Year</th>
<th>Themes and Topics</th>
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| 2007: STS University Patient Safety Symposium | Flight-Based Safety Programs  
|                       | Team Building                                                                        
|                       | Recognizing the Warning Signs of Impending Adverse Situations                      
|                       | Cross-Check Communications                                                          |
| 2008: STS University Patient Safety Symposium | Effective Team Decision Making  
|                       | Debriefing (Performance Feedback)                                                   
|                       | Conflict Management                                                                  
|                       | Implementing Hard-Wired Safety Tools                                                |
|                       | Analysing and Crunching Numbers: Can We Do Research in Thoracic Surgery Safety?     
|                       | Hazard Prevention vs Compensation from Adverse Events: Safety in the Cardiac Operating Room |
|                       | Near Misses and Crashes and the Human Factors Analysis of How These Events Occur    
|                       | Simulation in Cardiothoracic Training and Crisis Management                         |
| 2010: Patient Safety Symposium | Military Medical Transport Communication                                           
|                       | Friendly Fire: Communication Challenges on the Battlefield                           
|                       | Patient-Physician Communication: The Patient’s Perspective                          
|                       | Communication in the Operating Room with Special Emphasis on Perfusionist-Surgeon Communication |
| 2011: Using Simulation Training and Human Factors Management to Improve Safety and Performance in Cardiothoracic Surgery | Multitasking, Prospective Memory, Stress, and the Errors of Highly Skilled Experts |
|                       | Fatigue and Human Performance                                                        |
|                       | Simulation-Based Learning in Cardiothoracic Surgery, with focus on Cardiopulmonary Bypass |
|                       | Communication in the Operating Room: Can We Learn from Aviation?                    |
| 2012: Teamwork in Cardiothoracic Surgery Is More Important Than Ever | Why Teamwork Is the Point in Transcatheter Aortic Valve Programs                   
|                       | Teamwork in Trauma Surgery and What Cardiothoracic Surgeons Can Learn From It       
|                       | Team Training in Surgery: Why do it?                                                
|                       | The Big, the Bad, and the Ugly: Cases in Cardiothoracic Surgery: How Teamwork Saves Lives |
|                       | Robotic Surgery Requires Multidisciplinary Teamwork to Succeed                      
|                       | Transplantation and Mechanical Cardiac Support Programs: The Ultimate Multidisciplinary Team Model |
| 2013: The Nexus of Data, Outcomes, and Public Awareness | Patient Safety and Public Reporting: Are They Connected?                              
|                       | Public Reporting Has Improved Patient Safety in Cardiac Surgery: New York State     
|                       | Cardiology Referrals Should Only Be Based on Surgeon Mortality Rates                
|                       | Limits of Surgeon Profiling: What Are the “Best” Surgeon Outcomes?                 
|                       | Instituting a Culture of Safety at Your Hospital                                    
|                       | Administrative vs Clinical Databases: A Thoracic Surgeon’s Journey                  
|                       | A Method for Utilizing the STS National Database                                      |
| 2014: Safely Adopting New Technology in Cardiothoracic Surgery | Regulation of New Technology: Perspective of Hospital Administration                
|                       | What Is the Role of National Societies in Credentialing Surgeons?                   
|                       | Should Industry Be Responsible for Training Surgeons?                               
|                       | How to Safely Adopt New Technology: The Surgeon’s Perspective                      
|                       | Learning Robotic Cardiac Surgery                                                     
|                       | Challenges of Video-Assisted Thoracic Surgery Lobectomy                             
|                       | Innovation and Congenital Cardiac Surgery                                           |

(Continued)
available resources and reference materials on its website (www.sts.org/quality-research-patient-safety/patient-safety), which include surgical checklist templates for adult cardiac operations, general thoracic operations, and congenital heart operations based on the World Health Organization’s Surgical Safety Checklist.

In addition, the Society hosts several other activities at its Annual Meeting, including interprofessional education focused on patient safety. It continues to disseminate many of the principles of safety and reliability described in this article throughout its wide range of educational activities. For example, the Society, in conjunction with the American Board of Thoracic Surgery (ABTS), will soon make available a series of web-based modules for Continuing Medical Education credits that meet the patient safety requirements for Part 2 of the Maintenance of Certification process by the ABTS. Society members have also participated in interdisciplinary initiatives to improve safety such as the Flawless Operative Cardiovascular Unified Systems (FOCUS) Initiative created by the Society of Cardiovascular Anesthesiologists. FOCUS, which uses human factors engineering, social-field models of collaborative care, and other tools from the social sciences, is a long-term study and practice improvement initiative to examine and reduce human error in cardiac operating rooms. Several of the research findings presented in this article were generated as a result of this collaboration [4, 5, 10, 20, 39].

Conclusion

This is the first article in a series on patient safety that will appear in The Annals. Keeping patients safe from unintentional harm will require new approaches involving enhanced communication practices, workflow redesign, and leadership styles based on evolving knowledge generated by social science and engineering. Achieving a climate of safety and developing a systems-based approach to safety will require commitment from all stakeholders in an organization. The cardiothoracic surgeon of the future will be not only an expert technical surgeon but a collaborative leader with strong communication skills and a deep understanding of the complexity and interrelatedness of all parts of the system. Future articles on patient safety will introduce, in more detail, various conceptual frameworks and aspects of safety science, and they will highlight studies, tools, and techniques geared toward the practicing cardiothoracic surgeon. It is anticipated that these articles will serve to educate and encourage the cardiothoracic surgical community to strive to eliminate preventable patient harm and to facilitate a sense of collective mindfulness toward safety among our surgical teams.

References


